

*Presidenza del Consiglio dei Ministri*

SEGRETARIATO GENERALE

Italian National Bioethics Committee

## OPINIONS

2003 - 2006



*Presidenza del Consiglio dei Ministri*  
DIPARTIMENTO PER L'INFORMAZIONE E L'EDITORIA



## INDEX

1. Tobacco use .....	p. 9
2. Ritual slaughtering and animal suffering .....	p. 51
3. Advance treatment statements .....	p. 61
4. The precautionary principle: bioethical, philosophical, legal aspects .....	p. 79
5. Alternative medicine and the problem of informed consent .....	p. 119
6. The Cellular Therapy of Huntington's Disease through the implantation of fetal neurons .....	p. 131
7. Bioethics in dentistry .....	p. 139
8. Bioethical considerations on the so-called "ootide" .....	p. 155
9. Nourishment and hydration of patients in persistent vegetative state .....	p. 171
10. Bioethical problems concerning the use of animals in activities linked to human health and well-being .....	p. 183
11. Adoption for the birth of cryopreserved and residual embryos obtained by medically assisted procreation (MAP) .....	p. 205
12. Assistance to pregnant women and post-partum depression .....	p. 219
13. Bioethics and the rights of the elderly .....	p. 243
14. Differentiated diet and interculturality. Bioethical guidelines .....	p. 297
15. Bioethics and rehabilitation .....	p. 305
16. From pharmacogenetics to pharmacogenomics .....	p. 337
17. Ethics, health and new information technologies .....	p. 389
18. Caudectomy and conchectomy .....	p. 437
19. Conflicts of interests in biomedical research and in clinical practice .....	p. 443
20. Biobanks and research on human biological material .....	p. 457
21. Nanosciences and nanotechnologies .....	p. 463

**COMPILED AND REVISED BY**

**Dott. Agnese Camilli**

Coordinator

**Sig.ra Lorella Autizi**

**Dott. Giorgia Adamo**

**Dott. Marina Bonfili**

**Dott. Emanuela Midolo**

**Dott. Leonardo Nepi**

## **PRESIDENT**

**Prof. Francesco D'Agostino - NBC President**

Professor of Philosophy of Law

## **HONORARY PRESIDENTS**

**Prof. Giovanni Berlinguer**

Professor of Labour Hygiene

**Prof. Adriano Bompiani**

Professor of Clinical Obstetrics Gynaecology

**Prof. Rita Levi Montalcini**

Nobel Prize in Medicine

**Prof. Adriano Ossicini**

Professor of Psychology

## **VICE PRESIDENTS**

**Prof. Mauro Barni**

Professor of Forensic Medicine

**Prof. Cinzia Caporale** (2005 -2006)

Professor of Bioethics

**Prof. Angelo Fiori**

Professor of Forensic Medicine

**Prof. Adriana Loreti Beghè** (2003 - 2004)

Professor of International Law

## **MEMBERS**

**Prof. Salvatore Amato**

Professor of Philosophy of Law

**Prof. Luciana Angeletti** (2002 - 2004)

Professor of History of Medicine

**Prof. Dario Antiseri**

Professor of Methodology of the Social Sciences

**Prof. Luisella Battaglia**

Professor of Moral Philosophy

**Prof. Sergio Belardinelli**

Professor of Sociology of Cultural Processes

**Prof. Lucio Bianco**

President of the National Research Council (CNR)

**Prof. Paola Binetti**

Professor of History of Medicine

**Prof. Luisa Borgia** (2005 - 2006)

Coordinator of the Master in Bioethics

**Prof. Francesco Busnelli**

Professor of Civil Law

**Prof. Cinzia Caporale**

Professor of Bioethics

**Dr. Carlo Casini**  
Judge of the Italian Supreme Court of Cassation

**Prof. Isabella Maria Coghi**  
Professor of Gynecological Endocrinology

**Prof. Mario Condorelli**  
President of the Supreme Council of Health (CSS)

**Prof. Bruno Dallapiccola**  
Professor of Genetics

**Prof. Lorenzo d'Avack**  
Professor of Philosophy of Law

**Prof. Luigi De Carli**  
Professor of Genetics

**Prof. Giuseppe Del Barone**  
President of the National Federation of the Order of Doctors (FNOM)

**Prof. Renzo Dionigi**  
Rector of the University of Insubria

**Prof. Maria Luisa Di Pietro**  
Professor of Bioethics

**Prof. Luciano Eusebi**  
Professor of Criminal Law

**Prof. Giovanni Federspil**  
Professor of Internal Medicine

**Prof. Silvio Ferrari**  
Professor of Canon Law and Ecclesiastical Law

**Prof. Carlo Flamigni**  
Professor of Gynecological Endocrinology

**Prof. Romano Forleo**  
Professor of History of Medicine

**Prof. Renata Gaddini**  
Professor of Child Psychopathology

**Prof. Silvio Garattini** (2005 - 2006)  
Director of the "Mario Negri" Institute for Pharmacological Research

**Dr. Laura Guidoni** (2005 - 2006)  
Research Director, Istituto Superiore di Sanità

**Prof. Enrico Garaci**  
Director of the Istituto Superiore di Sanità

**Dr. Gianfranco Iadecola**  
Judge of the Italian Supreme Court of Cassation

**Prof. Aldo Isidori**  
Professor of Andrology

**Prof. Corrado Manni**  
Professor of Anaesthesiology and Intensive Care

**Prof. Luca Marini**  
Professor of International Law

**Prof. Benedetto Marino**  
Director of Cardiac Surgery

**Prof. Vittorio Mathieu**  
Professor of Moral Philosophy

**Dr. Simonetta Matone**  
Counsellor of the Court of Appeals serving as Deputy Prosecutor at the Juvenile Court of Rome

**Prof. Demetrio Neri**  
Professor of Bioethics

**Prof. Sergio Nordio**  
Professor of Paediatrics

**Prof. Anna Oliverio Ferraris** (2002 - 2003)  
Professor of Developmental Psychology

**Prof. Laura Palazzani**  
Professor of Philosophy of Law

**Prof. Alberto Piazza**  
Professor of Human Genetics

**Prof. Livia Pomodoro**  
President of the Juvenile Court of Milan

**Prof. Vittorio Possenti**  
Professor of Philosophy

**Dott. Stefano Racheli** (2002 - 2003)  
Judge of the Juvenile Court of Rome

**Prof. Pietro Rescigno**  
Professor of Civil Law

**Prof. Paola Ricci Sindoni** (2005 - 2006)  
Professor of Moral Philosophy

**Dr. Pasqualino Santori**  
President of the Veterinary Bioethics Committee

**Dr. Marco Lorenzo Scarpelli** (2005 - 2006)  
Odontologist - Italian Coordinator of the Dental Ethics and Law Society (IDEALS)

**Prof. Michele Schiavone**  
Professor of Bioethics

**Prof. Elio Sgreccia**  
Professor of Bioethics

**Prof. Bruno Silvestrini**  
Professor of Pharmacology

**Mrs. Annalisa Silvestro**  
President of the Order of Nurses

**Prof. Giancarlo Umami Ronchi**  
Professor of Forensic Medicine

**Prof. Tullia Zevi**  
Chairperson of the Committee for Intercultural and Interreligious Relations of the European Federation of Jewish Communities and member of the Italian Commission for UNESCO.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**TOBACCO USE**

21<sup>st</sup> of March 2003



## PRESENTATION

Smoking is one of the big problems facing society today, both because of its spread and because of the serious harm it causes. It also raises a number of difficult ethical issues, particularly concerning the responsibilities government leaders have towards the public.

The phenomenon afflicts more than 1 billion people, of which 300 million in the Western Hemisphere and more than 10 million in Italy. Tobacco consumption is declining overall in the more prosperous parts of the world, but there is a worrying countertrend among both young people and women. It is also rising sharply in developing nations.

The sales revenues of multinational cigarette manufacturers are roughly 60 times the entire budget of the World Health Organisation (WHO). Taxes on tobacco products also make a significant contribution to government revenues. In Europe alone, it is estimated that the industry employs some 1.5 million people. Tobacco is also one of the most important crops in developing countries, and for some it is their main source of income. It is therefore easy to imagine the serious repercussions that a social policy hostile to the production and consumption of tobacco would have.

In industrialised nations, tobacco consumption, and smoking in particular, causes more death and disease than all other environmental factors put together, including alcohol and other drugs, automobile accidents, occupational hazards, fire, poisons, murder and suicide, and AIDS. Nicotine is addictive and in fact produces a particularly strong degree of dependence. As such, the WHO has classified nicotine as a specific category of drug. The result is what some have called tragic consequences in terms of personal suffering, social costs and healthcare spending, which must not be oversimplified or passively accepted.

It is therefore our duty to understand nicotine addiction and to evaluate all aspects of the issue, a duty which even extends to those who, for whatever reason, feel they have no obligation to join the fight. This is because tobacco has a number of characteristics that set it apart from other substances of abuse. First of all, depending on the circumstances and other contingent needs it can both relax and stimulate, as well as facilitate learning and the ability to concentrate. Secondly, it readily leads to dependence, which means that it is no longer consumed just to enjoy the desired effects, but also to avoid the withdrawal symptoms caused by its absence. Thirdly, in the manner in which it is commonly used, tobacco does not produce symptoms of acute intoxication, such as loss of control of one's actions and socially dangerous behaviour, which are typical of alcohol and other drugs. Finally, the health damage caused by tobacco consumption emerges after long periods of time and in chronic form, meaning that alarm about the health risk it represents is not proportionate to the actual danger.

As mentioned above, tobacco consumption involves numerous powerful interests, producing wealth and well-being through a product sold in a free, unrestricted market. Together with the psychotropic effects of nicotine and the dependence that results, this social and economic aspect is the greatest obstacle in the fight against smoking.

Tobacco consumption raises a number of sensitive bioethical issues, as there is a clear *conflict of interest* between one segment of society and society as a whole. Health is at stake, both that of smokers and non-smokers: a precious gift, a basic right enshrined in the Constitution. But the principle of *self-determination* is also at stake; i.e., the limit to be recognised or defined for the political and social independence of conscious, individual lifestyle decisions, including, and above all, those that are harmful to one's health. As with

all bioethical issues, tobacco consumption is therefore, inevitably, a bio-political, bio-legal, and bio-economic issue. In that vein, the Italian National Bioethics Committee (NBC) has readily accepted the invitation of the Minister of Health, Girolamo Sirchia, to address this issue.

To this end, a working group was formed by members of the NBC (Isabella Maria Coghi, Luigi De Carli, Renata Gaddini, Aldo Isidori, Luca Marini, Vittorio Mathieu, Michele Schiavone, Bruno Silvestrini) as well as experts in the field (Michele Bonanomi, Giuseppe Cipolloni, Loredana Gandini, Antonio Leone, Vincenzo Mastronardi, Giorgio Meneschincheri, Joseph Rocchia, Luciano Saso, Piergiorgio Zuccaro). On behalf of the Committee, I would like to extend our warmest thanks to all of the members of this working group. The group was coordinated by Prof. Bruno Silvestrini, and for the work he has done and the passion, commitment, and time he has devoted, mere thanks is not enough. Prof. Silvestrini has been a member of the NBC from the outset, and the Committee is in his debt for some of the best documents we have produced. As such, on behalf of the entire NBC, I would like to express a very special thank you for all he has done.

Rome, 9<sup>th</sup> of April 2003

*President of the National Bioethics Committee*  
*Prof. Francesco D'Agostino*

## SUMMARY AND RECOMMENDATIONS

Nicotine addiction (or nicotinism), the result of the prolonged and excessive consumption of tobacco, is an addiction in the full sense of the term and is characterised by a high degree of dependence. The extent and seriousness of the problem, as well as the social cost of the related health risk and the strength of the interests involved, make this phenomenon one of the big problems facing society today. It also raises a number of sensitive ethical issues, notably as regards the conflict between the rights of the individual and those of society as a whole, as well as the responsibility government has towards the public.

At the invitation of the Minister of Health, Girolamo Sirchia, the National Bioethics Committee has approached this issue well aware of our responsibilities to both provide information and make recommendations for action. To that end, a working group was formed of NBC members and experts in the field in order to provide an objective overview of the phenomenon and to formulate a number of opinions and recommendations.

### Smoking

The problem of nicotine addiction, for the purposes of this Document, comes from smoking tobacco products, primarily in the form of cigarettes.

Estimates put the total number of smokers in Italy at anywhere from 10 to over 15 million, primarily men. Although smoking is on the decline overall compared with a few decades ago, it continues to increase among women and young people. According to a number of surveys, the percentage of smokers of secondary-school age has reached 35%.

The number of smokers throughout the world is estimated at over 1 billion, and despite anti-smoking campaigns this number is on the rise.

The main active ingredient in tobacco is nicotine, which the World Health Organisation has placed in a drug category of its own (WHO, 1991). As with all other drugs, nicotine has “pleasing, desirable effects, which are at times even helpful, but which are associated with a potential for abuse and other negative consequences both for the individual and society as a whole” (Silvestrini, 2001).

Tobacco’s “pleasing, desirable effects, which are at times even helpful” vary with the circumstances and may include either relaxation or stimulation, as well as an improvement in both concentration and learning. It is likely that the popularity of smoking is explained by its ability to meet a wide range of needs. In that respect, tobacco is more similar to alcohol and marijuana than to opiates or psychostimulants. There are two categories of risk associated with the use of tobacco products, namely dependence and the health hazard, with the serious negative consequences both to the individual and society as a whole. The use of tobacco is not normally thought of in terms of drug abuse, meaning the loss of control of one’s actions typical of other drugs, including alcohol, and this contributes to the overall risk to society.

### Dependence

Dependence is a critical element of the problem, both because it makes it very difficult to quit and because involvement of public health institutions varies based on the signifi-

cance given to this process. It should therefore be analysed in depth, not just in and of itself, but also, and primarily, in relationship with the tendency towards the abuse of drugs in general.

Drugs have always been a part of our history. This fact, together with the information gathered through various epidemiological studies and studies on animals, suggests that the tendency to use drugs is widespread in a significant portion of the population and may have a genetic component. One can see then why the availability of a drug will almost automatically lead to its use. In Italy, it is said that roughly 90% of the adult population drinks a certain amount of alcohol. As mentioned above, the percentage of smokers is lower, yet still significant, and after a period of decline it would seem to again be on the rise with the younger generations. In China, driven by Anglo - French colonial interests, opium use was widespread, so much so that according to contemporary sources it involved as many as 120 million people (Leonzio, 1969).

Obviously, if a drug is unavailable then the tendency to use it has no way of manifesting itself, nor is there any correlation with pathology or deviant behaviour. Nicotine addiction was unknown to Europe before the discover of the Americas, and we can also assume that alcoholism is essential non-existent in traditional Muslim countries, whereas it is relatively common in countries in which alcohol consumption is legal. This is the first fact to take into account, whether it be in relation to nicotine or any other addiction.

However, not all drugs lead to dependence. Furthermore, dependence not only varies from one drug to another, but from one person to another. LSD (Lysergic Acid Diethylamide), and probably other hallucinogens, appear to not produce dependence, but there are other factors which make them dangerous nonetheless. While 90% of the adult population drinks an alcoholic beverage on occasion, the percentage that develops a dependence is relatively low. The frequency of dependence rises sharply both for opiates and, apparently, for tobacco. The disclaimer “apparently” is necessary, however, because while it is well known that nicotine creates a high degree of dependence (Benowitz, 1992), there is no precise data on the number of people who smoke occasionally without developing such a dependence.

Common experience would suggest that this happens relatively infrequently and, in any event, less often than with alcohol.

Dependence is also linked to the manner in which a drug is consumed, as well as to the specific drug and traits of the individual. Opium dependence rose sharply when people began to smoke it and, later, to inject it as morphine, after having taken it orally for millennia with no particular problems. The same can be said of cocaine, the smoking of which led to the much more dangerous form known as “crack”.

As we will see below, dependence is one of the aspects which deserves further research, not just in terms of theory, but also in relation to nicotine addiction and drug addiction in general.

### Physical health risks

A great deal of literature now shows that smoking is the cause of more death and disease than all other environmental factors combined, including alcohol and drugs, murder, suicide, automobile accidents, occupational hazards, fires and AIDS.

The main causes of death are cardiovascular disease, tumours involving a variety of organs and systems, and chronic respiratory illnesses. Each year, the number of deaths due to smoking totals 90,000 in Italy and 3.5 million world-wide. The average life expectancy of smokers is reduced by 6.6 years. To this we can add recurring and chronic illnesses with the consequent medical costs.

Nor should we overlook a side effect of smoking once largely ignored or underestimated: the potential effects on reproduction, which involve both egg and sperm, as well as fertility and foetal development.

The physical damage caused of tobacco consumption are due both to nicotine and to other carcinogenic or genotoxic substances found in smoke as a by-product of combustion. The damage caused by nicotine is largely unavoidable as it is intrinsic to the pharmacological properties of this active ingredient in tobacco.

As for damage caused by the by-products of combustion, it is possible to intervene, both by improving the efficiency of cigarette filters and by turning to forms of intake other than smoking, such as chewing tobacco and nicotine gum.

### **An underrated problem**

Despite the dramatic scale of the problem, nicotine addiction is still largely underrated, not only by the public, but often also by those who are responsible for fighting it. Why is this?

In part, this is because the risks of tobacco consumption mainly involve health problems that arise in the relatively distant future and which may never manifest themselves. This fact tends to lead to a sort of resigned acceptance. And when the problems do emerge, they are of a chronic rather than acute nature, prompting us to lower our guard even further. In fact, people are generally much more troubled by car accidents caused by driving under the influence of alcohol or drugs than by deaths due to smoking, even though the latter are far, far greater both in number and the cost to society. This difference in perception should come as no surprise because it is a response to a fundamental physiological law which links the way we perceive reality more to change than to ongoing situations.

And as we have already seen, ordinary use of tobacco products does not result in the high levels of intoxication typical of alcohol and other drugs, which lead to a loss of self-control and thereby accentuate their danger. This aspect of tobacco consumption is to a certain extent a good thing, but it also causes us to downplay the importance of the problem.

To summarise, the spread of smoking is apparently the result of four factors:

- the specific psychotropic properties of nicotine;
- essentially unfettered access to tobacco, despite recent restrictions which are aimed primarily at reducing risks related to passive smoking;
- the high level of dependence;
- the downplaying of the problem due to the fact that the health risks of tobacco consumption are delayed in time and chronic rather than acute.

The first two factors are to some extent shared by alcohol consumption, while the third puts tobacco consumption in a similar category to opiates. It remains to be seen, however, to what degree dependence is linked to the intrinsic properties of nicotine and how much is due to the act of smoking and, above all, to how quickly smoking allows the body to absorb

the nicotine. The forms of nicotine used to treat smoking deserve further research in that regard. Finally, it is important to point out that dependence involves an “incapacity to maintain an acceptable level of physical and mental well-being without the aid of the drug” (Silvestrini, 2001). This generally accepted definition of dependence implies the morbid aspect of the phenomenon. Both for this reason and the fact that dependence transforms the use of tobacco from free choice to compulsion, as well as for reasons of pure convenience, dependence should be assessed in terms of the overall harm caused by taking the drug. This would then justify including treatment of the addiction as a high priority among the services provided by the public health system.

Prevention would certainly be less costly than the consequences generated by the lack of such measures.

### **Ethical issues and recommendations**

In conclusion, the issue of tobacco consumption concerns both the smoker and the relationship between smokers and non-smokers.

#### ***Smokers***

On one side, we have the smokers, who, although aware of the risks involved, assert their right to use a toxic substance which is legally sold and now a part of our daily lives. At the same time, it is equally important to acknowledge that tobacco consumption is associated with serious health risks, which have only recently been verified and which affect both the smoker and those who are exposed to second-hand smoke. It is therefore necessary to reconsider the implications of smoking and to take steps to reduce related risks, even if this partially limits individual freedom.

Smoking also leads to dependence, which both represents a health risk in and of itself and makes it more difficult for a smoker to quit, which in effect limits an individual’s freedom as well. So together with the right to smoke, we also need to be helped when we want to quit but are unable to do so alone. The health of an individual, which is a fundamental right of all mankind, is to be protected by helping smokers with all of their needs: not only, therefore, in terms of related health problems, which are often irreparable, but also by treating the dependence. The right to good health goes beyond the potential conflict between smoker and non-smoker because it is an issue that concerns both sides. It involves the non-smoker not only in terms of exposure to second-hand smoke, but also in terms of all of the other negative consequences of tobacco consumption which affect society as a whole. At the same time, it affects smokers who not only have to face the health risks of smoking, but who are also not truly free as a result of the dependence that nicotine creates.

With regard to protecting smokers, it is also important to note that the transposition into Italian law of EU directives and the Framework Convention of the World Health Organisation will require governments to introduce stricter controls on the production, advertising, and consumption of tobacco products.

Smoking is currently a legal choice of an individual that cannot be prohibited, except for minors, and which cannot result in a reduction in the healthcare to which every individual has a right, although increased awareness of the damage caused by tobacco consump-

tion places responsibility both on individuals and governments to discourage a phenomenon which presents an obvious health hazard.

### *Non-smokers*

On the other side, we have non-smokers, who need to be protected from the health risks posed by second-hand smoke. In addition to protecting the population of nonsmokers in general, as is already happening to a certain extent, we also need to take specific action for unborn children and minors, who are the most vulnerable and defenceless: an unborn child because it can be affected by damage which takes place during foetal development; and minors because, in addition to the direct harm of second-hand smoke, statistics show that passive smoking can lead minors to becoming actual smokers. As such, we not only need to prohibit smoking in the workplace and other public areas, but also need to discourage it in pregnant or nursing women, with an initial emphasis on providing specific information on the potential hazards (ACOG, 1979). These considerations also apply to the exposure of minors to second-hand smoke in areas such as the home or in cars, not only in areas open to the public.

In view of the foregoing, we must also consider the possibility that pregnant women who are unable to quit smoking could have feelings of guilt when they are aware of the risks generally associated with smoking. In such cases, we must address the problem of preventing depressive behaviour or other reactions, such as overeating in an attempt to compensate, from worsening an already difficult situation. Such situations need to be approached through an intelligent, sound doctor-patient relationship which takes these issues into account.

Turning once again to the fact that smoking inhibits fertility in both men and women, this once-neglected aspect deserves further consideration in that it involves not only smokers, but also their partners and society as a whole.

Finally, non-smokers also have a right to not be automatically forced to bear the social risks of tobacco consumption, which are currently a significant burden on society.

Death and disease caused by this phenomenon leads to a significant commitment of resources, both financial and human, which could be used to meet other legitimate, pressing needs. Only a small portion of this cost is covered by tax revenues related to the production and sale of tobacco products, so without undermining our duty towards the sick, the public is justified in calling for solutions that take the interests of society into account, not just those of smokers.

### *Government*

Our government leaders also have a responsibility to protect both individuals and the public as a whole, in observance of basic human rights. There can be no doubt as to the need for government to be committed to the fight against nicotine addiction. Any doubts only concern the most effective way to handle a situation which, even before the danger was fully understood, had grown to enormous proportions. In addition to smokers, the tobacco industry has a number of stakeholders in the production and sale of cigarettes: not only in terms of tax revenues and the profits of the multinational manufacturers, but also the lesser earnings of the millions of people who, particularly in developing nations, eke out a living growing this “green gold”. It is therefore ethically reprehensible that the government

should profit from the sale of tobacco and that the European Union and other international organisations should fail to take effective action to convert tobacco growers in other crops.

Both for this reason and the importance of the values and interests at stake, individual governments need to work together on an international level, through common strategies and action. Such action should move ahead on five fronts:

- promoting accurate information on the hazards of tobacco consumption. This campaign must involve both smokers and non-smokers. Through the school system, children can be transformed from victims into active players in a civic battle in the name of growth, solidarity and life. It is also essential to count on the full, committed support of the healthcare system, beginning with physicians;
- limiting the damage caused by tobacco consumption through focused anti-smoking campaigns, while at the same time increasing the effectiveness of measures aimed at limiting the extent of the phenomenon and at protecting people from second-hand smoke. We also recommend taking a close look at dependence and treating it as an illness that needs to be cured. Strict application of the quality standards for cigarettes and tobacco products in general is also needed, with particular emphasis on looking out for attempts to deliberately increase dependence;
- engaging in more research into the unknown or little understood aspects of tobacco consumption. For example, more research is needed on the mechanisms of dependence, not only with regard to individual differences, but also in relation to the methods of nicotine intake. In addition to discouraging young people from harming themselves through drug use and to providing assistance after dependence has set in, in-depth research is required into factors of primary prevention. A greater understanding of these and other critical aspects would help in the fight not only against nicotine addiction, but also against drug addiction in general. Taking this into account, the competent ministries should promote unbiased research subsidised by public funding;
- favouring reconversion in the sector, providing assistance to the various producers and companies in the industry. Wealthy nations, which pay the highest price for tobacco consumption in terms of death and disease, must take responsibility for this problem, which is the same as that of other drugs. This is not just a practical obligation, but an ethical one as well;
- prohibiting all types of marketing of smoking - related products and brands, and to enforce effective sanctions. One ethically reprehensible example of this kind of large-scale marketing which still exists today can be seen in motor sports such as Formula 1 racing. This prohibition should also apply to all forms of indirect advertising, such as the use of tobacco brands and trademarks to market other types of products.

Behind all of these, there is a general problem regarding research, in that it must be independent, transparent, accessible, and free of outside influence. It is our hope that the same ethics will apply to tobacco-related research as those that apply to biomedical research in general. The National Bioethics Committee will do what it can to address this issue.

## Conclusions

Nicotine addiction, as with other addictions, should be fought above all through prevention and, when this is not enough, through steps to limit its spread and the related harm. This complex operation involves society as a whole, with particular emphasis on doctors, pharmacists, and the overall healthcare system.

Prevention particularly involves providing information at all levels, including those that concern children and childbirth. In addition to being intrinsically accurate, this information must take account of the special characteristics of the phenomenon which make it difficult to appreciate its true scope and danger. This information needs to be in the form of education, actively involving our young people, not only because they can influence the behaviour of adults, but also because they are the first potential victims of tobacco consumption.

This education must be accompanied by measures aimed at limiting the use of tobacco and the harm it causes both to smokers and those who are exposed to second-hand smoke, particularly unborn children and infants. We should emphasise that the ready availability of tobacco products is in itself a factor which fuels tobacco consumption. While respecting individual freedom, we must consider decisive measures, fiscal and otherwise, aimed at limiting consumption, inhibiting sales and discouraging young people from smoking.

Harm reduction must not only involve treating illness, but also helping people to quit, because dependence limits the freedom of the individual and is the main obstacle in the fight against nicotine addiction.

The fact that the steps taken this far by the various governments, with the support of international and supranational organisations (the UN, WHO, EU), have yet to achieve the hoped-for results should not discourage us. In industrialised nations in which serious policies of information, education and aid to smokers have been implemented, as in Finland for example, smoking -related pathologies (notably lung cancer) have declined. In Italy, the 2001-2003 National Healthcare Plan calls for an institutional information campaign on healthy lifestyles, which deserves recognition and should be pursued with enthusiasm, particularly as regards prevention of the use of this and other drugs.

It is a complex problem, with aspects that go beyond ethical, social and medical to encompass the economy and employment. Therefore, along with all the other measures, we need to convert tobacco production into other crops that can provide sufficient income to everyone concerned, and to study the issue in depth from other points of view, including the therapeutic standpoint.

## I. THE ISSUE IN CONTEXT

### 1. Historical and introductory comments

Tobacco (*Nicotiana tabacum*) is an annual plant of the Solenaceae family originating in America. In pre-Colombian times tobacco was a deep-rooted part of all indigenous ethnic traditions, cultures and religious rites, from North to South America. The Aztecs generally smoked tobacco in decorated pipes or as cigars; priests chewed the plant until they entered a state of trance. The ancient Peruvians used to inhale tobacco powder for ritual and medical purposes. Many South American tribes burned or laid out tobacco powder as an offering to the spirits and gods. Tobacco was also one of the most common stimulants used to initiate shamanic contacts. North American tribes (Navajo, Hopi, Pueblo, Sioux and Plains Indians) adopted tobacco to induce visions that put them in touch with the extra-sensorial world. Tobacco was seen as a sort of gateway because of the symbolic value of smoking and the plant's intrinsic stimulant properties, which could even induce full-fledged hallucinatory states. Such states were probably generated after mixing tobacco with other ingredients such as *Cornus stolonifera* bark, or substances that are either unknown or little known to us. Since then, selection by growers has also probably altered tobacco's original properties.

Tobacco was first brought to Europe in 1500. To begin with it was a luxury, and for a while it retained specific (if understated) connotations of its initial psychotropic properties, uses, rituals and ceremonies. From Europe, tobacco spread around the world. Nowadays, *Nicotiana tabacum*, which is also available as a genetically modified congeneric, is almost exclusively grown to make smoking tobacco, consisting of the plant's dried and cured leaves. Unless otherwise specified, information in this document refers to this use of tobacco. It is estimated that every year Italians spend over 8 million on cigarettes alone.

The properties of tobacco are essentially attributable to nicotine, a liquid, oleaginous and volatile alkaloid. Present in the leaves at concentrations of between 1.6% and 9%, this substance acts on the ganglia of the nervous system, which serve as a gateway to a host of central and peripheral functions, both stimulatory and inhibitory, including paralysis. The impact of nicotine varies depending on the dose: at low doses it more often than not leads to stimulation, while high doses result in inhibition, and can even bring on paralysis. Vasoconstriction predominates at arterial bed level, along with increased blood coagulability. Individual responses to nicotine in part depend on genetic and environmental factors. An individual may at times obtain a sensation of pleasure and peace from a cigarette, and feel stimulated at other times. Beneficial effects have also been recorded in regard to learning abilities and focus. In the extraordinary breadth and variety of its effects, tobacco is similar to alcoholic beverages and cannabinoids, which explains the widespread uptake of these drugs wherever they are easily available. By way of comparison, the effects of opiates, cocaine and amphetamine-like stimulants are, generally speaking, much more circumscribed.

Over time, the body counteradapts to nicotine by developing opposite functions. Two closely-associated phenomena result: tolerance (also known as resistance), and dependence. As we shall see further on in this document, both of these reactions are to a large extent the expression of an originally defensive counteradaptation designed to restore the body to its original functional state.

According to the *Diagnostic and Statistical Manual of Mental Disorders Fourth Edition* (DMS-IV) and the *Pocket Guide to the ICD-10 Classification of Mental and Behavioural Disorders* (1994), nicotine is classified as a substance of abuse. It is, however, placed in a special category, because usage does not normally produce acute mental perturbations, such as loss of control over one's own actions, as has been observed with other drugs, hence their levels of danger (WHO, 1991). In addition to nicotine, the tobacco plant also contains low levels of other alkaloids such as lobeline, anabain and nornicotine, whose effects are fairly similar to nicotine.

Four developments led to the relatively recent awareness about how dangerous tobacco truly is: widespread tobacco usage and addiction among increasingly broad segments of the population; as life spans gradually increase, evidence of the delayed effects of smoking – particularly carcinogenic effects – which had previously remained latent; widespread and far-reaching epidemiological surveys, showing the correlation between tobacco consumption and specific pathologies; and scientific research, which as well as isolating, identifying and specifying tobacco's active ingredients at a toxicological level, have also confirmed the mutagenicity and carcinogenic effects of tobacco combustion.

Tobacco also has a number of positive characteristics. Nicotine continues to play a key role in pharmacological and physiological research. The history of tobacco, not to mention recent epidemiological surveys and experiments, suggest that it does have potential therapeutic interest; further experiments should be carried out with regard to its effects on certain neurodegenerative diseases. Nicotine and the powdered leaves of *Nicotiana tabacum* and its congener *Nicotiana rustica* were both used as insecticides for agriculture, before being superseded by more powerful – although not necessarily safer – artificial pesticides. The general principle that drugs and their active ingredients are harmful or useful not in themselves and for themselves, as a function of their intrinsic properties, but rather in relation on the dosage and use people make of them, applies as much to tobacco addiction as it does to alcoholism and other toxicophilia.

The Solanaceae family includes many other plants aside from tobacco. Some of these plants, such as the potato, tomato and pepper, are well-known foodstuffs. Others, including *Atropa belladonna*, *Datura stramonium*, *Datura sanguinea*, *Hyoshyamus niger*, *Scopolia carniolica* and *Mandragora officinarum* are predominantly of pharmacological interest. At high doses these plants produce psychotropic effects that can be similar to those originally ascribed to tobacco. One typical example is *Datura stramonium*, known in the Middle Ages as devil's trumpet weed owing to its hallucinatory properties. This effect was apparently produced by the scopolamine the plant contains – scopolamine is also known as “truth serum” because anybody who takes it becomes bewildered and loses their ability to exercise self-control. It is possible that such effects originally applied to tobacco when administered in high concentrations. As well as this substance, a number of plants in the Solanaceae family contain other substances of significant pharmacological interest.

Tobacco is an important issue with ethical, medical, social, legal, scientific and economic aspects. This Document, drafted at the request of Italian Minister of Health Girolamo Sirchia, examines the issue of tobacco from a bioethical standpoint, without losing sight of the twin responsibilities of this Committee: to provide information and submit

recommendations<sup>1</sup>. The first section of the document outlines the principal characteristics of tobacco addiction, while the second offers suggestions on how best to tackle this problem.

## 2. Reasons for smoking

Why do people start smoking?

Many people smoke their first cigarette when they are children, in their own home, hidden from their parents. Others have their first cigarette with friends at school.

There are many complex reasons why people start smoking. Only by careful analysis can we begin to understand these reasons: the natural curiosity we feel for anything that is new, particularly if it is forbidden; the symbolic value of conduct which, for young people, symbolises initiation into the adult world; for women, emancipation from a particular state of submission; man's two basic temperaments, which by different routes lead to the same result as the leader rules by thwarting danger and laws, while the follower imitates to be accepted as part of the group, and therefore feels more secure than he otherwise would be on his own; an act of rebellion against one's family and society, or, vice versa, the quest for a crutch to cope with difficulties at school, work or in any other context; boredom and dissatisfaction with one's life.

Yet other factors reinforce these reasons: the free availability of the drug in the form of easy-to-buy cigarettes, or in some cases, free availability at home.

All of these general reasons could equally be applied to other social phenomena: Saturday night street racing, which can often be fatal; fashion and the imitation of charismatic people, which prompts many young people to dress up like and mimic the body language of their models, often in large groups at concerts or night-clubs. This is not to devalue the reasons why people start smoking; on the contrary, precisely because these reasons are so deeply rooted in human nature shows how difficult it is to resist. Dogmatic opposition to smoking may even perversely reinforce these motivations. This would appear to be true of educational campaigns which, because they only emphasise how dangerous the drug is, can actually increase the appeal of smoking to young people, particularly those for whom smoking is a way of breaking the rules, rebelling against society, standing up for themselves and showing how reckless they are.

Whatever the initial impetus, everything changes when the effects of tobacco begin to manifest themselves. Many people remember a feeling of nausea, dizziness and palpitations when they smoke their first cigarette. Yet only rarely does this prevent people from trying again. This is partly because these feelings are perceived as a sign of weakness which is best concealed and overcome. These symptoms lessen the second time round, and then they disappear. This is when the hallmark effects of tobacco fully emerge.

---

<sup>1</sup> Pursuant to Article 1 of its founding Act, the National Bioethics Committee has been assigned the following duties:  
- preparing an overview of the programmes, objectives and results attained by research and experimentation in the field of life sciences and human health, where necessary by obtaining all necessary information (...);  
- formulating Opinions and recommending solutions, where necessary for the purpose of preparing legislative acts, (...) having regard to the protection of fundamental human rights, dignity, and other values as set forth in the Italian Constitution and in international agreements that Italy has signed.

Unlike other drugs, the mental effects of tobacco and nicotine are not associated with an appreciable risk of abuse. On the contrary, research carried out initially on animals (Bovet *et al.*, 1966) and then on human beings shows that effects include improved concentration and ability to learn, along with both calming and stimulating properties. It has been shown that nicotine interferes with the *Nucleus accumbens*, a structure in the brain that is involved in the perception of pleasure. These effects lend smoking its appeal, and explain why it is so widely prevalent.

It is worth remembering that despite their differences, all drugs are accompanied by pleasurable, desirable mental effects which, in some cases, may even be useful. These effects deactivate mechanisms that keep a number of major mental processes within certain physiological boundaries. Some drugs reduce unpleasant signals such as pain, anxiety and fear, and produce a feeling of relief that diminishes the perception of how dangerous the drugs really are. Other drugs deactivate the alarm signals triggered by fatigue, hunger and thirst, enabling people to exert themselves in ways that otherwise would be impossible.

These are the core characteristics of drugs, the fundamental reason why people start using them. Drugs open up a whole range of feelings and effects that, though they may be dangerous, are pleasurable and, in some cases, useful. Tobacco is no exception to this rule. It is impossible to fight tobacco addiction without bearing this in mind.

The harmfulness of drugs sometimes depends not just on their intrinsic characteristics but on other factors such as dosage, how the drug is taken, the environment, social context, constitutional factors and other inputs. In the case of tobacco smoking the list unfortunately includes exposure to serious risks, which it would be unforgivable to underestimate.

### 3. Addiction

Initially, smoking is the consequence of an essentially free and voluntary choice. Subsequently it tends to become a compulsive need, not so much to reproduce the initial effects but to avoid the withdrawal symptoms that occur when it is not possible to smoke. This phenomenon, known as drug addiction or dependence, is a common feature of most drugs, and is one of the most challenging and complex aspects of the whole issue.

A group of experts at the World Health Organisation have defined drug addiction as: “a psychic and sometimes physical state resulting from the interaction between a living organism and a drug, characterised by behavioural changes and other reactions, which include a drive to take the drug in a continuous or recurrent manner in order to recreate the psychic effects and avoid withdrawal symptoms.” (WHO, 1973). Incidentally, in addition to being included in the drug section of the *Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DMS-IV)* and the *Pocket Guide to the ICD-10 Classification of Mental and Behavioural Disorders* (1994), nicotine is also classified as a drug by the World Health Organisation in a special category.

Though not explicitly stated, the above definition implies the concept that drug addiction involves an inability to maintain a state of physical and mental well-being without taking that drug. If we accept that physical and mental well-being corresponds to good health, and that a lack of these elements corresponds to illness, then drug addiction becomes a disease: a disease that, paradoxically but hardly uncommonly, is alleviated by the very agent that caused it in the first place. These basic and elementary concepts will

be examined and discussed in relation to three issues of significant ethical importance: the so-called medicalisation of drugs, which in the case of tobacco addiction corresponds to the administration of nicotine; the more general medical characteristics of all drug addiction, tobacco addiction included; and the National Health Service's responsibility for treating such addiction.

Notwithstanding the negative consequences, drug addiction is an expression of homeostasis, a defence mechanism that underlies life in all of its manifestations, from the most basic to the most complex and highly organised. This ability makes it possible to maintain one's own inner state through functional adaptations designed to neutralise disturbances. For example, if the body temperature rises too much, it is reduced by dissipating excess heat through sweating and peripheral vasodilatation; if the body temperature goes down, opposite adjustments take place.

The same is true of drugs. The common denominator drugs share, despite their differences, is their ability to free the mind from the bonds that keep it on the safe if somewhat restricted plane of normal conduct. Depending on the drug, this can generate feelings of pleasure, freedom from physical and mental suffering, greater strength and selfconfidence, or an escape from reality. Pleasurable as they may be, these feelings also have a dangerous side. The body perceives this danger and, depending on the effects of that particular drug, takes measures necessary to neutralise it.

Opiates have a calming and relaxing effect; they soothe physical and mental suffering, reduce anxiety and lighten the burden of living. They also generate neurovegetative manifestations: miosis, a slowed heart rate and breathing; constipation; and low blood pressure. These alterations are counterbalanced by functional changes in the opposite direction: hypersensitivity to pain rather than analgesia; hyperexcitability rather than sedation; increased anxiety rather than sedation; mydriasis rather than miosis; more rapid breathing rather than slow breathing; diarrhoea rather than constipation, and so on.

The body reacts to sympathicomimetic psychostimulants – which have different, generally opposite properties to opiates – by depressing the central nervous system and making cholinergic rather than adrenergic neurovegetative changes: miosis, low blood pressure, slower breathing and heartbeat.

The nicotine in tobacco generates far more complex mental effects at its point of entry, the neuronal ganglia which regulate a host of central and peripheral nervous functions. These effects, which make smoking “pleasurable, desirable and sometimes even useful”, fall within a framework which, depending upon circumstances, may respond to the need to calm down, or, conversely, become excited. At the same time, concentration increases and learning abilities improve. In all likelihood, the popularity of smoking may be explained by the fact that it does not simply satisfy circumscribed needs, as is the case with other drugs. If anything, in terms of its effects smoking can be compared with alcoholic beverages and cannabinoids. The body's counteradaptation, which leads to dependence, is just as complex, as it is the mirror image of tobacco's effects on central and peripheral functions.

Manifestations of addiction are not perceived as long as the drug counterbalances them, although they are present within the body. This is demonstrated by the fact that as drug addiction progresses, the quantity of the drug needed to reproduce the initial effects increases, and tolerance begins to establish itself. In the case of tobacco, this can involve increasing from a few puffs on that first cigarette, which provoke a sensation of

stupefaction and dizziness, to 20, 40 or, in extreme cases, 80 cigarettes per day, a quantity that no longer causes any such problems. Describing drug addiction in terms of a homeostatic reaction (a natural defensive process) should by no means undervalue its importance. The body restores its own functional state by reacting to the drug and the changes it induces. In order to preserve its equilibrium these changes must be counterbalanced by an opposite force. What this means is that the body enters an unstable balance that is not the same as physiological balance, because the drug is necessary to maintain equilibrium. The withdrawal symptoms the body suffers if the drug ceases to be available are the exact opposite of the drug's initial effects. Simply stated, the counteradaptations express themselves with violence. During withdrawal from smoking people become irritable, find it hard to concentrate, suffer from sometimes high levels of bradycardia, and so on. Withdrawal from opiates includes hyperalgesia, increased sensitivity to physical and mental pain, excitement and adrenergic stimulation. Withdrawal from adrenergic psychostimulants leads to dejection, narrowing of the pupil and other similar effects.

The explanation is simple enough. Addiction only applies to drugs because they are the only substances that can deactivate highly unpleasant alarm signals, such as physical and mental pain, while at the same time offering a mental perception that makes it possible to recognise this at a conscious level. In order to return to its initial state, the body must hyperactivate them. This functional counteradaptation is not perceived as long as it is offset by the drug's opposite effects, but if the drug is no longer taken, the result is an intolerable sensitivity to pain and other highly unpleasant psychic and physical phenomena. This is the reason why only drug addicts undergoing withdrawal associate their suffering with the lack of the drug, and have such a clear and insistent need to procure it.

The strength of these effects varies from drug to drug. It reaches a peak with opiates, which act on a mechanism that is indispensable for survival, the alarm signal inherent to physical and mental pain. Psychostimulants, which intervene on mental processes for which the body allows a certain leeway in either direction, generate intermediate-level affects. There are practically no such effects for hallucinogens, because their point of entry is not subject to any strict control; dreams, for example, allow our mind to wander physiologically, completely detached from reality, without any restrictions whatsoever.

The withdrawal effects from smoking vary considerably, but they can be so strong that for some people giving up is an extremely arduous task. There are documented cases of people who have continued to smoke after suffering smoking-related maladies, such as heart attacks or the necrosis of a limb from Burger's disease, which can be directly associated to the effects of nicotine.

How strong addiction to a drug actually is varies from person to person as well as from drug to drug. Some people become addicted after just a few exposures, while others require longer exposure. Some people can walk away from drug addiction easily; others are unable to do so even when they suffer its devastating effects.

In all likelihood, susceptibility to drug addiction is linked to hereditary factors, though this is not easy to ascertain with any degree of certainty. What we can say is that people generally fall between two extremes. Drug addicts lie somewhere between a strong constitutional predisposition on which external influences have only a minor impact, and the opposite tendency, when external factors play a key role.

## 4. Harm

### 4.1. General features

It is estimated that there are more than 1 billion smokers in the world. The number is in decline in Western industrialised nations, while among lower income population groups the trend is moving in the other direction, as it is in developing countries. Bearing this in mind, unless current trends are reversed, by 2025 it is forecast that there will be more than 1.6 billion smokers world-wide.

Around 25% of Italy's adult population smokes: 32.2% of men and 18.2% of women. Geographically, 26.2% of people living in North-western and Central Italy are smokers, 24.5% of Italy's island residents, and 23.8% of the population in the South and North East.

Education levels are a predictor of smoking in men: 27.4% of male university graduates smoke, against 31.8% of men who left formal education after school, and 36.8% of men who left school early.

Women started to take up smoking in the late 1920s. The number of women smokers increased gradually, until it had doubled by the 1950s. To begin with, smoking was more common among the more educated classes. This tendency is still evident among women who are now aged sixty or more: 18.6% of university graduates are smokers, compared with 14.5% of women who did not continue education after school and 13.2% of women who left school early. Among later generations, 20.4% of university graduates are smokers, compared with 23.5% of secondary school graduates and 28.7% of women who left school early. These figures provide food for thought, as they indicate that awareness of the dangers of smoking increases with levels of education.

By age, 6.2% of smokers began before the age of 14, while 44.7% started between the ages of 14 and 17. Overall, more than half of the smoking population began before they were 18. On average, men smoke 16.3 cigarettes a day, and women smoke 12.1; 14.3% of men and 4.6% of women smoke more than one pack per day. Interestingly, the average age at which men give up is 37.1, against 57.1 for women.

The profile of smokers that emerges from ISTAT data indicates that the typical young smoker has medium to low-level education, lives in North or Central Italy, and both of his/her parents are smokers. Maternal behaviour seems to have the greater impact: 31.3% of children smoke when only their mother is a smoker, compared with 22.2% if only the father smokes. This gap is even more pronounced, in relative terms, for daughters: if the mother is a smoker, 29.2% of daughters become smokers, as against 14.0% when only the father smokes.

In the past, young people attempted to conceal their smoking from their parents. Nowadays, it is parents who try not to smoke in front of their teenage children, because of increased awareness about the health dangers of passive smoking, and because they do not want to provide a negative model. In the United States custody decisions take into account whether or not parents are smokers; attitudes remain very different in Italy, thankfully so in the eyes of some observers.

Tobacco smoke contains more than 4000 substances, many of which are carcinogenic or harmful to breathing, such as carbon monoxide. As explained elsewhere, nicotine is responsible both for tobacco addiction and its complex mental effects, including improvements to cognitive processes, concentration and psychomotor performance. Nicotine also

has tranquillising and euphoric properties. These effects bring the feeling of pleasure that prompts people to smoke: nicotine's positive reinforcement.

Then there are the withdrawal syndromes, characterised by anxiety, poor concentration, irritability, insomnia and physical symptoms such as bradycardia, all elements of negative reinforcement: people smoke not because they like smoking, but because they do not want to suffer withdrawal.

Tobacco smoke addiction is acknowledged as a pathological condition in the 10<sup>th</sup> revision of the World Health Organisation's international classification of diseases, and in the American Psychiatric Association's Diagnostic and Statistic Manual.

It is difficult but not impossible to give up smoking. There are around 6 million ex-smokers in Italy at present, most of whom gave up because they became aware of its ill effects on health. Some people can quit by force of will alone; others require some kind of support, whether it be psychological or pharmacological, in the latter case generally nicotine-based (nicotine replacement therapy or NRT). Both of these options are examined elsewhere in this document.

In most developed countries cigarette smoking is the largest single cause or joint cause of avoidable death. Every year tobacco consumption is responsible for the death of around 3.5 million people around the world: that is 7 every minute.

Smoking-related pathologies are responsible for 10% of adult deaths. Active smoking is the main predictable cause of morbidity and mortality in Italy and the rest of the western world. The most common smoking-related pathologies are chronic obstructive pulmonary disease (COPD) and cardiovascular diseases. It has been documented that dose-dependent cardiovascular diseases increase fatal and non-fatal ischaemic cardiac events. It is estimated that every year in Italy around 90,000 deaths are caused by tobacco smoking, over 25% of which involve people between the ages of 35 and 65.

Awareness of tobacco addiction's ill effects on health, in addition to its social and economic costs, has led to a lively debate about what measures should be put in place to contain these ill effects and distribute the social and economic cost fairly. The main areas of discussion are:

- the prevention, diagnosis, treatment and rehabilitation of smoking-related pathologies;
- lost earnings as a result of time away from work owing to smoking-related pathologies;
- loss of future earnings owing to early death.

It is extremely difficult to assess these costs with any precision, owing to the considerable complexity, variability and subjectivity of the factors involved. Nevertheless, even rough estimates are staggering, which is why more and more effort is being put into fighting tobacco addiction. Moreover, in addition to the smoking-related pathologies listed above, smoking is also deleterious to reproduction – something that has only emerged relatively recently. This aspect of smoking deserves a section apart, as it concerns the very heart of life itself, and might in future have devastating effects.

#### ***4.2. Smoking and reproduction***

Chronic exposure to cigarette smoking can seriously damage reproductive functions. Smoking affects not just the gonads – in different ways for each sex – but also embryonic, foetal and postnatal development.

Research into natural and assisted fertility has expanded our understanding of the effects of smoking on gametes, embryos and ovulation.

Various epidemiological studies show that on average female smokers take more than one year to conceive, much longer than is the case for non-smokers (Weinberg *et al.*, 1989). After five years of unprotected sexual relations, 10.7% of women smokers have failed to conceive, compared with 5.4% of women non-smokers (Hughes and Brennan, 1996). A meta-analysis (Augood *et al.*, 1998) of 11 different clinical studies backed up these results. It is believed that infertility and delays in conception are the result of the influence of smoking on gametogenesis, fertilisation, implantation and very early subclinical loss of embryos after implantation.

The meta-analysis also came to similar conclusions regarding assisted fertilisation. The number of oocytes retrieved from smokers was 17.2% lower than from non-smokers; in many cases, it was necessary to administer higher doses of gonadotropine to induce multiple ovulation. Both of these phenomena seem to indicate depletion of the ovarian follicular reserve (El-Nemr *et al.*, 1998). Age and smoking may act in concert to accelerate follicular atresia. Epidemiological evidence that the age of menopause is 1 1/2 years earlier in smokers (Midgotts and Baruh, 1990) would tend to indicate follicular depletion and this hypothesis. The same phenomenon has also been observed in rodents following exposure to benzopyrene.

Reduced fertility has also been perceived to be the result of interference in the maturity levels of oocytes. This tallies with the results of tests on animals, in which meiotic development was blocked following the administration of nicotine and cadmium.

Studies on unfertilised human oocytes as part of an assisted conception programme revealed a high dose-related frequency of diploid oocytes among smokers (Zenzes *et al.*, 1995). It is probable that because meiotic division takes longer, this increases exposure to external attack, and therefore provokes modifications to cytoplasmic structure and in consequence the lower levels of maturity associated with increased numbers of diploid oocytes.

Cotinine, a metabolite of nicotine, and benzopyrene, which is known to be carcinogenic, have been found in follicular liquid and granulosa-lutein cells.

Studies conducted on couples undergoing assisted conception yield data on the effects that smoking has on male fertility (Josbury *et al.*, 1998). In cases where only the male partner was a smoker, there was a reduced number of conceptions per year, and a reduced incidence of pregnancies that continued beyond the 12th week. These figures are probably ascribable to the presence of sperm with chromatinic modifications, which prevent the zygote from developing normally.

If we look more closely at damage to testicular functions, we find that cigarette smoking interferes with a number of different phases of gametogenesis. From puberty to old age, human spermatogenesis is characterised by the continuous production of germinal cells. These cells become vulnerable to environmental toxin exposure when they enter into meiosis I and II. Spermiogenesis – the process that turns spermatids into spermatozoons – is another period of increased susceptibility to point mutation. Of all the cells that form the germinal line, spermatogonium and spermatocyte cells have the ability to repair DNA damage. They also incorporate other mechanisms that can eliminate distorted cells and cells that have reduced vitality. During the final phases of differentiation, spermatids have practically no ability to effect repairs: once the chromatine has condensed DNA damage can no longer be repaired. This is why ejaculated spermatozoons risk passing on genetic damage (Zenzes, 2000).

A number of epidemiological and research studies have shown that cigarette smoke can also negatively impact male fertility by altering the characteristics of seminal fluid. This suggests that certain components of cigarette smoke directly or indirectly interact with male gametes by modifying their function and vitality. A number of scholars have described the alterations generated by smoke on the amount of ejaculate, as well as on nemasperm concentration, motility and morphology (Evans *et al.*, 1981; Shaarawy and Mahmoud, 1982; Pacifici *et al.*, 1993). Differences between one research project and another may reflect not just the number of subjects taken into consideration, but the type of cigarettes smoked; furthermore, different criteria apply to the classification of smokers according to how many cigarettes they consume on a daily basis.

We do not yet know precisely what mechanisms are affected by the toxicity of substances contained in smoke. As we have already seen, tobacco combustion generates more than 4000 chemical compounds (including nitrosamine, polycyclic aromatic hydrocarbons, cadmium and carbon monoxide) which can affect spermatogenesis and directly or indirectly damage nemasperm DNA.

It has been reported that certain elements of cigarette smoke have been found in seminal plasma. Nicotine, cotinine and trans-hydroxycotinine (THOC) have been measured as markers of smoke intake using specific sensitive methods such as HPLC and RIA. Concentrations of cotinine and THOC prove to be similar in seminal plasma and serum, indicating an exchange between these two elements. These observations support a paper (Pichini *et al.*, 1992) that reports a high correlation between concentrations of cotinine in various sections of the body (serum-saliva, serum-urine, saliva-urine). Nicotine concentrations in seminal plasma is higher than in serum, which suggests that because nicotine is a stronger base than cotinine and THOC, like other basic substances it can accumulate in seminal plasma (Pacifici *et al.*, 1993).

It has also been observed that the negative effect that smoking has on the vitality and motility of spermatozoa is not so much caused by nicotine and cotinine, but by the combined action of a number of compounds including the hydrocarbons, aldehydes and ketones present in cigarette smoke (Gandini *et al.*, 1997).

Cigarette smoke contains a high concentration of oxidising agents which are capable of altering the quality of semen. All of these effects may be correlated to the dosage and duration of smoking involved. As these oxidising substances are highly reactive mutagens, it follows that heavy smokers run an increased risk of DNA damage.

Bibliographic evidence shows that smokers suffer a significant rise in oxidative damage to nemasperm DNA compared with non-smokers. This increase is proportional to the concentration of oxidising substances present in cigarette smoke (Fraga *et al.*, 1996).

Because spermatozoa are unable to repair this damage, the oxidising agents that accumulate during the final spermiogenesis phases may increase the likelihood of passing mutations on to the zygote.

However, the greatest risk factors associated with smoking are those which take place during pregnancy, between conception and birth, owing to their impact on natal and perinatal development.

One in four women of fertile age is a smoker (ISTAT, 2000). Of these, 62% of women stop smoking during pregnancy, 30% cut down on their daily cigarette intake, and 7.4% continue smoking as before. These figures indicate a certain degree of awareness that smok-

ing is harmful. Italy's 2001-2003 National Health Plan set a target of reducing to zero the number of expectant mothers who smoke.

As we have already seen, cigarette smoke has a large number of toxic substances. Extensive studies conducted into carbon monoxide and nicotine show that these substances can cross the placental barrier. Carbon monoxide bonds with the foetus's haemoglobin to form carboxyhaemoglobin, reduce oxygen supplies and cause chronic foetal hypoxia. Because it is a vasoconstrictor, nicotine reduces utero-placental circulation and negatively impacts foetus development, particularly central nervous system development (Mooichan and Robinson, 2001).

The negative effects of smoking span the entire pregnancy, and give rise to a variety of pathologies:

- an increased risk of spontaneous abortions, with a relative risk of 2 for women who smoke more than 20 cigarettes per day (Coste *et al.*, 1991). We have already covered the damage that takes place during the early phases of fertilisation and implantation, leading to early termination. Experimental data also indicates a generalised dysfunction of the trophoblast. Specifically, reductions have been observed in placental aromatase activities and growth factor receptors involved in differentiation processes;
- risk of extra-uterine pregnancy, which reaches a relatively high figure in women who smoke more than 20 cigarettes per day (Bouyer *et al.* 2003);
- a delay in intrauterine growth, with an average reduction in birthweight of around 200 g from active smoking and 80 g from passive smoking (Roquer *et al.*, 1995);
- breakage of membranes and the risk of premature birth in around 15% of smokers. On the contrary, it appears that the risk of pre-eclampsia is lower in smokers, with a reduction in relative risk of 0.38% in women who smoke more than 20 cigarettes per day, though this data is neither easy to interpret nor confirm. It should also be noted that where this pathology does occur, it can be harder to tackle: specifically, perinatal mortality rises from 24 to 36 per thousand;
- an overall increase in perinatal mortality, from 23.5 per thousand in non-smokers to 28.2 per thousand in women who smoke fewer than 20 cigarettes per day and 31.8 per thousand in women who smoke more than 20 cigarettes per day (Andres and Day, 2000);
- sudden infant death syndrome (SIDS) is three times more likely in the presence of smoking (Wisborg *et al.*, 2000). Recent data suggests that this is the result of exposure to nicotine during foetal life, which has an adverse effect on the regulation of respiration in sleep.

It should nevertheless be noted that not all agree that there is a direct correlation between smoking and perinatal mortality, spontaneous abortion, malformations, and the probability of illnesses occurring in early infancy. It has, for example, been observed that a high number of women smokers are also at risk from factors of a socio-economic nature: often, they are underweight when the pregnancy commences; there are many unemployed women smokers – and the wives of unemployed men – who might have diet and stress problems; many women smokers eat in an irrational fashion and suffer from a lack of essential vitamins, amino acids and fatty acids; all stressful events in pregnancy may be mediated by smoking. Many women smokers have respiratory problems which show up in gas analysis, while in some cases there seems to be a tendency for smokers to drink a great deal of coffee, ignore certain rules of hygiene, and so on. Nevertheless, the fact remains that smoking

exposes the mother and baby to harmful substances in addition nicotine, which is universally classified as a drug. Disappointingly, persuading women not to smoke has proven to be a relatively unsuccessful and sometimes even contradictory practice. Many women react in a “psychologically adverse” fashion, and unconsciously turn to other bad habits such as a diet excessively high in sugar. It is not hard to understand how bad a woman may feel, assailed by feelings of guilt and subjected to continuous family pressure, when they discover that they are incapable of giving up their vice. In consequence, it is even more important to tackle this problem in all of its complex ramifications, as part of a healthy relationship between the pregnant woman and her doctor.

A number of smoking by-products, including nicotine, have been detected in maternal breast milk. Additionally, the presence of the cotinine metabolite has been reported in baby biological fluids.

The negative effects of smoking on babies after birth and during early infancy are well known. Children of smokers have been shown incontrovertibly to suffer a significant increase of up to twice the incidence of acute respiratory problems in the upper and lower airways. Surveys carried out in Italy indicate that passive smoking is involved in 15% of child asthma cases. More generally, statistics show an increase in the hospitalisation of children who have been exposed to passive smoking.

## 5. Detoxification and recovery

Increased awareness about the harmfulness of smoking, allied with the large number of smokers who are keen to give up, have transformed quitting into one of the cornerstones of the fight against tobacco addiction. In the frontline of this battle are doctors and pharmacists during their daily contacts with the public, other health workers and researchers, who are working to improve currently available treatments. Greater involvement by the Italian National Health Service would be a boon. The National Health Service should take this task on because addiction is in itself a disease, and because the costs of intervention would be amply offset by the medical and social benefits. To cite just one aspect of the problem, it has been calculated that halving the number of smokers in Italy would prevent between 15 and 18 million premature deaths over the next 50 years. The main methods that have proven to be effective are:

- Advice from physicians and pharmacists;
- Medical and paramedical assistance;
- One-on-one counselling;
- Group therapy;
- Nicotine replacement therapy;
- Bupropion.

Insufficient grounds exist to enable recommendation one of these activities over the others. We consequently offer a general overview below, on the basis of a Cochrane Review that followed strict criteria and which have been incorporated into the latest UK and US guidelines. Greater detail is available in the Italian document provided in the Appendix, which also references Medline, Embase and Cochrane Library databases between 1990 and March 2001.

### 5.1. *Intervention by physicians and nurses*

The effect of straightforward doctor's advice has been analysed in an assessment of 31 controlled and randomised studies (Silagy, 2001). Some of the smokers were at risk of pulmonary pathologies, diabetes and coronary heart disease, while others were unselected. Doctors' advice proved to be effective, particularly during intensive (rather than short) sessions.

A second review analysed the effect of recommendations and other interventions by nursing staff, compared with no intervention or other treatment (Rice and Stead, 2001).

Undertaken predominantly in hospital outpatient facilities, such action proved to be effective, and influenced patient behaviour outside the hospital environment as well. In such cases, more intense, frequent and longer-lasting interventions were no more effective than less intensive forms of intervention.

### 5.2. *Counselling*

A systematic review of 11 controlled and randomised studies showed the effectiveness of one-on-one counselling, which is defined as an individual session lasting longer than 10 minutes with a counsellor skilled in this particular field (Lancaster and Stead, 2001a). No significant difference was found between one-on-one counselling and so-called minimal interventions (sessions lasting fewer than 10 minutes, self-help material and standard assistance).

A further systematic review of 19 studies analysed the effectiveness of group therapy, lasting at least two sessions, during which attendees received information, recommendations and encouragement, and underwent cognitive-behavioural therapy reinforced by reciprocal support (Stead and Lancaster, 2001). Group therapy proved to be more effective than self-help material alone. No significant difference was detected between group therapy and even a brief intervention by a doctor or nursing staff. Both one-on-one counselling and group therapy differed so greatly from one study to the next that it is not possible to recommend one method of treatment over the others.

### 5.3. *"Aversion" therapies*

A number of methods were developed in the 1970s based on the association of an unpleasant stimulus with the pleasurable stimulus to smoke:

- "rapid smoking": asking a person to smoke many cigarettes in quick succession (inhaling every 6-10 seconds) and focus on the unpleasant sensations;
- asking the person to smoke more than they want;
- asking the person to smoke while concentrating on the negative sensations or visualising the harmful effects;
- "rapid puffing": rapid puffing without inhaling.

Unfortunately the 24 published studies (Hajek and Stead, 2001) were of a low methodological standard (low statistical power, self-referential measures and similar). Silver acetate in pills, sprays and chewing gum, which makes cigarette smoke taste unpleasant, did not prove to be any more effective than a placebo in two studies (Lancaster and Stead, 2001b).

#### 5.4. Self-help material and telephone counselling

Several different types of self-help material have been developed in recent years, ranging from audio and video cassettes to more recent computer programs (Lancaster and Stead, 2001c). According to nine studies, personal contact appears to have only a minimal influence on the effectiveness of these tools. Eight studies, however, show a statistically significant difference between standard material and material that has been tailored to suit individual characteristics.

A recent review published by the Cochrane Library (Lancaster and Stead, 2001d) which analysed the effectiveness of telephone counselling drew a distinction between active counselling, when the counsellor contacts the person, and passive counselling, consisting of so-called help-lines or hotlines which smokers or family members call. Active telephone counselling does not appear to be any more effective than other forms of intervention or nicotine replacement therapy; nevertheless, it should be borne in mind that these studies are too heterogeneous to offer firm conclusions.

#### 5.5. Alternative therapies

Hypnotherapy and acupuncture are the main alternative or unconventional therapies people use to stop smoking. The Cochrane Review on hypnotherapy (Abbot *et al.*, 2001) examined nine studies which, unfortunately, were too heterogeneous in regard to session length and the total number of sessions. Overall, this practice appears to be of dubious effectiveness. At best, it appears to be of only modest interest compared with other types of action.

Eighteen papers on acupuncture were assessed, covering a total of 20 comparisons with other treatments (White *et al.*, 2001). Overall, the results achieved were modest, and indicated a substantial placebo effect when acupuncture was compared against simulated acupuncture.

#### 5.6. Pharmacological therapy

The most common pharmacological treatment is nicotine replacement therapy, about which greater detail is provided in the section on research.

Various tranquillisers and antidepressants have also been used to help people quit smoking (Hughes *et al.*, 2001). Tranquillisers proved to be of little use. However, in four studies, two of which have not yet been published, the antidepressant bupropion proved to be more effective than a placebo. Nevertheless, available data and the medicine's sideeffects mean that we are not able to say whether it is beneficial compared with nicotine replacement therapy and other types of therapy (Jorenby *et al.*, 1999).

Clonidine, a compound that has also been studied in relation to opiate addiction, proved to be of significant effectiveness in six studies, but clinical use is hindered by its side-effects, notably postural hypotension and drowsiness (Gourlay *et al.*, 2001).

In conclusion, a number of pharmacological treatments are available for giving up smoking, some of which still require further study. Some of these treatments have proven to be effective and worthy of consideration, as indeed are all available treatments.

## 6. Legal aspects under Community Law and Italian Law

### 6.1. Community Law

Since 1 November 1993, the European Community has had specific responsibilities in the field of public health<sup>2</sup>. Under Article 152 of the Treaty of Rome, community action includes improving public health, preventing illness and obviating sources of danger to human health. For these purposes, and together with the efforts of the Member States in this area, the Community promotes the fight against major health scourges by encouraging research into the causes of their transmission, supports action to reduce drug-related health damage and fosters information, education and prevention in the field of health<sup>3</sup>.

Community responsibility in the field of public health is horizontal, in that the definition and implementation of all other Community policies and activities must be inspired, as specifically stated in the Treaty of Rome, by the need to ensure a high level of protection for human health<sup>4</sup>. Community responsibility is also concurrent with that of the Member States because, as specifically envisaged in the Treaty, Community action complements that of national governments<sup>5</sup>. It should be noted, in this respect, that the concurrent nature of Community responsibility derives not only from the provisions defining its limits, but also from those governing the way in which it is exercised in practice. It is significant that the Treaty did not give the Council the power to adopt binding measures to harmonise the laws and regulations of the Member States concerning the protection and improvement of human health<sup>6</sup>, but gave it instead the power to adopt simple recommendations on the subject, through which the Council is limited to urging that the Member States follow its suggestions rather than being able to impose rules of conduct<sup>7</sup>.

The Recommendation of the Council of 2<sup>nd</sup> of December 2002 on the prevention of smoking and on initiatives to improve tobacco control has its legal basis in Article 152 of the Treaty of Rome<sup>8</sup>. This Recommendation, after recalling that smoking remains the biggest form of preventable death in the European Union, and progress in reducing the incidence of tobacco use is still disappointing, emphasises the need to adopt a comprehensive anti-smoking strategy in order to reduce the prevalence of smoking-related diseases. The Recommendation states “smoking is damaging human health, as smokers become addicted to nicotine and suffer fatal and disabling diseases such as cancers of the lung and other

---

<sup>2</sup> On that date the Maastricht Treaty establishing the European Union entered into force amending the Treaty of Rome that established the European Community. Among other things, it introduced the new Title X (now XIII) of Part Three, dealing with “Community policies”. This title was significantly amended by the Treaty of Amsterdam, which came into force on the 1<sup>st</sup> of May 1999, introducing the wording examined below.

<sup>3</sup> The Community is also assigned the tasks of promoting and coordinating cooperation among the Member States and between these and third countries or the international organisations competent in the field of public health (see Article 152, par. 2, sub-sections 1 and 2, and par. 3).

<sup>4</sup> See Article 152, par. 1, sub-section 1.

<sup>5</sup> See Article 152, par. 1, sub-sections 2 and 3. Art. 152, par. 5, states that community action in the public health sector fully respects the responsibilities of the Member States for the organisation and delivery of health services and medical care, without prejudice to any national provisions on the donation or medical use of organs and blood.

<sup>6</sup> See Article 152, par. 4, sub-section 1c).

<sup>7</sup> See Article 152, par. 4, sub-section 2. To this end, as provided for under Article 205 of the Treaty of Rome, the Council decides by qualified majority on a proposal of the Commission.

<sup>8</sup> Official Journal of the European Communities (“OJ”) no. L22 of the 25<sup>th</sup> of January 2003.

organs, ischaemic heart disease and other circulatory diseases, and respiratory diseases such as emphysema.” The number of smoking-related deaths (500,000) annually in the European Community is still too high.

Before returning to the contents of the Recommendation, it is important to note that it gives a comprehensive unity and consistency to other non-binding anti-smoking measures adopted by the Council in recent years, even before the European Community was endowed with specific competence in the field of public health protection. These acts include: the Resolution of the 7<sup>th</sup> of July 1986 of the Council and the representatives of the Member States meeting within the Council regarding the first European action plan to improve the health and quality of life of its citizens by reducing the number of cases of cancer, giving priority to anti-smoking measures<sup>9</sup>; the Resolution of 18<sup>th</sup> of July 1989 of the Council and ministers of health of the Member State, meeting within the Council, on banning smoking in places open to the public, providing guidelines for the Member States to protect non-smokers from environmental tobacco smoke<sup>10</sup>; the Council Resolution of 26<sup>th</sup> of November 1996 on reducing smoking in the European Community, recognising the need to develop an effective strategy against tobacco consumption<sup>11</sup>; the Council Conclusions of 18<sup>th</sup> of November 1999 on combating tobacco consumption, underscoring the need to develop a comprehensive strategy to protect minors in particular<sup>12</sup>; and the Council Resolution of 29 June 2000 on action on health determinants. The latter resolution, in particular, took note of the results of the debates held at the European Conference on Health Determinants in the European Union, held at Evora on 15 and 16 March 2000, which placed particular emphasis, *inter alia*, on the role of tobacco in this context and which recommended a series of practical and targeted steps to address the challenges in this sector<sup>13</sup>.

Although prevention of smoking and anti-smoking measures are priorities for the health policies *strictu sensu* of the European Community and the Member States, the tobacco industry’s advertising, distribution and promotional strategies nevertheless foster tobacco consumption, and help to increase the already high level of mortality and morbidity associated with tobacco products. To address these issues, which cannot be dealt with by legal means on the basis of Article 152 alone in view of the previously mentioned limits to this provision, the Community has adopted other anti-smoking measures in the context of the internal market and the removal of barriers to ensure the proper operation of the market. These include a series of binding measures based on other provisions contained in the Treaty of Rome such as Article 47 on the right of establishment, Article 55 on the free provision of services, Article 95 on the approximation of the laws of the Member States, and Article 133 on the common commercial policy. Separate mention should be made of Articles 36 and 37 under which numerous acts have been adopted since the 1970s with the basic aim of sup-

---

<sup>9</sup> See also, more recently, the “Europe Against Cancer” programme, referred to in the Decision of the European Parliament and the Council no. 649/96 of 29 March 1996 (in *OJ* no. L95 of 16 April 1996).

<sup>10</sup> *OJ* no. C189 of 26 July 1989.

<sup>11</sup> *OJ* no. C374 of 11 December 1996. See also the Communication of the Commission on the present and future role of the Community in reducing tobacco consumption [document COM(96) 573 of 18 December 1996].

<sup>12</sup> *OJ* no. C86 of 24 March 2000. See also the report on the Recommendation of 8 September 1999 on progress made in protecting public health from the harmful effects of tobacco consumption.

<sup>13</sup> *OJ* No. C218 of 31 July 2000.

porting community tobacco production and the market, in line with the protectionist goals of the Common Agricultural Policy<sup>14</sup>.

The first of these measures was Council Directive 89/552 of 3 October 1989 on the coordination of the laws, regulations and administrative provisions of the Member States as regards television broadcasts (the so-called “Television without Frontiers” directive), banning any form of television advertising of tobacco products and establishing that television programmes shall not be sponsored by natural or legal persons whose main activity is producing or selling tobacco products<sup>15</sup>. More recently, the European Parliament and Council adopted Directive 98/43 of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States on the advertising and sponsorship of tobacco products<sup>16</sup>, and Directive 2001/37 of 5 June 2001, on the manufacture, presentation and sale of tobacco products<sup>17</sup>. The first directive was struck down by the Court of Justice judgement of 5 October 2000<sup>18</sup> and, in its place, in May 2001 the Commission made a proposal for a directive on the advertising and sponsorship of tobacco products which is currently at the approval stage in the Council<sup>19</sup>. This is a proposal to prohibit tobacco advertising in print media, radio broadcasting and information society services (i.e. Internet), and to ban sponsorship, on the part of the tobacco industry, of radio programmes or events taking place in - or with participants from - more than two Member States, or which have in any case cross-border effects. Directive 2001/37, on the other hand, is limited to making the legal framework created by other Community directives more consistent and harmonious, taking account of trade flows between the Community and third countries<sup>20</sup>.

The need to adopt measures to reduce the demand for tobacco products, in the context of a global anti-smoking policy, was reiterated by the Council in the Recommendation of the 2<sup>nd</sup> of December 2002 concerning, in particular, the advertising, marketing or promotion practices used by the tobacco industry to promote tobacco consumption among consumers and non-consumers and, in particular, among children and adolescents. Such practices and strategies include, for example, the use of tobacco brand names on non-tobacco products or services (brand-stretching) or clothes (merchandising), the use of promotional items (such as ordinary objects like ashtrays, lighters, umbrellas and other similar objects) and of tobacco samples, the communication of sales promotions (such as discounts, free gifts,

---

<sup>14</sup> This is the case of Council Regulation no. 2075/92, of 30 June 1992, on the common organisation of markets in the raw tobacco sector (*OJ* no. L215 of 30 July 1992), most recently amended by Council Regulation no. 546/2002, of 25 March 2002 (*OJ* no. L84 of 28 March 2002).

<sup>15</sup> *OJ* no. L298 of 17 October 1989. This directive was amended by the Directive of the European Parliament and Council no. 97/36 of 30 June 1997 (*OJ* no. L202 of 30 July 1997).

<sup>16</sup> *OJ* no. L213 of 30 July 1998.

<sup>17</sup> *OJ* no. L194 of 18 July 2001.

<sup>18</sup> See Case C-376/98, in *European Court Reports*, 2000, p. I-1345 and ff.

<sup>19</sup> *OJ* no. C270 of 25 September 2001.

<sup>20</sup> The acts that were repealed and recast in Directive 2001/37 were Council Directive 89/622 of 13 December 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of certain types of tobacco for oral use (*OJ* no. L359 of 8 December 1989), amended several times, and Council Directive 90/239 of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes (in *OJ* no. L137 of 30 May 1990). It should be noted that the Court of Justice has also ruled on the validity and interpretation of Directive 2001/37: see the judgement of 10 December 2002, case C-491/01, in *European Court Reports* 2002 p. I-11453.

bonuses or an opportunity to participate in a promotional contest or game), the use of billboards, posters and other indoor or outdoor advertising techniques (such as advertising on tobacco vending machines), the use of tobacco advertising in cinemas, as well as any other forms of advertising, sponsorship or practices directly or indirectly intended to promote tobacco products. The Council Recommendation begins by noting that in cases where only certain forms of direct tobacco advertising are prohibited, the tobacco industry tends to shift its advertising expenditure to other marketing, sponsorship and promotion strategies, using creative and indirect ways to promote tobacco products, especially with young people<sup>21</sup>. To counter such practices, which limit the effect of partial bans on tobacco advertising, the Council recommends that Member States, in accordance with national legislation and practices: adopt appropriate legislative or administrative measures to prohibit tobacco sales to children and adolescents<sup>22</sup> as well as certain forms of tobacco advertising and promotion<sup>23</sup>; require manufacturers, importers and wholesale traders in tobacco and in products and services bearing the same trademark as tobacco products to provide Member States with information concerning their expenditure on advertising, marketing, sponsorship and promotion campaigns not prohibited under national or Community law<sup>24</sup>; guarantee protection from exposure to environmental tobacco smoke in indoor workplaces, enclosed public places, and public transport<sup>25</sup>; develop strategies and measures to reduce the prevalence of smoking, such as strengthening overall health education, particularly in schools, and general programmes to discourage the initial use of tobacco products and to overcome tobacco addiction<sup>26</sup>; make use of young people's contributions to health-related policies and actions, especially in the field of information, and encourage specific activities which are initiated, planned, implemented and evaluated by young people; implement appropriate price measures on tobacco products so as to discourage consumption; implement all necessary and appropriate procedures to verify compliance with the measures set out in the recommendation; and inform the Commission every two years following the adoption of the Community act, of action taken in response to the recommendation.

Lastly, the Council Recommendation takes due note of the efforts being made at international level, in the context of the World Health Organisation (WHO), in drawing up and adopting a framework convention on tobacco control<sup>27</sup>. The preparatory work for this convention began in 1999 and that the draft agreement, approved in March 2003, established

---

<sup>21</sup>The World Health Organization and the World Bank are well aware of these practices and have invited countries to prohibit all forms of tobacco advertising and promotion. The World Bank, in particular, concluded that advertising increases cigarette consumption and that legislation banning advertising would reduce consumption provided that it is comprehensive and covers all media and uses of brand names and logos.

<sup>22</sup> For a purely indicative list of the main types, see point 1 of the Recommendation.

<sup>23</sup> See point 2 of the Recommendation.

<sup>24</sup> Indeed, as stated in the preamble to the recommendation, information on the global expenditure of the tobacco industry on the promotion of tobacco products is an important prerequisite for monitoring the effectiveness of tobacco control policies since it is then possible to determine if the restrictions have been circumvented, in particular by the diversion of budgets towards new and unrestricted forms of promotion.

<sup>25</sup> According to the Recommendation, priority should be given, *inter alia*, to educational establishments, health care facilities, and places providing services to children.

<sup>26</sup> This is the case of health education programmes to improve awareness of the risks of smoking and other prevention programmes to discourage the use of tobacco products.

<sup>27</sup> See also the Council Conclusions of the 5<sup>th</sup> of June 2001 on the WHO Framework Convention on Tobacco Control (*OJ* no. C174 of the 19<sup>th</sup> of June 2001).

that signatory states should introduce legislation into their own national systems to prohibit, essentially, tobacco advertising and the sale of cigarettes to minors, as well as to promote higher taxes on smoking, to strengthen action against smuggling, and to emphasise the concept of producer responsibility. The text was due for signature in mid-2003, but its entry into force depends on a large number (at least 40) of ratifying countries<sup>28</sup>. Aware of the importance of ensuring that its recommendation be consistent with the proposed contents of the framework convention, the Council invited the Commission to monitor and assess the developments and the actions undertaken in the Member States and at Community level; to report on the implementation of the proposed measures, on the basis of the information provided by the Member States, not later than one year after receipt of Member States' information submitted in accordance with the recommendation; as well as to examine the effectiveness of the measures set out in the recommendation and consider the need for further action, particularly if internal market disparities appear in the areas covered by the recommendation.

## 6.2. Italian Law

Turning to the Italian situation, it should first be noted that the general regulation of tobacco smoking dates back to Law No.548 of the 11<sup>th</sup> of November 1975, which placed a total ban on smoking on public transport and in certain public places<sup>29</sup>, with the aim of protecting citizens' health<sup>30</sup>.

In practice, smoking was prohibited in certain places from the mid-1950s under measures applying to certain categories of enterprises where particular kinds of manufacturing were carried out or which involved specific dangers<sup>31</sup>. It was precisely the need to extend and generalise the protection of workers from the dangers related to or caused by smoking,

---

<sup>28</sup> For the draft text of the framework convention see <http://www.who.org>.

<sup>29</sup> Law 584/75 was complemented by the Prime Minister's Directive of 14 December 1995, which will be discussed shortly, and by the Ministerial Decree of 18 May 1986, concerning air conditioning and ventilation systems. It should be noted that since 1975 there has been an absolute ban on smoking in hospital wards, school classrooms, vehicles owned by the state, public authorities and private licence-holders providing public transport services for groups of people, underground systems, railway, tram, seaport and airport waiting rooms, railway compartments reserved for non-smokers (which must be provided in every passenger train run by the State Railways), passenger trains operated under license by private owners, compartments with couchettes or sleeping car compartments occupied by more than one person during night journeys, enclosed cinemas, theatres and dance halls, betting shops, museums, libraries, portrait galleries, art galleries and reading rooms open to the public, and enclosed premises used for public meetings.

<sup>30</sup> The D.P.R. of 11 July 1980, No. 753 had the same general aim with new regulations covering the safe management, security and regular service of the railways and other transport services, prohibiting smoking in train compartments and open plan carriages not reserved for smokers, in buses, trolleybuses and trams, in funicular railway cars and aerial cable cars, and in underground trains, as well as in the waiting rooms at stations and stops.

<sup>31</sup> Cf., amongst others, D.P.R. 24 April 1955, No. 547, containing regulations for the prevention of accidents at work, D.P.R. 20 March 1956, No. 320, with regulations for the protection and safety of work underground, and D.P.R. of the 9<sup>th</sup> of April 1959, No. 128, containing regulations for the safe management of mines and quarries. Previously, the only relevant provision was Article 25 of the royal decree of the 24<sup>th</sup> of December 1934, No. 2316, containing the consolidation act on protection and assistance for mothers and children, imposing administrative sanctions on sellers and providers of tobacco to under-16s and prohibiting these minors from smoking in public places.

including passive smoking, that inspired subsequent legislation. In addition to Presidential Decree No.303 of the 19<sup>th</sup> of March 1956 containing general regulations on workplace hygiene, there was also Legislative Decree 277 of 15 August 1991 transposing a series of Community directives into Italian law dealing with the protection of workers from risks deriving from exposure to chemical, physical and biological agents at work<sup>32</sup>, as well as Legislative Decree No.626 of the 19<sup>th</sup> of September 1994 implementing another series of directives aimed at improving health and safety conditions in the workplace<sup>33</sup>. The 1994 Decree requires employers to limit workers' exposure to carcinogenic agents, including by means of no-smoking notices and by adopting appropriate measures to protect non-smoking employees in places where workers spend their break times<sup>34</sup>.

The overall legislative framework described above has been further developed by the courts, with a general trend towards an evolutive interpretation of the provisions (Zeno-Zenchovic, 2002). In fact, following a number of rulings by administrative judges, who gave a broad interpretation to the provisions of Law 584/1975, the directive of the Prime Minister of the 14<sup>th</sup> of December 1995 was adopted, prohibiting smoking in certain government or public service facilities. This directive established that government departments shall implement the ban on smoking contained in the above-mentioned law, exercising their administrative, regulatory and disciplinary powers as well as their policymaking, supervisory and control powers over companies and institutions they control and over licensed or contracted private companies. The directive also established criteria for the identifying premises where the ban should apply and established that the government departments referred to in the measure could, in any case, extend the ban to other areas not specifically mentioned in Law 584/1975 on the basis of their autonomous regulatory and disciplinary powers.

Finally, it should be noted that in addition to the legislation covering tobacco advertising and warning messages on packages, which was also adopted to implement Community directives<sup>35</sup>, the recent Law 3 of 16 January 2003 contains provisions regulating government departments<sup>36</sup>. Article 51 of this Law, entitled "Protection of non-smokers' health" prohibits smoking in enclosed places with the exception of private areas not open to users or the general public and specifically marked smoking areas. These areas must be equipped with a ventilation system for air exchange whose technical specifications are to be defined in an administrative regulation to be adopted, acting on a proposal of the Minister of Health, no later than 180 days following the publication of the law in question (i.e. no later than June 2003). Furthermore, the law requires bars and restaurants to provide non-smokers with one or more zones with a surface area greater than that of smoking areas<sup>37</sup>. It is important to note that in order to give industry associations the time to provide appropri-

---

<sup>32</sup> Council Directives 80/1107, 82/605, 83/477, 86/188 and 88/642.

<sup>33</sup> Council Directives 89/391, 89/654, 89/655, 89/656, 90/269, 90/270, 90/394 and 90/679.

<sup>34</sup> Legislative Decree 626/91 was amended by Legislative Decree 242 of 19 March 1996.

<sup>35</sup> See, for example, Ministerial Decree 425 of 30 November 1991 incorporating certain provisions of the Television without Frontiers directive, and Council Directives 90/239 and 89/622.

<sup>36</sup> *Gazzetta Ufficiale* No. 15 of 20 January 2003, S.O., no. 5.

<sup>37</sup> The law establishes that, on the proposal of the Minister of Health, further enclosed areas where smoking is permitted may be specified. In particular, par. 4 of Article 51 establishes, in wording that does not appear consistent with the spirit of the law, that "in all facilities where people are obliged to remain, smoking areas must be provided."

ate information and create awareness of the problem, the abovementioned provisions will enter into force a year after the law is passed (i.e. no later than June 2004). The law also provides for the definition of new procedures for ascertaining infringements of current smoking restrictions and confirms the provisions governing smoking bans on government premises.

## II. INDICATIONS AND PROPOSALS

### 1. Information

Although education is an ethical duty, its overriding purpose in the case of tobacco use should be a practical one. It should neither aim to improve people through abstention from tobacco nor bring about abstention through moral perfectionism. It should aim simply to reduce the percentage of smokers gradually. In other words, making smokers feel guilty could be counterproductive.

The outlook today is favourable. Thanks to social pressure and greater awareness of the dangers of smoking, the number of smokers has decreased slightly or stabilised in some countries. This makes the fight against nicotine addiction easier since there is a tendency towards imitation with this type of drug. It is difficult to abstain in a social environment where most people are smoking, and vice versa. For example, when smoking became acceptable for women, smoking spread in this segment, where it continues to grow. The urge to smoke comes from a need to assert oneself or socialise. Alcohol, on the other hand, is more harmful for those who get drunk alone than for those who drink socially.

Education will therefore achieve results by separating smokers from non-smokers wherever possible. This will be viewed as punishment born of a need to protect nonsmokers, something which smokers all too often ignore. This solution has been implemented for some time now by the Italian State Railways. Encouragingly, smoking carriages are less busy than others. Swiss Railways used to have blue-painted first-class carriages for “non-speakers”. Such carriages are no longer in use, but they do underscore the need to emphasise the “nuisance” rather than “harm” that smokers often cause others, even without realising it. For example, those who drop cigarette butts on the ground might never dream of doing the same thing with an ice cream wrapper.

Focusing on the immediate threat of tobacco use may act as a shock cure, but only in individual cases where the intention is to stop smoking at once. A more effective approach is to underscore the advantages of not smoking (even for long-term smokers) and, more importantly, of not starting in the first place. Of these advantages, which include better health, the economic benefits (more money available for other purposes) should not be underestimated.

The liberal concept of an adult capable of choosing how to behave after weighing up the costs and benefits is itself an ethical postulate that, while much debated in theory, is fundamental in practice. Its validity presupposes the ability to understand and choose, which we acquire gradually in the first two decades of life. This in turn prompts the adoption of strict legislation prohibiting conduct aimed at fostering tobacco use in minors.

While ethically correct, such protection of minors is often ineffective and, in any case, must be accompanied by education based more on suggestion and influence than rules. It is worrying that smokers more or less consciously pass on their dependence to the people they love (especially spouses) rather than those to whom they are indifferent. As a result, verbal warnings not to smoke from parents who smoke are regarded by children as false, even if given in good faith. In dealing with this general problem (unlike smoking overall, which is in decline, it is actually getting worse), social psychology should focus on the more specific parental duty to protect children from dependence on tobacco.

## 2. Information for education and proposals

The future of the world will depend on how adults communicate with children and young people, who are the only group that can improve the planet in a significant and sustainable manner. This applies to all important issues, including the fight against tobacco use.

Positive signs of such a change are scarce on the ground, given the increased violence registered in all age groups, with recurrent tragedies even within the home.

Adults, who should be dealing with these developments and searching for solutions, are themselves a direct cause. Both parents are absent from the home because of the economic structure of global society, which forces mothers to work outside the home to make ends meet. As a result, parents have been substituted by television, which has become the main educator, friend, role model and point of reference for children, who have been left irretrievably alone. "Latch-key" kids eat fast-food meals alone and shut themselves indoors in front of the television. Television, however, does not aim to educate children and make them into mature, happy adults. The sole aim of television is to attract viewers and beat the competition to maintain and possibly increase advertising rates. The result is a programming on all channels - shown in the afternoon and early evening slots that attract the highest number of child viewers - which features stories hyped beyond belief in the quest for the most gruesome and disturbing aspects of terrible events often involving other children and teenagers both as victims and perpetrators, are. It is widely argued that journalists have one duty: to seek and report facts. Yet we forget that child viewers are not mature enough to exercise critical judgement. They are simply subjected to the negative aspects of horrible events without parents to help and guide them. They are literally left alone to process behaviour that seems entirely normal through the distorting lens of television, which can artificially magnify or shrink events and images as it pleases.

General action is therefore vital, if only to prevent the situation from degenerating further. Globalisation generalises and amplifies positive and negative trends.

The fight against tobacco use should begin with these preliminary considerations on communication with children and young people to identify the most efficient tools for intervention.

Thorough knowledge of the scope and nature of the problem is essential if we are to respond correctly. This requires collecting and analysing all available data, and identifying trends and origins in order to decide strategy. A preliminary, objective overview of the current situation, developed by gathering and cataloguing all available data, is needed to prepare the ground for specific or general surveys and research. Changes in the communication sector are so rapid that the actions needed to pursue this aim can quickly prove inadequate or obsolete unless constantly updated. This requires an analysis of emerging trends in this sector in order to foresee problems as early as possible. On this basis, the planning of appropriate measures can then be continually and swiftly adapted. The fight against tobacco use has to begin with these general premises on communication with young people and children so that data collection can be focused on the growing problem of smoking in this category. The second phase is the critical elaboration of the information gathered. This is a highly specialised task requiring an ability to identify and isolate the most significant messages in the midst of the enormous flow of data. These have to be analysed, interpreted and developed to establish their scope and social impact, and to forecast future develop-

ments. This must then be placed in context with other sectors (even very different ones), from the economy to the arts, in order to trace an overall picture. Parents, teachers and other persons in contact with young people are inundated with partial or contradictory messages. This forces them to find their own forms of communication after evaluating the vast range of media aimed at the children and young people in their care: an individual effort whose outcome is increasingly inadequate to what is required, given the continual expansion and diversification of the world of communication. In order for this individual effort to be scaled down to ensure an acceptable relationship between effort and result, a consulting service should be planned. This could be general or specific to certain needs, and made available to groups concerned with positive communication for children. This would be particularly useful to help government departments intervene in this sector. In the third phase, the results of this activity would be translated into the language of institutions (in order to facilitate necessary intervention) as well as that of the communications industry to guide it, as far as possible, towards respect for childhood and young people. The aim, one which will hopefully attract ever greater consensus, is to promote healthy and balanced child development. Continuing to apply this approach to tobacco use, it is by no means difficult to identify actions which should be adopted. The problem should be dealt with on the basis of a collection of data that covers all aspects of young people's lives (which are closely intertwined), including smoking.

### **3. Children: from victims to protagonists**

The United Nations' Food and Agriculture Organisation (FAO) recently launched an educational initiative entitled "Feeding Minds, Fighting Hunger" geared towards children and young people. The initiative promotes a vision of a world where everyone can grow to become healthy, active and responsible members of society. The programme aims to demonstrate how education and information on world hunger, food security and nutrition constitute key factors for change. The aim is to give life to a symbolic international classroom where students examine and discuss the same problems, in the hope of preparing them for active participation in the creation of a world free from hunger. Under the project, teachers all over the world will have contemporaneous access to the same teaching materials at three levels of education. The materials will be produced by an international group of experts from the project and translated into different languages. They will deal with hunger, malnutrition and measures needed to help young people develop their understanding of the world's interdependence, as well as their own capacity to contribute effectively to world change, whatever their age. The objective of education, therefore, is to form generations of young people capable of becoming responsible world citizens who are united in a universal effort of solidarity and aware that there is no problem in the world, including world hunger, which cannot be solved provided that we commit ourselves to solving it. The teaching method produced during the development of this FAO initiative could be adopted as a model to facilitate the successful prevention of, and fight against, tobacco use. On this basis, improving the quality of life (which is also the framework of our initiative) is considered a realistic and sustainable goal if founded on a vast, widespread effort of education and information which begins with children, young people and their families. To this end, it seems appropriate to produce educational programmes which can be dis-

cussed at special awareness meetings, following the principles which inspired the FAO initiative. The implementation of such programmes could be then monitored. Above all, these programmes will develop practical activities, on-site learning and play activities at different levels which involve families as much as possible. Teachers could follow up discussions with drawings and written pieces that provide a focus for meetings, exhibitions and other activities. These can involve scholastic, regional, national and international institutions, as well as citizens themselves, with the full participation of students' families, and foster awareness of the issues involved. There is nothing like drawing and healthy competition to encourage children to do their best. A big concluding event is the best way to leave everyone with a lasting memory, confirming that, in the middle a crowd that shares our hope, we are not alone.

#### 4. Research

The study of nicotine addiction is the subject of a sensitive and intense debate that once again calls into play those who believe that science should be independent and free from external influences and those who feel that it needs to be bound by the same obligations as apply to any other form of human activity. This debate would require more space than is available here but needs to be mentioned, at least in broad terms, because it touches closely on the fight against tobacco use.

##### 4.1. Basic research

The free and autonomous side of science is basic, or pure, research, the objective of which is knowledge in and for itself. Basic research is not subject to ethical or other constraints because it limits itself to exploring and describing that which exists.

This concept is summed up in a famous expression:

“And yet it moves” as whispered by Galileo Galilei who, forced to retract his claim, at the same time quietly observed that the earth revolves in any case, regardless of the will and responsibility of those observing it.

This is basic research, which is essentially free not by reason of a right won or granted by those who govern us, but by reason of an intrinsic quality, without which it ceases to be science. Ethical judgements are applied not to what science reveals, but to the means used to achieve its objectives and to its “goodness”, meaning its capacity to translate reality into knowledge that is true and can be checked and verified by anyone who so wishes. The thirst for knowledge, an intrinsic part of human nature, is also free or, to put it more precisely, irrepressible.

However, while basic research is free, researchers are not: as Bolinder reminds them (1997) “*you can never be entirely independent of your paymaster*”. Research is never entirely free because it needs resources to operate, and resources inevitably create an obligation towards their provider. This obligation does not concern knowledge in and for itself, as we have just seen, but can affect the choice of field of exploration.

Moreover, resources are not unlimited, which means that they need to be diverted from other uses relating to needs that are usually more pressing than knowledge in and for itself. To divert resources to basic research, scientists not only have to compete with others to con-

vince those holding the purse strings of the merits of their project, but also to take on a moral obligation towards those providing the resources and towards society in general. This means that basic research is subject to strong ethical constraints which, without distorting it, create a commitment to operate for the good of society by multiplying, and returning to that society, the resources it has received. Galileo described research as the light and benefit of reason, while Daniel Bovet speaks of the thirst for knowledge and the need to put it at the service of mankind (Bignami, 1993).

These elementary and basic concepts also apply to nicotine addiction. There are still many obscure sides to this phenomenon: the mechanisms of dependence; its genetic and environmental causes, which determine the differences between one individual and another and from one life-period to another; its roots in pre- and post-natal development, as mentioned in the appendix to this document; and similarities with and differences from other forms of addiction. Basic research is costly, demanding and its outcomes uncertain, but without this knowledge it is impossible to provide the correct framework to combat nicotine addiction and addiction in general. The necessary epidemiological and experimental studies research should therefore be encouraged and supported, not to influence the research but to direct it where it is most needed, in the knowledge that the investment made is not just wise but will also be profitable in the longer term.

#### *4.2. Applied research*

Applied research translates knowledge into practice in the pursuit of ends that may be subject to ethical evaluation. Unlike basic research, therefore, it immediately brings into play the moral duties both of the scientist and of all those involved in the process. It also calls into play a second ethical principle – one that is usually neglected – concerning the duty to put knowledge to good use, since it is an asset that should be exploited for the benefit of mankind in general and, most importantly, for those who have committed their community's resources to its acquisition. Perutz (1989) wrote that European scientists are often obliged to emigrate to America to exploit their discoveries. This dislocation also has a strong ethical component that deserves to be analysed and discussed in the light of the responsibilities not just of science but of all the sectors involved, starting with industry, within the framework of a valid scientific research policy. A great deal of knowledge is already available on nicotine addiction and smoking, even more, perhaps, than that still to be acquired.

This knowledge concerns, for example, the health and social aspects of the phenomenon; many of its primary and secondary causes; and its social, economic and employment implications, which cannot be neglected. The technology and other instruments, including financial ones, needed to translate this knowledge into practical applications are also available.

A smoke-free society: this is the primary objective. It is, however, an objective that does not seem to be within reach in the medium term. In the meantime, applied research is seeking to reduce the harm caused by smoking by adopting a strategy already applied successfully in the fight against other forms of addiction (Marlatt, 1996). A report (2001) by the distinguished Institute of Medicine, available for consultation at [www.iom.edu](http://www.iom.edu), assigns a key role to the development of potential reduced-exposure products (PREPs), which as their name suggests can potentially reduce the harmfulness of smoking, and to treatments

that can help smokers recover from their dependence. The industry also needs to be converted by nudging it towards different processes or uses of tobacco than those currently adopted.

#### 4.2.1. PREPs

PREPs have a number of aims: to reduce the harmfulness of smoking by using less harmful tobacco blends (produced through selection or genetic modification); developing increasingly selective filters; reducing the combustion temperature of cigarettes; diluting smoke with air, and so on.

In recent decades considerable progress has been made in terms of introducing low-nicotine blends or nicotine-retaining filters, but the advantages to smokers' health are uncertain or unsatisfactory. Light or mild low-nicotine cigarettes are as harmful as traditional ones (Gottlieb, 2002; Pollay and Dewhirst, 2002) as a result of a compensation mechanism (Scherer, 2001) that leads smokers to inhale more deeply or smoke more cigarettes (Shields, 2002a). In a number of court decisions, tobacco companies have been found guilty of deceiving consumers by leading them to believe that the new products are less toxic than older ones (Charatan, 2002).

With respect to the reduction of the toxic effects of the products of cigarette combustion, the results are just as disappointing. The incidence of adenocarcinoma of the lung seems to have increased since the introduction of "light" cigarettes. Similar considerations also seem to apply to "eclipse" cigarettes, in which the tobacco does not burn but is heated from inside (Slade *et al.*, 2002).

Another important aspect of the problem concerns the evaluation of the effectiveness and toxicity of the new PREPs. This should be done through trials conducted before such products are put on the market, rather than after the event, using the tragic figures produced by epidemiological studies, as has been the case thus far.

With the knowledge currently available, it is possible to carry out studies *in vitro* (on single cells or organs) or *in vivo* (on laboratory animals or volunteers), using validated biomarkers that can reliably predict the chronic damage caused by smoking (Shields, 2002b). One question that still remains to be clarified is which authority should be responsible for authorising the marketing and sale of PREPs. Many commentators consider this to be a task for the bodies with responsibility for regulating medicinal products, following the classic procedure of pre-clinical and clinical trials. The U.S. Supreme Court recently denied the Food and Drug Administration this authority (FDA, 2000), thereby creating a regulatory vacuum that is holding back the development of effective PREPs.

#### 4.2.2. Smoking cessation

The spread of smoking is linked not just to the mental effects of nicotine, which make smoking pleasurable and desirable, but also to the strong dependence that it creates in smokers (Benowitz, 1992). Many instruments are available to treat this condition. The most common are nicotine-based substances used in nicotine replacement therapy (NRT), which is administered through chewing gum, patches, nasal sprays or inhalers (Kotlyar and Hatsukami, 2002). This treatment eliminates exposure to the other toxic substances present in tobacco smoke, especially combustion products, and in this respect has some similarities with the controlled administration of drugs such as methadone (Dole, 1981). The available data also suggest that it is more effective than placebos in helping smokers to quit (Silagy *et al.*, 2001).

However, many questions remain to be answered, especially as regards the importance of dosage levels and the forms and means of administration. With respect to this last question, dependence seems to be linked not just to the intrinsic characteristics of nicotine and other drugs, but also to their speed of absorption. Opium addiction increased enormously when users turned from taking the drug orally to smoking and then injecting it, in the form of morphine. These forms had the effect of increasing the speed of absorption of the active ingredients. A similar phenomenon emerged with cocaine, the smoking of which led to the development of crack. The effectiveness of the nicotine formulations and means of administration used in dependence-reduction methods needs to be evaluated in the light of this knowledge. Bupropion, an anti-depressant that reduces nicotine withdrawal symptoms and the compulsive need to smoke (Nichols, 1999; Jorenby, 2002) opens the way to a different approach to smoking cessation.

#### 4.2.3. Converting the industry

Research has a part to play in the reconversion of a sector which, if we consider the full range of activities revolving around tobacco, employs millions of people, for many of whom, especially in developing countries, it is the only means of subsistence. A considerable body of data, which does not yet enable us to draw unequivocal conclusions, suggests that nicotine has potential therapeutic uses, especially in certain neurodegenerative conditions. The clinical studies conducted to date mainly concern the effects of smoking, which involves the absorption not just of nicotine but also of a number of other substances with undesirable effects: this means that we need to promote targeted investigations using nicotine-based preparations. Another opportunity that deserves closer study concerns the potential application of nicotine and other substances contained in tobacco both for other uses, for example as pesticides in agriculture, and as intermediates in the synthesis of compounds that could have a number of different applications. Working closely with the world of basic research, the applied research community needs to address these problems, which are also posed by other drugs.

#### 4.3. The shadow of pseudoscience

Research into smoking and tobacco in general is intensive (Nardini and Donner, 2000), but distorted by funding provided to a large extent by the tobacco industry. Many feel that this has influenced the path followed by the research and in some cases obscured or even altered its findings. As we know, for example, nicotine dependence was identified in the 1960s but it took 20 years for the phenomenon to be accepted by the official scientific literature and enter the public domain.

The tobacco companies have funded epidemiological studies and publications that cast doubt on the true danger of passive smoking (Barnes and Bero, 1998). In 1988, a group of multinationals set up the Center for Indoor Air Research, without troubling themselves over the inherent conflict of interest (Barnes and Bero, 1996). These and other situations explain the abysmal reputation that has been earned not just by the tobacco industry but also, naturally, by the studies and researchers revolving around them. Many distinguished public institutions have decided not to accept funding from tobacco companies and many funding bodies reject applications from researchers receiving support from the industry (Cohen *et al.*, 1999; Cohen 2001). Richard Smith, the editor of the *British Medical Journal*,

recently resigned his medical journalism chair at the University of Nottingham after the University accepted funding from British American Tobacco (Ferriman, 2001). Some argue that scientific journals should not even publish articles funded by the tobacco industry (King and Yarney, 2000), a policy adopted by the two official journals of the American Thoracic Society (Roberts and Smith, 1996).

To understand why individuals or organisations adopt such positions, we need to bear in mind the power accruing to the multinationals through their profits. These profits amount to billions of dollars, about a thousand times greater than the funding available for public research. Between 1954 and 1966 more than 300 public institutions and nearly 1100 researchers in the US obtained funding from tobacco companies. In 1994 alone, 375 scientific articles on research promoted and supported by the industry were published (Roberts and Smith, 1996). Even without going so far as to alter or conceal findings that from their point of view are negative – which would be offensive to science, even more than to the industry – all the industry needs to do to deflect research is to nudge it towards futile or innocuous objectives. This problem arises each time science is contaminated by economic, political or ideological interests: in such cases, it is transformed into pseudoscience. To avoid these risks, it is not enough for biomedical research to be conducted only by public institutions, as some authors suggest (Bolinder, 1997). The greater, primary need is to tirelessly advance the ethical debate on science, undue influence, freedom and the responsibilities of science to society.

## GLOSSARY

**Drug abuse:** an abnormal, dangerous and generally prohibited use of drugs. Not all drugs give rise to abuse.

**Drug:** an agent that has pleasant, desirable and sometimes useful physical effects that are, however, associated with the risk of abuse, dependency, tolerance and other adverse consequences for the individual or society. Drugs are part of the broader category of pharmaceuticals.

**Pharmaceuticals:** compounds that, when introduced in a living organism, are capable of modifying one or more of its functions.

Whether the effects of pharmaceuticals are beneficial or harmful depends not just on their intrinsic properties, but also on the dosage and on the manner and circumstances of use.

**Gametes:** or gonocytes, specialised cells for sexual reproduction, male (spermatozoon) and female (egg cell or ovum). In gametes the chromosome number is halved during the maturation process.

**Gonads:** the basic reproductive glands in both sexes, which produce gametes (spermatozoa and egg cells).

**Meta-analysis:** the statistical analysis of a large collection of analysis results from individual studies for the purpose of integrating the findings (Glass, 1976).

**Mutagen:** agent that can cause a mutation in a single gene (genic mutation, consisting of an alteration to the sequence of nucleotides in DNA), in an extended chromosomal region (chromosomal mutation) or in the entire chromosomal structure (genomic mutation).

**Prevalence:** in statistical language, the term prevalence indicates the number of persons affected by a given disease at the time of the study. By contrast, incidence stands for the number of new cases of a disease over a period of time, usually one year.

**Syndrome:** a group of symptoms that occur together and are connected with the onset of a particular disease

**Withdrawal syndrome or crisis:** psychological and physical disturbances caused when a drug for which dependency has developed is discontinued abruptly. Withdrawal symptoms tend to be the opposite of those caused by the drug: for example, hyperalgesia (extreme sensitivity to pain) as opposed to analgesia, excitement as opposed to sedation, miosis as opposed to mydriasis (contraction and dilation respectively of the pupil) and so on.

**Nicotinism:** Toxic syndrome produced by the prolonged and excessive use of tobacco, mainly in the form of cigarettes.

**Tolerance:** progressive resistance to the effects of a drug, usually after the repeated use of the substance. Tolerance is closely linked to dependency, since both are caused by the functional adaptation of the organism to the effects of the drug. Tolerance to several drugs can occur simultaneously. Tolerance can also develop to many other substances, but only with drugs is the condition associated with a lucid and uncontrollable need to increase the dose in order to reproduce the initial effects and avoid the effects associated with their absence.

**Drug addiction or dependency:** the compulsive and conscious need, which generally arises after repeated exposures, to take a drug not just to reproduce its initial effects but also to avoid the unpleasant effects caused by its absence and maintain an acceptable state of physical or psychological well-being. Drug dependency may involve one or more drugs. Not all drugs give rise to dependency. Many other substances give rise to dependency, but do not cause the compulsive and conscious desire that is typical of drugs. The term drug addiction/dependency therefore serves to distinguish drug addiction from other forms of dependency.

**Toxicomania:** compulsive desire or need to take a drug to reproduce its effects or avoid the unpleasant effects caused by its absence. Those affected by the condition are called drug addicts. The term drug addict is used for those cases where the compulsion to take the drug is caused by a state of dependency on that drug, as defined above.

**Zygote:** The first cell of the embryo, formed by the union of the male and female gametes at fertilisation.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**RITUAL SLAUGHTERING AND ANIMAL SUFFERING**

19<sup>th</sup> of September 2003



## PRESENTATION

Despite having never been *quantitatively* predominant, the commitment of the National Bioethics Committee concerning the field of bioethics and ethical significance that should be recognized to the animal world (and more generally to the non-human living) has always been attentive and deep. The Committee has never deluded to intervene in these matters in an ultimate way or to bring back to unity very different and often conflicting views of the world, but has always considered possible (possible because behaving) to intervene with intellectual honesty in a debate that has taken on completely new dimensions in the last decades. Our relationship with animals cannot, in fact, continue to be thought, or rather, *confined* (as was done for centuries, with rare sporadic exceptions) in an essentially *private* and *pre-moral* dimension; even people less sensitive to animal welfare issues must still recognize the public relevance it has acquired today in a complex society like the one we live in. Such aspect needs to be evaluated according to non-individualistic criteria, but capable of perceiving that specific dimension of *good* that we should consider inherent to the dimension of *public* (otherwise such dimension will degrade into arbitrariness or, even worse, into violence). This is the reason why classical (and inauspicious) dichotomy *people/things* cannot be used anymore, if we take into consideration the juridical relevance we should recognise to animals; this is the reason why bioethics, whose *gaze* embraces, in principle, the whole living world, has the duty to fight against what was effectively named the *anthropocentric prejudice*: a prejudice which can be ethically stigmatized, not to the extent to which it recognises the undoubted *excellence humaine*, but to the extent to which, in order to support this excellence, it considers (unjustifiably) to deny the animal world the objectively due moral respect it deserves.

The National Bioethics Committee, aware of the difficulties (and some say the impracticability) of a general and brief discourse on *intercultural bioethics*, considers more appropriate and fruitful to proceed by examining individual and specific issues of significant and urgent relevance. In September 2002, the Committee decided, in a decision taken in a Plenary session, to set up a working Group concerning the problem of *ritual slaughtering and animal suffering*. The working Group, which started meeting in December 2002, was entrusted to the care of Profs. Sergio Belardinelli and Silvio Ferrari with the active participation of Profs. Salvatore Amato, Luisella Battaglia, Renata Gaddini, Pasqualino Santori and Tullia Zevi. During the works, the Group sought and obtained the assistance of external experts to the Committee: Prof. Maurizio Severini of the University of Perugia, Dr. Riccardo Di Segni, Chief Rabbi of the Jewish Community of Rome, Dr. Gianluca Felicetti, Head of the LAV and Member of the Commission for the Rearing and Slaughter of the Ministry of Health, Ambassador Mario Scialoja, Head of the Muslim World League in Italy. The contribute of all these, whom I warmly thank for their generous support, was crucial in drafting the Document, as well as that of all the members of the Committee, who participated in its final development. On the 19th of September 2003, the text of the Document was finally adopted by the Committee meeting in Plenary. It is now published, together with a large number of attachments, some of which strictly documentary, others of critical and thoughtful content, that will help the reader to better perceive the complexity and the implications of the issues addressed. I extend my sincere thanks to those who have compiled the attachments as well as to the experts heard by the Committee which drew up the text placed in the Appendix.

I believe that this new contribution from the National Bioethics Committee, on an apparently marginal, but ethically unavoidable subject, will contribute to a further growth of bioethical consciousness in our country.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## INTRODUCTION

As the title explains, this document does not intend to consider ritual slaughtering in its entirety. It simply aims at examining this practice from a specific standpoint, i.e. the increased pain and suffering it may provoke to animals. For some time now, in fact, the CNB (National Bioethics Committee; hereinafter 'CNB') has become aware of the ties between the ethical debate on human beings and the whole of living beings by defining two guiding principles: according to the first, "of all forms of life, human life (has ] a primacy, not only factual but especially axiological and such primacy justifies, although to a limited extent, the subjection of every other living being to human beings" (Animal testing and health of living subjects, 17 April 1997); the second principle stresses that such primacy should be seen as "a sign of responsibility, not power", meaning that it cannot "give rise to or, even worse, justify cruel, violent practices on animals" (Bioethics and veterinarian science. Animal well being and human health, 30 November 2001).

We believe that any debate on ritual slaughtering and animal suffering should be placed within the framework of these two principles. The primacy of human beings over any other form of life underlies our attention to ritual slaughtering as an expression of religious freedom, a fundamental dimension of human life; the principle of responsibility implies the need to seek and enhance every possible way to minimize or eliminate animal suffering in any form of slaughtering and, more specifically, in ritual slaughtering.

Before commencing our debate, it is worth to make a few remarks on the meaning of ritual slaughtering with an eye to the inter-cultural dimension of bioethics.

On several occasions, the CNB has underlined the need to address this issue starting from the balance between the respect of a few universal values and the attention given to the peculiarities of each individual culture. This approach prevents from rejecting a practice deeply rooted in the culture and traditions of any community on the mere grounds that it is different from the practice followed by another segment of the population, were it even the majority: it is necessary to justify why such difference would make a practice ethically unacceptable. When no reason can be found or it is not sufficiently sound, the respect for diversità may turn out to be quite positive for the social integration of a number of communities that have recently settled down in Italy (suffice to think of Muslim immigrants).

In the next pages, the issue of the compatibility of ritual slaughtering with the ethical and legal principles of the Italian society will be addressed. It is worth to note that in the event these two principles turn out to be compatible, a significant (and growing) proportion of the population living in Italy would no longer be forced to abandon a major element of its own traditions. Most importantly, this could be a good example of integration, i.e. respecting the religious and cultural traditions of a community as long as they fit the key principles of a harmonious social co-existence.

### 1. Ritual slaughtering

Ritual slaughtering is a common practice particularly for the Islamic and Jewish religions. It consists of killing an animal by cutting its trachea and esophagus with a very sharp blade, to ensure an immediate, deep and blunt resection of blood vessels. This act is per-

formed in compliance with specific rules of religious origin and is accompanied by a series of actions (blessings, invoking the name of God, etc.) underlying its ritual significance and sacred nature. In principle, ritual slaughtering may be performed by any Muslim and Jewish; in actuality – except for a few specific cases that will be addressed later (see par. 6) – it is performed by specially trained people inside abattoirs authorized to do this type of slaughtering.

An animal eligible for ritual slaughtering must be intact: this rules out any technique that might cause some lesions. During ritual slaughtering, the animal is first restrained and then immediately killed by resecting its trachea, esophagus and the neck large blood vessels. On the other hand, in ordinary slaughter the animal is immobilized (albeit less strictly), stunned with a captive bullet gunshot (in case it is a bovine breed) that perforates the brain cortex and then killed by cutting at least one carotid artery or the blood vessels they originate from; as to other animal species (like birds and pigs), different stunning methods are used like electro narcosis.

Both stunning techniques (gunshot and electroshock) impair the animal's intact nature and are therefore rejected by the Jewish community and, despite some diverging positions about the electric shock, by the Muslim community as well.

## 2. The ethical meaning of ritual slaughtering

Ritual slaughtering brings a fundamental problem to our attention: the legitimate killing of an animal for human nutrition. The present social and economic organization tends to deny this problem, even though it is at the core of a specific area of bioethics, the so called “ethics of bioculture”, dealing with the moral issues regarding the way humans handle their relations with other non human beings.

After losing the direct relationship between man and farm animals that characterized our past and that in some way “humanized” the killing of an animal, slaughtering for nutritional purposes has been depersonalized and organized around procedures that are largely driven by economic and industrial considerations. This diminishes the practical effect of those provisions – although these deserve our appreciation and we can only wish they are enforced more and more often and broadly – aimed at protecting the animal well being in the course of such procedures.

In ritual slaughtering, the animal killing is seen as a sacred, very serious and solemn act: not an ordinary, trivial act that anyone can perform without thinking about the fact that it amounts to kill a living being. Slaughtering, within a religious context, is a reminder for human beings: they cannot arbitrarily decide upon the fate of other living subjects; they are simply allowed to use them within the framework of a specific reference. Such reference, for both religions, is the reference to God. This is precisely the profound meaning of the ritualized slaughtering or the blessing and invoking that come with it. It is appropriate to wonder to what extent the modern industrial slaughtering methods have changed (or reduced and even misled) the original meaning of ritual slaughtering; however, its ethical value cannot be lost.

The care paid (sometimes with a very high degree of detail) to the different steps of ritual slaughtering has also another meaning: to reduce the animal suffering. The emphasis put on the sharpness of the blade that resects the blood vessels, the way resection must be performed and the slaughter man's technical expertise is meant to do whatever one can do

to make the animal die as fast and painless as possible. Clearly, these rules should be considered in the light of the knowledge and techniques that existed when they were created: hence, one may question whether the progress in such knowledge and techniques would call for a revision of some of these rules without affecting in anyway whatsoever the profound, essential meaning of ritual slaughtering. At any rate, it is worth to stress that in ritual slaughtering there is no intention to be cruel with animals: on the opposite, avoiding any useless suffering has always been a target.

All these elements demonstrate that ritual slaughtering is, for the Islamic and Jewish culture and religion, much more than a mere dietary practice whereas it constitutes a true element of worship.

### 3. The ethical meaning of animal suffering

As already noted, human beings have specific responsibilities vis-à-vis animals: in this respect, the animal suffering acquires a specific ethical value and poses a few difficult questions to the human conscience.

Elsewhere, the CNB has affirmed the need to start from the responsibility of man towards the animal world to develop an ethics of care, based on an attitude of availability vis-à-vis the other and the recognition of a constitutive, essential inter-dependency between human beings and animals.

Generally speaking, the expression 'to take care of' has multiple meanings. It seems to refer to a fundamental availability vis-à-vis the other; an attitude stemming from the recognition of an essential, constitutive inter-dependency which translates into a serious commitment to understand the real needs of the other and take responsibility for it.

Thus, the ethics of care:

- a. Insists on needs (not simply on interests);
- b. Attributes a crucial value to compassion;
- c. Places dedication (vs performance) at the core of the debate;
- d. Leverages on the notion of responsibility (not on the notion of right);
- e. Does not imply reciprocity (vs the rights/duties correlation);

For such reasons, it looks especially suitable to constitute a bioethical paradigm of relations with the non human world. It is a matter of interpreting the notion of care in a strong, constructive way; not a mere call for sentimentalism or an idyllic vision, but a responsible commitment to reduce the suffering of animals and promote their well being, paying attention to the unavoidable question of inter-specific conflicts, capable of setting ethical limits that cannot be exceeded, to guide and regulate our relationships with the living world.

In this perspective, a reference to bioethical responsibilities cannot forget the concrete, real commitment to match such responsibilities with regulations on the protection of animals.

### 4. Ritual slaughtering and religious freedom

One additional aspect of ritual slaughtering should be underlined, especially within the framework of an intercultural bioethics: its relationship with religious freedom.

Religious freedom not only consists of acts of worship but also of behaviours and activ-

ities that followers deem to be implicitly requested by the rules: for examples, rules on clothing, not working on religious holidays or the refusal to serve the army, etc. For the Islamic and Jewish religions in particular, ritual slaughtering is one of these activities: eating animal meat is allowed only when the animal has been slaughtered in full observance of some prescriptions established by their respective religious laws. This practice is not simply allowed or recommended, it is binding for every follower of the two religious communities, as recently acknowledged through a decision issued by the federal constitutional Court of Germany (1 BvR 1783/99, 15 January 2002).

The fact that a given behavior is a manifestation of religious freedom does not make it automatically lawful or morally acceptable. When religious freedom translates into behaviors, it must respect some limits, particularly those concerning the freedom of others and the protection of rights, public order, morals and health: in such a context, also the attention to the needs of those special “moral patients” that animals are, passive targets of human obligations of a legal and moral nature, becomes important. More specifically, these limits are set by making a comparative judgment of the religious freedom and the other values protected by our legal system, to decide from time to time whether a specific manifestation of religious freedom clashes against other fundamental needs.

As for ritual slaughtering, any comparison should be referred to a principle that has become increasingly important for the social consciousness of the Italian population: the protection of animals. This principle has been partially made explicit in the provisions punishing the ill-treatment of animals (see, *inter alia*, art. 727 of the Criminal Code and law 22 November 1993 n. 473, New rules against the ill treatment of animals). Such provisions are insufficient, even within the limited notion of animal protection; this is also why the Italian Parliament is presently debating new bills on this subject. These provisions look even more insufficient when the emphasis shifts from the protection to the well being of animals (from a standpoint that is not solely legal): in fact, this approach requires an ethics of animal care that “translates into a serious commitment to understand the real needs (of living beings) and responsibly take care of them”. Reference to such responsibility cannot forget “the resolve and concrete commitment to appropriately translate intentions into the regulations on the protection of animals” (*Bioetica e scienze veterinarie cit.*).

These days, ethical awareness goes beyond the human species, being the result of an evolving selfconsciousness typical of human beings. We are heading for an ethics of animal treatment which, for human beings, is well rooted and consolidated.

We can now try and make a comparative judgment, implying a number of fundamental steps.

a) first of all, ritual slaughtering does not exceed the above limits unless one demonstrates that suffering caused to ritually slaughtered animals is greater than the suffering caused by other forms of slaughtering allowed by our legal system.

There is no sure method to measure the pain of animals and this is why no firm conclusion can be drawn. Based on scientific studies in this field, most authors believe (even though a minority of researchers holds a different opinion) that slaughtering after animal stunning causes less pain than slaughtering with no previous stunning: the Italian legislation is based on this assumption. Following the pattern outlined by the European Union directives, stunning is generally imposed despite a number of exceptions (including ritual slaughtering, involving a rather small fraction of animals slaughtered with no previous stunning).

b) secondly, if one hypothesizes that ritual slaughtering implies more suffering, it is necessary to quantify this excess suffering that is part of a chain of pain, at times very long, experienced by the animal to be slaughtered.

While any suffering, however small it can be, is always significant from an ethical viewpoint, we cannot neglect the findings of scientific research (although inconsistent). According to these latter, the time difference in terms of animal suffering slaughtered with or without stunning is a matter of seconds. Nonetheless, however short this suffering time can be, being a prelude to death, it might have a highly significant bioethical value; also the restraint of animals to slaughter with no previous stunning requires special mechanical operations that are, in their turn, stressful. Precisely because suffering is inherent in slaughtering, each increment of this pain represents an additional burden that should be avoided in the name of the bioethical principle called *non maleficenza*, i.e. the duty not to intentionally harm any “moral patient”.

«You cannot claim you are truly taking care of someone –Bioetica e scienze veterinarie reports– unless you are prepared to worry and personally commit to reduce his suffering, to every extent possible, and promote his well being, especially when the individual in question does not know or cannot defend itself».

c) Finally, if you believe that the excess suffering of an animal due to the absence of stunning is significant, you also need to evaluate whether it is acceptable to safeguard religious freedom in the name of slaughter. In other words, it is necessary to repeat the same comparative process that the CNB has already completed on other occasions, to decide whether it is acceptable to inflict pain to animals in playful or entertainment activities or in the pursuit of high level scientific objectives.

Since the particular constitutional safeguard recognized by our system to religious freedom implies that ritual slaughtering is legally acceptable, the CNB believes it is bioethically acceptable provided that its related practices are not in conflict with the very ritual of slaughtering while being conducive to the minimization of animal suffering.

## 5. Ritual slaughtering and animal well being: can the two go together?

The conclusion reached in the previous paragraph can be furthered. In fact, everyone should manifest their own religion through ways that have the minimum negative impact possible on every other living being and, more generally, on the human habitat. This obligation persists even when, by comparing the different values at play, a specific manifestation of religious faith is legally lawful. In ritual slaughtering, the key issue seems to be the lack of animal stunning and the restraint techniques employed. As already noted, throughout the European Union member states, the legislation assumes that an animal will suffer less if made unconscious prior to slaughtering: the bioethical principles of precaution and responsibility impose to consider this possibility.

Therefore, the CNB hopes that:

- a) research will be furthered to achieve conclusions in both the scientific and religious fields; the goal is to strike a balance between religious practices and the minimization of animal suffering. In particular, the CNB wishes to specify the notion of animal integrity, typical of each religion and different from the mere animal’s state of vigilance. In fact, based on previous experiences in other European regions, it may be pos-

sible to identify techniques that limit the animal vigilance without causing any lesion that may impair its integrity;

- b) more research is conducted on forms of stunning possibly acceptable by religious rules, as it seems to happen already in some cases;
- c) the legitimate economic needs of slaughter houses do not prejudice the observance of time and techniques required for a proper performance of slaughtering, especially ritual slaughtering. The need to avoid useless suffering to animals, the need to observe elementary health and sanitation rules and the need not to offend the sensitivity of people, induce the CNB to reject spontaneous and uncontrolled ritual slaughtering, carried out outside authorized abattoirs, with no proper veterinarian control.

The problems rising in countries where the Muslim immigration is more substantial call for an urgent set up of specific ritual slaughtering facilities, quite numerous on the occasion of some religious holydays; for example, slaughter houses could remain open also on those dates. However, one should not forget that the spontaneous, uncontrolled slaughtering of animals is not exclusively practiced by the Muslim community: actually, it is performed on multiple occasions on both religious and secular grounds and reasons. This is why any observation on ritual slaughtering should be the tip of the iceberg for a broader debate on a more responsible relationship between humans and animals. It is necessary to address the issue of the higher economic costs for consumers resulting from a correct bioethical approach of this relationship. It is the entire legislation (and even more its enforcement) on animal breeding for slaughtering to raise doubts, requiring structural interventions to actually respect the ethics of care that has been mentioned earlier: in fact, the way these animals, increasingly part of the industrial production process, are forced to live as they grow up, the way they are carried to the slaughter house and the way slaughtering is performed often times are less than ideal in terms of respect owed to animals.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**ADVANCE TREATMENT STATEMENTS**

18<sup>th</sup> of December 2003



## INTRODUCTION

This Document concerns advance treatment statements, the importance of which has grown constantly in recent years and which are frequently referred to in the national and international literature on bioethics with the expression *living will*. Other expressions used include biological will, life will, prior treatment wishes, etc. These expressions all refer to a document through which individuals, in full possession of their mental faculties, express their wishes regarding the treatments that they would or would not want to undergo to in the event that, in the course of an illness or as a result of sudden trauma, they were no longer able to express their informed consent or dissent. The different forms that an advance treatment statement can take (some of which have been legally recognised in a number of countries) have been discussed in the literature.

To give these documents public (although not necessarily legal) status, they are required to be drawn up in writing in such a way that there can be no doubt as to the identity and capacity of the person signing them, their authenticity and the date of signing. They should if possible be countersigned by a physician, who should guarantee that the signer has been fully informed of the possible consequences of the decisions he is taking in the document. It is desirable for the signer to indicate a date for the confirmation and/or renewal of the statement, without prejudice to their right at any time to withdraw or amend the instructions it contains. The person drawing up these documents is considered to be responsible for establishing the arrangements for their safe-keeping and the number of authentic copies to be produced, and for selecting the persons to whom the documents should be entrusted for safe keeping and who, if and when the need arises, should present and use them. For those who so request, lawmakers should establish a procedure for these documents to be deposited and/or registered with a public institution. Signers should also establish, in the event that these documents are actually used, whether their content can be made public.

### 1. Reference texts

The Italian National Bioethics Committee (NBC) has not previously devoted any single document specifically to the question of living wills.

However, useful reference material can be found in previous documents produced by the Committee on related subjects, for example in the Document *Information and Consent to Medical Procedures*. Of particular relevance is the third chapter of the document entitled *Bioethical Issues on the End of Human Life*, approved by the NBC on the 14<sup>th</sup> of July 1995. This will be referred to in the present Document, for example to identify which points it will be examining in greater detail in the light of the most recent thinking in bioethics and significant new developments in the bio-legal field.

Of these, particularly worthy of mention is the European Union's Charter of Fundamental Rights, which establishes that the patient's free and informed consent to medical procedures must no longer be seen merely as a requirement for the treatment to be considered lawful, but should be considered first and foremost as an actual fundamental right of European citizens, pertaining to the more general right to the integrity of the person (Chapter I Dignity, Article 3 Right to the integrity of the person). With specific regard to the

issue under consideration, it should be borne in mind that the Italian Parliament has ratified the Convention on Human Rights and Biomedicine (through Law No.145 of the 28<sup>th</sup> of March 2001), which was signed in Oviedo on the 4<sup>th</sup> of April 1997. Underscoring the centrality of the protection of the dignity and identity of all human beings, Article 9 of the Convention attributes particular significance to the patient's previously expressed wishes, and establishes that these shall be taken into account<sup>38</sup>. It can also be observed that even before approving the law ratifying the Convention, the principle expressed by Article 9 had already been espoused in Italy, in 1998, by the Italian Code of Medical Ethics. Article 3 of the Code, under the heading Autonomy of the Citizen, establishes that: "Physicians are required to follow, in full respect for the principles of dignity, freedom and professional independence, the wishes freely expressed by individuals regarding their treatment. If patients are not able to express their preferences in cases where their lives are in grave danger, the physician must take into account the wishes previously expressed by patients". It should also be borne in mind that this code of ethics states, at Article 36, that "the physician, including at the patient's request, must not carry out or facilitate treatment intended to cause the patient's death" and at Article 35 entitles the physician to take action in the form of assistance and indispensable treatment in emergency situations and in cases where the patient's life is in danger ("in the event of an emergency or of danger to the life of the person, who is unable at that time to express his or her wishes to the contrary, the physician must provide assistance and any indispensable treatment"). It follows that for the National Federation for the Orders of Physicians and Dentists (FNOMCeO), any previous expression of the patient's wishes will be applied to the case at hand.

## **2. Advance statements in the light of Article 9 of the Convention on Human Rights and Biomedicine**

The social issue that has prompted the need to engage in an in-depth discussion not just of the bioethical aspects but also of the bio-legal aspects of advance statements to the top of the agenda is, therefore, the need to fully and consistently implement the spirit of the Convention on Human Rights and Biomedicine. In doing so, we also need to ensure that the dignity and integrity of the individual is accorded the maximum protection possible in all situations where the increased opportunities created by advances in medicine might give rise to doubts, not just of a scientific but above all of an ethical nature, on the type of treatment to be adopted in the presence of reliable declarations of intent formulated by the patient before losing their natural capacity to express their desires. With the intention of respecting the provisions of the Convention as faithfully as possible, the NBC has decided to adopt the expression advance treatment statements in the present document to indicate the various forms of self-determination that might derive from a deed that is compatible with the ethical and legal model expressed by Article 9 of the Convention.

---

<sup>38</sup> The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account. In the French version: *Les souhaits précédemment exprimés au sujet d'une intervention médicale par un patient qui, au moment de l'intervention, n'est pas en état d'exprimer sa volonté seront pris en compte.*

As the NBC has stated previously, the “fullest possible participation by citizens in decisions that concern them” applies throughout the entire treatment process and is especially necessary when the patient might be deprived of their cognitive faculties and even of consciousness, and thus be completely dependent on the will of others. Such situations are particularly dramatic when the action might put the patient’s life or quality of life at risk. Advance treatment statements tend to foster the “socialisation” of the most dramatic moments of our existence and to avoid situations where the incapacity of a patient might lead physicians to consider that individual, perhaps unconsciously and against their best intentions, no longer as a person with whom the best possible treatment programme can be discussed and agreed upon, but merely as a body to be subjected to anonymous treatment. For this purpose it would be advisable to provide physicians, healthcare personnel and patient’s relatives with information to help them make decisions that, where possible, are in keeping with the wishes and preferences of the person to be treated. It can therefore be said – as the NBC observed in its document on the end of human life – that the various forms of advance statement “are part of a positive process of adapting our concept of medical procedures to the principles of decision-making autonomy on the part of the patient”.

In actual fact, advance statements cannot be considered merely as an extension of the society that has introduced the informed consent model to the physician-patient relationship; they also have the much more sensitive and complex task of making it possible to establish a personal relationship between the physician and the patient in those extreme situations where it does not seem that any link might exist between the solitude of the person who is unable to communicate and the solitude of the person who has to take the decision. The fundamental aim of the statements is therefore to provide an instrument that can be used to recover as fully as possible, in situations where the patient is incapable of making decisions, the role that is ordinarily played by the informed dialogue between the patient and physician. This dialogue enables the former, through a process whose outcome is an expression of consent (or dissent), to acquaint the physician with all information judged to be significant for the purpose of ensuring that the rights connected with the protection of health and, more in general, the overall good of the individual, are respected. In a sense, such advance statements make it possible for the physician-patient dialogue to continue even when the patient is no longer able to take part consciously. In saying this, the NBC also means to emphasise that while the assessment task that the physician and medical personnel have to perform as a result of advance statements is made all the more complex by the fact that it is impossible to interact with the patient, this same task also enhances their professional autonomy (including the humanistic dimension). It also seeks to emphasise that advance statements should not in any way be seen as a practice that can lead to or facilitate “therapeutic abandonment”, even indirectly: indeed, the instructions provided by the patient, even when expressed (as is to some extent inevitable) in a general and standardised form, should never be applied bureaucratically and obtusely but always need to be inserted into the specific circumstances of each individual patient and his or her actual clinical situation.

One final consideration on this point is that although advance statements raise numerous and complex bioethical questions, from the ethical point of view they do not give rise to any fundamental objections of principle, even though different ethical theories may well have formulated different reasons and grounds in support of their respective positions. The literature subsequent to 1995 has not brought any new developments on this point, and the

NBC concurs in confirming the topical relevance of the opinion set forth in its 1995 document.

Against this consensus, in principle, it is however possible, as we have just mentioned, to advance a number of doubts and reservations with respect to the structure and conditions of implementation of advance statements, which inevitably come to assume a significant, but diverse, ethical relevance. Without claiming to cover the entire range of problems that have emerged in a debate that has been running for over thirty years, in this document we examine four themes that need to be analysed if an acceptable procedure is to be introduced. These can be summed up as follows:

- A) How can we avoid the “abstract” nature of advance statements and the inevitable “ambiguities” arising from the language in which they are formulated, especially when the patient does not seek the help of a physician or other expert when preparing them?
- B) What operational instructions need to be included in these documents?
- C) How reliable should these documents be deemed to be? How binding should they be on physicians, from the ethical and legal points of view?
- D) What instruments should be used to implement advance statements, should this be deemed desirable?

### 3. Abstraction and ambiguity in advance statements

One of the most frequent objections to advance statements or similar documents concerns their inevitably abstract nature. This abstract and generic quality is a consequence of the psychological and temporal distance between the situation in which the declaration is drawn up and the situation of actual illness in which it has to be applied. The grounds for this objection are stronger if we consider that in many respects it might actually be desirable for advance statements to be drafted at a time when the person is not only in full possession of their decision-making faculties but also in good health and free from the stress caused by the onset of illness and/or admission to hospital. In this way, the decision to draw up (or not to draw up) an advance statement – which is obviously not considered merely as a bureaucratic act – can provide an important opportunity for reflection on the individual’s own values and view of life and on the meaning of death as a sign of human finiteness, and thus help to avoid the “repression of death” that many stigmatise as one of the negative features of our era and culture.

However, even if it is clearly not possible to establish in abstract terms the best time to draft an advance statement, concerns over the abstract nature of these documents prompted by this distance in time and circumstances can be mitigated if it is envisaged that the person may at any time withdraw their previous wishes or amend them in response to changes in the way they perceive their personal circumstances as a result of their actual experience of illness. In this latter case – and independently of previous drafts – advance statements might usefully take the form known as “advanced healthcare planning” or “advanced treatment planning”. Hard questions regarding therapy and treatment decisions can undoubtedly be, if not resolved, then at least facilitated by this type of document, if they are formulated during the early stages of the illness and applied specifically to certain slowly developing conditions (AIDS, Alzheimer’s, cancer). The typical progress of these conditions is sufficiently well known and, on the basis of current medical knowledge, there are a range of

diagnostic-therapeutic options available for them, none of which prevails in absolute terms over the others, but each has its own specific benefits and related burdens. The overall effects of each treatment therefore need to be weighed up, a task which, at least in the first instance, should be the responsibility of the patient himself.

It is clear that while a carefully considered and informed drafting of advance statements can significantly reduce their abstract nature, it is not however possible to eliminate this in full. This is just one (but certainly not the only) decisive argument against viewing advance statements as rigidly binding instruments, since, even if drafted with extreme care, they could in the event fail to match the patient's actual condition closely enough.

#### 4. The proxy

Another objection that is often raised in the debate on advance statements concerns their language and scope. Since, commentators observe, it is difficult for patients to correctly define the clinical situations to which they intend their declarations to apply, this situation can give rise to ambiguity in their instructions and, as a result, to doubts when the time comes to follow them. This objection touches on a particularly thorny question and, if it is taken to its extreme conclusion – that is, if it is used to argue that advance statements should only be acceptable if the language in which they are drafted is absolutely precise or the person drafting them is fully capable of predicting the details of the situation in question – would in itself deprive the statements of any bioethical and above all practical value. However, this would be an overly drastic conclusion, which if applied, by analogy, to the major ethical issues of information and consent, could empty them of all meaning. And no one should forget Aristotle's advice to the effect that we should never search for a greater degree of precision than that which the nature of the subject admits.

Another serious problem, which is very similar to but does not fully overlap with the former, is that of the actual form that the physician's decision on treatment would have once a patient's statements had been observed. If this were to consist of a cold and formal decision to follow the wishes expressed in the declarations to the letter, an automatic mechanism would be created which, since there is no dialogue, would weaken, if not entirely undermine, the ethical and medical-therapeutic value of the medical procedures while exacerbating their bureaucratic nature.

The strategy adopted to solve these difficulties has been for the drafter of the advance statement to appoint a proxy or agent. This figure is included in many of the model statements proposed in Italy and abroad, some of which have already been legally recognised in a number of countries. In the United States in particular, the proxy mandate (Durable Power of Attorney for Health Care in the State of California; Health Care Representative in the State of Oregon; Patient Advocate for Health Care in the State of Michigan) is the cornerstone of these documents, while the statements themselves are formulated in terms of limits placed by the patient on the action of their proxy or agent.

A large variety of responsibilities can be attributed to the proxy, but all of them are linked to the very general task of acting, always and solely in accordance with the legitimate intentions expressed by the patient in their advance statement, to make these wishes and

intentions known and to carry them out. The physician should inform the proxy of the therapeutic strategies that he intends to adopt for the patient, and demonstrate that these are compatible with the patient's advance statement or – if applicable – properly justify why he considers it to be his duty (and not merely appropriate) to depart from them. One of the principal tasks of the proxy is to guard against the very real possibility of the patient, especially if terminally ill, being abandoned by the physicians and health structures regardless – obviously – of whether abandonment has been specifically mentioned in the statements. In this framework, the role of the proxy appears to be much fuller than that of the power of the attorney and fairly close to the role that family members already play, or should play, in these situations. The essential difference here is that – in the light of the explicit mandate contained in the advance statement – the proxy has a full right-duty to act as the physician's point of reference with respect to the treatments applied to the patient. In short, the task of the proxy is to comprehensively protect patients (starting with the statements they have drawn up) rather than simply overseeing the correct and formal execution of the procedure through which the statements are expressed (naturally, however, there should not be any difficulty in principle in reconciling these two commitments).

Of course, the figure of the proxy can create subtle problems, which must be pointed out. To start with, the proxy appears to be modelled on the legislative paradigm currently used to govern the protection of rights and interests of legally incapacitated adults. This reference is, however, both unsatisfactory and inadequate since the protective measures (disqualification followed by the appointment of a guardian) envisaged by the legislation for such persons reflects an approach that focuses more on the protection of property rights and the interests of family members and third parties than on the rights and needs (not just property-related) of the incompetent person. This explains the insistence of those who maintain that a law is absolutely necessary to introduce the new figure of the proxy or agent to the Italian legal system. The previous tendency to differentiate clearly between the sector of property interests, dominated by issues of transferability, and that of personal interests, which refer to the state and capacity of the person, would in fact be reversed. It is of course within the framework of this change that this new figure of the proxy could be set, as the actor formally entrusted with the task of protecting the interests of a person who has become mentally incapacitated in the event of any doubts arising as to the interpretation of their wishes.

Recognition of legitimacy, and for some of the advisability, of appointing a proxy still leaves the question of the precise ethical-legal significance of their function unanswered. While there is no doubt that the decisions taken by the proxy regarding the treatment of a patient who has become incompetent acquire an ethical value through the very fact that the author of the advance statement has entrusted such a very delicate task solely to this person, it would not be appropriate for these decisions to have binding legal force. As for any other bioethical evaluation, the proxy's opinion should aspire to true authoritativeness, rather than to a legally sanctioned authority, and his tasks should be limited, in an on-going dialogue and debate with the physicians in charge of the case, to identifying the best interests of the patient based on the instructions laid down in the advance statement. The proxy would also have the task of ensuring that the physician did not fall into the temptation to practice any form of heroic treatment and of agreeing with him or her on the actual course of action to be followed in those cases where different, equally legitimate diagnostic and therapeutic options are available. There is, however, no question of the proxy being able to

take decisions that could not have been legitimately taken by the patient himself in their advance statements<sup>39</sup>.

## 5. The content of advance statements

While advance statements are connected with the consolidation of a bioethical culture that has already taken effective action to introduce the informed consent model in physician-patient relations and to overcome medical paternalism, their sphere of impact coincides with that in which a conscious patient can validly express their consent or dissent with the treatments proposed. The general principle that should inspire the content of advance statements can be formulated as follows: each individual has the right to express his or her wishes, including in advance, with respect to any therapeutic treatment or medical procedure about which they can legitimately express their current wishes.

From this definition, it appears immediately clear (but should be underscored) that this principle precludes any chance of a situation arising where advance statements might contradict positive law, good clinical practice or medical ethics, or might seek to actively impose practices on physicians that they find unacceptable in terms of science or conscience. It should be remembered that the Italian legal system includes constitutional, Civil and Criminal laws that recognise the principle of the inalienable nature of human life. As a consequence, the patient cannot be legitimised through advance statements to request or obtain medical action that implies euthanasia. Moreover, in some countries the ambiguity of laws legally recognising advance statements, or the unacceptably broad interpretation of these laws by the courts, makes any proper analysis of the point in question extremely complex and has fostered the idea with many that the recognition of the validity of advance statements is equivalent to legalising euthanasia. For this reason the NBC deems it essential to eliminate any ambiguity and emphasises that the right being proposed – for patients to influence the treatment to which they might be subjected in the event of their being considered incompetent – is not a right to euthanasia, or a right to die which the patient can invoke in their relations with physicians (exemplary in this regard is the European Court of Human Rights ruling of 29.4. 2002, *Pretty v. the United Kingdom*). It is, rather, a right solely to ask physicians to interrupt or not to undertake therapeutic actions even in the most extreme, tragic cases of life support, practices which patients would have the full moral and legal right to refuse where capable of so doing. Examples are practices whose effectiveness is not properly proven, or which involve serious risks, are not proportionate to the effective clinical condition of the patient, are extremely invasive or would seriously affect the serenity of the dying process<sup>40</sup>.

---

<sup>39</sup> According to Prof. Renata Gaddini, lawmakers should place a strong emphasis on the legal status of the proxy (if possible a physician, especially the patient's own or family physician) and make it obligatory for his or her identity to be recorded in a document specifically designed for this purpose. The right of the proxy to evaluate, along with the person in charge of treatment, the arguments for or against the implementation of the advance statements, should be formally recognised (where, obviously, patients are no longer able to express their own current preferences in person).

<sup>40</sup> Prof. Silvio Ferrari argues that the document should also mention the patient's right to refuse treatment that is not compatible with his or her religious beliefs.

Taking all this as given, we need to focus on various types of treatment and procedures which, in principle, are encompassed by the above principle. Without necessarily carrying out a complete comparative analysis of the content of the existing models of advance treatment statements, we can however highlight some elements:

1. statements on religious care, the intention to donate (or not) organs for transplant, the use of the body or parts of it for research and/or teaching purposes;
2. statements regarding ways of humanising death (palliative treatments, request to be treated at home or in hospital, etc.);
3. statements that reflect the individual's preferences regarding the range of diagnostic-therapeutic options that might be available during the course of the illness;
4. statements on the implementation of palliative treatments, following the recommendations made by the NBC in its document of 14 July 1995 on Bioethical Questions on the End of Human Life;
5. statements intended to formally request the non-activation of any form of heroic treatment, i.e., of life support treatment that appears to be disproportionate or unjustified;
6. statements requesting the non-activation or the suspension of life support treatment which, in the case at hand, does not necessarily constitute heroic treatment;
7. statements requesting the suspension of artificial feeding and hydration.

The first two types of statements do not pose any particular problem, and may be formulated with a sufficient degree of precision to ensure that those who are called upon to put them into effect are not faced with doubts or difficult choices. The third type of statement does not raise great difficulties either, especially when it consists of the advance planning of treatment and stays within the area of the diagnostic-therapeutic options that may be applied during the course of a given disease. The fourth and the fifth statements do not give rise to moral dilemmas, given the unanimity of belief in the desirability of making palliative treatment as widely available as possible and unanimous censure of excessive treatment.

The last two statements, however, are highly controversial; the last most of all, especially if we consider the symbolic significance that attaches itself to feeding and hydration, even if by artificial means. Some members of the NBC believe patients, for reasons that will vary but relate to people's most intimate and unassailable convictions, should be accorded the right to express in advance their wish to accept or refuse any type of treatment, and to indicate the conditions in which their wish must be put into effect. Those that favour this view stress the necessity of ensuring that advance statements are drawn up, or at least discussed, within the context of a physician-patient relationship, so that the patient is fully aware of the consequences of the enactment of his or her wish. Other members of the NBC, however, believe the patient's power to issue statements should be limited exclusively to those treatments that, in varying degrees, include forms of invasive procedures, on the grounds that they may be disproportionate or even futile. On this view, the patient's right to issue instructions should not refer to non-extraordinary medical intervention in support of life, nor to artificial feeding or hydration which, unless they cause the patient suffering, are ethically and morally mandatory, because, if proportionate to the clinical condition of the patient, they contribute to eliminating the suffering of a terminally ill person, and their omission would constitute passive euthanasia.

## 6. The reliability of advance statements

Assuming that the issues mentioned above have been resolved, there is widespread consensus that advance statements have great moral force. The same cannot be said, however, about the value of such statements in relation to medical ethics and the law. Above, we touched on two closely connected yet distinct points, which we shall now look at in more detail:

- a) the issue of the reliability of the choices made in advance of the time of their implementation;
- b) the issue of whether such choices should be considered binding on the physician or merely indicative.

In relation to the first issue, advance statements protract the effects of a patient's choice over a period of time, but clearly do not assure that the choice remains current in time, i.e., the wish expressed is not contemporaneous with the moment in which conditions are such that the physician is obliged to act. For this reason, the criminal law literature often looks askance at advance statements on the grounds that they cannot guarantee that the real wishes of the patient are being realised. The physician can never be certain that declarations made under prejudicial circumstances and particular personal conditions, often when in a state of full psychological and physical health, truly correspond to the wish that the patient would express if of sound mind at the moment it becomes necessary to apply the medical procedure or treatment. The risk for patients is that, on the basis of a choice that was legally improvident, they will be deprived of indispensable assistance that they might have good reason to want if only they could take stock of the realities of the situation, in which new scientific knowledge or therapeutic techniques capable of curing an illness previously considered incurable may have been developed, or, at any rate, in which different cures from what they had originally expected may be available.

Two counter-arguments can be advanced against this.

The first is that if a person has been properly warned of the need to take the risks mentioned above into account, and recognises that all advance decisions relating to treatment must inevitably carry an element of hazard, contingency and uncertainty, yet firmly resolves to impart statements nonetheless, that person's signature is an unequivocal attestation of his or her intention to take personal and full ethical responsibility for the risk. If the person in question is an adult, autonomous, informed and of sound mind, and firm in his or her intention to impart advance statements, it is hard to see why the risk that the person has consciously elected to take should render the statements invalid.

The second counter-argument is that if we insist that the manifestation of consent or refusal can only be valid if concurrent with the moment in which the medical act is to be executed, the logical implication is that the patient's will deserves to be respected for as long as he or she is fully conscious and capable of expressing his or her wishes without reservation. This causes no difficulty for what is likely to remain the majority of patients, those who sincerely wish to commit themselves entirely to the competence and wisdom of the physician if they themselves should become incompetent, and therefore to the physician's subsequent unquestionable decisions. This principle, however, causes significant and paradoxical difficulties when the patients, having signed a document giving advance statements, have, through the exercise of their autonomy, given explicit proof of their wish to guide the medical procedures visited upon them after they are no longer competent. For these patients

and for them alone, the problem is one of medical paternalism, which they consider unacceptable and contrary to contemporary bioethical thinking, which favours the autonomy of patients and the centrality of the individual. In other words, in an effort to avoid the indubitably considerable risk of a mismatch between the substance of a patient's wish and the realities of the situation in which it is to be implemented, we run into the equally serious risk of failing to give due recognition of the patient's autonomy. The only way out of this difficulty is to understand that the requirement that a wish should be current does not refer merely to chronological time. Italian law (for example, the 1999 law referring to organ transplants) has already breached the concept, albeit in reference to a different, though analogous, concept, that legal recognition may be given to a wish expressed by the person while alive, even if the wish was expressed by silence.

As with any form of expression that gives voice to a person's will or, more generally, preference, an advance statement is contingent on the principle that a person retains the right to withdraw consent or change position, right up to the final moment of losing consciousness. It must, however, be accepted that at that point, the known wish of the patient that has been implicitly or explicitly confirmed is to be considered the final valid wish, and no one has the right to make conjectures about whether the patient might have changed his or her mind after the loss of consciousness. In any case, given that the decision whether to intervene or not has to be made, it is preferable to follow the indications given by the patient when still in full possession of his or her faculties, since these indications will presumably accord with the person's conception of life, rather than ignore them on the strength of a presumed and unprovable change of will after the loss of consciousness.

On the basis of this reasoning, therefore, we have good reasons for arguing that if a patient gives or withholds consent at a time other than the moment of decision proper, the patient's wish should be accorded the same respect that is due to a wish expressed concurrently with the medical intervention. A number of other conditions also apply, and we shall define them in detail below.

## **7. The binding nature of advance statements**

Let us now consider the question of whether advance statements should be considered as (absolutely) binding or (merely) indicative. This theme, too, has been widely explored in national and international forums, which has inevitably given rise to a wide range of opinion and divergent views. Even so, as the adverbs in parentheses preceding the adjectives "binding" and "indicative" above demonstrate, it is the NBC's view that the disagreement is more conceptual than ethical. The issues at stake have been posed in an improper manner that neither corresponds to the spirit of Article 9 of the Convention on Human Rights and Biomedicine, nor to the interests and needs that, presumably, prompt a person to draw up advance statements. The starting point of the argument must necessarily be a sense of respect for "general good of the human person" and the therapeutic alliance between physician and patient, which is a necessary corollary of the first condition. We can make a case for saying that when a person composes and signs an advance statement, the person is not just giving clear indication of a desire to have his or her wishes honoured but is also indicating, with equal clarity, that he or she does not intend these wishes to be absolutely binding in a deterministic and mechanical sense, regardless of the situation. This is why Article

9 of the Convention uses the French and English words *souhaits* and *wishes*, which refer to *what is desired* rather than *what is imposed by third parties*. A person asks that his or her wishes be respected, but also asks that they retain their current validity, i.e. that the conditions that the patient intended actually exist. Indeed, it is reasonable to assume that no patient intends to encourage an attitude leading to the abandonment of treatment that would deprive him or her of the possibility of enjoying the benefits of methods of treatment that might become available when he or she is no longer capable of expression. To consider a patient's wish as neither (absolutely) binding nor (merely) indicative is not a violation of patient autonomy, which, on the contrary, is thus given full expression. Nor does it constitute, as some fear, a violation of the autonomy of the physician and medical professionals. In fact, this approach leaves room for physicians to exercise their independent judgement, without having to respect the patient's wishes mechanically. Rather, the physician has the obligation to assess the currency of previously articulated wishes with reference to the patient's clinical state and any advances in medical technology or pharmaceutical treatment that may have taken place in the meantime, or of which the patient was evidently unaware. This, moreover, is the most accurate interpretation of the meaning of Article 9 of the Convention, as may be seen quite clearly from point 62 of the *Explanatory Report* which we transcribe here: "The Article lays down that when persons have previously expressed their wishes, these shall be taken into account. Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid, taking account in particular of technical progress in medicine."

It is worth observing that a previous version of the Convention had defined the patient's wishes as "decisive", an adjective that gave rise to considerable misgivings in many quarters, including the NBC. In the first place, the adjective seemed to constitute a violation of the professional autonomy of the physician; secondly, it did not even appear to correspond to the real motives for which, as we have seen above, a patient formulates advance statements. The change in the wording from "decisive" to "taken into account" should not, however, be taken to indicate a shift from treating wishes as (absolutely) binding to (merely) indicative. If it is right to rule out the first formulation, the second, too, should also be ruled out whenever it is construed in so weak a sense as to amount to the restitution of full decision-making and operational liberty to the physician, because this is the equivalent of granting the physician inappropriate *paternalistic* power, with the result that very idea of patient statements is emptied of all meaning.

These observations should help take some of the sting out of the controversy over the degree to which advance statements should be considered binding. The ethical value of these declarations depends exclusively on their retaining their relevance during the physician's autonomous assessment of whether the precise conditions indicated by the patient actually obtain. It follows that if the physician, on the basis of his or her knowledge and conscience, is firmly convinced that the patient's wishes were not only *legitimate* but remain *current*, then honouring the wishes not only fulfils the compact made with the patient, but also becomes a matter of ethical duty. If the circumstances have not changed, doing the opposite to the patient's wishes would be a very strange way indeed of taking them into

account. Just as obvious is the point that if physicians, acting autonomously, should come to a different decision, they are bound to provide an exhaustive explanation and justification so as to allow whoever is acting as the patient's proxy or agent to take action.

## 8. How to implement advance statements

The issue of implementing advance statements can be considered from two perspectives. Some bioethicists believe that, in light of the growing complexities of situations involving terminal cases, *all* or *most citizens* should make use of advance statements. Those that hold this view feel that it is important not only to decide upon the most accurate forms of statement and the limits that should be imposed, but also to take action in society to encourage people to prepare statements, in a manner similar to the campaign inviting citizens to make their organs available for post-mortem transplant.

It is also possible, however, to say that equal bioethical respect should be given both to those prepared to draft such statements and to those who are utterly repelled by the idea. Statistical data demonstrates that even in those countries where the possibility of imparting advance statements has been legally formalised for some time, only a very small number of people have wanted to use them. Further, certain practices by which people are pressured into preparing statements are, beyond doubt, highly repugnant. One such example is a famous London hospital that, when taking in very old people (i.e. more than 75 years) requests (or requires?) the patients, who are particularly fragile both physically and, above all, psychologically, to sign a declaration renouncing their right to life-sustaining therapies if, in the course of treatment, unfortunate, though not extreme, mishaps (such as sight or mobility loss) should occur.

At the present stage of bioethical thought, it seems reasonable to recommend that advance statements should be implemented, but with a view to ensuring only that they are correctly formulated for and applied to those that intend to use them. This avoids the risk that, on the pretext of carrying out previous wishes, a surreptitious attempt will be made to inculcate among patients, especially the more elderly, an attitude of surrender in the face of death, which would transform the care of the terminally ill into an appalling and undignified bureaucratic acceleration of the process of dying.

Once we accept, within the limits set out above, that advance statements may be implemented, we need to bear in mind that Article 3.1 of the law ratifying the Convention on Human Rights and Biomedicine delegates the Government the power "to adopt, within six months of the coming into force of the present law, one or more legislative decrees containing further necessary measures for adapting the Italian legal system to the principles and rules of the Convention and the Protocol referred to in Article 1." The question that arises here is whether, for the sake of giving practical effect to the principle outlined in Article 9 of the Convention, we should wish to see the enactment of formal legislation to put advance statements on a legal footing.

It is a question that touches on many different issues and is open to many interpretations. It has been quite rightly pointed out that if the law is to be framed correctly, the legal classification of patient statements should be preceded by an adequate set of rules to address the very general and fundamental problem of what legal weight should be given to the patients' wishes in relation to the power of medicine to cure, and set down the limits,

faculties and obligations inherent in this power (i.e. the purpose and content of what is commonly referred to now as the physician's "guarantee role"). Once these issues have been taken into consideration, the legal recognition of advance statements may be justified in full only if it forms part of a more general set of rules referring to the importance of patients' wishes in relation to medical and surgical treatment, which is something that medical science, the medical profession and the law have needed for some time. A remedy is needed for the current situation, which leaves too many legal grey areas.

Further important observations that have been made is that the real bioethical problem relating to advance statements is practical and operational, not doctrinal. The achievement and consolidation of correct practice in this area is more a cultural than a legal challenge. Although we must take the principles set forth in the Convention as definitively acquired and shared (for how could we do otherwise?), the very fact that so much effort had to be made to frame the principles and then formally and authoritatively proclaim them suggests that they cannot be taken as obvious or self-evident. It is therefore legitimate to argue that much time will have to pass before they shape the general beliefs of physicians, patients, and the public at large. Given that this is the case, one of the most advanced principles of the Convention, that referring to the value of advance statements, should not be treated as if it represented a clear and unproblematic resolution of a broad debate in bioethics and biopolitics, but, rather, as one of the intricate, complex and occasionally contradictory premises that will always be in need of further painstaking clarification, as part of the unending attempt to make respect for the dignity of patients the cardinal point of all healthcare practice. If we do not start out by being aware of this, we risk reducing the struggle for the promotion and defence of bioethical values in general and advance statements in particular to a purely formalistic battle. The experience acquired over the years shows that, for example, the obtaining of informed consent has, in most cases, been diminished until it consists of no more than the signing by the patient of a document that is often written using terminology that is extremely remote from common understanding of the phenomena involved. If this is the case, then we must not delude ourselves that legislative action to formalise the legal grounds by which advance statements may be considered valid can on its own produce an outcome any different from the inevitably and intrinsically formal results that the law is already capable of providing. Without wishing to deny the usefulness of legal provisions to give effect to the principles of the Convention, the NBC is nonetheless adamant that a prior effort has to be made to extract all the ethical resources that are implicit in Article 9, so that full value may be given to the physician-patient relationship, not only when a statement is being formulated but also at the rather more traumatic moment when it is being put into effect.

Advance statements should act as a powerful reminder to physicians of their professional duties and offer an opportunity for inaugurating a new model of healthcare for situations of extreme difficulty (except, of course, in those welcome cases where new practices have already been put in place). Healthcare should be regarded as a dynamic structure of relations, not as a static system of procedure. Article 9 should be treated for what it is: the simplest means available for guaranteeing the best possible ethical result with the smallest possible number of rules. We should support an open-ended and flexible approach to legislation whenever the situations that need to be regulated are ethically controversial or social expectations are extremely uncertain. With a view to this, it is to be hoped that any law dealing with advance statements will accompany and not precede far-reaching efforts (which

should be extended to medical schools, hospitals and civil society in general) to inculcate awareness of the bioethical complexities of the issue.

Some members of the NBC welcome the opportunity of rapidly eliminating the legal uncertainty that is such a torment for many healthcare workers and leads many citizens, who are firmly persuaded of the utility and necessity of preparing advance statements, to conclude that the current legal framework provides few guarantees that their wishes will be heeded. In the area of advance statements, many simple but also essential questions can only be given uncertain and imprecise answers. For instance, do patients have to express their wishes in writing, or will an oral declaration do? In either case, how is it done? Who is responsible for the taking and safekeeping of such statements? Should mention be made of them in medical records? How can a physician be sure that the advance statements that he or she has received were not withdrawn or substituted? How can the physician be sure they were made by persons genuinely competent to do so? If the patient has named someone to act as their representative, what are the consequences of the appointed person refusing to accept the responsibility? Clearly, these and other questions that arise time and again in the debate are not answered by the Convention, nor by the Code of Medical Ethics. Yet, without comprehensive and unequivocal answers, the risk is that the principle of respecting previously expressed wishes will not be observed in practice.

To conclude, in addition to raising cultural awareness, it is also necessary to ensure that legislative action is wide-ranging, exhaustive, able to resolve many of the outstanding questions relating to medical-legal responsibility, provides legal support for advance statements and regulates the procedures for their implementation. This would give physicians clear guarantees for their professional practice, especially for extreme situations. Legislation would also give patients a reasonable certainty that their wishes will be carried out. Only precisely-worded regulations that unequivocally define the contents and limits of the *guarantee role* that healthcare professionals play in their dealings with patients can restore the equanimity of professionals who are called upon to make decisions, and can help them through legal and professional dilemmas that would otherwise be insoluble. In some instances, insoluble dilemmas have led healthcare professionals to conduct themselves in a manner that they regard as morally right and justifiable, yet, in the absence of clear and explicit regulations, leave them open to legal challenge, with possibly dire consequences for their private and professional lives. In an even greater number of cases, however, the absence of legislation induces them to adopt the practice of “maximum caution”, not for any ethical or professional reasons, but rather to protect themselves against the legal repercussions of actions they might take. In the aforementioned document from 1995, the NBC advised physicians to conduct themselves in this way, for the sake of prudence rather than for bioethical motives, given the “disappointing” and “insidiously flawed” nature of Italian legislation relating to the “principles of personal autonomy in the exercise of the right to health.”

## 9. Concluding bioethical recommendations

Briefly stated, the NBC believes that advance statements are bioethically legitimate, provided that they comply with the following general criteria:

- A. they are public, i.e. include a date, are made in written form only and never orally by

adequately informed persons of adult age, sound mind, who are autonomous and not subject to any family, social or environmental pressure;

- B. they do not contain any instructions whose intent is to obtain euthanasia, or that violate the law, the rules of medical practice or professional ethics. In no case may physicians be forced to do anything that conflicts with their science or conscience;
- C. to ensure that they are prepared properly and in compliance with point B above, statements should be compiled with the assistance of a physician, who may countersign them;
- D. they should be as personalised an expression as possible of the wishes of the future patient, and should therefore not consist of the mere addition of a signature to a pre-printed form or document; they should not be written in generic terms that might leave room for misinterpretation of their content, and should be as clear as possible about the clinical situations that should obtain before they are taken into consideration.

The NBC also recommends:

- a) that lawmakers act in this specific area to give effect to the statements of the Convention on Human Rights and Biomedicine, and to prepare the way for the future introduction of general legislation referring to bioethics and the health professions, for whose preparation the NBC can offer its contribution;
- b) that the law will oblige physicians to take advance statements into account, but also expressly specify that the statements are not binding, and will compel both those who carry out statements and those who do not to provide formal and adequate explanation of their decision in the medical records;
- c) that advance statements may appoint one or more proxies, whom the physicians must consult when taking decisions relating to patients who have become incapable of comprehension or communication;
- d) that in the very possible event of advance statements containing sensitive and private information, the law will lay down the procedures that must be followed for preserving and consulting them.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**THE PRECAUTIONARY PRINCIPLE: BIOETHICAL,  
PHILOSOPHICAL, LEGAL ASPECTS**

18<sup>th</sup> of June 2004



## PREMISE

In the last few decades, as is known, several episodes have given rise to deep concern for the protection of the environment and the human habitat, human safety and health. They are, to name just some examples, major ecological disasters (the sinking of the tanker Amoco Cadiz, Prestige), the release in the environment of chemical or toxic products (Bophal 194, Seveso 1976, Mexico 1988), the leakage of radioactive material (Three Mile Island, Chernobyl), the explosion of industrial plants (Toulouse, 2001), the alterations in the food chain, also due to accidents (according to the imaginative language of the “media”: mad cow), etc.

This led to:

- 1) the growing focus of public opinion on the potential implications (also long-term) of the current model of technological and industrial development;
- 2) a climate of progressive mistrust towards public control mechanisms;
- 3) the need for governments to identify new principles (also with regards to procedures) able to facilitate, on the one hand, the assessment and containment of the risks and, on the other, their management not only for the purpose of their social acceptability, but also to enable truly sustainable development.

It must be clarified that the severity of the episodes mentioned above, some of which reoccurring with a different intensity over the years, has sometimes caused emergencies and catastrophic events, but at other times only emerged long after the manifestation of the risk linked to the event in question, giving rise to “delayed” health or ecological consequences, the causal connection of which has been ascertained.

And it is significant to highlight that the current epidemiological research increasingly emphasises the fact that even contained levels of risk, and agents globally defined as toxic, can operate with an effect of so-called accumulation, both combining simultaneously with other risk factors (also of a genetic type), or at work for a very long time, so that they cause, even after a long time from exposition, manifestations of pathologies in humans, that is, harmful effects and damage to the environment.

It emerges in this way a different dimension of risk, more subtle and not only qualitative (“toxic”), but also quantitative, which reaffirms the fundamental need to precede industrial development with a more articulated phase of research, in which, as demonstrated by experience, it is easier to achieve the margins of safety necessary to verify the initial scientific hypothesis.

These pressures produced two types of consequences: on the one hand, the citizens’ demand to be informed in advance and participate in decisions that affect both technical-scientific development and industrial growth. Attention must also be given to the public opinion’s preoccupation about the possibility of leakage of toxic or radioactive products from the appropriate facilities (cf. the recent case of Scansano Ionico); on the other hand, governments’ greater awareness to take into account behaviours and decisions aimed to prevention, where possible, or to the “new” precautionary principle, if there are significant margins of uncertainty about the relationship between the risks and harmful consequences of certain activities (or procedures or products) for humans and the environment. Thus, in addition to approaches inspired by the so-called zero-tolerance, it has been established the need to carry out a more careful evaluation of the proportion between risks and benefits, capable of guiding the technological-scientific development, which is still necessary for

mankind's material and social progress, according to a principle of mediation between the different needs and attitudes of science, industry and civil society.

From a bioethical point of view, the above considerations call into question not only and obviously the general principle of responsibility, but also and especially the need to combine this principle, usually attributed to governmental bodies, with a shared common sense, in order to identify a new "governance" of civil societies aimed at supporting preventive rather than reactive actions.

To contribute to the surfacing of a more mature sense of responsibility in public opinion, the NBC has seen fit to investigate – in this document – some ethico-legal aspects affecting the so-called "post-industrial society", which is developing a new awareness of risk and of the control of some of its expressions through the "precautionary principle".

The NBC, which has already in the past dedicated its attention not only to the issue of safety in biotechnologies, with special regard to the release of genetically modified organisms in the environment (which at the moment of expressing an "opinion" was debated and of current actuality, 1991)<sup>41</sup>, but it also dealt with the properly medical "risk" inherent to the clinical activity of a single individual (see the document "Aims, Risks and Limits of Medicine, published on the 14<sup>th</sup> of December 2001)<sup>42</sup>, now intends to examine the general issue controlling the application of the "precautionary principle" from a dual point of view: environmental safety; collective health protection (public healthcare), namely, environmental health. This investigation will be conducted with specific reference to the international and European Community context, more sensitive to the solicitations underlying the application of the precautionary principle than the Italian context so far, which however recently saw the adoption of legislative measures inspired to the principle under examination. Amongst these measures, which may be examined in a future document by the NBC, it is possible to recall for example law n. 36 of the 22<sup>nd</sup> of February 2001, on the protection from exposure to electric, magnetic and electromagnetic fields, which contains, in art. 1, an explicit reference to the "precautionary principle", or the Decree of the Ministry of Health of the 22<sup>nd</sup> of November 2000, which declares ineligible to donate blood all individuals who stayed in the United Kingdom for a few months between 1980 and 1996, also based on the precautionary principle.

From this perspective, the first part of this document will outline in broad terms the "scenario" of the "precautionary principle". After recalling the factors that contributed to the notion of "risk society", established in the current use regardless of its doctrinal elaboration<sup>43</sup>, we will try and highlight the ways in which modern technical-scientific research perceives the risk within the applications of human activities and how it deals with it when it is unable to quantify it with sufficient probability.

Therefore, we will examine criteria of risk identification and assessment, with the objective of protecting the collective safety-health, taking into account the criteria adopted by "experts", as well as, in other ways and giving them the right importance, the views widespread in public opinion and amongst the citizens-users. In the second part, we will instead

---

<sup>41</sup> National Bioethics Committee, *Safety of Biotechnologies*, Presidency of the Council Ed., Rome 1991.

<sup>42</sup> National Bioethics Committee, *Aims, Risks and Limits of Medicine*, Presidency of the Council Ed., Rome 2001.

<sup>43</sup> Cf. U. Beck, *Risikogesellschaft*, Suhrkamp, Frankfurt am Main, 1986.

examine the social tools (philosophical, legal and organisational) through which contemporary society reacts when faced with risks in the vast field of the human activities considered. This analysis will be conducted, in particular, in light of the criteria developed by the law in order to illustrate the action tools provided to policymakers. To this end, a further warning seems appropriate: the investigation by the NBC is as far as possible limited only to the illustration of the “precautionary principle”.

Moreover, in the document, you will encounter extremely important concepts, which it is not possible to linger on in this document: we cite for example the issue of “sustainable development” or that of the organization of legislative powers on the environment, which in the new version of art. 117 of the Constitution are vested in the State with the formulae “protection of the environment, ecosystem and cultural heritage”.

This warning – in any case – interests the discussion of the “precautionary principle” in so far as – as the strategy of primary protection of the environment is entrusted to the State due to a European Community regulation – also the concrete application of the precautionary principle on issues that are environmental in the widest sense, is due to the State. The fact remains that a cautious approach should guide every individual to consider the effects of his/her actions towards the environment!

The NBC investigation, the results of which are aimed primarily at a public opinion now made more aware and mature by the events mentioned, intends to state that the current technological society should increasingly equip itself to assess and prevent the risks accompanying its development and that, if a true prevention is not possible, should adopt, in view of a rational allocation of resources, at least more suitable measures from a precautionary perspective, to immediately ascertain not only the occurrence of phenomena producing adverse effects – the causes of which must obviously be removed – but most of all to monitor those activities that could, in the absence of conclusive scientific evaluations, prove to be feasible only with great caution and only if they anticipate limited risks, waiting for solid scientific evidence.

The precautionary principle attracted a lot of criticism and raised contrasting opinions<sup>44</sup>. Amongst the concerns expressed, there is in particular a “political inference in the open and free discussion of not yet well defined scientific arguments; but in effect it is the precautionary principle that will hold back economic development, in particular in developing countries, and that could lead to an imbalanced if not distorted discussion on environmental risks” (With an overestimation of the chemical or nuclear risks in comparison to the more common and therefore more accepted ones as road accidents). In response to these criticisms, other authors argue that the precautionary principle, and in general a policy of regulation, contributed both to the development of new technologies and cost reductions.

In conclusion, in line with the development of a culture of collaboration, it is necessary to identify the convergence of will and action in some key parts of society: decision makers, scientific experts, “informed” public opinion, financial operators.

It must be stressed from the outset that the application of the precautionary method intends to produce not an interruption, but rather an increase in scientific research activities, by overcoming critical issues and removing the uncertainties that currently make it dif-

---

<sup>44</sup> Cf., for example, the recent controversy in “Nature” magazine 2003, 425, pp. 663-4; and 2003, 426, p. 227.

difficult to reach the level of clarity necessary to allow or apply a policy of prevention (which would even lead to prohibit certain activities when the gravity of the risk cannot be improved) or the development of systems that, as far as possible, can minimise the situation of risk, making it compatible with economic (sustainable) development.

## CHAPTER I: THE SOCIAL OUTLOOK

### 1. The “risk society”: brief outline of the widespread feeling of risk

In recent decades, the theory of the “risk society”, which would characterise the era in which we live, is strongly taking hold.

We cannot deny that, even in the past, it affected the often un-measurable relationship between the advantages of bold individual action and the risk of damage and loss deriving from it, but it is undeniable that the evidence with which this dilemma is introduced in a more enveloping and social dimension, leads to consider it a recent dilemma.

Theorisations on the relationship daring/risk can be found – for example – in Condorcet<sup>45</sup> in the essay on the progress of the human mind; in Kant<sup>46</sup> in “Idea for a universal history from a cosmopolitan point of view. Gleanings of political philosophy” and more recently in Emile De Girarden<sup>47</sup> in “Politique universelle” and finally in Luhmann<sup>48</sup> and other authors.

This evolution seems to have several components that can be briefly summarised as follows:

1) – First of all a moral philosophical interpretation of the notion of risk has been refined but also generalised – breaking away from and expanding the notion of “danger”: existing is already a risk; choosing the values to live by is a risk; transforming man in a “human act” is a risk (Ewald and Kessler, 2000)<sup>49</sup>; any vital – and unavoidable – involvement of the individual is essentially a risk. Already Blaise Pascal<sup>50</sup>, linking in a metaphor the notions of betting and risk, wrote: “You must wager. It is not optional. You are embarked”.

2) – A considerable contribution to the understanding of the phenomenon of accepting risk as an ordinary condition “searched for” by mankind has been given by anthropological reflection. An authoritative trend recognized human reactions when faced with the uncertainty of the future (which has always existed) “from practicing divination which, although it could not guarantee reliable certainty, could in any case guarantee that our decision did not anger the gods or other divine powers and was instead protected by the contact with the mysterious forces of destiny” (Luhmann, 1996)<sup>51</sup>, as a model of the game that would always rule the real world (Huizinga, 1967)<sup>52</sup>, just as it rules dice combinations (“chance”, in fact).

Starting with this interpretation, R. Caillois, 1981<sup>53</sup>, stated that the pair “agon” (competition)-alea (chance) structured all western civilisation: “western man, putting risk at the

---

<sup>45</sup> Quoted by F. Ewald e D. Kessler, *Tipologia e politica dei rischi*, in “Parole Chiave”, n. 22/23/24 (2000), pp. 15-39.

<sup>46</sup> I. Kant, *Idea for a universal history from a cosmopolitan point of view, Gleanings of political philosophy*, La Nerva, Firenze 1973, Italia.

<sup>47</sup> E. De Girarden, *La politique universelle*, Brussels 1982, pp.16-17.

<sup>48</sup> N. Luhmann, *Il concetto di rischio*, in “Parole Chiave” n° 22/23/24 (2000).

<sup>49</sup> F. Ewald, D. Kessler, *Tipologia politica del rischio*, Parole Chiave”, n° 22/23/24 (2000).

<sup>50</sup> B. Pasca, *Oevres completes*, Gallinard, Paris 1936, p.1213.

<sup>51</sup> N. Luhmann, *Il concetto di rischio*. cit., p. 14.

<sup>52</sup> J. Huizinga, *Homo ludens*, Il Saggiatore, Milan 1967, p.14.

<sup>53</sup> R. Caillois, *I giochi e gli uomini. La maschera e la vertigine*, Bompiani, Milano 1981.

centre of his actions, produced a process of civilisation in which the model of the game is at the root of the law, both in the definition of fair rule (justice) and in how we play (the process)". (Ewald and Kessler, 2000).

3) – An important innovative contribution consists in the use of the notion of “objective measure” of the risk, linked to the advent of probability calculations (P. Bernstein).

It has been rightly said that this form of mathematical rationality participates to the genesis of the modern notion of risk: “There is no risk without a certain form of calculation, analysis, expertise: it is a form of knowledge” (Ewald and Kessler). The development of the objective measure has emphasised the need to compare the risks, and it has consequently highlighted the inexistence for “zero risk”. Acting is a risk, but also not acting – in certain conditions – is not avoiding risk, but introducing one that can also be quantifiable.

4) – The risk, born from the game theory and objectified by the calculation of probability, has become sociologically a theory of modernity, a theory capable of assessing the value of acting using the ethics of responsibility, which requires each of us to make judgements on the morality of our choices towards others.

It has been acutely observed that in this dynamic, the economy has derived all the benefits: this discipline has “the ambition to give, within the universe of risk, a general theory of its value and this starting with a decision theory.

The hypothesis made requires that, if the value is expressed through the choices of the acting individuals, they are dominated by the relationship they have with risk, by their more or less strong aversion towards it. When there is uncertainty, the value of values depends on risk”. (Ewald and Kessler, 2000)<sup>54</sup>.

5) – On this broad basis, an explicit “sociology of risk” was created, and a deriving “theory of reflexive modernization”, which has enjoyed a growing interest, although maintaining various ambiguous characteristics.

In extreme simplification, the theory predicts a reversal of trend with regards to the binomial “production of wealth” – “production of risk” in the sense that: “While in classical industrial society the logic of wealth production dominates the logic of risk production, in the risk society this relationship is reversed”. (Beck, 2000)<sup>55</sup>.

This author continues: “The growth of the power of techno-economic progress is increasingly overshadowed by the production of risks. In a first stage they can be legitimised as latent collateral effects. But with their universalization, with the criticism by public opinion and (anti)scientific analysis, the risks emerge once and for all from their latency and acquire a new and central significance for social and political conflicts”.

In conclusion, as it was already highlighted in the 80s by Niklas Luhmann, our society, because of its progressive differentiation, tends to take shape at every level as a risk society, which is more and more difficult to find unambiguous ethical or cognitive criteria to assess. Risk is something we cannot escape in any way, because it represents the essential feature of a complex society. And “complexity means a need to select, a need to select means contingency, contingency means risk” (Niklas Luhmann, *Social Systems*, Stanford, California, 1995). We can choose, in other words, if we run this or that risk or even the risk not to choose, but we cannot avoid risk as such. To use a nice image by Niklas Luhmann,

---

<sup>54</sup> F. Ewald, D. Kessler, 2000, cit.

<sup>55</sup> U. Beck, *La società del rischio. Verso una seconda modernità*. Carocci, Roma 2000.

the first original sin condemned man to temporality, sweat and dangers of various nature, the second original sin, the “technological” one, condemned man to live at risk. Better therefore that we are equipped to live with the uncertainty of the unavoidable, even if “controllable”, rather than chase after a safety that is now impossible.

It is outside the scope of this analysis to assess every aspect of these reflections developed, as well as by Luhmann, especially by Beck (2000)<sup>56</sup>, Giddens (1990)<sup>57</sup>, Lash S. et al. (1996)<sup>58</sup>, Lupton D. (2003)<sup>59</sup> and by other authors; but the NBC was interested, here, to draw attention to this attempt at sociological analysis as a sign of a desire to look in more depth at the relationship between the various “actors” of the social definition of risk: scientists (researchers, technicians, experts), jurists (relationship between law and science); philosophers (bioethics); politicians (mediators of sustainable development); citizens (public opinion).

## 2. Science between risks and uncertainty

Potential sources of risk associated to human action or inaction are inherent to any type of intervention and transformation wrought in the physical environment and on living organisms. It is therefore essential to arrive at a classification of the risks that exist, or are produced, by human actions that are the object of this review by the NBC.

Science has tackled this issue, which presents various aspects:

- How to classify the risks;
- Which tools the researcher has to identify and quantify the risks.
  - Classification

According to a classification initially applied to the case of environmental risks, intended in the wider sense (collective safety, health, etc.), we can distinguish the risks that are certain, and can therefore be considered unacceptable from the point of view of caution and prevention, which express the link of causality between the event and the scientifically proven damage resulting from it; residual or concurrent risks, those relating to carrying out normal and daily activities, towards which we can only have tolerance; uncertain or supposed risks, which are however unproven scientifically, towards which it is not meaningless to suppose that they exist and that –therefore – only a precautionary attitude can ward them off (De Sadeleer, 1999)<sup>60</sup>.

Modern reflection, obviously, focuses on this category, which – in the end – denotes the current lack of scientific certainty about certain issues that are being tackled.

The status of ignorance, like the absence of knowledge, was traditionally configured like a simple negative data, not better defined. But the need to predict the impact of new and potentially dangerous technologies prompted the search for a more detailed epistemo-

---

<sup>56</sup> U. Beck, l. cit

<sup>57</sup> A. Giddens, *The consequences of modernity. Faith and Risk, safety and danger*, Polity Press Ed, Cambridge 1991.

<sup>58</sup> S. Lash, B. Szerszynsky, B. Wynne (Ed.), *Risk, Environment and Modernity*, London 1996.

<sup>59</sup> D. Lupton, *Risk: Perception, Symbols, Culture*, Routledge, New York 1999.

<sup>60</sup> N. De Sadeleer, *Les principes du polluer-payer, de prévention et de précaution*, BRUYLLANT/PUF, Bruxelles 1999.

logical classification for the unknown. According to the recent report by the European Environmental Agency<sup>61</sup> - which incorporates the distinctions already introduced by Brian Wynne<sup>62</sup> - the lack of knowledge can have four different connotations: risk, uncertainty, ignorance, indeterminacy.

In the case of a decision under risk conditions, the variable characterising a problem is known and the respective probability of different outcomes, positive or negative, is qualified (known impacts, known probabilities).

In the hypothesis of a decision in uncertain conditions, instead, although the possible damage is known, the probability of occurrence is unknown (known impacts, unknown probabilities). The lack of knowledge refers to situations in which not even the negative event is foreseeable, nor its relative probability (unknown impacts, unknown probabilities).

Indeterminacy, finally, is the concept summarising the generally open and conditional character of all knowledge, in particular its contextual value, its socio-cultural determinability. Funtowicz et al.<sup>63</sup> and Ravetz have coined the expression post-normal science to identify situations in which “typically, facts are uncertain, values in dispute, stakes high and decisions urgent”. Unlike the “incremental” model – the science that progressively unravels the knots of knowledge – the idea of post-normal science considers uncertainty as the element that is co-essential to the science destined to public choices, the operative context of which is always linked to uncertain facts, conflicts of values and interests. A timely decision can be, if necessary, unavoidable.

- The uncertainty of scientific knowledge

It can be useful to briefly dwell on the concept of the “uncertainty of scientific knowledge”, which is definitely called into question when we want to identify and quantify the risk inherent to some of the more innovative human activities.

We see, in fact, an area of uncertainty in the knowledge of life sciences, and in particular in the relationship environmental-biotechnological sciences, also due to the speed with which new technologies are applied, according to some because of the impetus of the economic forces regulating the development of the industrial process.

These attitudes have repercussions also on the so-called “social impact” of science on public opinion, which is profoundly ambivalent towards the science and the safety of applying new technologies and on the efficiency of the relative public controls. The phenomena of the development of technology and science are for many reasons linked and it is therefore important to spend a few words of further investigation. With the expression “the uncertainty of science” we allude to various forms of indeterminate knowledge in science: the complexity of the knowledge, the lack or inadequacy of data, the unpredictability of the outcomes and the stochastic character of the predictions in many sectors of naturalistic investigation.

This means that ever more often and in many areas of the scientific community, called

---

<sup>61</sup> EUROPEAN ENVIRONMENTAL AGENCY, *Late Lesson from Early Warnings: the Precautionary Principle* (1896-2000, 2001).

<sup>62</sup> B. Wynne, *Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventative Paradigm*, in “Global Environmental Change”, 1992, June, pp. 77-85.

<sup>63</sup> S.O. Funtowicz, *Post-Normal Science. Science and Governance under Conditions of Complexity*, in M. Tallachini, R. Doubleday (a cura di), *Politica della scienza e diritto: il rapporto tra istituzioni, esperti e pubblico nelle biotecnologie*, “Politeia” (2001), XVII, 62, pp. 77-85.

to pass judgement in relation to an issue of applied science or technology that needs legislative regulation, is not able to express a certain and unambiguous point of view, at least when questioned.

The always open character of the scientific journey is without doubt its defining trait, but the complexity of some fields of research radicalised this character towards different forms of uncertainty (Talluccini, 1996)<sup>64</sup>.

The difficulties encountered in the development of scientific knowledge in the environmental and food sectors have particularly contributed to reinforce in public opinion the aspects of complexity and uncertainty of knowledge, in the awareness, in any case, of the strong social impact linked to choice, especially with regards to environmental health and food products: GM food is a classic example of this situation, as it gives rise to widespread fears about the consequences on the nature of the environment and food.

### 3. Some preliminary remarks on the attitude of the law towards scientific-technological applications and the risk problem

The tumultuous evolution of industrial society first, of risk society after, have profoundly affected also the direction taken by the law (always entrusted with promoting the harmonious development of society, in the respect of human values and interests) when faced with serious disorders in the environment, the ecosystem, in human safety and health, etc., which we have recalled above.

It seems clear – in the last decades – a profound rethinking of the relationship between the law and science in the field under investigation.

The most traditional relationship between science and law has developed in the name of an apparent neutrality between the two types of knowledge. This involved, for the law, the mediation of the so-called “technical regulations”: regulations in which the law simply gave legal effect to the contents (mainly technical and scientific) foreign to its competences (Giannini, 1973)<sup>65</sup>.

Some phenomena are at the basis of a different awareness and a strong change in perspective, which is emerging in recent decades.

This regards first of all the effects created by the epistemologically recognised growing uncertainty of scientific “truth”; by the awareness gained by jurists of the specificity that characterises the regulation of environmental issues in a pluralistic society and finally also by the realisation – on the occasion of some environmental disasters – of the insufficient provision for the risks that applied science – entrusted to technocrats – should have taken into consideration before acting. The law, then, becomes the interpreter of people’s uneasiness for the uncertainty of life, the environment, health and the climate of suspicion that the increasingly aggressive character of research, with the manipulations of living matter, causes towards science “tout court”. In this way, a radical subversion of the conditions that made possible the respectful, distant relationship between science and law has occurred.

---

<sup>64</sup> M.C. Tallacchini, *Diritto per la natura. Ecologia e filosofia del diritto*, Giappichelli Ed. Torino 1996.

<sup>65</sup> Quoted in F. Spantigati, *La gestione della strategia ambientale*, “Riv. Giur. Ambiente” XVII, 245-257, 2002.

Where areas in which technology – assimilated tout court to science – created relevant risks and has shown itself to be incapable of controlling them with the desired certainty, as scientific data are uncertain, insufficient, or susceptible to extremely different interpretations, the situations in which the law has to “integrate” science in its social function have increased.

In fact, more and more public opinion has felt it necessary for the law to intervene with protective measures for the citizens, when the possible verification of a damage has not been confirmed by science in its factual improbability.

All this constitutes the symptom of an important change in the epistemology of the legal regulation of the technology applied at the level of industrial realisations.

It is the passage from an acritical view of scientific knowledge, taken as objective and devoid of uncertainties, to a position of awareness of the non-neutrality of technological solutions, when they are in contact with production activities, which can affect safety, the protection of the environment, living creatures, man.

In any case, the law in its jurisprudential expression traditionally based on a view of “certain science”, deterministic in its causes and consequentialist in the effects – tends today in the environmental field to adopt the encoding of methods defined by some as “good science”, as they are not only validated with technical procedures, but characterised also by a democratic participation to decisions, realising – in essence – a relationship of co-production due to the cross between knowledge that occurs in the confusion of the boundaries between various systems (Jasanoff, 1990<sup>66</sup>, Tallacchini, 2002)<sup>67</sup>.

This attitude outlines an approach to the management of science as answer to the crisis of confidence by citizens, aware of the errors made in the field of health and safety committed by the government. The repetition of events, in which the collaboration between these scientific experts (or scientists) and policy-makers appeared inadequate to manage situations of uncertainty also in Europe, has made the problem of trust of the civil society in science a crucial one. The idea of “science destined to public purposes” is in this way assuming precise theoretical and operative outlines (policy-related science, De Marchi and Tallacchini)<sup>68</sup>: a notion that, although recognising the privileged character of the language of science, it is aware of the political nature of social decisions about science. The science linked to, and implicated with, public choices reveals a peculiar methodological status, having to contribute to defining issues that, with regards to society, are connected to much broader evaluations, also where they receive a scientific-technical formulation.

This is a definite model of public, civic science, the legitimate management of which entails both an extension of scientific expertise and the citizens’ participation in decision-making processes.

During this evolution, which could begin – at least in Italy – with a reflection on the Seveso (1976) episode, the law has developed – in any case – procedural and substantive regulations that are increasingly analytic and “penetrating” for the protection of the envi-

---

<sup>66</sup> Sheila Jasanoff, *The Fifth Branch. Science Adviser as Policymakers*, Harvard Univ. Press, Cambridge, Mass., 1990.

<sup>67</sup> M.C. Tallacchini, *Giudici, esperti, cittadini: scienza e diritto fra validità metodologica e credibilità civile*, “Quaderni di Politeia”, XIX/70, 2003, pp.83-94.

<sup>68</sup> B. De Marchi, M.C. Tallacchini, 2002, l.cit.

ronment and human health, fundamental “targets” of “public science”, the detailed analysis of which is beyond the scope of this document.

- Italian policies have also – in these last decades – offered numerous contributions to:
- the classification of the provisions in relation to the production systems of environmental technical regulations;
  - the identification of the issues, also constitutional, that the growing recourse to environmental technical regulations involves.

In turn, the Courts focused on environmental technical regulations in two situations, different from each other:

- when damage has already occurred, and it is about establishing if there is a responsibility;
- when we want to prevent a certain activity, for fear that damage could occur: and therefore it is about establishing whether the fear is founded, or, more exactly, if what is known and certain about whether the fear is well-founded, justifies a prohibition.

Often, as we can easily imagine and is in part inevitable, the level of scientific investigation in these circumstances it is not entirely satisfactory.

But most of all in the European Community, we have made an effort to elaborate – in theory – the “principles” adequate to set up the action of the individual states and guide it towards reaching common levels of protection (see in attachment the definitions of the principles of user/payer; polluter/payer; prevention; mitigation; precautionary; sustainable development, etc.).

Let’s not forget that – in Europe – the protection of the environment finds its foundation in art. 174 (ex art. 130 R) of the Treaty establishing the European Community on the basis of which European Community environmental policies aim at a high level of protection, taking into account the diversity of the situations in the various regions of the European Community.

The protection is founded on the precautionary and preventive action principle, on the correction principle, first of all at the source of environmental damages, as well as on the principle that “those who pollute, pay” (Pozzo, 2000)<sup>69</sup>.

The “cautionary criteria” resulting from ecological instances – also as an ethical need of hesitating towards non-repairable damages – resulted in any case in the necessary preventive evaluation of the risk, and of all the effects that human activity (assessment of the environmental impact, first of all) has on the environment (intended in the broadest sense).

As clearly say Vineis et al. (2002)<sup>70</sup>:

“Mainly, we can take two attitudes faced with a choice regarding environmental risks when we don’t have reliable information. The Environmental Impact Assessment has a neutral attitude towards the risks and it includes the uncertainty of the calculable risk in terms of statistical probability (assuming that we can always reach an objective scientific opinion). Instead, the Precautionary Principle does not claim to be neutral faced with a chronic lack of information, but it rather expresses a clear bias in favour of a careful monitoring that

---

<sup>69</sup> B. Pozzo, *Verso una responsabilità civile per danni all’ambiente in Europa: il nuovo libro bianco della Commissione della Europea*; “Riv. Giuridica ambiente” XV, 623-665, 2000.

<sup>70</sup> P. Vineis, M. Ghisleni, *Rischio, scienza, giustizia*, in “Notizie di Politeia” XIX (2003), pp.75-82.

can lead to times of inaction (that is, it recognises the epistemic importance of scientific ignorance and it accepts it as a data of knowledge amongst others)”.

We will develop the “rational” and the theme of this principle in more detail in chapter III of this document.

One last, brief note seems appropriate with regards to the role and characteristics of the “expert”, who – in this new structure of governance – has certainly not abandoned his/her role as scientific mediator of the policy-maker, even though it is at his/her level especially that the role has changed.

#### 4. The policy-maker, the characteristic of the expert and expert advice

It seems appropriate, now, to briefly examine this relationship. We have already highlighted the fact that administrative-political decisions often have to be taken in a context characterised by significant risks and by scientific knowledge that seems particularly incomplete or uncertain in the cases studied.

Frequently the decision-maker finds it difficult to know (identify exactly) the facts or to interpret them, because, according to Barre<sup>71</sup>:

- lacks in knowledge (at least sufficient knowledge) of the biological, chemical, etc. processes susceptible of determining direct consequences of various nature;
- has problems in identifying indirect effects;
- has uncertainties about the applicability of the scale of the real world to laboratory experiences;
- has difficulties in identifying the groups of interest that could be mostly exposed to the consequences deriving from the abovementioned uncertainties.

Despite the reservations that recently have developed towards the experts, for the decision-maker, expert consultation is an irreplaceable practice. Adopting, for the sake of brevity (and because it has become part of the Italian linguistic habit) the expression “expertise”, we will recall that this is the production of a specific knowledge for action, designed in any case according to the ideal model of rational decision: it is a procedure destined to give elements of clarification to an authority that has the task of taking responsibilities and decisions.

The expert, in principle, is the one who has a particular knowledge recognised within a given profession and it is for this reason that he/she is called to offer the policy-maker his/her knowledge.

If the definitions are clear, the practice is sometimes less straightforward, in the “choice” of the expert (inside or outside the administration, etc.), in his/her real “competence” regarding the specific problem under consideration, in his/her complete “independence” from the political power, etc.

Therefore, a functional “characterisation” of the figure of the expert has gradually developed (eventually valid also for legal purposes when the expert is called by a judge), which in continental law responds to the following elements:

---

<sup>71</sup> R. Barrè R. *Expertise et avis scientifiques: les dangers des pseudo-sciences et des pseudo-politiques* – The IPTS Reports. Institut de prospectives technologique (IPTS) Commission Européenne N° 60, dec. 2001.

- independence from the decision-maker; recognised authority (in relation to his/her unquestionable specific and/or technical competence); neutrality from the emerging interests of the issue under consideration; personal integrity.

In Anglo-Saxon Law, the expert is rather a partial “advocate”, and the expertise is conducted in accordance with the adversarial principle, whilst requiring that the expert remains objective and loyal in the framework of his/her competences.

In any case, the expert must respect the deontological rules of his/her profession, correctly express not only personal opinions, but also those resulting from the experience of others (in literature); have the right to carry out his/her mission in freedom, without being eventually removed; being able to publish (make known) his/her opinions to the public.

It has now become common practice to nominate “expert committees” including different disciplines and with members inspired to different cultural trends, in order to overcome the various objections that the public opinion addresses to politicians-administrators.

More and more often, representatives of environmental associations are also invited and “FORUMS” are organised to collect opinions valid to contribute to the decision-making.

It must be emphasised that – in any case – the ultimate responsibility for the decisions belongs always to the administrators and the politicians, even though we should not minimise the responsibility of those who give the opinions that form the basis of the decision.

In conclusion, much has been discussed in recent years, about the “expertise” process, with regards to environmental risks, of the introduction of new industrial and food technologies (see for example the case of GMOs). Whilst some schools of thought strongly defend the “scientific” characteristics of the expertise, according to a rational method that is not influenced by socio-political opinions and believe that an eventual “reversal of proof” – where introduced by law – would prevent the possibility of establishing a difference between an hypothesis and a simple assumption, to destabilise the current technical-scientific culture and create a conceptual confusion that is regressive for society, other schools of thought argue the benefits of participating to the procedures of expertise of that “common knowledge”, which matures more than we realise in public opinion, and it allows the enhancement of communication, the clarification of uncertainties and suspicions towards a haughty and paternalistic science, the restoration of the lack of reliability. In this way, the policy-maker meets the demands of public opinion and – a fact that has been judged of no little interest – experiments new forms of governing and possible worlds.

The “philosophy” of this last approach is based – in any case – on the recognition that science, certainly, remains a relevant form of knowledge to resolve the risks of the practices and technologies that affect the community, but it is not the only one.

The citizen does not want to be excluded from the decisions that affect his/her “quality of life”. On the other hand, in countries with a high technological standard, there are amongst common people (as those who do not belong to the decision-makers are often called) many people who are scientifically prepared and experts in various professional fields, able to speak on an equal footing with official “experts”.

Treating these people as ignorants is not only politically wrong, but ineffective and counterproductive because it wastes a potential which could, in the right proportions, be of considerable use in a democracy.

Finally, the way public opinion perceives risk is, in general, more extensive than that of the experts, and it covers hypothesis that sometimes are overlooked by the experts, but

on which it wants answers. All this still moves in the realm of reason and it has nothing to do with “panic attacks”, or especially with motives (for example to ward off economic competition) that are passed off as “risks”.

The policy-maker has every interest in finding new forms of compatibility with widespread reasonable opinions (“governance”) (S. Jasanoff, 2003); Liberatore and Funtowicz, 2003, etc.); on the other hand it cannot know whether, and in what time – science (research) will be able to resolve uncertainties, whilst it is urgent to give a precise guide to the questions asked (Christoforou, 2003).

The “precautionary principle” operates in this context, and – in certain circumstances – it can represent that mediation that the policy requires to avoid dangerous fractures amongst the so-called decision-makers and those who are involved in other people’s decisions (De Marchi, 2003; Christoforou, 2003; Tickner and Wright, 2003)<sup>72</sup>.

---

<sup>72</sup> S. Jasanoff, *(NO) Accounting for expertise*, in “Science and public policy”, 30/3, pp.157-162, 2003; A. Liberatore, S. Funtowicz, *Democratising expertise, expertising democracy: what does this mean, and why bother?* in “Science and public policy” 30/3, pp.171-176, 2003; T. Christoforou, *The precautionary principle and democratizing expertise: a European legal perspective* in “Science and public policy” 30/3, pp. 205-211, 2003; J. Ticker, S. Wright, *The precautionary principle a democratizing expertise: a US perspective*, in “Science and public policy”, 30/3, pp. 213-218, 2003; L. Sjöberg, *Factors in risk perception* in “Risk Analysis” 20, 1/6, 2000.

## CHAPTER II: ETHICO-PHILOSOPHICAL EVALUATIONS OF THE “PRECAUTIONARY PRINCIPLE”

The “precautionary principle” comes from the request to “act with a precautionary approach” in order to protect the environment (Rio Conference, 1992: “United Nation Conference on Environment and Development”) and it invites to analyse the notion of precaution together with that of caution and responsibility.

In common language, there is a considerable “interchangeability” in the use of the expressions “caution” and “precaution”, which however are not equivalent in the history of thought.

In philosophy, the term “caution” indicates the ability for wise deliberation, and corresponds to the Greek *phronesis*, sometimes translated directly as “wisdom” (Pfeifer, 1999)<sup>73</sup>.

The concept of “precaution” can be considered as the application, in certain circumstances, of the virtue of caution to concrete decisions, which require (after careful analysis) an attitude of care about the possible consequences both of the action, as well as inaction.

If the term “precaution” has rapidly disseminated in the legal and biolegal spheres (as well as in the media), the same has not happened in philosophy. Philosophers are reticent to use this expression: only recently a bioethical discussion is developing on this principle, or rather, on the precautionary approach to bioethical issues. The reticence can maybe be explained by the novelty of the language, not easily placed in traditional philosophical categories (like wisdom and caution). The problem is that if the traditional categories (although theorised in a different way by different thinkers) in some measure offer a contribution to the explanation of the meaning of precaution, they are not however enough to rigorously frame the principle, which has been specifically seen in the context of the recent issues emerging in bioethics and biolaw, with particular reference to human health and the protection of the environment.

If we start from the more general semantic value of the precautionary principle, that is, the exhortation to have a careful approach with regards to the speed and unpredictability of the development of technical-scientific progress when faced with the perception (even only intuitive) of the possible negative consequences and with the foreshadowing of possible future damage, we can say that this principle coincides with bioethics, born precisely from the ethical need to reflect on the legality or illegality of certain practices and interventions of manipulation of life in general against the naive permissiveness of technological science. In a sense, we could say that the precautionary principle, in its general validity, comes from the same context as bioethics, namely, within the reflection on the issue of man’s relationship with nature when faced with the onset of an increasingly close link between theoretical knowledge and practical applications. This reflection was prompted by the emergence of the awareness that the effects of certain manipulative interventions on life (human and non-human) can affect the most intimate composition of reality, causing an alteration of individual and specific human identity, as well as an irreversible modification of other animal and vegetal living species, with the eventuality that this could even jeopardise the survival of humanity and the continuation of life on earth. The synchronic and diachronic expansion of bioethics has increasingly led to extend ethical reflection beyond man (also to animals,

---

<sup>73</sup> J. Pfeiffer, *La prudenza*, Brescia-Milano 1999.

plants, the environment, the ecosystem) and expand it beyond the existing (to future, current or remote generations) calling into question biolaw as well, in order to regulate the practice of collective behaviour.

Biolaw has been invested with a task which maybe it was not yet ready for: the accusation that is often aimed at it is one of delay, if not also of absence, when faced with the urgency of bioethical questions in the social sphere. It is not rare that biolegal interventions happen through quick and conditional provisions that at times serve as temporary instruments to halt emergencies, make up any eventual deficiencies, quickly control fears and worries, caused by scientific novelties, but that inevitably hide the need for a more systematic intervention. Moreover, the acceleration of medical and biological technical-scientific progress, constantly poses new problems, contrasts inevitably with the well-known slowness and inflexibility of the law-making mechanisms, amplifying more and more the asynchronicity between techno-science and the law. This is one of the reasons that led to a different biopolitical and biolegal attitude, marked by the intention to speak beforehand about the occurrence of possible negative consequences and characterised by caution when faced with risky situations, with still imprecise outlines, due to the fear that the non-pronouncement can be harmful.

In this sense, in bioethics but especially in biolaw and biopolitics, the appeal to the precautionary principle, which proposes to overcome the economist individualistic logic (conceiving the environment like a property to exploit), has consolidated, going towards an holistic solidarity that stimulates the citizen to become aware of a collective, universal and global ethics, which sees the environment as a good to preserve and maintain for man and its descendants.

At times it happens that the precautionary principle is confused or even identified with Hans Jonas' "responsibility principle". This overlap is incorrect: not all those who support the precautionary principle agree with Jonas' philosophy. Even though it must be undoubtedly recognised that the elaboration of the responsibility principle has in part helped the birth of the precautionary principle (or at least contributed to preparing its acceptance in the bioethical, biolegal and biopolitical sphere). Jonas starts by denying the moral neutrality and indifference of modern technology, highlighting the impossibility of separating the immediate intentional benefits from the involuntary, subsequent harmful effects. The starting point of the responsibility principle is the same as that of the precautionary principle: the awareness of the dangers we are exposed to because of the human technical-scientific power at the cosmic level and the ethical need to assess (teleologically) the risk of the consequences of human actions towards nature. The heuristic of fear, the anticipation of a threat, namely, the uncertainty of the continuity of the human species and the survival of life itself on earth, the question on the destiny of others and the fate of our planet, become the precise object of responsibility, formulated by the imperative: "act so that the consequences of your actions are compatible with the permanence of an authentic human life on earth" or, in a negative sense "act so that the consequences of your actions do not destroy this life's possible future". Jonas stresses how the threat to human identity is one of the main causes prompting the surfacing of an awareness of the value of safeguarding our anthropological identity (we indirectly recognise the value in light of the non-value we immediately perceive).

It is a theoretical elaboration based on the metaphysics of being (or teleological naturalistic metaphysics, according to which every living individual ontologically tends towards

an immanent end that coincides with good), which, starting from the idea that it is better to be rather than not to be (the aim of all aims is life), transfers the categorical imperative (namely, the duty to be) from the individual to the human species: because humanity (present and future) has a right to be respected and to a general ethical protection, as the condition for defending existence, the earth, as human beings' abode, must be safeguarded. Man, being the only creature on earth who has the possibility of choosing between different ends (being able to make choices sacrificing an immediate end for an ulterior end), is called to perceive the objective need of the (human and non-human) being and to guarantee it the achievement of the goal. On this philosophical basis Jonas founds his "macro-ethics" for the technological society: the recognition of the theological structure of the being and the ontological axiom of the superiority of the presence of the aim in comparison to its absence, establish man's obligation to take on the self-affirmation of the being, through the responsibility towards the indigent, a total responsibility, extended to living beings and projected to future generations. The gap between the power of technology and predictive knowledge, between the "utopian promise" of technology and the "apocalyptic threat" of ecology, force us to extend to the environment and posterity, intended as human (and non-human) remote (as well as close) descendants, our duty of responsibility in order to ensure the future integrity of human nature, warding off the eventuality of the planet's destruction. The responsibility of the parents towards their children is the ontogenetic and philosophical archetype of the duty towards entities without a direct relationship of mutuality: the responsibility implies the direct duty of man to "take care" of nature unilaterally.

In this sense Jonas' philosophy stimulated in bioethics the call for an interspecific and intergenerational ethics, reformulating the category of the symmetry (between human rights, where a right claimed by one man can be claimed by any other man in the same situation) and of mutuality (between rights and duties, where exercising a right is guaranteed by the individual's and others' observance and fulfilment of their duties). Symmetry and mutuality are the basis of a moral obligation not only towards those who have rights and duties; these categories must be broadened by defining the principles of responsibility and care that justify the fact that symmetry and mutuality, as well as (spatial) proximity and (temporal) simultaneity, are compulsory. Responsibility means recognising the duty of also taking care of those who are not capable of taking care of themselves, is not able (and never will be) to reciprocate our moral actions (therefore also animals, plants, the environment, future generations); respect means the obligation to protect (with the prohibition to destroy and damage, at least without an adequate reason) also those who are most vulnerable and unable to fend for themselves (therefore non-human beings and inanimate objects), even just on the basis of their aesthetic, symbolic or historical value. It is a "joint responsibility": every man, as a member of a cooperating community (therefore not acting as a single individual) is called to extend his care globally and to increase it in time: every individual is called to answer to others (human and non-human). In this sense responsibility brings together, it strengthens relational, as well as inter-individual connections, even between species and generations.

In this sense the responsibility and precautionary principle have a semantic value that partly coincides. But if the precautionary principle in some way leads to deferring or regulating a scientific decision (not to abandon it, rather to control it in proportion to the seriousness of the risk) the responsibility principle could, for reasons of care and solidarity, not legitimate certain behaviours, also in the absence of potential risks. According to Jonas, the

interest to preserve nature is in itself an absolute moral interest towards which it is legitimate to limit human technological power. If Jonas' philosophy condemns technological power to the point that it suggests an antiscientific and anti-technological abstention, precautionary philosophy does not arrive to such extreme consequences: it does not condemn technological power, but tries to regulate it, limit it, control it (especially with regards to long term effects).

In the context of a philosophical analysis of the precautionary principle, we can say that the contribution of philosophy can be found in having outlined the context and having created the conceptual basis on which this principle and its subsequent use in the law have emerged. Therefore we must not confuse the political-legal dimension (that has explicitly appealed to the principle and has translated it operatively into rules applicable to specific and concrete practices) and the philosophical dimension that has justified the precautionary approach and attitude. We can say that the biopolitical and biolegal dimension of the precautionary principle, although born in the context of the ethics of responsibility, have progressively distanced themselves from it from the point of view of applicative proposals. In other words, if the ethics of responsibility leads towards a strong interpretation of caution, the biolegal precautionary principle (although diversified in its interpretations) represents a weaker version of it. In this sense it would be philosophically wrong to deduce the precautionary principle from the ethics of responsibility: the first leads to practical rules that legitimise behaviours of abstention (also authoritatively imposed) when faced with catastrophic scenarios; on the contrary, precautionary rules discipline the assessment procedures on the risk of the action from an applicative point of view, stimulating science to investigate its knowledge and society to participate democratically to deliberations. If there is a theoretical convergence between the precautionary principle and the responsibility principle, we can say that often there is or there can be a practical divergence. In any case the precautionary principle acts like an anticipation principle (Ewald, 2001).

The precautionary principle outlines the need of an attitude of caution intended as a preventive anticipation of the risk when faced with the epistemological uncertainties of scientific knowledge. The awareness of the relativity of scientific knowledge and the intrinsic inability of science and technology to offer definite results, with the consequent possibility that science is unable to calculate, predict and control the (involuntary negative) consequences of certain applications, and that such negative consequences can cause serious (technically) irreparable damage, leads to the need of giving an ethical basis to the obligation to tackle threats before they happen, on the basis of the duty to anticipate the knowledge or the awareness of the risk when foreseeing potential or eventual future damage, having at our disposal strategies to respond to urgent situations probable in the future (in order to avoid or reduce the risk).

The precautionary philosophy is based on the awareness of the ontological temporal limitation of man and on nature's fragility (present and future) when faced with science and technology, which increasingly manifest their ambiguous status (of growing power on the one hand and structural uncertainty on the other). The precautionary principle is philosophically founded on the awareness of the asymmetry (between man and nature on the one hand and science and technology on the other) and on the commitment to research practical strategies to overcome it in order to recreate the (bioethical and biolegal) conditions to guarantee a symmetric relationship. On the one hand, society feels the need and inevitabil-

ity of technical-scientific advancement, but on the other it sees in progress a potential threat to man and nature, to human dignity and the protection of the environment.

The precautionary principle therefore coincides generally with an attitude of caution, which intends to avoid on the one hand technical-scientific abstention and on the other its intervention. Grows in bioethics the awareness that any biotechnological experimental intervention on human and non-human beings – and so the introduction of new technologies in the processes of production and management of natural resources – must be preceded by a scientific risk assessment, according to uniform parameters and procedures, and by risk management, namely, by the evaluation of the epidemiological data from an ethico-political and social point of view, in order to put in place the necessary measures if not to prevent, at least to minimise possible damages. Therefore, it is about promoting only those interventions the risks of which (on man, the environment and future generations) have been assessed and controlled, guaranteeing the safety of the laboratories, the balance of the ecosystem, the control and minimisation of the harm for other organisms, seeking the good for today's society, avoiding possible negative effects for the society of the future. The objective must be to optimise the risk, that is, to contain the damage in proportion to the social benefits that can be obtained for the protection of human life and health, for the safeguard of the existing and not yet existing human community.

Precautionary philosophy is therefore not a global utopia, but a concrete way to answer the needs and threats to man and the environment, with the precise aim of fixing the limits of the power (the decisions of the researchers, scientists, experts, in public policies and individual deliberations), as long as such decisions can affect (human and non-human) life and health. The precautionary principle is therefore a biolegal instrument of regulation, but also indispensable to creating the conditions of social acceptability of the risk, opening scientific controversies to public debate, favouring social cooperation and the democratic participation to the public discussion on scientific problems and demanding transparency in the communication between science and society.

## CHAPTER III: LEGAL ASPECTS OF PRECAUTION

### 1. Introduction

As already mentioned in the previous chapters, the contrast between potential benefits, potential risks and the harmful effects deriving from the progress of science and technology, which can be found at every stage of the evolution of human activity, has appeared as obvious as ever in these last few years, on the basis on the ongoing consolidation of trends of socio-economic and technological development, susceptible not only of damaging the human habitat, but also of altering the ecological balance of the entire planet. Even disregarding well defined catastrophic events, we cannot avoid recalling, with regards to this, more relevant critical phenomena linked to the abovementioned trends, like the reduction of the ozone layer, the raising the earth's temperature deriving from the so-called greenhouse effect, the progressive desertification of vast areas, the impoverishment of the biological diversity (so-called biodiversity), the destruction of entire ecosystems.

Together with these "global" environmental risks, specific relevance has the food and health crisis that has considerably affected the conditions of public health protection (infected blood, mad cow, dioxin in chickens, hormones in meat). As widely stated, the appearance of these risks has produced a dual order of consequences, initiating, on the one hand, a new perception of the relationship between man and nature, based on the awareness that economic and technological progress cannot happen at the expense of environmental health, and highlighting, on the other hand, the inadequacy of purely reactive protective interventions and of improbable restorations.

Of particular significance on the perspective mentioned seems, for example, the comparison between the 1977 United Nations General Assembly Resolution n. 32/50 and the 1988 Council of Europe Parliamentary Assembly Resolution n. 1068, both regarding the use of nuclear energy. Whilst the first stressed the importance of this source of energy for the economic and social development of mankind, the second (adopted following the tragic Chernobyl incident) defined nuclear energy as "potentially dangerous" and recommended, a little more than ten years after the ONU Resolution, a moratorium on the construction of new nuclear power stations. Just as significant seems the attitude taken by the international Community with regards to the problem of climate change, seen as, still in 1961, the United Nations National Assembly recommended member states to promote the development of atmospheric science and technology in order to perfect the knowledge of the fundamental physical forces that would have allowed, amongst other things, "changes in large scale meteorological conditions".

Instead, the preoccupation regarding climate change is evident in the United Nations Framework Convention, signed in Rio de Janeiro in June 1992, the Premise to which states that "change in the earth's climate and its adverse effects are a common concern of mankind".

To the increased awareness of the consequences that modern human activities can produce, in terms of serious and irreversible damages to the environment and human health, corresponds a gradual increase in the need to favour preventive actions and cautious approaches, able to eliminate at the root, as much as possible, of the foreseen risks. It is on the basis of these solicitations that the "precautionary method", although not new as a theory or as a practical approach, encountered in recent times the renewed interest of those

studying and working within the law. We can instead state that the re-evaluation of this method through the definition of a “precautionary principle” has been such to motivate (rectius, insist on) the expansion of the principle’s field of action also to new and different issues from those first elaborated, relative, as is known, to the protection of the environment.

And, in truth, talking about the precautionary method today usually means referring to a line of action, in the field of political and regulatory decisions, concerning the management of scientific uncertainty on the probability that, in the long term, certain risky events would actually happen, both with regards to the protection of the environment and natural resources, and the protection of human health. From this point of view, and with specific reference to the outlook in biomedicine, it is important to remember that Recommendation No. (2003)10 of the Committee of Ministers of the Council of Europe, adopted on the 19<sup>th</sup> of June 2003, repealed the moratorium on xenotransplants (transplants in humans of genetically modified organs, tissues or cells of animal origin for therapeutic purposes), which the same Council of Europe had previously adopted, with Recommendation No.1399 (1999). With the new Recommendation, the Council of Europe gave some indications and guidelines inspired to the precautionary method in relation to the possible risks of spreading to humans known or unknown illnesses or infections. In particular, the Council of Europe invited member states to adopt the appropriate measures, in conformity with proportionality and necessity principles, to monitor the health conditions of the so-called receiving subjects, in order to responsibly answer eventual adverse reactions. This is a particular point of view, directly linked to the protection of the dignity and integrity of the human being with regards to biomedicine applications, which however clearly shows in which sectors the precautionary principle will be mostly used in the future, in consideration progress in the field of the so-called life sciences (think, finally, about the interaction between genetics and informatics in the so-called nanotechnology sector).

## **2. The origins of the “precautionary principle” in international and European Community law**

Brought into play initially in marine environmental protection, the precautionary principle appeared first of all in the Ministerial North Sea Conferences, presided over by the Organisation for Cooperation and Economic Development (OCED) in 1984. But it is in the 1992 Earth Summit, in Rio de Janeiro, that the principle under examination was universally recognised in the field of environmental protection, with the following formula: “in order to protect the environment, the precautionary approach shall be widely applied by the States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be the used as a reason for postponing cost-effective measures, to prevent environmental degradation”. The United Nations Conference on Environment and Development (UNCED), in fact, adopted a series of Recommendations with which the states participating in the Summit took the commitment to promote an economic and social development compatible with the need to safeguard the environment. In particular, the Rio Declaration on Environment and Development, in its twenty-seven general principles, sanctioned the absolute need for development and envi-

ronmental protection to be compatible, according to a criterion of “sustainable development” at the basis of the international cooperation of the protection of the environment since the well-known 1972 Stockholm Declaration. In order to realise a development model, the Rio Declaration formally included the “precautionary principle”, used beforehand in many international Recommendations and conventions, amongst the general principles on which to base national environmental policies. The Rio Convention on Biological Diversity also confirms the application of the precautionary method in relation to the need to protect environmental and natural resources, with particular reference to the adverse effects of the loss of the so-called biodiversity.

Following the Rio Conference, the precautionary principle (almost always together with the principle of sustainable development) was received in the modifications made to a large number of pre-existing conventions as well as in a series of agreements relative to the management of natural resources and environmental protection, both universally and regionally. In particular, in the context of the so-called Multilateral Environmental Agreements, particular importance for the purposes of this document has the Cartagena Protocol on Biosafety, additional to the Rio Convention on Biological Diversity and in force since 2003, which disciplines the trans-border movement of modified living organisms, anticipating the recourse to risk assessment procedures aimed at ensuring, on the one hand, the preservation and sustainable use of biological diversity and, on the other, the preservation of human health, “in accordance with the precautionary approach” and in the sense of recognising the right of the participating states to ban the import into their territory of modified living organisms.

In European Community law, the precautionary principle finds its first recognition in some rulings by the Court of Justice adopted since the 1980s, in relation to cases of restrictive measures on European Community trade based on uncertain scientific knowledge.

It is, however, a small legal *acquis*, not devoid of contradictions and only in 1993, due to the modifications made to the Treaty of Rome by the Maastricht Treaty, the precautionary principle has had a formal recognition within European Community policies on the environment. The modifications introduced reinforced the statement in principle and the substantive directives relative to the environmental policy contained in the Treaty establishing the European Community, favouring the integration of assessment and ideas regarding economic development in the context of the principles applicable to the protection of the environment, in line with the experience matured internationally. From this point of view, the new directives explicitly link, on the one hand, to the “sustainability” of economic growth amongst the objectives assigned to the European Community by Article 2 of the Treaty of Rome and to the European Union by Article 2 of the Maastricht Treaty, and, on the other, the “precautionary principle” amongst the founding principles of the environmental policy of the European Community, without however defining characteristics and premises to apply such a principle. This was done by the European Commission on the 2<sup>nd</sup> of February 2000, which, without giving a formal definition of the precautionary principle, attributes to it a very wide field of applications. Since then, the precautionary principle has quickly become part of all the policies of the European Community, the basis of which is the clarification of the risks inherent to technical-scientific development. With regards to human health, for example, the focus of European Community institutions and bodies on the precautionary principle is such that a document by the European Environment Agency published in 2001, aimed at linking the premises of this principle to a series of case studies

going back to the XIX century (cf. Late lessons from Early Warnings: the Precautionary Principle 1896-2000, Luxembourg, 2001).

Emblematic example of an application of the precautionary principle in the European Community is offered by the legislation regarding the limited use, the deliberate release in the environment and the introduction on the market of genetically modified organisms and the products (especially food) made up of, containing or obtained with these organisms. This legislation is inspired to the “strong” version of the principle under examination, because it disciplines a procedure of advanced authorisation for carrying out activities based on the overturning of the probationary duty regarding the scientific evidence of the harmlessness or harmfulness of certain products (or production processes): in other words, whilst the responsibility to demonstrate the nature of a danger and the level of risk associated to a product (or to a procedure) is generally given to the consumer or the public authorities, European Community directives on GM food transfer to the subject intending to carry out a certain activity the responsibility of providing scientific proof of the products’ harmlessness (or of the safety of the procedures in question). This means that certain substances (not only GM food: from antiparasitics to medicines, only to give some examples) must be considered potentially dangerous, at least until it is not possible to prove the contrary with enough certainty. And it is useful to observe that said “radical” interpretation of the precautionary method, also accepted by many international organisations of environmental law, gives rise to the most heated discussions on its practical scope.

### **3. The European Commission Communication of the 2nd of February 2000**

In order to identify the situations in which the precautionary principle can be called upon and to define effective guidelines for the application of such principle, the European Commission adopted, on the 2<sup>nd</sup> of February 2000, a Communication in this regard (cf. Document COM(2000) 1 of the 2<sup>nd</sup> of February 2000). Although it does not give a formal definition of the principle, the communication indicates the conditions in which it is possible to bring it into play: a scientific assessment has occurred, such assessment has identified the lack or deficiency of available data (or the differences with regards to their interpretation in the scientific community) and there are sufficient reasons to believe that from the assessed phenomenon (or product, or procedure) could derive potentially dangerous effects for human, animal or plant health, or the environment. According to the Commission, therefore, the field of application of the precautionary principle is very broad, so that it can be applied, in practice, in all those circumstances in which scientific proof is insufficient, inconclusive or uncertain and there are reasonable grounds to fear that the risks for the environment and human (but also animal and plant) health are incompatible with the level of protection chosen by the European Community.

Defined in this way, the conditions of application and the scope of the precautionary principle is called to carry out a structured strategy of risk analysis, comprising of the risk assessment, risk management and risk communication phases. With regards to this, the Commission highlights first of all the dishomogeneity of opinions that exists about the importance to be given to “scientific uncertainty”, which derives from the confusion created by the prudential approach, which scientists use in the phases of analysis and evaluation of scientific data, and the precautionary method, which must find its application in the risk

management phase. According to the Commission, therefore, where the condition of scientific uncertainty does not make it possible to completely assess the much-feared risks (and, consequently, the possibility that damage can actually take place), it is the politicians' duty, on the basis of the precautionary principle, to identify what is the minimum level of "acceptable risk" for society. And it is in this assessment that, according to the Commission, the principle under examination comes into being: politicians, faced with scientific uncertainty, an indefinable risk and public opinion's preoccupations, have the duty to give answers, taking into account that the "precautionary" aspect goes beyond the temporal horizon of short or medium term, to invest issues the scope of which can be found in the long-term, and it concerns the well-being of future generations.

We must not however believe that the application of the precautionary method, so intended, legitimises arbitrary decisions. In the European Community, in fact, the precautionary principle prefigures general rules for the management of potential and uncertain risks, aimed at becoming, case by case and in effect, norms of behaviour valid both for the public authority and for economists, as well as for techniques and instruments of social action aimed at communicating and sharing the risks linked to technological development. In other words, the precautionary principle allows us to go from a generic disposition to caution and care in identifying a route, even with regards to procedure, which public authorities must follow in situations of uncertainty.

After all, the European Community Court of Justice has taken steps to stress the premises for the application of the precautionary principle, ensuring at the same time its role of parameter for the legitimacy of the deriving acts of European Community law. In fact, in a number of rulings the Court confirmed, on the one hand, that scientific uncertainty is the essential premise for the application of the principle and, on the other, that the precautionary method refers to the long-term consequences and inaction can cause irreparable damage. Leading case of the Court of Justice legislation is the contentious caused by the adoption, by the European Community, of restrictive measures against the export of beef from the United Kingdom in order to limit, in this way, the risk of spreading bovine spongiform encephalopathy (so-called mad cow disease or BSE). In this as in other cases, in fact, the Court established, talking to other European Community institutions, that "where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".

In order to follow the affirmation of the precautionary principle with action, the communication finally indicates the guidelines destined to overlook the choices politicians are called to make. According to the Commission, the precautionary principle must not necessarily be translated in the adoption of directives aimed at producing legal action and susceptible to the control of the law. In some cases, in fact, the most appropriate solution can be the adoption of directives that are not legally binding, like Recommendations, or the recourse to a wide variety of "political" actions, like funding research programmes or the decision to inform public opinion of the possible adverse effects of a product or procedure. In other cases, instead, the adoption of adequate protective or preventive measures can be necessary, which should be inspired to the general principles and criteria indicated in the communication under examination. They are, as stressed by the Commission, criteria that can be applied with reference not only to the precautionary principle, but to any risk management measures and that require the recourse to democratic and transparent decision-

making procedures. In particular, the principles recalled by the communication should allow the adoption of decisions proportionate to the chosen level of protection, not discriminatory in the application of the measures that have been set up, coherent with the measures already adopted in similar circumstances, subjected to revision on the basis of the evolution of scientific knowledge and based on a comparative analysis, also economic, of the advantages and duties deriving from the chosen action or inaction (cost-benefits analysis). Therefore, precautionary measures should be: Proportional: measures must be proportionate to the chosen level of protection; Fair: measures must be similar in similar situation and different in different situations, unless there are objective reasons to behave otherwise; Coherent: measures must be of a strength and nature comparable to those already adopted in similar areas, in which all scientific data are available; Based on an assessment of the potential advantages and duties: measures must come from the comparison between the general costs for the collective of the action or the inaction and their acceptability by the public. In any case, the protection of health must come before economic considerations; Subjected to revision: precautionary measures must be maintained for as long as scientific information is incomplete, and they must be revised in the light of new data; Able to attribute the responsibility for giving scientific proof: where is in force the “upon approval” requirement on the products under consideration, we anticipate overturning the duty of proof – so that it is the economists’ duty to prove the product’s safety; otherwise, the duty of proof can be allocated to the users or public authorities, however this cannot be a general rule.

On the basis of the trends we have examined, European Community institutions widely use the precautionary principle. The Commission called upon the principle under examination first of all to assess national measures restricting the marketing and use of certain products, also in light of European Community regulations for unilateral dispensations to directives aimed at harmonising the functioning of the domestic market. From the relevant practice emerges the Commission’s stance, aimed at denying authorisation for national measures of dispensation based on the generic appeal to certain dangers, but devoid of specific demonstration, and to acknowledge unilateral restrictions based on completely verified scientific data, confirming in this sense the need to have scientific evidence that is able to prove the rationality and objectivity of the much-feared risks.

Subsequently, working with the clear formulation of the precautionary principle, the law has been more favourable to generally recognise the premise of scientific evaluation, and therefore also towards European Community institutions. So, even when it is not plainly mentioned, the precautionary principle can be seen between the lines in many rulings made by the Court of Justice to evaluate the compatibility of national directives and European Community law or to question the legitimacy of European Community measures. This jurisprudence has particular importance because, on the one hand, legitimises health protection measures, broadening the field of material applications of the precautionary principle and, on the other, justifies the adoption of measures restricting the free circulation of goods. Think, from this point of view, to the Court’s statements, also recalled in the Commission’s Communication discussed above, according to which “in the absence of harmonisation in Community rules, member states must decide what degree of protection they intend to ensure to public health”, as well as the means to achieve such protection, taking in any case into account that “the needs linked to the protection of public health should undoubtedly be given greater weight than economic considerations”.

In the current state of development of European Community law, therefore, we can say that the Court of Justice aimed at excluding, on the one hand, any application that potentially abuses the precautionary principle (those, for example, masking restrictions to exchanges or commercial barriers), and, on the other, the “minimalist” versions of this principle, susceptible to reducing the useful effect. It is a trend that puts the precautionary principle at the heart of an evolutionary process that marks the passage from a model of legal control of logical-formal legality to a teleological model, aimed at finding more adequate solutions to the concrete case in function of the objective pursued case by case by the legislator.

However, it is true that the Court has never expressly approved the precautionary principle as a general principle of European law, whilst some legal acts show a tendency to a progressive consolidation of the precautionary principle (like for example the regulation that institutes the European Food Safety Authority), which is now hoping (although it might not be able to) become an independent legal regulation, but not without falling again into domestic law.

For the purposes of the future consolidation of the precautionary principle in the European Community, particular importance has the political support given to the Commission’s communication by other European Community bodies and, particularly, by the Resolution on the precautionary principle adopted by the European Council that took place in Nice from the 7<sup>th</sup> to the 9<sup>th</sup> of December 2000. This Resolution invites first of all the Commission to systematically apply the guidelines issued in its communication in every sector of future European Community activity, developing, together with the member states, the most appropriate initiatives to support the international recognition of the principle under investigation. The European Council Resolution highlights, in addition, the responsibility of public authorities to guarantee European citizens the most complete information with regards to the scientific knowledge and the risks affecting the environment and the human habitat, ensuring at the same time the level of health and environmental protection believed to be most appropriate. In this sense we can say that the Resolution highlights the autonomy of the political power towards scientific expertise, especially when decision-making authorities, to which the precautionary principle is mostly aimed, are faced with fears or solicitations coming from the public about irrational or scientifically unproven risks. The European Council Resolution, finally, hopes for a more explicit development of European Community law with regards to precaution, stating, in line with the Court’s law, the need to formally define the principle under examination and other directives of the Treaty of Rome.

#### **4. The international scope of the precautionary principle**

Very different is the interpretation of the precautionary principle given by the World Trade Organisation (WTO). In the framework of the multilateral trade agreements administered by the WTO, operating the difficult attempt to merge the application of the principle of free exchange with the safeguard of the need to protect the environment and human, animal or plant health, the principle under examination did not have, in fact, the same ability to infiltrate. Placing itself in the fracture between the assumption at the basis of the liberalisation of exchange and the need to ensure a high level of environmental or health pro-

tection, it is instead in the context of international trade law that the precautionary principle fights a battle for survival.

It is easy to observe, with regards to this, that the level of environmental, health or consumer protection varies considerably from one state to the next (we only need to think about the “hormones in meat”, freely sold in the United States and contested in Europe) and that the measures of one state nominally aimed at ensuring certain levels of environmental or health safety can appear, in the eyes of the less “prudent” states, as discriminatory or protectionist measures, aimed at hiding unilateral restrictions to business exchanges. Within the WTO, therefore, exercising the right of member states to adopt policies aimed at the protection of the environment and human life or health intertwines and must come to terms with an objective, the liberalisation of business exchanges, which in some cases can seem to be in conflict with the protection of more general interests.

It is for this reason that, within the WTO, the 1994 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) implies the reference to the precautionary principle where it recognises the right of the participating states, where “the relevant scientific evidence is insufficient”, to adopt temporary measures of sanitary or phytosanitary protection on the basis of the simple “available pertinent information”. In this way, the SPS Agreement clearly expresses the need to ensure a scientific foundation of sanitary and phytosanitary measures able to limit business exchanges, overturning the approach at the basis of the precautionary principle found in international law regarding the environment and in European Community law, according to which, in case of doubt concerning the harmfulness of a product (or a procedure), the protection of the environment or human health should prevail on any other need (and specifically on economic interests. In other words, in the system of the SPS Agreement, the legitimacy of the measures of sanitary and phytosanitary protection finds its basis not on scientific uncertainty about the existence of risk, but on the definite harmfulness of a product<sup>74</sup>. It is also significant to observe that, whilst the SPS Agreement refers to “provisional” measures, the Commission’s Communication does not give temporal limitations to the duration of the precautionary measures created. It is true that the adoption of such measures involves, according to the Commission, the duty to investigate the scientific knowledge on the issue, in order to overcome the situation of uncertainty, but the communication requires not an explicit declaration of time for the measures in question, but a regular scientific check on them (so-called monitoring), which allows a new assessment of the measures adopted in light of the new information obtained. So, as stated by the Commission, the temporary nature of the precautionary measures is not linked to a mere temporal factor, but to the evolution of scientific knowledge.

From this point of view, it is possible to identify one of the most relevant differences between the interpretations of the precautionary principle adopted by European Community institutions and that adopted by the WTO, which reflect the contrast existing

---

<sup>74</sup> Cf. Art. 5, paragraph 7 of the SPS Agreement, according to which “in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review of sanitary and phytosanitary measure accordingly within a reasonable period of time”.

on this issue in the different European Countries (which however have very different points of view) on the one hand, and United States of America on the other. And the differences seems destined to translate in litigations, as demonstrated by the fact that the United States contested the recent European Community regulation on the labelling and traceability of genetically modified products (which in effect allows the citizens to decide whether they want to buy certain products or not), on the premise that this regulation gives American manufacturers and exporters excessive responsibilities, as it is essentially aimed at limiting business exchanges with Europe.

## 5. The effects of the precautionary principle on Italian Law

The precautionary principle has not yet been openly received in national legislation, where there isn't a general rule that, on the example of art. 1 of the French Code de l'environnement – according to which “the absence of certainty, based on current scientific and technical knowledge, must not delay the adoption of effective and proportionate measures aiming to prevent a risk of serious and irreversible damage to the environment at an economically acceptable cost” –, defines such principle.

This does not mean, however, that the problems linked with it have not been felt. We can therefore talk about precaution as a need that deserves protection rather than of a defined legal principle.

This explains the confused and sometimes conflicting approach to the relative operative solutions.

See, with regards to this, some classic examples that have in common the extension of the need of precaution from the protection of the environment to the safeguard of health.

A standard example of conflict occurred on occasion of a regional law (Regional Law Marche, 13<sup>th</sup> November 2001, No. 282) which, calling upon a precautionary need, ordered the interruption on all the regional territory of electroconvulsive therapy, raising an issue of constitutional legitimacy which ended up in being deemed unconstitutional (Constitutional Court 26<sup>th</sup> of June 2002, No. 282), in which the Constitutional Court, without openly naming the precautionary principle, stated that, according to art. 117, subsection 3, Constitution, “the fundamental principles are laid down in State legislation” and, in any case, they could not come “from purely discretionary assessments of policy by the legislator”, but should “anticipate the creation of trends founded on the assessment of the state of scientific knowledge or acquired experimental evidence, by institutions and bodies – usually national or supranational – entrusted with this task”.

In another case, which asserted the “almost certainty of the biological consequences of electrical and magnetic fields” induced a judge to order “the movement of electro-ducts if easy to carry out” (Milan Court, 7<sup>th</sup> of October 1999), Cassation Court – which had subsequently stated in general terms the judges' obligation to not refuse to “ascertain if the right to health of those exposed to the danger of being compromised by being exposed to an electro-duct magnetic field” (cassation, 27<sup>th</sup> of July 2000, n. 9893) – was shortly after deprived of authority in its natural nomophylactic function by the intervention of the national legislator, who issued a “framework law on the protection from being exposed to electric, magnetic and electromagnetic fields” (Law No. 36, 22<sup>nd</sup> of February 2001): a law that raised contrasting reactions between those who saw favourably the end of the autonomy of the legal

power on this issue<sup>75</sup> and those who highlighted the fact that the precautionary limit established by the law is arbitrary, so that, paradoxically, “below the threshold, by legal definition, electromagnetic waves would not be harmful, or in any case they would not be with regards to possible legal consequences”<sup>76</sup>.

The mixed fortune of “genetically modified organisms” (GMO) is, finally, characterised by a variety of regional laws that, although motivated by “an indisputable unity of intent” for the protection of the environment and of health, are “incoherent, full of gaps and contradictory”, and especially “demonstrate serious defects in systematic coordination” often showing that they “ignore the existence of national and European legal sources that for the protection of health and the environment have disciplined the release into the environment and the introduction on the market of GMOs”<sup>77</sup>.

The doctrine has still not initiated a process of critical reinterpretation and reconsideration of the existing norms, in the open perspective of the precautionary need, mostly preferring to entrench itself in a sterile juxtaposition between those who believe in “a precautionary principle applied according to the zero risk criterion”<sup>78</sup> and Italian sympathisers of the known definition of the precautionary principle as “a wolf in sheep’s clothing”<sup>79</sup>.

But a similar process cannot now be given up, seen as the need for precaution, if it still cannot be defined a principle of national law, is without a doubt an essential hermeneutic criterion founded on European Community law, which will act in particular on the issue of civic responsibility.

With regards to this, two significant examples can be mentioned.

Art. 2050 of the Italian Civil Code, which with a “far-sighted” regulation (for the time – 1924 – in which it was formulated) and innovative compared to the main codes in effect in Europe at that time, anticipates an inversion of the duty of proof with regards to “responsibility for exercising dangerous activities” could be extended, in a precautionary perspective, to exercising “only dangerous” activities, if we agree with the premise that “the protection of the right to health must in these cases prevail compared to the freedom of economic initiative”<sup>80</sup>.

The same point of view could lead to critically reconsider – also in view of an eventual legal modification – the norm that, when carrying out European Community Directives “on the liability for the damage due to dangerous products” (85/374/EEC, art. 7, letter e), stated the exclusion of responsibility “if the state of scientific and technical knowledge, at the moment in which the manufacturer put the product into circulation, was not such as to enable the product to be clearly considered as contemplated in the abovementioned

---

<sup>75</sup> C. Consolo, *Il rischio da ignoto tecnologico: un campo arduo per la tutela cautelare (seppur solo) inibitoria*, in *Il rischio da ignoto tecnologico*, Acts of the XIII seminar of the quarterly Journal of Civil Law and Procedure, in process of publication.

<sup>76</sup> F. Merusi, *Dal fatto incerto alla precauzione: la legge sull'elettrosmog*, in “Foro amministrativo”, 2001, p.223.

<sup>77</sup> G. Galasso, *Il principio di precauzione nella disciplina degli OGM*, ed. provv., Giappichelli, Torino, p. 178 and following.

<sup>78</sup> H. Corradini, D. Broussard, *Il “principio di precauzione” e il problema della brevettabilità*, in process of publication.

<sup>79</sup> M. Pollan, *Precautionary Principle*, in “The New York Times”, 9<sup>th</sup> of December 2001.

<sup>80</sup> A. Pizzorusso, *Il patrimonio costituzionale europeo*, Zanichelli, Bologna 2002, p. 68 and following.

Directive (art. 15, letter h) and so causing since then the fierce criticism of the most authoritative commentators<sup>81</sup>.

In conclusion, Italian law has not yet made official the introduction in the national system of the precautionary principle; but the system cannot ignore the need implied by it, and it is called to rationalise the protective measures for the environment and health that are direct expression of it, involving with distinctive roles the (national and regional) legislator, (constitutional, civil, administrative) jurisprudence and policy: from which, in particular, we expect a systematic reconstruction of the current legislation, which takes into account an hermeneutic criterion founded (if not on the principle, certainly) on the need of precaution solicited, or imposed, by European Community law, and by European Constitutional law, as can be seen by the European Union Charter for Fundamental Rights (so-called Nice Charter), which recommends “a high level of protection” for human health (art. 35) and for the environment (art. 37).

---

<sup>81</sup> R. Pardolesi, G. Ponzanelli (ed.), *Commentario*, in “Le nuove leggi civili commentate”, 1989, p. 565 and following.

#### **CHAPTER IV: SYNTHESIS AND CONCLUSIONS: PUBLIC OPINION AND THE POLITICAL RESPONSIBILITY IN RISK MANAGEMENT FOR THE SOCIAL ACCEPTABILITY OF IT (COSTS/BENEFITS ASSESSMENT) AND APPLICATION OF THE PRECAUTIONARY PRINCIPLE**

What has been said so far is already more than enough to outline the role of the “precautionary principle” in today’s society. We think it appropriate – going towards the conclusion – to present the following summative reflections:

1. In the trend prevalent in today’s society, it is hoped for each individual to take on their responsibility for appropriate ecological and lifestyle choices, as they are in line with their most genuine interests.

In this sense, the knowledge and quantification of the environmental risks that can be controlled by the individual, or by small communities, promoted by communication agencies with appropriate and convincing methods – should lead to feeling that many risks of this type (for example pollution from agricultural or city refuse, etc.) not as unchangeable fatalities, but as removable or at least diminishable dangers, by simply using criteria of appropriateness and caution in the actions of every citizen.

This involves great a dedication to education in order to harmonise the State’s institutional duties with committed initiatives of protection also to reassure the public.

A constant action of information and formation of the individual, starting at school age, for the correct management of the environment and of the methods relating to it, is the first duty of political and administrative activity.

2. Beyond the common and widespread source of risk “manageable” by the individual, there are problems of generalised risks on which we exercise – traditionally – control and the responsibility of public administrators and Governments with a series of interventions of various nature, not only linked to the classical instruments of civil and penal law, but also to “principles” that seemed – with experience – more suitable to manage human activities on the environment and territory. For instance, the user/payer principle; the polluter/payer principle (in general applicable for low risk activities), the mitigation principle; the prevention principle and finally the “precautionary principle”.

If the main responsibility to manage generalised risks belongs in any case to public administrators, today the situation is much more complex compared to the past, amongst three actors: the decision-maker, the expert, the citizen (who appears in the dual role of economic producer and consumer) and it is characterised by the fact that – at least for a long time (and in some cases still today) – the consumer has been kept in the dark about decisions that can affect the safety and health of the environment in which he/she lives and with regards to his/her health, and this can no longer be acceptable.

We can state – globally – that whilst the doubt of the public towards the reliability of “expert” opinion has increased (as documented before), the participation of public opinion to the non-“scientific” analysis of the problems and its importance in the decision-making process has also increased.

In this sense, we can say that the main objective of the “precautionary principle” is that of forcing the decision-maker to explain, quantifying them, his/her objectives and to inform in the most objective way possible. In the framework of political decision-making this poses the problem of exercising democracy, because it is a way of managing risk that it is also a rethink of public ethics, economy and social protection.

For these reasons, the demand for “transparency” has also increased, forcefully presented to the public administration by citizens’ conscious of being “consumers” often unaware of even the indispensable manufacturing processes, as in food.

Labelling – introduced by the European Community – answers these needs and documents the application of a “principle of respect of the informed choices made by the consumer”, the introduction and dissemination of which in business regulations is more and more supported also by the national political power. A significant example is the recent European Community legislation concerning genetically modified food and animal feed.

3. The change relative to the treatment of environmental and health risks has been the object of detailed evaluation by the European Community which, following the Communication on the precautionary principle (see chapter III), issued many directives aimed at highlighting the widespread and constant need for European citizens’ participation to the management of the programmes concerning the applications of research activities that have industrial effects. The reflection of the European Community, if aimed at giving responsibility to the government, must make sure that the population is not considered a passive object, the interests of which have to be looked after, in a paternalistic manner, only by experts or scientists.

We can therefore conclude stating that the precautionary principle, as identified in the European Community, has highlighted new ways to interact between citizens, scientific expertise and public powers through the continuous and constant adaptation of decision-making processes, also reinforcing a democratic participation to the creation of the regulations.

The distinction between pure and applied science must be increasingly evident in public management with regards to the precautionary principle: applied science cannot forgo the assessment of the risks linked and resulting from large scale experimentation on the environment. From this point of view it becomes a duty for the government to behave responsibly towards the prevention and at times the application of the precautionary principle, in conditions of scientific uncertainty.

Already in the White Book on European Governance (European Commission, 2001) the Commission launched a programme aimed at carrying out the reform of the European governance defined as “the way in which the Union uses the powers given to it by its citizens”. The document clarifies the regulations, procedures and behaviours within the competences and they are identified as “principles of good governance”, those of openness, participation, responsibility, principles that must be applied at all levels of government, European, national, regional or local.

Also in the Commission’s VI Framework Programme of Research and Development (2002-2006) public participation in environmental issues is encouraged and the difficulty, in the absence of a general and continuous commitment of society overall, of achieving the results. The seventh Priority Area of the Programme is clearly dedicated to “Citizens and Governance in a Knowledge-based Society”.

4. The notions of the scientific assessment and scientific uncertainty of human activities, especially industrial ones, have been discussed in detail in the last few years both in America and Europe, both in society and by the political power.

Also the reflection carried out in Europe on the application of science in conditions of

uncertainty has highlighted a dual need: the first regards the democratization of scientific expertise (which must be increasingly open, able to include minority or dissenting scientific opinions); the second one concerns, instead, the need for correct and transparent information aimed at including, if possible, the participation of society to the decision concerning it. Scientists and experts should not be the only ones qualified to make ethical decisions that are at the basis of civil and social transformations and that can involve risks able to harm the fundamental right of man like the right to health and a healthy environment.

Already the Council of Europe in Nice, in December 2000, stated the need for public authority to take on risk organisation and assessment guaranteeing a plurality of perspectives, independence and transparency: in addition, minority opinions must be presented in “expertise” documents, where they highlight the lack of adequate scientific research (pp. 9 and 10) as it is necessary... “that society must be involved and that all interested parties are involved, as much as possible from the earliest phases (European Council 2000 p. n. 15)”.

Of particular interest is the Plan of Action on Science and Society (European Commission 2001) where the strong interrelation between science, technological innovation and social change are stressed and where the objectives and actions for the promotion of European scientific culture and the development of a research that is closer to the public, is indicated. The document, talking about a responsible science at the basis of scientific progress, highlights that “science is often perceived as dealing with certainty and hard fact; whereas in reality this is rarely the case, particularly at the frontier of research” (Action 35, point 3.3). This would make a more open approach, systematic in nationally and in Europe, necessary to identify the most adequate competences, opening to public consultation procedures and to the interested parties at the right time, giving them opportunities and tools to allow them to contribute to the debate and to contest the experts or their opinions. Moreover, it is quite surprising that governments continue to promise “certainties”, when the symbolic universe of today’s society is increasingly more imbued by “risks” and “uncertainties”.

5. For the decision-making power, in light of these trends, but faced with the paradigm of “sustainable development”, there is the need on the one hand to simplify and rationalise the procedures – on the other to have more cautious authorisations and in effect to be of more assistance and have more control of the management of human activities dangerous for the environment and health, recurring to the by now differentiated legal tools available today. Amongst them, also the “precautionary principle”, the use of which should be reserved to governments (in line with European Community legislation and – for Italy – with what is indicated in the reformed art. 117 of the Constitution), finding also a more accurate legalisation.

6. In general, the precautionary principle was accepted favourably by public opinion, and it has been called upon as new episodes of not sufficiently prevented risks have appeared in human activities.

Also information and the investigation of the principle’s meaning have progressed.

The focus of some very prestigious journals has been in many occasions aimed at the problems of risk, prevention and precaution in different European Countries, and many are by now the doctrinal elaborations regarding both the “expert” and the scientific reflec-

tion and inherent to the role of public opinion and the tasks it gives to politicians. It is growing both in culture and in public opinion, the awareness that a generic appeal to “responsibility” is no longer enough, a term that has also become full of ambiguities and mental reservations, but what are needed is precise commitments and actions, on the basis of clearer and firmer principles.

Much of the most recent literature regarding the application of the “precautionary principle” mentions not only the by now “classical” risks of nuclear and industrial plants, but especially of those many forms of interest in food (for example GM foods and the polluting agents of industrialised agriculture) of the possible risks on the biology of living beings caused by other pollutants (consider for example electromagnetic energy, etc.) or other by now appreciated environmental risks for human health, which – although in the presence of a variety of opinions – still require a more decisive scientific assessment.

To strengthen this favourable response of public opinion, it is not devoid of meaning the fact that the European Community Court of Justice, with the ruling of the 21<sup>st</sup> of March 2000, interpreted Council’s Directive n. 90/220 of the 23<sup>rd</sup> of April 1990, relative to the deliberate release into the environment of GM foods, in the sense that it allowed the States to deny their consent to the release on condition that there are sufficient scientific data able to prove that the product, object of the notification, can be dangerous for the environment and human health. In any case, the State in question must inform without delay the Commission and the other Member states to start the European Community procedure disciplined by directive n. 90/220<sup>82</sup>.

7. Some researchers have seriously doubted the “legal value” of the “precautionary principle”, at least from a point of view of positive law, although they do not deny its value of “tendency” especially in those phases in which administrative authority (at various levels for some, only “centrally” and for national decisions for others) must apply positive and statutory regulations<sup>83</sup>.

It is certainly necessary to stay away from any unmotivated recourse to the precautionary principle, as zealous supporters would like to impose it wherever they can.

We must instead give a reasonable explanation of this principle, which will have to be rigorously applied only when a specific risk is identified (although not yet exactly estimated) by the community of experts.

It is also true that it is the task of the Community of citizens – in the heterogeneous composition of different and at times contrasting interests that characterises it – to establish what level of safety it wants, also at the cost of giving up economic development, and it is just as true that – also in the European Community – the considerations regarding the protection of health have precedence on economic and business ones. However, in the European Community – is in force the application of the general principle of proportionality, which must harmonise with that of precaution.

8. Looking to the future, there is much to do at the level of information and formation

---

<sup>82</sup> Cf. *Greenpeace’s ruling*, in “Environmental Legal Journal”, 2000, p. 457 and following.

<sup>83</sup> M. Gros, D. Demarbe, *La controverse du principe de precaution*, “Revue du Droit public”, 118/3, 2002, pp. 321-345.

of conscience (awareness and motivation) on the objectives and methods to ensure the protection of the environment and the health of the living, in the framework of a truly sustainable development.

Amongst the development tools (and not only “defensive”) we must also list the “precautionary principle”.

We are, in any case, in a moment of transition about the scope of the legal efficacy of such a tool.

It must be recognised that the precautionary principle is exercising a profound influence on the legislation of risks producing – in some sectors – two legislations with distinct and sometimes contradictory objectives. The objective of the first is that of reducing the exposition to old risks, of the other that of stopping the changes in technology that could lead to new risks for our lives, without completely eliminating the previous ones, although diminishing their importance.

In any case, the “precautionary principle” must be applied wisely, without forgetting that it should be a regulation limited in time, suspended, waiting for scientific clarification. The objective to pursue, in fact, is that of bringing back the trust between politicians, administrators, technicians and citizens, in the awareness that trust is an important resource, fundamental in complex societies.

9. Concluding this analysis, we think we can state that the work to be done for an even more effective protection of health and the environment, despite the positive start, is considerable and can be summarised in the following points:

- a) We appreciate how today’s society is developing a new sensitivity towards risk, the methods with which technical-scientific research perceives it, tackles it when it is not possible to quantify it, must (or can) answer to the eventual threats (real or potential) in urgent situations.
- b) The awareness that the assessment of the risk comes with a variable level of scientific certainties must increase. Zero risk does not exist. Only a systematic study of the biological effects consequent to being exposed to certain agents, manipulations, treatments (including medical-surgical ones in continuous evolution, implicitly burdened by various types of risk often not clearly foreseeable), carried out with rigorous scientific methods, can significantly reduce the unforeseeable margin of risk.
- c) In adjusting the most accurate methods of control, industries, universities, public and private research institutes must collaborate to define high standards and for the elaboration of criteria and guidelines for the interpretation of data. This collaboration, nourished by scientific dialogue and debate, is a necessary condition to face the preoccupations that arise with the development of anthropic activities on the environment and biotechnologies.
- d) To this end, it is essential to have technically defined control criteria, which must be specific to the problem under consideration.
- e) The researcher’s duty is to determine the efficacy, reliability, efficiency and breadth of the interval of variability within which the feared effects, for the purpose of control and security, can manifest themselves.
- f) Specific research programmes aimed at evaluating the controversial aspects to ascertain that the precautionary procedure adopted is straightforward.
- g) Every public authority’s decision regarding the issue under investigation should be

preceded by an expert evaluation carried out also looking at conflicting arguments, which should not overlook taking into account minority opinions.

- h) The definition of acceptable risk does not strictly concern the scientist but it depends on a joint judgement of experts in legal, ethico-moral, economic and political disciplines, formulated in an open and transparent dialogue with public opinion, particularly if directly interested in the surrounding environmental risk (for example dangerous industrial settlement).
- i) National and European legislation concerning the assessment procedures for risks associated to interventions on living organisms and to the dissemination of products destined to consumption is increasingly broad and articulated. Object of particular attention are – today – genetically modified organisms and their derivatives, but the focus must be shifted to other significant sources of risk for human health.
- j) In general, the assessment of the risks linked to new technologies (carried out by comparison) should not slow down and stop the introduction on the market of new products that can show how to overcome old risks.
- k) The “precautionary principle”, the ethico-legal value of which is reinforced by clear scientific justifications can be a very useful tool in this reflection fully aware of contemporary society, but it must be “properly” used – waiting for scientific clarity on the controversial topic – and not as simple current tool in social Governance. In addition, the “specific gravity” to give to this principle in positive law, not being foreseeable – at least in the continental system – to abandon the legislation founded on authorised standard parameters.
- l) The correct application of the precautionary principle can stimulate scientific research also for the purpose of making industrial applications safer.

## TABLE 1: SHORT GLOSSARY OF DEFINITIONS

**Risk:** it is defined as the sum of the probabilities and the seriousness of an adverse effect.

**Scientific-rational approach of risk assessment:** (generally) distinguishes three procedural phases:

Risk identification;

Estimation of the level and scope or the risk's potential damage;

Assessment of the acceptability of the risk compared to other risks.

**User/payer's principle:** Stated by the OCDE in 1989 ascribes to the user the cost of an activity that is the source of pollution.

**Polluter/payer principle:** Stated by the OCDE (1972), mainly ascribes to the individual who pollutes the costs of the measures of prevention and fight against pollution.

**Preventive principle:** Principle according to which, in the presence of real risks, the dangerous induced effects of which are already established, even though the probability for the risky event to happen could be assessed in a different way, is carried out with adequate measures to avert/contain the risk.

**Mitigation principle:** Even if it can demonstrate that the risk of incident is low, it is supposed nevertheless that the accident can happen. Procedures are put in place to allow the decrease in the consequences of the incident for man and the environment.

**Precautionary principle:** Principle according to which the absence of certainties, taking into account the scientific and technical knowledge available at the time, must not delay the adoption of effective and proportionate measures aimed at preventing the risk of serious and irreversible damage in the environment for an economically acceptable cost.

**Foreseen applications for the "precautionary principle":** In the protection of the environment and the safeguard of human, animal and plant health. The Communication of the Commission on the precautionary principle (N1,2000) says:

(Maastricht/Amsterdam)

"Although the precautionary principle is not explicitly mentioned in the Treaty except in the environmental field, its scope is far wider and covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection".

**(Durable) sustainable development:** Introduced in the Rio Conference (1992) is considered as the fundamental principle (Art. 1) of every policy of environmental treatment and protection. It says:

“durable development tends to satisfy fairly the needs relative to the development and environment of present and future generations” (art. 3).

**A more concrete formulation states:** “development is durable (sustainable) if future generations will inherit a quality environment at least equal to the one received by previous generations”.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**ALTERNATIVE MEDICINE AND THE PROBLEM  
OF INFORMED CONSENT**

18<sup>th</sup> of March 2005



## PRESENTATION

The dispute between “scientific” medicine and so-called “non-conventional” medicines has lasted for decades (maybe it has always existed), it remains strong and bitter even though some scholars try to attenuate and appease it. It is an erroneous common belief that the dispute concerns the effectiveness of medicine in general and alternative therapies in particular: anyone who has participated in a debate among experts of both one or the other schools of thought will have inevitably noted that despite its starting off on a high tone, it ends up being reduced to a series of testimonies (negative, that is, failures for some, and positive, that is, therapeutic triumphs, for others). Testimonies that are generic at times, but sometimes also incredibly accurate, at other times inconclusive, but at times indisputable, all of them almost always fascinating at the level of common experience regarding the “passion” which inevitably emerges (and how could it be otherwise, in a cause that has no other object other than that of the relationship between health/illness, the most engrossing and perturbing combination of human experiences?), all epistemologically, however, out of tune, because from none of them emerges anything concerning the nodal point of the question, that is not factual (if it were, a well-linked chain of testimonies could definitely resolve it), but of principle. The point is that the core of the matter does not concern medicine as a social practice, but the status of medicine as a science. And it is obvious that you do not become scientists through *vox populi*, but through forms of institutional recognition, that the modern era has legalized, giving to medical schools legal and public status. The attempt, which is typical of recent years, to include non-conventional medicine within the institution of scientific medicine has relevant pragmatic reasons, but it is fragile from the theoretical point of view, as are all generally based mediation efforts based more on the convergence of interests, than on respect for intellectual coherence.

Naturally, it is not for the National Bioethics Committee to establish itself as the referee of disputes of such complexity, which should rightly remain entrusted exclusively to specialists in epistemology. But there is a profile, inherent to the practice of unconventional medicine, that of informed consent, which is of an extremely important ethical value. The NBC dealt with this subject in the document *Information and Consent to Medical Treatment*, as early as 1992. If from that day to this the awareness has definitively been established that the foundation of the ethicality of any medical practice must be (except for extreme cases) constituted by the dialogic and competent agreement between the patient and the therapist, this is not to say that the patient’s informed consent should be regarded as an easily manageable problem: both consent and especially information are extremely complex and often ambiguous. In the case of non-conventional medicine, other problems, more specific and perhaps even more subtle, are added to common problems that these issues give rise to, that are, partly touched upon in the document *Aims, limits and risks of medicine* of 14<sup>th</sup> December 2001. The decisive request for the NBC to take charge of the issue came in September 1992, when Girolamo Sirchia, Minister of Health, included the issue of informed consent in medicine with particular emphasis on non-traditional medicine within the group of subjects to be addressed and discussed by the NBC. The Committee, at its plenary session held on the 20<sup>th</sup> September 2002, launched a working group, which was entrusted to the coordination of Prof. John Federspil. Many members of the NBC joined the group, demonstrating how this issue was considered as essential and urgent: Dario Antiseri, Mauro Barni, Luisella Battaglia, Sergio Belardinelli, Paola Binetti, Adriano

Bompiani, Cinzia Caporale, Isabella Maria Coghi, Lorenzo d'Avack, Giuseppe Del Barone, Luisa Di Pietro, Angelo Fiori, Carlo Flamigni, Renata Gaddini, Laura Guidoni, Gianfranco Iadecola, Vittorio Mathieu, Demetrio Neri, Pasqualino Santori, Michele Schiavone, Bruno Silvestrini, Giancarlo Umami Ronchi. The group's work lasted from 20<sup>th</sup> March 2003 to 16<sup>th</sup> December 2004 and benefitted from a hearing held on the 18<sup>th</sup> June 2004, during which doctors and scholars representing different positions within the sphere of non-conventional medicine were heard.

The draft document was prepared by the coordinator of the group Giovanni Federspil along with the essential contribution of Dario Antiseri, and Angelo Fiori and Mauro Barni for the part relating to informed consent, and which I, the writer, subsequently revised; it was then brought to the attention of the Committee, in the plenary session, and after lively discussion was unanimously approved on the 18<sup>th</sup> March 2005.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## ALTERNATIVE MEDICINE AND THE PROBLEM OF INFORMED CONSENT

1. In this text the term *alternative medicine* is adopted – *without making the claim that it is undoubtedly the most correct* - to describe the diagnostic and therapeutic practices, *performed by doctors*, which are based on concepts, theories and principles currently irreducible to established scientific knowledge pertaining to the Western epistemological tradition and whose claims of efficacy and safety, while widely claimed and argued by many in different ways, are not supported in the opinion of the majority of the members of the NBC (or are nevertheless not satisfactorily sustained) by evidence carried out with rigorous and experimentally reliable methods. By choosing the term *alternative medicine*, the NBC is also well aware that there are others, that could usefully be used, e.g. *complementary, parallel, gentle, natural, holistic, integrative, green, non-conventional, non-scientific and “other”* medicines etc..., all terms that in one way or the other are expressive of significant aspects of a different way of considering medicine. Even the adjective which is commonly used to describe (sometimes antagonistically) the medicine from which alternative medicine intends to differentiate and distance itself from can be very diversified: one speaks of medicine as *scientific, official, formal, academic, and orthodox*; but for some it would be appropriate to abandon all such adjectives and simply speak *tout court of medicine*. In this text the term *scientific medicine* will be used, as the Committee has done on other occasions and for the reasons indicated below.

2. By using the term *alternative medicine* in this document the NBC exclusively refers to practices whose effectiveness can not be ascertained by the criteria used by scientific medicine, such as pranotherapy, Ayur-Vedic medicine, anthroposophic medicine, homotoxicology, homeopathy, Traditional Chinese and Tibetan medicine, chromotherapy, Bach flowers, Reiki, iridology, etc. Instead, the NBC believes it would be more appropriate to use the term empirical rather than alternative for other therapeutic practices, such as reflexology acupuncture, phytotherapy and manual medicine, which in some cases appear beneficial for patients and are not substantially far away from other forms of physical therapy (mud therapy, crenotherapy, diathermy, massage therapy, etc.). The considerations made in this text do not refer to empirical medicines, which the NBC reserves the right to address on another occasion, but rather it seeks, more generally, to be a renewal and close examination of the issues developed in particular in § 4 of the document *Aims, limits and risks of medicine*, approved by the NBC on the 14<sup>th</sup> December 2001.

3. The NBC is aware that the massive and growing diffusion in the Western world of alternative medicine (a social phenomenon that can not be studied as such by the NBC) also depends on (and for some only on) the fact that many patients *subjectively* benefit from such therapeutic indications: *these experiences, however, deserve attention and respect*. The right to autonomy and freedom of treatment is in fact a primary right of all citizens, not only exercised by those who regularly or occasionally, but however consciously, identify as their doctor an expert of alternative medicine, but also by all patients with equal awareness who decide to disregard the limitations of scientific medicine.

4. The NBC notes, however, that the patient's primary right to autonomy and freedom of treatment, whether it be directed towards scientific medicine or makes recourse to alter-

native treatments, can never be substantiated in claims that are incompatible with the dignity and rights of the patient and with the respect due to the professional position of the doctor: the latter, in complex societies, is morally, ethically and legally the guarantor of health, as well as of his professionalism, and can not be bound to the merely and passively carrying out the patient's will.

5. Compared with the benefits subjectively experienced by many patients who use alternative medicine, there are significant and worrying cases in which its use must be regarded as objectively and specifically *harmful*. In addition, it may well be the case that a patient is actually harmed by the use of such practices, due to the fact that the use of alternative diagnostics and therapies may unnecessarily and unfortunately sometimes *irremediably* delay the use of more rigorous and effective diagnosis and scientific therapies. The members of the NBC insist to stress on this possibility, which they consider one of the most serious ethical problems faced by the advocates and devotees of these practices.

6. The national and regional public institutions, universities, medical orders and colleges of health professions and also accredited medical and scientific associations, have, even in bioethical terms, the duty to inform citizens not only about the dangers of each medication and any recourse to illegal operators of medicine, but also concerning the validity, limits and risks that are inevitably included in *any* kind of practice – “scientific” or “alternative” - ??which has diagnostic and therapeutic aims. In particular, the NBC reiterates the essential role of the *public health service* (established and regulated by European and national directives) regarding the testing of drugs and pharmacovigilance. The not uncommon withdrawal from the market of initially-considered beneficial drugs, but that subsequently prove to be risky or definitely harmful, or ineffective, is a typical example of the exercise of obligations incumbent on the Health Authority. The same official subdivision of drugs into categories, for reimbursement purposes, - through the distinction between essential drugs and others considered as less essential – is indicative of how, even in this area, scientific medicine constantly remodels its concepts and the rules of conduct that derive from them.

7. According to the NBC it is a bioethical and deontological requisite that no medical and therapeutic practice should elude the obligation of systematic experimentation, implemented according to strict protocols that are methodologically correct and binding, in the name of the constitutional right to health. It should also be a requirement for each trial to be subject to public controls, implemented through the work of experts, third parties and independents. This duty lies, in the opinion of the NBC, on every medical practice, and *therefore also on those related to alternative medicine*. It is essential that the remedies utilised by the practice of alternative medicine correspond to the same required standards of efficacy as the prescribed medicines utilised in conventional scientific medicine, for the institutionalization of a *double standard* for the pharmaceutical market is unacceptable.

8. It should also be noted that some alternative medicines do not consent to be subjected to the experimental verification protocols commonly used by scientific medicine and often claim particularities that should exempt or not make feasible such controls regarding them. On this point, the epistemological debate is particularly lively and a rapid and shared

solution certainly does not appear likely. The NBC does not believe it has jurisdiction to comment on purely epistemological and methodological matters, but can not abstain from giving the right significance to the worrying positions adopted by various Scientific Associations and Medical Faculties, and is aware of the unease that such controversial issues arouse in those called on to develop bioethical evaluations. Many members of the NBC hold the opinion that, given the epistemological fragility (the greater part at least) of alternative medicine, which, according to them, seems currently demonstrated, this places a particular and further responsibility on the physicians that resort to these practices, in relation to those normally assigned to doctors who exclusively apply the methods, Guidelines and protocols of scientific medicine.

9. The public opinion must necessarily receive as a priority the basic information that the medicine that is mostly practiced in the world is *modern scientific* medicine. It must be recognized (without indulging in triumphalism, for many are the errors and sometimes tragedies caused by practice of scientific medicine) that the worldwide diffusion of this medicine, along with the additional fundamental factor of the different conditions of hygiene, food and, in general, of way of life of many populations, has allowed the increase in life expectancy, the correct diagnosis, optimal treatment and often the cure of a large number of diseases (including in particular epidemic and infectious diseases). And it is on the development of such medicine that hopes are based on finding successful treatment for the current ominous diseases, such as many cancers, AIDS or Alzheimer's disease. Scientific medicine, since the adoption of the experimental method, is based on the entirety of those knowledge related to the structure and functions of the human body that can be developed through the interaction and integration of various methodologically based disciplines such as physics, chemistry, biology and in particular molecular biology, genetics, physiology, anatomy, general pathology, and psychology. This medicine, which day by day increases its knowledge thanks to the research of many scholars, also deserves to be called *scientific*, for it is able, thanks to a public debate which in principle excludes all sectarianism and every esotericism, to correct itself and modify its concepts and practices with great flexibility, based on the experience of mistakes made and the development of always new paradigms.

10. It is right, according to the NBC, that citizens should be informed on the status, improvements, successes and failures of scientific medicine, similarly, it is also behaving to inform them that alternative medicine - regardless of the successes claimed by their supporters, which in the context of this document the NBC does not intend to call into question - do not have an epistemological statute characterized by the same rigor. Many of these are elaborated in a philosophical and/or spiritual form, occasionally of a highly suggestive nature, but irreducible to any empirical test. Some don't justify their efficacy with reference to a *public doctrinal corpus*, that can be taught, learned and then *transmitted*, but to faculties or *powers* that are inborn, *personal*, assumed to present in the therapist and which the same therapist is unable to indicate the cause or objective source. Others, like many forms of *folk*, *ethnic* or *traditional* medicine, have not experienced any significant progress that is historically documented, as evidenced by the fact that they remain crystallized in their concepts and in their ancestral centennial or even millennial practices (e.g. Ayur-Vedic Medicine or Tibetan Medicine). While others are committed to seeking confirmation by referring to the common notions of physical and chemical sciences, however without being

able to establish any real connection between their practices and claims and those of science itself endowed with methodologically consolidated statutes. It should not be omitted that a number of alternative medicines not only assume antagonistic attitudes, that are sometimes very harsh and ungenerous, with respect to scientific medicine, but are mutually irreducible, basing themselves on principles that are radically alternative to each other and therefore it is logically impossible to simultaneously defend and justify them *due to the contradiction which does not consent it*.

11. This does not mean that, as already noted, in a significant number of cases, thanks to the use of alternative medicine, many patients do not obtain some alleviation of their symptoms (only in those cases – as pointed out by many – where these ailments are of minor importance). It is also well known that some proposers of alternative medicine insist to stress how their greatest contribution consists in the symptomatic treatment of chronic cases that are difficult to treat with scientific methods. On the contrary, much more controversial is the assessment of the *real* effectiveness of alternative medicine in patients with particularly severe diseases or diseases with a rapid course for which there is no hypothesis of psycho-somatic causes or contributory causes. According to the opinion of some members of the NBC, the effectiveness of alternative medicine, when detected, can be explained with the well-known *placebo* effect, as well as the stronger commitment that in general (and *commendably*) the experts of these practices devote to the care and comfort of all their patients. In fact, it is well-known that some experts of medical science ignore the psychological needs of the *sick person*, in the search for the correct diagnosis and treatment of the *disease*, while generally the experts of alternative medicine more frequently make use of a closeness in relation to the sick that is sometimes absent in practices of scientific medicine.

12. It is the unanimous opinion of the NBC that it is bioethically behoving that all these aspects of *alternative medicine* - in both their positive and negative dimension – should be made known to all citizens and in particular to all patients. It is also behoving that these aspects are also well known even to physicians: they must always be able to provide fair and honest information about the efficacy and limitations of the services provided by any medical practice and therefore also by those that are not or not yet scientifically based.

13. Alongside the *doctor's duty* to provide all the necessary information to the patient so that he can take his decisions independently there is, as is known, the *patient's duty* to provide the doctor with all possible information in his possession to ensure correct diagnosis and appropriate therapeutic indications. In the field of alternative medicine, this duty of the patient assumes a crucial importance in relation to the possible interactions between the substances prescribed according to the paradigms of alternative medicine and those prescribed according to the protocols of scientific medicine: these interactions may prevent physicians to make a correct diagnosis and indicate the optimal treatment for the patient. Often the patient is led to underestimate the duty to provide this information, both because he ignores the possible effects of pharmaceutical products (which he himself sometimes takes, without medical supervision), or brought about by an undue, but sometimes unsurpassable form of “reticence” to tell the doctor who is treating him about his (sometimes occasional) adherence to a model of medicine that he knows the doctor does not approve of. Reliable surveys show that especially those patients who use regularly prescribed antide-

pressants, often, on their own initiative, add alternative adjuvants, ignoring the fact that natural products against anxiety and depression can have dangerous effects when taken together with other drugs. The NBC, aware of the extent of this problem, insists on the importance of making the public opinion the need to establish the doctor-patient relationship on mutual and honest information, as an indispensable element for the establishment of a true “therapeutic alliance”.

14. It is taken for granted that it is the duty of every clinician to behave according to his best *knowledge and consciousness*, as regards his patient. This ancient motto ties together two different entities - knowledge and consciousness - in a professional *unicum* and binds the physician -as holder of a *public* degree certificate and *public qualification* to practice medicine - to treat the patient not following his subjective and private intuitions, even though suggestive, but by what is dictated by scientific knowledge publicly validated in each and every historical moment. The NBC recognizes every doctor’s right to the so-called *freedom of treatment* (which is indeed to be seen as one of the factors in the progress of medicine), but that freedom must necessarily be exercised within the fundamental perspective of the protection of the health of the patient and therefore should foresee *in primis* patient’s proposal of remedies of proven effectiveness. Only in the event of a total absence of such remedies or a lack of efficacy in the actual clinical case or the existence of evident contraindications or following refusal by the adequately informed patient, could it seem legitimate, with the required consent of the patient, to change to other therapies, provided that, they are never the result of subjective or arbitrary choices of the therapist; *it is an essential bioethical principle that the freedom of treatment must always be combined with the professional guarantees that the code of medical ethics imposes on the physician in relation to the patient.*

15. It is without doubt, in the opinion of NBC, that in some circumstances (particularly in the case of non-serious forms of disease or hypochondriac patients or palliative therapy) it would seem justified to resort to the administration of substances or to the carrying out of practices that are not scientifically validated, *provided that the patient is competent and informed, and makes an explicit request for it.* The NBC, however, unanimously reiterated that *in the case of undoubtedly serious morbid situations*, for which there are known and effective remedies, *it does not appear in any case lawful, either legally or deontologically, or bioethically for the doctor not to carry out the investigations designated by scientific medicine and not to make every effort to clarify to the patient the consequences of his possible refusal of the care deemed useful or even indispensable by this medicine.* The NBC is therefore unanimous in their belief that *in these cases* the medical practices that are not founded on scientific evidence are unable to *substitute* those of scientific medicine.

16. The NBC is of the opinion that if a patient, who is properly informed, expressly intends to refuse the treatments of scientific medicine, and prefers to rely on the therapeutic indications of an alternative medicine prescribed by a physician, the costs of the preparations and services rendered should not be charged to the National Health Service.

17. Particular attention should be paid by physicians to the use of alternative medicines when the patients are minors or incapacitated, even when they are requested by their

parents or guardians. If the least important pathologies are excluded, which may also suggest the possibility of not proceeding to therapeutic treatments, waiting for the more than likely spontaneous healing process of the sick person, doctors should always prescribe the use of therapies that are more scientifically validated.

18. It is hoped that Universities and more generally all research institutions autonomously develop research programs on alternative medicine, on its history, on its prevalence, on its epistemological plausibility, on the sociological implications of its use and on any other aspects relevant to the spread and increase of knowledge. The teaching or the disciplines that have as their object these aspects of medicine should be aimed at introducing the students to an issue of great importance in the context of contemporary health care, and not at conveying to them the idea, epistemologically unjustifiable and inconsistent with the prestigious *legal* value of the *unitary* degree awarded at University, that the pluralism *in science* is equivalent to a plurality *of the sciences*. Nor is it acceptable that the teaching of these aspects of medicine may have a particular professionalizing value, spent on the market differently from that which ordinarily is enjoyed by every doctor.

19. It is also essential that the teaching related to alternative medicine should be entrusted to scholars identified according to the regular methods of recruitment of university teachers, without giving the decision-making powers (which would constitute undue privileges) to the reference associations of alternative medicine (and this is in full analogy with what happens for the medical and scientific associations, which, however great their prestige may be, they do not have and should not have the power to formally identify the university teachers for their reference disciplines). Each physician (and not an *ad hoc* doctor) should obtain during his formative years an adequate knowledge of the reasons that militate in favor of and those against the claims of alternative medicine. The NBC on this point confirms the view previously expressed with the *Motion on non-conventional medicines and practices*, approved on 23<sup>rd</sup> April 2004.

## PERSONAL REMARK

Some members of the NBC believe they should better clarify their position, in the following terms. First of all, medical treatment should be assessed as regards effectiveness and safety, and documented in accordance with the established and indispensable criteria dictated by the scientific method. The theoretical basis and explanation of the mechanism of action of treatment are guides for medical practice, but their absence does not exclude recourse to documented treatment in a faultless manner in terms of efficacy and safety. Moreover, it should be noted, that many drugs of modern scientific medicine were introduced in therapy without knowing the mechanism of action.

Based on these principles, encoded by so-called “medical evidence”, it is believed that alternative or non-conventional medicine should be judged primarily according to the documentation supplied by the methodologically sound criteria of the efficacy and safety of treatment. The guiding principles of alternative or non-conventional medicine, may have a cultural value, and be the subject of courses on the history of medicine, but they are secondary in terms of current medical practice and the interest of the patient.

In conclusion, the opinion of the Director of the Centre for Complementary and Alternative Medicine, NIH - National Institutes of Health, seems acceptable, according to which alternative or non-conventional medicine offer many interesting opportunities, which must be assessed in an “appropriate manner”, whereas the term appropriate indicate with respect to the scientific method.

Prof. Bruno Silvestrini  
Prof. Luisella Battaglia  
Prof. Cinzia Caporale  
Prof. Isabella Coghi  
Prof. Renata De Benedetti Gaddini  
Prof. Giuseppe Del Barone  
Prof. Carlo Flamigni  
Prof. Enrico Garaci  
Dr. Laura Guidoni  
Prof. Demetrio Neri  
Prof. Pietro Rescigno  
Dr. Pasqualino Santori

## PERSONAL REMARK

In approving the document, Prof. Demetrio Neri expressed his doubts on the content of paragraph 4, which is here reproduced in the form acceptable to him: “The NBC notes, however, that the patient’s primary right to autonomy and the freedom of treatment, whether it be directed towards scientific medicine, or to the use to alternative treatments, must merge with the respect due to the professional position of the physician: the latter is, in complex societies, ethically, deontologically and legally guarantor of health care, as well as of his professionalism, and can legitimately refuse services which conflict with his conscience or with his clinical convictions”.

Prof. Demetrio Neri

## PERSONAL REMARK

In the text, at point 17, concerning minors or incapacitated patients, “it is stated that” ... the inability to obtain or however, to consider as valid consent to such practices by such patients should prompt physicians to always suggest the use of scientifically validated therapies.

It is true that adults can, better than children, evaluate risks and advantages, and may reject what, in their view, is not useful and, as such, is not worth the discomfort or suffering that it entails. This is true, but it is acknowledged that children, almost until adolescence, think through their parents. If the physician to whom they have been entrusted has confidence in alternative medicine, why not consent their use also for children? Reflecting on this point, I ask myself why they also are not entitled to make use of the medicine in which their parents have placed their trust and which they see them use.

One of the accusations made regarding alternative medicine is that they have no demonstrable scientific basis. But in order to have a scientific basis what is required is research and funding of diverse nature from private industries to state public bodies, to which alternative medicines have, until now, only had limited access. But children believe valid (good) only what they see their parents do and, while they are able to have their own informed consent, they do exactly what their parents do and give greater trust to the alternative medicine they see their parents use than to the medicine prescribed by a different physician, despite it being “scientific” medicine.

Prof. Renata De Benedetti Gaddini



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**THE CELLULAR THERAPY OF HUNTINGTON'S DISEASE  
THROUGH THE IMPLANTATION OF FETAL NEURONS**

20<sup>th</sup> of May 2005



*The NBC's response to the question raised by Dr. Alessandro Nanni Costa, the Director of the National Transplant Centre regarding the ethical problems connected to the source of the cells used in the multicentre study "The cellular therapy of Huntington's disease through the implantation of fetal neurons" in which the National Neurological Institute of Milan "Carlo Besta" is participating. (Responsible: Dr. Stefano Di Donato, Medical Director of Level II, Director of the Operating Unit of Biochemistry and Genetics and Director of the Department of Experimental Research and Diagnostics).*

## PREMISE

### Huntington's disease

Huntington's disease or Huntington's chorea is a degenerative disease of the Central Nervous System, of genetic origin and with a prevalence of about 1 in 10,000, which occurs in most cases around the age of 30-40 and is clinically characterized by motor signs (bradykinesia, and hyperkinesia) and psychiatric disorders (depression, irritability), and cognitive impairment. Cognitive deficits include attention disorders, difficulty in using their newly acquired skills and slowing of mental processes. The outcome of the disease is fatal within 10-20 years, during which the patient undergoes cachexia in a context of postural rigidity and dementia.

The gene responsible for the disease has been localized on the short arm of chromosome 4. The molecular defect is represented by the expansion of a CAG repeat sequence in the gene IT15 type that encodes a protein called 'huntingtin'. The function of this protein is still unknown, although it is supposed to intervene in some mechanisms related to apoptosis (programmed cell death).

Huntington's chorea primarily affects the degeneration of an area of the brain called *striate*; it is situated in the basal area where the "central command system" that coordinates body movement lies.

There is no effective treatment for this disease today. However, numerous clinical trials on mice, rats and non-human primates, have demonstrated that transplanted fetal striatal neurons are able to restore the clinical deficit on animals with induced neurodegenerative lesions. On the whole, the clinical trials confirm the therapeutic potential of the grafts of homologous fetal neurons in the case of induced neuron degeneration in the animal models with Huntington's disease.

With regard to man, the general elements on which the attempt to treat Huntington's disease with intracerebral implantation of fetal neurons were published in the international scientific journal *Neuroscience* (Peschanski et al., 1995). A first pilot study on this type of testing was published in the journal *Lancet* (Bachoud-Levi et al., 2000). The results of this first study - which have also served to organize the multicenter study on a larger number of patients which is the subject of the NBC opinion - have been encouraging: in five patients, three showed marked objective clinical benefits after two or three years, and also the positron emission tomography showed that the implant was operating. These improvements have affected both the motor symptoms (reduction of chorea and increased speed of muscle movement) and cognitive deficits (improvement in the level of attention, executive function, attention, planning, memory and language).

In terms of overall functional, three patients recovered many capabilities which they had lost for many years. In a fourth patient a significant improvement occurred only transiently which then was lost due to the destruction of the implant, probably caused by microbleedings. In the last patient the graft appeared to be present but was not working for unknown mechanisms. There are also two other ongoing pilot clinical trials with promising results: the first in the United States (Hauser et al. *Neurology*, 2002, Greenamyre and Shoulson comment, *Neurology* 2002), the other in Great Britain (Rosser et al. *J Neurol Neurosurg Psych*, 2002).

### The multicentre project

The multicentre project concerns six clinical research centers that have already begun testing coordinated by the local Services of Neurology, or Neurosurgery. Five are located in France: the *Centre Hospitalier Universitaire (CHU) Henri-Mondor* of Créteil, the *CHU Rangueil* of Toulouse, the *CHU* of Nantes and Rennes together, the *CHU* of Lille, and the *CHU* of Angers. A center is located in Belgium, at the *Erasmus* Hospital of Brussels.

In total, in these centers there will be 60 patients involved of both sexes aged between 18 and 65, of which 50 in France and 10 in Belgium. Other centers, in Germany and Switzerland, are also about to join the study.

The National Neurological Institute “Carlo Besta” intends to participate in the multicenter study with 10 patients. The research group has an extensive general and specific experience in the study of genetic degenerative diseases, and as pointed out by Dr. Alessandro Nanni Costa, Director of the National Transplant Center, it is at the highest level in the international scientific panorama in this field.

The aim of the experimentation that is the subject of the opinion drafted by the NBC, is to demonstrate the existence of a direct clinical benefit to patients, both as regards cognitive and motor skills, resulting from the replacement of degenerated striatal neurons in patients suffering from Huntington’s disease with counterpart neurons from human fetuses, comparing a treated group with an untreated control group. The assessment of therapeutic effectiveness requires the use of a series of functional, physiological and anatomical criteria as described in scientific literature.

The treatment applied to patients consists in the graft of intra-striatal tissue (neurons, macroglia, microglia, endothelial cells and neuronal precursors and microglia) from the lateral ganglionic eminences of human fetuses during the period between the seventh and the ninth week after conception (see Law 194 / 78<sup>84</sup>). Two grafts are performed, the first in the striatum of the right cerebral hemisphere, the second, two weeks later, in the left striatum.

---

<sup>84</sup> Law No.194 of the 22<sup>nd</sup> of May 1978, “Regulations on the social protection of motherhood and the voluntary termination of pregnancy.” Art. 4 - In order to undergo termination of pregnancy during the first 90 days, women whose situation is such that continuation of the pregnancy, childbirth, or motherhood would seriously endanger their physical or mental health, in view of their state of health, their economic, social, or family circumstances, the circumstances in which conception occurred, or the probability that the child would be born with abnormalities or malformations, shall apply to a public counselling centre established under item (a) of Section 2 of Law No. 405 of the 29<sup>th</sup> of July 1975 or to a social-health facility that is fully authorized by the Region, or to a physician of her choice.

For Italy, the fetal tissues are obtained from voluntary terminations of pregnancy performed at the Mangiagalli Clinic - Clinical Specialization Institutes of Milan, in accordance with the regulations in force. In any case, for each of the research centres participating in the project - including the National Neurological Institute "Carlo Besta" - the preparation of the product of cell therapy involves two different structures that operate independently: an obstetrics department in which voluntary interruption of pregnancy is carried out under the laws in force in different countries, and a cell therapy centre (or a biologist associated with the Department of Neurosurgery) that prepares the tissue to be grafted, that is, the dissection and fragmentation of ganglionic eminences, and the immersion of the obtained tissue in a special solution.

Voluntary interruption of pregnancy is performed by aspiration through a Karman cannula using ultrasound guidance.

The woman's right to privacy is guaranteed under the laws in force in different countries.

The virological checks made on the starting material are indirect in that the voluntary interruption of pregnancy procedure provides the possibility of carrying out a series of tests on the mother's blood (fetuses are only potential carriers of viral infections transmitted from the mother).

The use of fetal tissue requires the informed consent of the woman and its acquisition does not involve any form of remuneration or compensation, or any kind of economic incentive or any other sort of incentive.

#### **The question submitted to the NBC**

The question submitted to the NBC only concerns an assessment of the ethical issues related to the source of the cells used in the project under examination. The question does not deal with the bioethical issues related to recruitment, consent and the safeguards for patients, nor does it deal with the therapeutic efficacy and the risks associated with the provided treatment, or any other ethical or deontological matter connected with the protocols of clinical trials. In this regard, the NBC acknowledges that all these aspects of the Project should be appropriately placed under the scrutiny of the apposite ethical Committees which it hopes will be as extensive and thorough as possible in relation to the particularly sensitive and critical nature of the experimentation in question.

Further clarification is also appropriate. The question does not concern an ethical evaluation of the voluntary interruption of pregnancy itself. The Opinion does not, therefore, make any direct reference to this devastating and dramatic bioethical issue.

#### **Response to the question**

The retrieval of fetal tissue from dead fetuses deriving from voluntary interruption of pregnancy and its use for scientific and / or treatment purposes, is regarded as bioethically acceptable in principle, however, it does raise some serious doubts regarding the risk that such practices could in some way constitute an incentive to abortion.

The NBC therefore considers that the bioethical acceptability of these practices should

be subordinated first and foremost to the ascertainment of the full independence and distinct separation of the respective decision-making processes between medical staff and / or the health institution engaged in the voluntary interruption of pregnancy, and the researchers and/or the research institute conducting the scientific and clinical experimentation.

Once this independence has been asserted, that is to say, that there is the absolute guarantee that the carrying out of voluntary interruption of pregnancy is in no way intentionally aimed at the use of fetal tissue for experimental and /or therapeutic purposes, the retrieval of fetal tissue from voluntary interruption of pregnancy and its use for the aforesaid scientific and/or therapeutic purposes are to be regarded as *morally acceptable practices*, only, when complying with the following conditions<sup>85</sup>:

1. There should be no advantage, incentive or benefit of any form for those involved, that is, the medical staff and/or health institution carrying out the voluntary interruption of pregnancy and the researchers and/or the research institutes conducting the scientific and clinical experimentation.
2. The woman's consent, and where possible, that of both the parents, should be obtained after being adequately informed. This consent should only be requested after the voluntary interruption of pregnancy has taken place, in order to prevent that the foreseen use of fetal tissue for scientific and/or therapeutic purposes might constitute an undue inducement to resort to this practice.
3. The method and procedures of the voluntary interruption of pregnancy are not modified or adjusted, in relation to the need to retrieve fetal tissue and the scientific or therapeutic purposes. No preventive treatment functional to the scientific or therapeutic purposes of the use of fetal tissue may be carried out on the woman and/or on the fetus during the course of the pregnancy.
4. The right to privacy of the woman should be guaranteed by the laws in force.
5. The use of fetal tissue should only be for highly important scientific and/or therapeutic purposes for which no alternative methods with comparable requirements exist. In any case, where possible, it is always preferable to resort to fetal material from miscarried fetuses rather than from voluntary interruption of pregnancy.
6. Each project which foresees the retrieval of fetal tissue, deriving from voluntary interruption of pregnancy or spontaneous abortion and its use for scientific and/or therapeutic purposes, should be subjected to preventive ethical evaluation on behalf of the relevant competent committee. The evaluation also concerns the scientific reliability of the team proposing the research or application of treatments for therapeutic purposes, as well as the ascertainment of full independence of the medical staff and/or health institution engaged in the voluntary interruption of pregnancy, and the researchers and/or research institution engaged in scientific or clinical experimentation.
7. The donation of fetal tissue from interruption of pregnancy or spontaneous abortion for scientific and/or therapeutic purposes should not involve any form of commercialization, remuneration or compensation. Fetal tissue must not under any circumstances be bought and sold by the mother and third parties.

With regard to this last point, the NBC hopes for intervention on a national and

---

<sup>85</sup> See also the NBC document on *Identity and Status of the Human Embryo*, 22<sup>nd</sup> of June 1996.

European level, in order to impose a ban on the commercialization of fetal cells and tissues deriving from voluntary interruption of pregnancy or miscarried fetuses as soon as possible by means of specific and unambiguous regulations which consent to counter the growing and concerning phenomena of “fetal tissue brokers,” specifically, the “mediators of fetal tissue,” who - in the absence of rules, or the harmonization of rules within the territory of the European Union - derive substantial profits from procurement and storage of fetal tissue from abortions. This could surreptitiously induce significant changes in abortion techniques in order to facilitate the collection of certain types of fetal tissues and organs, and could provide an incentive, albeit difficult to quantify but nevertheless realistic, to the recourse to voluntary interruption of pregnancy.

## NOTES

While agreeing in principle with the content of the Opinion on Cellular Therapy of Huntington's disease through implantation of fetal neurons, I must express my concern as to the use of fetal tissue deriving from voluntary interruption of pregnancy, since it is - in practice - difficult to attain total independence between the team performing the interruption of pregnancy and the team that works on the obtained tissue given the need to program the timing and methods of such intervention and the subsequent procedures of dissection and suspension of the tissue.

Maria Luisa Di Pietro



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**BIOETHICS IN DENTISTRY**

24<sup>th</sup> of June 2005



## PRESENTATION

Urged to examine the problems of bioethics in dentistry, the National Bioethics Committee hosted two experts in the plenary meeting of the 19<sup>th</sup> of September 2003, the dental surgeons Marco Lorenzo Scarpelli and Giorgio Berchicci. The wealth of issues and subjects arising during this meeting convinced the Committee to set up a specific working group on the subject, at which the two guests were invited to participate, bringing a positive spirit of collaboration and valuable friendship. The group, coordinated by Prof. Giancarlo Umani Ronchi, along with the participation of Profs. Adriano Bompiani and Cinzia Caporale, and the collaboration of Prof. Carlo Mario Miani, Full Professor of Dentistry at the Università Cattolica del S. Cuore – to whom I extend my thanks and gratitude on behalf of the Committee for his precious contribution – convened in nine sittings from November 2003 to February 2005. The draft of the document, drawn up and repeatedly edited by Prof. Umani Ronchi, was finally brought to the attention of the NBC in the plenary meeting, and definitively and unanimously approved on June 24 2005. In publishing this document I am pleased to highlight the Committee's satisfaction at having begun the examination of an area of bioethics of such subtle importance, and until now unduly neglected by scientific literature in general.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## Bioethics in dentistry

The “specific educational objectives” of the specialist degree in Dentistry and dental prosthesis foresee that the graduate is ‘introduced to the knowledge of the basic notions of treatment and assistance according to the pedagogical principles of psychology, sociology and ethics’. In the relationship with patients, ethics represents a way of approach and primary aim in dentistry too. A similar programme, including cultural visions coming from different horizons, is also to be found in other European Countries, particularly in Spain and Latin America where the teaching of the principles of bioethics is an integral part of the student’s curriculum in dental school.

In Italy the exercise of the dental profession, Law No. 409 of the 24<sup>th</sup> of July 1985, is reserved also for graduates in medicine and surgery who enrolled in the degree course before the 28<sup>th</sup> of January 1980 and qualified to practise, and for doctors specialised in odontostomatology and dental prosthesis. If from the point of view of their general training the various figures present considerable differences giving graduates in medicine a wider professional practice than the one set down by Art. 2 of the institutive Law<sup>86</sup>, all those practising the profession of dentistry are listed in one single Medical Association, that of medical and dental surgeons, and are subject to one single deontological code.

## Bioethical issues

The exercise of medicine and surgery, along with that of dentistry, must refer to the same ethical principles in the defence of man and the protection of humanity.

The NBC does not consider that the issues, already dealt with in various documents and Opinions, can justify a peculiar branch of ethics applied to dentistry. The ‘Ethical Codes’ of the dental profession which were proposed at international level do not seem to present anything new with respect to what was already foreseen by the deontological codes for the medical profession. In particular the Ethical Code of the American Dental Association refers to the patient’s autonomy, good faith, the principles of charity, justice and truth<sup>87</sup>. Along general lines therefore, despite the specific and different operational

---

<sup>86</sup> Law No.409 of the 24<sup>th</sup> of July 1985, Art. 2: ‘The dental profession deals with the activities referring to the diagnosis and treatment of illnesses and congenital and acquired abnormalities of the teeth, mouth, jaws and relative tissues, as well as dental prevention and rehabilitation. Dentists can prescribe the medicines necessary for the exercise of their profession’.

<sup>87</sup> We furthermore remember the Code of Professional Conduct is the set of binding rules for the members of the ADA and derives from the resolutions adopted by the Chamber of Representatives of the ADA. In many respects, except from its different layout and complexity, it is like the Italian Deontological Code. The EU Ethical Code (Dental Liaison Committee) approved in September 2000, sets out the guidelines based on the principles of subsidiarity of the EU, in the respect of the self-government of the national associations. The fundamental ethical principles to which the ethical codes of the national associations should refer concern the dentist-patient relationship, the dentist’s conduct towards the public, the dentist’s attitude towards colleagues and the exercise of the profession. Moreover, in 2002, the ‘ethical-behavioural code’ of the National Association of Italian Dentists (ANDI) was presented; this code develops the concepts expressed by the EU code and was the result of an interdisciplinary study carried out by the a committee made up of dentists, medical examiners and bioethicists. The code deals extensively with the ‘patient-dentist relationship’, the ‘conduct of the dentist towards the public’, the ‘attitude of

techniques of the medical-surgery specialisations, it is not possible to imagine situations that do not come under the general ethical norms relative to the doctor-patient relationship<sup>88</sup>. The problems of ethical interest and moreover those of bioethical importance, even though in practice crossing the different specialisations of medicine and surgery and above all of biology, regard universal values and principles whose meaning can be revised and modified, but which go beyond the particular disciplines and specific fields of application.

The ethics applied involves the doctor just like any other practitioner, for example by means of the informed consent to surgery, even if in a less dramatic way, bearing in mind that the nature of the pathology does not usually produce great concern with regard to the life of the patient, even though it can undoubtedly cause concern about the person's health, negatively influencing their overall wellbeing. Some treatment in fact, even though being scientifically appropriate, could harm essential personal values, such as to represent a source of even serious malaise to the point of causing serious existential anxiety, above all in subjects who are prone to this. An example is the case in which the decrease in aesthetic efficiency may represent the price to pay in order to obtain a better masticatory function.

The dentist, like any other surgeon, can and sometimes must refuse to practise his profession (Art. 19 Code of Medicine)<sup>89</sup> in cases where he is asked to perform surgery that goes against his conscience or his clinical conviction, nonetheless taking into consideration the overall state of the patient'. 'If the case is not urgent, in some particular cases a suitable psychological test could be advisable to support the therapeutic choice, which otherwise could be unjustified and the forerunner of possible judicial problems'.

Therefore, some situations typical of dentistry, especially in aesthetic dental treatment, deserve particular bioethical examination, considering that the face and above all the mouth, as "a poly-functional instrument, source of eroticism and the physiological centre of the formation of words"<sup>90</sup>, represents a primary element of approach and exchange with the world of other people, but primarily the only image of ourselves – even if incomplete and unilateral – that we carry inside us as the symbol of our identity able to condition us in our relationship with others. The *verbum* and the *vultus*, both subject to direct or indirect treatment by the dentist by means of a clear explanation to the patient, constitute essential means of expression and the external projection of cultural identity, so much so that a slight problem of pronunciation can represent 'almost the inability to project oneself properly', like a changed physiognomy is "to a great extent manifest of what the general tone and degree of feelings or ideas is"<sup>91</sup>. Every possible change – even

---

the dentist towards his own colleagues', the 'practice of the profession', 'the scientific and technological research and the relations with companies'. Another fundamental document is 'Medical Professionalism in the New Millennium: A Physician's Charter' (February 2002) which deals with the 'pre-eminence of the wellbeing and autonomy of the patient, social justice, collaboration of colleagues' and represents a point of reference and guideline of the professional ethical codes for doctors and dentists.

<sup>88</sup> See the NBC documents: *Aims, limits and risks of medicine* (14 December 2001); Informed consent to medical treatment (20 June 1992).

<sup>89</sup> Art. 19 – Refusal to treat a patient: 'The doctor who is asked to give treatment that is in contrast with his conscience or with his clinical conviction, can refuse that treatment, unless this conduct causes serious and immediate harm to the health of the patient'.

<sup>90</sup> Th. Kleinspehn, "*Kein Mund wei, sich selbst zu küssen*". Über das Essen, Bei, en, Saugen und Lutschen, in "Ästhetik und Kommunikation", 15, 1985, No. 57-58, pp. 141-148.

<sup>91</sup> M. Borri in A. Cevidalli, F. Leoncini, *Trattato di medicina legale*, Vallardi, Milan 1922.

one of betterment – of our appearance or of its dynamism that does not correspond with the scheme of ourselves can be the source of great malaise. In fact, it is important to bear in mind that the psyche of some patients interprets and mediates on the perception of 'beautiful', living worse off every true or presumed sensation of change in the case in which this brings about concerns with the 'image of oneself' that represents one's individual and incontestable patrimony, at the cost – in subjects prone to this – of even serious imbalances. If one considers that one's image is made up of the facial expressions, tone of voice and the formation of words, the dentist's potential to enrich or to irreparably compromise the patient's appearance and therefore their identity becomes even more evident. "The dentist is at the same time therapist and custodian of this dimension of physicality, which is expressed symbolically in eating on the one hand and in smiling and kissing on the other"<sup>92</sup>. Therefore the biological part of the health of the mouth and teeth, but also the communicative and anthropological importance and its symbolic meaning justify a serious bioethical commitment in the resolution of a number of professional contingencies, by reason of the fact that the concept of human beauty cannot yet be tied down to a well-defined parameter and, as such, be univocally understood and unanimously accepted. It is in fact a question of an 'evanescent postulate that cannot be shown owing to its peculiar subjectivity and relatività'<sup>93</sup>. It was Croce who said "...just imagine that this relativity should not be true for the human body, which is the source of the most varied charms"<sup>94</sup>.

There is no doubt therefore how the relationship between dentistry and aesthetics is particularly delicate, so much so that any possible negative outcome of the treatment could create situations that do not correspond with the original body scheme experienced by the patient as 'abuse', as mentioned in Munchausen's Syndrome by proxy.

The idea of pain must not be neglected, which is a constant and intolerable presence for many people and often automatically associated with the figure of the dentist and the surgery itself, which could represent in particularly sensitive patients the cause of the temporary disintegration of the set of perceptions of the ego, notwithstanding more readily used anaesthetics and the use of better quality drills which, in recent years, have marked a definite advance in analgesia. It must be stressed that better pain management represents an ethical imperative for dentistry, though presenting intolerable shortcomings even nowadays.

One other aspect must be taken into consideration in the dentist-patient relationship: the fact that invariably from the examination of the mouth not only can past and present pathologies be seen, but also the patient's lifestyle and habits, almost a biographical reconstruction which owing to the dentist's intervention could undergo a change involving the patient's very lifestyle. By means of dental treatment, not only to cure but also to improve,

---

<sup>92</sup> Th. Kleinsphen, idem.

<sup>93</sup> E. Hofmann, A. Kolisko, *Trattato di medicina legale*, S.E.I., Milan 1905. F. Antoniotti, G. De Petra, *Basi dottrinali del danno fisiognomico nei diversi aspetti giuridici*, Collana Monografica Zacchia, Rome 1973.

<sup>94</sup> B. Croce, *Estetica*, Laterza, Bari, 1902. E. Croce added: "Certo, queste questioni sul bello di natura e sulla bellezza della geometria, come le altre analoghe sul bello storico e sul bello umano, appaiono meno assurde nell'estetica del simpatico, che con la parola bellezza estetica intende, in fondo, la rappresentazione del piacevole. Ma non è meno erroneo, anche nell'ambito di quella dottrina e poste quelle premesse, il pretendere di determinare scientificamente quali siano i contenuti simpatici e quali gli irrimediabilmente antipatici...A ciascuno il suo bello (=simpatico) come a ciascuno la sua bella...".

there could be an authentic “transition from a dentistry of cure to a dentistry of care”<sup>95</sup>, which is to be bioethically hoped for. The dentist can thus carry out preventive tasks besides therapeutic ones having huge social importance, and therefore it is all the more vital for the dentist to remain faithful to the medical origins of dentistry. Nor must the fact be neglected that the dentist could come across lesions in the mouth and the teeth – particularly in children but also the elderly – which can be indicative of voluntary lesions in a domestic context. Considering that in the case of a private relationship, the practitioner is not obliged to make a medical report insofar as being a non-indictable offence, this does not mean that he must not speak to the family about it, with the due caution. When the dental treatment is carried out in a public structure, the dentist is instead obliged to give notification of cases of presumed abuse to the authorities. The duty to report the case also lies in the possibility of maltreatment of children and elderly within the family<sup>96</sup>.

### Information and consent

Some aspects of consent to medical treatment and preliminary information are of bioethical interest – apart from what has been fully dealt with by the NBC’s document “Information and consent related to medical treatment” of the 20<sup>th</sup> of June 1992 – which can present particular connotations in dental practice owing to the essentially private and therefore contractual nature (in 96% of cases)<sup>97</sup> of the relationship, one of the few left in medicine. The fact that the dental appointments and relative treatment take place in the dentist’s surgery, that they can go on for months or years and often cure various overlapping pathologies and require different treatment, that the treatment may take place in the same sitting and thus be limited to a single appointment, sometimes lengthy treatment can foster the establishing of a friendly relationship and even familiarity born from previous treatment, or sometimes from a custom that is handed down from relatives or friends being treated by the same dentist. In cases like this one goes to the dentist with the same trust and confidence with which one went to the family doctor, readily accepting treatment and advice, seeking and even expecting the solution to general ailments. In the dentist-patient relationship, often openly paternal aspects are to be found, perhaps in the form of ‘weak paternalism’ or of a ‘paternal-fraternal’ relationship, deeply linked to situations of particular trust in the practitioner treating the patient, in the belief that wisdom allows the dentist to make the best choice for the patients he knows well.

A relationship of this type often shuns detailed formal information, since it is possible that in previous meetings the possibility of a future corrective operation had been mentioned, but not completely, and which can now no longer be put off, that the length and difficulty of the treatment were discussed together with the cost, rather than the possible complications and the likely outcome which the patient often considers taken for granted at a

---

<sup>95</sup> F. Manti, *La cura e i principi per una bioetica dell’odontoiatria*, in G. Berchicci, F. D’Agostino, P. Giustiniani, F. Manti, *Verso una bioetica per l’odontoiatria?*, Edizioni Scientifiche Italiane, Napoli 2004. Vedi anche: L. Battaglia, *La voce femminile in bioetica*, in: S. Rodotà, *Questioni di Bioetica* Laterza, Rome-Bari 1993.

<sup>96</sup> Art. 572 c.p. “Child abuse and maltreatment in family”.

<sup>97</sup> *Gli Italiani promuovono i dentisti, ma il rischio-infezioni è in agguato*, Doxa survey, in “Il Sole 24 Ore Sanità”, 7, 2004, No. 15, p. 24.

friendly level. Thus at the right moment when the treatment can no longer be postponed, it is wrongly taken for granted that the patient has been informed of the details of the treatment and has given his “valid” consent.

Instead, in the relationship of trust between dentist and patient, the formal nature of the contract for treatment cannot be disregarded following the giving of adequate information on the diagnosis, the prognosis, the prospects of the treatment, the likely consequences of the therapy or lack of therapy, on possible alternative treatment – as set down in the Code of Medical Deontology, Art. 30-34. This information must be given to the patient together with an estimate of the costs and method of payment as this is also the patient’s right, considering that economic problems can often result in court cases. The consent form is of primary importance, and indispensable in non-routine treatment with a certain amount of risk. In the case of routine dental cure with little risk of adverse effects, the dentist is reasonably exonerated from getting written consent, as this is implicit in the request for that specific treatment. On the other hand, the most frequent complications must be carefully explained and specified in writing on the form. As these are usually planned operations and therefore not urgent, the form could be given to the patient to be read or to be examined by a trusted person so that, before signing for and starting the treatment, the patient can ask for further explanations. It would be furthermore opportune that the patient does not just sign at the bottom of the page but declares in writing that he has understood the type, the aims and the risks of the treatment and his commitments following the treatment like check-ups, hygiene, the need for further operations etc. The ‘patient’s duties’ can assume particular importance in implantology and orthodontics, insofar as the success is greatly linked – perhaps more so than in other branches of medicine - to the scrupulous observance of well-defined rules.

It is furthermore necessary that the dentist regularly fills in the individual medical record to which all the patient’s clinical, photographic documentation and x-rays must be attached<sup>98</sup>. Over the years, during which various kinds of treatment by different practitioners overlap, the lack of a reliable records can make it difficult for the patient to reconstruct his own medical history and jeopardise future treatment. Moreover, such practice could contribute to the proper defence of the dentist who may be accused of malpractice in a court case<sup>99</sup>.

---

<sup>98</sup> No norm explicitly foresees the obligation for the dentist to keep a card or medical record for each patient. However the Ministerial Decree - Health of 14.9.1994, No. 669, Ruling concerning the identification of the figure and relative professional profile of the dental hygienist, foresees - Art. 1. point 2.: ‘The dental hygienist: b) shall collaborate in the filling in of the odontostomatological medical record and shall see to the gathering of technical-statistical data’.

<sup>99</sup> According to a survey by the National Association of Italian Dentists, the processing of the data obtained from samples taken in Italy, even though partial, showed that: 1. The annual incidence of judicial and extra-judicial court cases in dentistry is equal to 7% of the cases treated, higher than that recorded in medicine, with a proportion of about 7:1; 2. in most of the cases the contentious procedure is formulated as tort, the possibility of criminal proceedings instead (<1%) represents the exception if compared with other medical specialisations even if with a recent tendency to increase; 3. the majority of cases of professional liability ascertained in contentious procedure is high (about 90% of cases): in most of the judicial procedures the negative outcome for the practitioner was foreseeable at the beginning of the case; 4. the average economic value of the contentious procedure, as regards the medical-legal assessment, is considerably lower with respect to other specialist branches, often limited to the repayment of the fee paid by the patient for unnecessary treatment (resolution of the contract by default, art. 1453 c.c.); 5. the reasons for the contestation are represented by treatment characterised by a greater request for results and considerable economic obligation by the patients (50% prosthesis, 20% implantology) (G. Di Rosa, ANDI, 2002).

## Informed consent and critical cases

The case of the adult patient must be examined who presents a condition of natural incapacity in relation to contingent, permanent or transitory situations making him incapable of taking care of his own interests. In this case the dentist cannot consider a relative's or the spouse's consent valid with regard to a potentially dangerous operation. He could however intervene should the treatment not present particular problems or foreseeable negative consequences and should it be necessary to alleviate the suffering of the patient and anyway in cases of non-deferrable treatment (in situations of contingent or transitory incapacity). In more complex cases the preventive authorisation of the tutelary judge is always obligatory. The recent law relative to the trustee<sup>100</sup> should greatly simplify the problem, considering the 'aim of safeguarding, with the least limitation possible of the ability to act, persons completely or partly lacking autonomy in the carrying out of the functions of daily life, by means of temporary or permanent support interventions'.

The frequent refusal by the dentist to carry out the treatment on psychopathic and in particular autistic subjects must be highlighted, as this is not always justifiable except in particular environmental conditions and in the absence of proper collaboration by the surgery personnel able to guarantee the safety of the operation.

Analogously, according to the NBC the preconceived refusal is unacceptable on the part of the dentist to treat patients with known infectious diseases such as HIV or hepatitis C, whose prophylactic measures have been established by precise provisions of law making the therapy compatible with ordinary routine dentistry, with the adoption of special precautions.

In the case of children, the Opinion already expressed on various occasions by the NBC must be remembered concerning the peculiar nature of the minor's consent<sup>101</sup>. In these cases it is a question of assessing their 'competence' – and therefore the ability to decide, to reason and to foresee the consequences of their own choice – the equilibrium of which is established progressively over the years<sup>102</sup>. Therefore, even though a conduct is considered prudent and advisable that requires the full capacity to act for the formulation of consent (or dissent) to medical treatment, established at the completion of the age of eighteen, the principle of informed consent must be considered and the expression of the will of the minor

---

<sup>100</sup> Law No. 6/2004, Official Gazette No. 14 of 2004. Art.1: "This act shall have the aim of safeguarding, with the least possible limitation of the ability to act, persons completely or partly without autonomy in the carrying out of the functions of daily life, by means of temporary or permanent support interventions". Art. 404 Civil Code: "The person who, as the result of infirmity or physical or psychic disability, is in the impossibility, even partial or temporary, of taking care of their own interests, can be assisted by a trustee, appointed by the tutelary judge of the place in which he/she resides or is domiciled". Art. 405 Civil Code "... should the need arise, the tutelary judge can adopt urgent measures for the care of the person in question and for the conservation and administration of his patrimony. He can proceed to the nomination of a provisional trustee setting down the actions he is authorised to carry out..."

<sup>101</sup> See in particular the Document *Bioethics with childhood*, (22<sup>nd</sup> of January 1994).

<sup>102</sup> National Bioethics Committee: *Informed consent to medical treatment*, in: Riv. It. Med. Leg., 15, 171, 1993. Furthermore: 'it seems logical to infer... the impossibility of an autonomous consent before the age of 6-7. Consent is to some extent conceivable between the age of 7 and 10-12, but still not completely autonomous and to be considered together with that of the parents. Only entering adolescence can one consider that consent becomes progressively autonomous'.

who must take part in decisions regarding treatment that concern him, even though still not in a decisive way<sup>103</sup>. It must be considered that jurisprudence foresees the abuse of authority for operations on seventeen-year olds of a sound mind. The positions of the *European Convention on Human Rights and Biomedicine* are similar<sup>104</sup>, along with those of the Code of Medical Deontology<sup>105</sup> and the World Medical Association<sup>106</sup>.

In prosthetic operations too the information must be as detailed as possible above all in relation to the aesthetic aims. The Court of Cassation<sup>107</sup> ruled with regard to this that on the one hand “the context of the information must cover all the necessary area so as to avoid the essential basic error, the one that is constituting *condicio sine qua non* of the giving of consent”, stating furthermore that – in the case of the lack of consent – “the psychological element of the offence must be characterised in a wilful sense, also possible and generic but always with *animus laedendi...*”, on the other hand to not consider valid the justification whereby the impairment of the body or the mind is wilfully caused for scientific aims or research, and above all in the case of impairment for exclusively aesthetic purposes. That is to say that in operations for purely aesthetic purposes the lack of consent – which alone is a very serious issue at a bioethical level – represents the grounds for wilful lesion and possibly manslaughter. The problem is particularly important, considering also the data gathered from market surveys according to which in dental care today the sectors with greatest development are those of preventive treatment and cosmetic surgery.

With regard to implantology, the information given to dentists seems to be rather insufficient and often based on an excessive kind of optimism. On the contrary, even though advances in this technique have eliminated numerous possible complications linked to the integration of the implant, the information must be detailed in all its complexity and concern numerous local, general and psychological factors which can interfere with the outcome of the treatment. Periodontitis for example, represents an often uncontrollable risk so much so that proposals have been made for a genetic test able to define the patient’s susceptibility to periodontal disease<sup>108</sup> which can be influenced by oral hygiene, stress, the taking of medicines, nutritional deficiencies. These are all elements that the patient must be

---

<sup>103</sup> M. Barni, *Diritti-doveri, responsabilità del medico. Dalla bioetica al biodiritto*, Giuffrè, Milan 1999; V. Fineschi, *Il rapporto medico-paziente: consenso, informazione e segreto*, in G. Giusti, *Trattato di medicina legale e scienze affini*, CEDAM, Padua 1998, Vol. I, p. 494; A. Fiori, La G. Monaca, *L’informazione al paziente ai fini del consenso: senza più limiti*, in “Riv. It. Med. Leg.”, 22:1302, 2000; G. Iadecola, *Potestà di curare e consenso del paziente*, CEDAM, Padua 1998; A. Santosuosso, *Il rapporto medico paziente nel diritto e nella giurisprudenza*, in AA.VV., *Guida all’esercizio professionale per i Medici Chirurghi e gli Odontoiatri*, Edizioni Medico Scientifiche, Turin 1994; G. Umani Ronchi, *Il consenso all’operazione deve essere esplicito e non filtrato dalla mediazione dei familiari*, in “Guida al diritto-II Sole 24 Ore”, 8.2.97, 4, 67, No. 5.

<sup>104</sup> Art. 6, point 2.

<sup>105</sup> Art.34: “It is the doctor’s duty to give information to the minor and to consider his will, compatibly with his age and the ability to understand, the respect of the rights of the legal representative being understood...”.

<sup>106</sup> World Medical Association, *I Diritti del paziente*, Bali, 22 September 1995, in “Riv. It. Med. Leg.”, No.19, p.443, 1997: ‘If the patient has not yet come of age or if legally incapable, it is necessary that there is, in the cases foreseen b the law, the consent of the legal representative. The patient must however take part, within possible limits, in the decisions ...’.

<sup>107</sup> Cass., Crim. Sez. IV, 12.7.2001.

<sup>108</sup> Kornam et al. demonstrated that specific genetic markers associated with the increase in the production of interleuchina-1 are indicators of the susceptibility to serious periodontitis in adults. The genetic test can complete the information obtained until now by means of microbiological and immunological tests.

aware of and responsible for. Smoking abuse, particularly if associated with alcohol consumption, represents a contraindication which patients often underestimate and about which dentists do not always give adequate information. Cigarette smoke can cause serious periodontal harm so much so that in the United States dentists refuse treatment if the patient does not attempt to stop smoking. Drug abuse and in particular heroin addiction is often associated with an extremely bad oral condition which absolutely contraindicates implants; the same is true for some systemic pathologies such as diabetes, immunodeficiency, but also endocarditis, hepatitis and above all cirrhosis which can be responsible for changes in tissues and the immune system. Assessment must furthermore be made of the presence of dental plaque, occlusions, endodontal problems, dental caries and above all the state of the bone which must be carefully examined by x-ray. An evaluation of the patient's motivations is also essential when dealing with clinically unnecessary interventions subject to complications, and of his psychological profile which could have a negative effect on the outcome of the operation or be responsible for the non-observance of the maintenance protocol or indispensable rules of hygiene. The psychological selection of the patient can take on great interest, also owing to the difficulty in diagnosing some possible disturbances: some psychiatric pathologies like psychotic syndromes, behavioural problems, dismorphobia, brain damage including senile cerebropathy, are considered potential contraindications for the use of implants. It must be considered that the success of implantology is related to motivation and therapeutic needs. If the information given by the dentist is essential, it is just as important that the patient in turn informs the dentist without reticence of any problems regarding his health. Sure aesthetic success can be invalidated by the patient's psychological refusal to the outcome of the implant that he feels and considers incompatible with his own 'bodily scheme' and therefore with the image he has of himself, so much so as to be unable to accept the different facial expression and smile. The dentist therefore, like the cosmetic surgeon, must be capable of refusing certain treatment in the cases of "particular" patients and before requests for unrealistic operations.

It must be stressed however that in the resolution of problems of a functional type, the dentist has certain obligations with regard to his conduct to which, in cases of cosmetic treatment, guarantees of result could be added should the information be inadequate and not take into consideration all the possible complications in relation to individual reactions independent of the culpable conduct of the dentist. The problem was recently clarified by the Court of Cassation<sup>109</sup>: "It is from the will of the doctor that his obligation derives and the agreement between the parties is the source of his obligation and the limit of his responsibility". Hence the importance that the commitment which the dentist, like the cosmetic surgeon, intends to take on in a contractual relationship be perfectly clear.

There is therefore an absolute need to describe the former state of the patient in detail (also with orthopantomography of the dental arches, plaster models, photos of the mouth and teeth, recording of tooth colour etc.), to specify the possible treatment (also alternative ones), the results that can be really achieved, the clear reference to possible drawbacks and relative risks, bearing in mind for the positive outcome of the proposed solution not only the 'objective beauty' but also and above all the "subjective beauty", so as to avoid upsetting that absolutely personal bodily scheme that the patient must be able to keep (in this sense

---

<sup>109</sup> Cass. Pen. Sez IV, 12<sup>th</sup> of July 2001.

the choice must be left to the patient as he/she alone must decide how he/she wants to appear). Quite often these considerations lead the dentist to just correct the “natural” look and, duly, to renounce any attempt to objectively improve that look.

Similar assessments are valid for orthodontics, given the coexistence of functional and aesthetic goals. The correct orthodontic dynamic-functional diagnosis must be associated with the complete medical history of the patient, if necessary with the help of a psychologist too especially for children, considering the enormous impact that the application of a brace can have in their relationship with others. It is therefore indispensable to propose the treatment plan, discussing aesthetic and psychic motivations. The information must concern, as for the implant prosthesis, also the patient’s and parents’ duties with regard to the use of the brace, its maintenance and oral hygiene, considering also the complete dependence of the minor on the parent for the consent to treatment. The NBC considers that, should the minor not collaborate in the treatment, the parents’ coercive intervention cannot be permitted, considering that this is usually preventive treatment, not required by ongoing pathologies and often difficult to make the minor to accept.

The exasperated technicality of some practitioners, less consideration for techniques of clinical and instrumental assessment and the prevalence of mechanistic principles over organicist ones is the source of great criticism, as a proof of the presumed tendency of dentistry to distance itself from the medical background at least as far as concerns the reduced consideration of the general causes of mouth pathologies. Dentistry is accused of this above all when the dentist frequently uses the same technique independently of the patient’s local and general situations with the risk of incongruous results under an aesthetic and functional profile, rather than following specific differentiated criteria even in the same case avoiding the correction of a particular defect and position of the teeth altering their facial identity.

It must be stressed furthermore that disabilities and particularly serious dimorphisms with dysfunctions of the mouth need greater attention, considering that the necessary surgical and rehabilitative operations come under reparative orthodontics not subject to the limitations of treatment for aesthetic reasons.

Neither the elderly nor children, except for a few exceptions, are sufficiently considered in industrialised societies. Elderly people need special attention that goes beyond a benevolent ‘taking care’, as they often suffer from pathologies of the mouth that are sometimes the expression of much more serious systemic diseases having significant repercussions on daily life. Minors, especially those with a disability, deserve to have more attention paid to prevention which in some Countries is even absent. It must be remembered that ‘the best way to identify a human society, which is different from the animal one, is by means of its enabling work, or one which enables people to survive who, otherwise would not manage to stay alive’<sup>110</sup>. Negative situations of this type not only exist in the developing countries but even in some of the recent new entries to the European Community.

In dentistry there is often a similar process of marginalisation to be found due to the absence of a real public dental service, able to satisfy the needs of the weaker members of society. It suffices to think that in the “Essential Levels of Healthcare” in Italy, dental care is practically non-existent, which furthermore is not supplied by the local health authori-

---

<sup>110</sup> Z. Bauman, *La solitudine del cittadino globale*, Feltrinelli, Milan 2004.

ties, while in open competitions the state requires, among the elements for qualification, a minimum dental formula as a proof of the importance that is given to correct mastication.

### Research in dentistry

It is well known that the diseases affecting the teeth and their support apparatus (periodontium) are essentially caries and periodontopathies, and that the same pathogens are involved in both, streptococcus mutans and lactobacillus casei. These greatly widespread pathologies are caused by the so-called *dental plaque* where such bacteria proliferate, decalcifying the crystals of apatite that make up the enamel (caries) or by irritating the marginal gum that facilitates the formation of tartar which goes into the periodontium until it mobilises the dental element (periodontopathy).

For decades now the scientific community has had a scheme for the prevention for these diseases which is set out in different strategies: from the fluoridation of water, to oral hygiene, a diet rich in fibres and poor in sugar, to the use of tablets that show up dental plaque, to the use of drinks like black tea which would hinder the appearance of caries. Even though prevention has worked remarkably in the Western world, thanks also to the huge press campaigns which have for years made society aware of the importance of dental protection, the same does not happen in the developing Countries where water, essential for oral hygiene, is often such a precious good that it cannot be used for the brushing of teeth. Scientific research aimed at the discovery of an effective therapy for these pathologies has not had any definite success until now. The so-called anti-caries vaccines, the sale of which has been announced on various occasions, have not yet completed the experimental phase. Stem cells could also be used in the therapy of periodontopathies but research on this is still in its first stages. It is furthermore probable that any possible benefits of the experimentation will hardly reach poorer Countries in the near future.

Experiments on animals is regulated by the Legislative. Decree No. 116 of the 27<sup>th</sup> of January 1992, which puts into effect Directive 86/609/EEC on the subject of 'Protection of animals used for experimental and scientific purposes', and sets down the contexts of use of experiments and the bioethical and scientific recommendations. Dentists complain of the lack of graduates in dentistry among the professional figures qualified to carry out experiments on animals. It must be noted however that the experiments using instruments and technologies are often carried out on rodents whose buccal apparatus works completely differently from the human one, as it has no movements of retrusion, protrusion or laterality. These experiments are for the most part useless and inopportune from a bioethical point of view, if one considers that even rabbits are used for the study of the osteointegration of implants.

### Conclusions

1) The NBC considers that a medical ethics exists in which dentistry can be recognised too, even with the composite features of its specialisations, ranging from the more technologically advanced ones like implantology, to traditional surgery and ad hoc dental surgery that is aimed mostly at cosmetic dentistry or at the correction of serious functional defects

(orthodontics, prosthesis, preventive dentistry) which all find their natural place in the field of medicine.

2) Nonetheless, dentistry deserves a special bioethical reflection by reason of the peculiar nature of the doctor-patient relationship, owing to the prevalent free-lance activity (much higher with respect to other branches of medicine and surgery), the autonomous university course introduced in the 80s with a degree course which is now (until the differences cease to exist) the cause of the mixture of operators of different scientific and technical extraction who all flow into one single professional Medical Association, and are subject to the same deontological code. If, therefore, it is not possible to hypothesise, despite the different specific operational techniques of the surgeon with respect to those of the dentist, situations that do not come under the general ethical laws of medicine, it is opportune to draw the attention to the problem of informed consent which can be affected by the often friendly relationship between dentist and patient and which, by virtue of this, risks being involuntarily neglected.

Strict observance of the duty to obtain the patient's informed consent is recommended; outside routine dental care it is opportune that the consent be given in writing, in detail, and written by the patient himself; the documents presented must also fully inform the patient of the cost of the course of treatment in advance.

3) Other situations relative to dentistry must be carefully considered by reason of the fact that the face and above all the mouth represent the first element of approach and appearance to the world of others, and especially of the image we have of ourselves, even though incomplete and unilateral. The care of 'human beauty' is increasingly the subject of the dentist's work, which must wisely mediate between "objective beauty" and "subjective beauty" in the choice of particular treatment which could sacrifice the functional or aesthetic aspect. In the extreme hypothesis the careful examination of the patient's motivations must also take into consideration the involvement of other specialists (for example a psychologist) in order to have the right approach to real problems. It is therefore necessary to stress once again that the work of the dentist should give priority to the therapeutic approach.

4) The NBC points out that the exasperated technicality (often caused by the prevalence of mechanistic principles over organicist ones) can alter the ethical balance of the doctor-patient relationship, neglecting that sense of existential well-being and that sense of subjective and/or objective beautiful, which define the actual success of the treatment and constitute the constant objective of the professionalism of the dentist.

5) The NBC brings the attention to the low interest shown by governments with regard to the pathologies of the teeth and the periodontum, particularly concerning the elderly, and to the inadequacy of preventive measures which are reflected above all on the frail and children. The absence of research is cause for concern also owing to the lack of drinking water in some regions of Italy and organisational and structural problems that continue to be unresolved. Such problems are particularly felt in some of the EU Countries where the quality standards in the rural communities are great cause for concern.

6) The NBC also highlights the lack of dental experimentation (often inadequate owing to the choice of animals that cannot be compared to man, and also concerning the physiology of the mouth). If on the one hand it is to be hoped that the professional figure of the dentist will be included among those qualified to carry out experiments on animals, on the other a more limited use of such practice is recommended due to the poor evidence of its benefits in dentistry, the effectiveness of Law No. 413 of the 12<sup>th</sup> of October 1993 being understood, which recognises the right to conscientious objection. It is necessary however to distinguish between the experimentation of merely aesthetic practices, the prohibition of which must be shared, and practices having therapeutic aims and which could have an ethical justification, in compliance with the laws in force and with the right precautions set down today in animal experimentation.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**BIOETHICAL CONSIDERATIONS ON THE SO-CALLED “OOTIDE”**

15<sup>th</sup> of July 2005



## 1. Premise

Requested to draw up a bioethical opinion on the so-called 'ooides', with particular reference to the ethicality of their freezing during assisted fertilisation procedures, the National Bioethics Committee debated at length on the biological aspects that are today available in scientific literature on human fertilisation which can be obtained with artificial insemination techniques, expressing its opinions in the general description proposed below, which – by the very nature of a document aimed at a wider diffusion – does not highlight a number of details.

However, with regard to the interpretation of the importance of the stages which usually describe fertilisation, contrasting opinions arose which will be mentioned hereinafter.

## 2. The events

In nature, man's biological cycle – like that of all mammals – begins from germinal reproduction, or that is, from the fusion of two gametes of different sex (fertilisation). This type of reproduction (sexual reproduction) realises the transfer of the genetic features from one generation to the next.

According to the description given by biologists, fertilisation – understood as a process – is characterised by microscopic and submicroscopic-molecular events that are all indispensable and of varying length, which develop continuously, beginning with the close interaction between the spermatozoid and the cellular and acellular linings of the oocyte, continuing with the fusion of the gametes and giving place in a variable time of between 16 and 30 hours to the first cellular division (two-cell embryo).

In vitro fertilisation has made it possible to study the succession of bio-molecular events that intervene in its coming about, at microscopic and submicroscopic resolution level. It is thus possible to establish even a chronological sequence that is summarised in the following table:

Phase	Post insemination time
Penetration of the pellucid zone	Within 30-40 min. p.i. (only standard IVF)
Fusion of cell membranes	Within 45-60 min. p.i. (only standard IVF)
Formation of the PB II	From the 2nd to the 8th hour p.i.
Formation of the PN	From the 3rd to the 12th hour p.i.
Juxtaposition of the PN	From the 5th to the 13th hour p.i.
Replication of chromosomes	From the 8th to the 17th hour p.i.
Disappearance of the PN	From the 15th to the 30th hour p.i.
First cellular division	From the 18th to past the 35th hour p.i.
<b>Total insemination time ICSI</b>	From the 16th to past the 33rd hour p.i.
<b>Total time of standard IVF</b>	From the 18th to past the 35th hour p.i.
Key – IVF: in vitro fertilisation; PB II: second polar globule; PN: male and female pronuclei; ICSI: intracytoplasmatic sperm injection.	

In particular:

1. The penetration of the spermatozoid into the pellucid zone of the ovocyte begins as soon as the gametes come into direct contact and takes about 30-40 minutes (only standard: IVF).
2. The fusion of the cellular membranes of the ovocyte and the spermatozoid supposes: the reaching of the perivitelline space by the spermatozoid, the fusion of the plasmatic membranes of the two gametes, the incorporation of the spermatozoid into the ooplasm.
3. The so-called 'cortical reaction', by means of physical-chemical modifications of the mucoprotein layer of the perivitelline space, makes the fertilised ovocyte impenetrable to other spermatozoids.
4. The activation of the oocyte, triggered by the incorporation of the spermatozoid, is manifested by the increased permeability and oscillation of the intracytoplasmatic concentration of the calcium ion ( $Ca^{2+}$ ) and determines the completion of the meiosis, the emission of the polar globule (PB II), with the consequent haploid configuration of the maternal genetic patrimony which will be formed, together with the haploid genetic patrimony carried by the spermatozoid, the genome of the zygote.
5. The removal of the membrane which surrounds the two male and female nuclei, the decondensation of the respective chromosomes and the formation by means of the use of molecular constituents of maternal origin of a new membranous covering which surround them and limit them clearly constitute an extremely complex process in which the two male and female 'pronuclei' (PN) are formed and become microscopically evident (according to some embryologists this point must be further clarified).
6. Within 3-6 hours of the incorporation of the spermatozoid, starting from the sperm aster, polymerised microtubules are organised in radial array from the male centrosome, which, by means of the transport exercised by suitable cytoplasmatic molecules, permit the approach of the two pronuclei.
7. The two pronuclei, starting from peripheral positions, move centrally and are partly juxtaposed, however remaining separate entities.
8. While the perinuclear membranes dissolve and the centrioles are identified, the chromosomes of the two pronuclei double their own DNA, preparing for the first cellular division (mitosis).
9. When these phases have reached completion, the chromosomes that are free in the cytoplasm but still hooked onto the tubular apparatus of the spindle are lined up on a single plane (metaphysical plate) which contains the diploid chromosomal order resulting from the male and female genetic patrimonies: this the amphimixis phase.
10. The paired chromatids of each chromosome separate and move towards the two poles of the cell beginning the anaphase. The cellular division of this new biological entity, called zygote, begins. At the end of the division two cells are formed, each with its own genome (two-cell embryo).

### 3. Bioethical evaluations

In the light of the above elements, some members of the NBC give the following considerations:

Firstly, in literature the uncertain nomenclature is still to be found characterising the description of the first stages of human development, a phenomenon that at times facilitates the use of the same terms to support different interpretational hypotheses or – on the contrary – the use of different terms (often the coining of money is newly coined, but not of terms) to indicate already known phenomena classified under previous names.

This behaviour is not obviously excluded in the subject considered, nor does it seem unproductive if directed at better defining and indicating the stages and processes that the evolution of research has further characterised; However, it becomes particularly sensitive in cases in which – from the simple change of definition – there can derive consequences in the juridical or ethical field which do not correspond either to the reality of the biological facts nor to the substantial modifications of state.

In the case in point being examined – by way of example – the use of the words 'conceived' and 'human being' is generally considered appropriate, both having a wide meaning. They do not interfere with other semantic specifications which – within the conceptual field that such terms suggest – can be adopted for the most precise description of biological facts.

Furthermore, the expressions 'conceived' and 'human being' have the advantage of being used and easily understood in current language, as the reference to the generative act of man (by whatever means it is obtained) is transparent.

The expressions 'ovocyte with 2 pronuclei' (2PN) or also 'ootid' – the latter recently adopted only by some authors – on the other hand appear limited to the indication of a stage of fertilisation; nonetheless, this should not create the impression that – in this stage – it is an inert cell, into which the nucleus of another has simply penetrated.

It is considered more appropriate (owing to reasons that will be discussed later on) to speak of zygote<sup>111</sup> or 'unicellular embryo'.

Having made these premises, it must be considered that the studies which have been carried out on the first stages of man's life cycle have advanced not only by means of morphological tests, even the most sophisticated ones, which characterise the first steps of the research, but also by means of biochemical and bimolecular contributions which today are essential for an exact understanding of the characteristic phenomena of the first hours of development of the human being. Therefore, many of the descriptions which – above all in text books or publications for public opinion by media and of a high cultural level – are mainly based on the series of 'apparent' morphological modifications with ordinary means of investigations, appear incomplete if not accompanied by the corresponding bimolecular analyses.

Owing to a series of reasons which will be presented during this analysis, it must be considered that a 'reply' to the question about how this document came to be can be given in strictly scientific terms through the description of the biological events and the rational reflection on the same.

Obviously, in such a way the ethical considerations cannot be avoided, even if they can be examined and usefully discussed once all the elements that a biological analysis can give are at hand. In any case, it is not a question of making every ethical or juridical position

---

<sup>111</sup> In reality one must speak of zygote only when the chromosomes are situated on the same metaphysical plate.

depend on scientific evidence, but of recognising that – in the case in point, that is, in the first hours of development of the human being – the conceptus arouses interest by its nature and biological individuality which is an unavoidable factor for any bioethical or juridical judgement that concerns the life and/or health of man.

From these premises it is considered that the following interpretation of fertilisation can be given:

### 3.1. *The interpretation of events*

Even though what has been described can be considered as a series of objectively perceivable and ultimately sharable events by any biologist-observer (albeit the description – based on the data available – was carried out only along general lines, given the nature of this document), the interpretation does not seem to be unanimously shared by the National Bioethics Committee of what is understood as the process of fertilisation in its entirety, even though it is in agreement on a 'diachronicity' of the stages, in any case limited to the space of some hours.

For the members of the NBC who propose this interpretation, the event of the meeting-penetration of the spermatozoid inside the cytoplasm of the ovocyte is the event to be considered fundamental, since it is the one that in space and time joins and literally 'fuses' two gametic cells each having a haploid genetic patrimony and makes a biological 'unit' of them that was not there before, given by the genetic molecular structures carrying the necessary information to lead (changing and interacting with the environment) each phase of the successive development.

Once the sperm has penetrated the ovocyte, a *continuum* of events takes place which continues without the need for further genetic impulses external to the unit itself, as seems to be moreover sustainable considering the inclusion of the ovocyte in a thick glycoprotein membrane (called 'pellucid zone') and the rapid realisation of the 'cortical reaction' of the ovocyte itself, which usually stops the penetration of other genetic material carried by sperm into it.

The fact that this process – which today can undoubtedly be described with greater accuracy than in the past owing to the in-depth analyses, not only morphological but sub-microscopic and by molecular biology, that have been acquired – begins with the penetration of sperm and then goes on with perfect continuity is substantiated also by that unitary 'functional' index characterising it in its duration, represented by the immediate onset of oscillations in the cellular concentration of the  $Ca^{2+}$ , with higher and more frequent waves at the beginning, more infrequent and with less intensity when the metaphysical plate has been formed.

In short, according to this interpretation, as the two gametes are biologically 'predisposed' to this meeting, all the phases following the penetration of the sperm in the first hours of life of the new 'being' have the same 'need' to take place as they are regulated along a line of development that appears clearly directed, continuous, progressive, and which at least in natural conditions cannot retrogress to already crossed stages (risk of the interruption of the process and the material dissolution of the entity involved).

This interpretation is not hindered but is rather strengthened by:

- the fact that in the very first phases, the 'penetrated' ovocyte uses its own genetic material (RNA and mitochondrions) accumulated for this purpose for as long as they last, to realise the 'conversion' to a new functional structure.

- phenomena taking place for the remodelling of the biochemical structure of the chromatin of the two pronuclei, of the organisation of the cytoplasmic organelles of the oocyte and other submicroscopic phenomena (only some of which were mentioned in the paragraph 'A description of the events').

Furthermore, this interpretation is corroborated by the widely demonstrated 'co-participation' of factors deriving both from the ovocyte and the spermatozoid in the realisation of the development which – in the space of just a few hours – from the fertilisation of the ovocyte leads to an embryo with two blastomeres.

For the ovocyte factors, one can mention as an example, the substitution of the nuclear envelope without the 'pore complexes' of the sperm head with a membrane whose molecular constituents are maternal, which makes it possible to restore the communication channels (pore complexes) necessary for the metabolic exchanges, with the rapid incorporation and substitution of maternal histones with sperm protamines: this is what leads to the so-called 'male pronucleus'.

For the sperm factors one can mention as an example the giving of the 'centrosome' of paternal origin to the new monocellular complex, which is the active one in the human species: the centrosome is the organelle necessary for the organisation of the fibres (microtubules) of the spindle and the successive activation of the molecular 'engines' which will allow the coming together of the two pronuclei and then the migration of the chromosomes during the course of the first mitotic division of the zygote.

In short, the 'principle of continuity' of the development is applied immediately from the spermatic penetration onwards, and clearly goes over the temporal limit of what is didactically called fertilisation, pervading the whole life of the individual, even though changing in time and according to the age in question.

On the other hand, philosophical reflection offers a further argument in support of the principle of continuity in the measure in which it recognises that the beginning of a human being's life constitutes a 'quality leap' (a passage from not being to being) and that, once such passage has taken place, there are only accidental modifications (quantitative) and not substantial transformations (qualitative).

Lastly, this interpretation is not hindered by the fact that the possibility appears of deviations or standstills in development at various stages (now recorded even in IVF); these events must be considered as errors in the working of an extremely delicate (and still in many ways not completely known) balance of molecular actions.

The significant spontaneous 'selectiveness' of human reproduction has never however been denied; the divergences that are recorded in the evaluation and the interpretation of the extent of the phenomenon in nature must be highlighted, which can hardly be compared with what happens in-vitro, owing to the undeniable artificiality of the in-vitro conditions.

### ***3.2. Ethical and juridical consequences***

The members of the NBC who agree with these considerations, share the opinion that the counter posing of the biological phenomena in the interpretation that today can be analysed in the first stages of development of the ovocyte, from the 'spermatic penetration' to the formation of two blastomeres cannot be considered a simple theoretical debate (like many others that exist in scientific activity), since the interpretations adopted are given a

different ethical meaning, in relation to the operational choices that could be made for the protection of the embryo.

It seems opportune to remind these members of the elements needed to formulate a reasoned opinion on the subject.

Taking for granted that we are dealing with evaluations concerning the protection to be given to the embryo, those who consider that the entire diachronic process of fertilisation shows a substantial unity in its *telos*, that is the concatenation and articulation of the microscopic, submicroscopic and bimolecular events (which modern technology has made possible to ascertain to a large degree) – such as to lead without solution of continuity to the first mitotic division of the zygote (formation of the first two blastomeres) and then to the segmentation, the differentiation of the cell's destiny and to the successive stages in the continuation of the embryonic development – cannot but accept a unique tutionist ethic of the human being, as such 'recognised' on the basis of its very 'existence' independently of the stage at which it came about at the moment of observation. And if one accepts that the human being must be recognised and guaranteed dignity and identity – as the Convention on Human Rights and Biomedicine (The Oviedo Convention, 1997) states in article 1 – those who maintain the afore mentioned line of interpretation consider that such conditions are satisfied by the 'penetration' of the ovocyte by the spermatozoid.

The consequent practice deriving from this lies in the fact that any 'manipulation' carried out even during the short diachronic process of fertilisation, which is not directed at the 'good' of the human being on whom it is conducted, exposes the latter to unjustified risks, according to the goals pursued and the rules that any prospective laws, regulations or deontological norms should consider it opportune to apply.

Those who support this line of interpretation consider that such judgement and a precautionary approach – and in the 'tutionist' case – must be applied, as a rule, to cryoconservation too, the effects of which on the embryo, at least at the moment of the techniques and at the 4-8 blastomere stage, are not without risk and sometimes prove to be harmful.

This does not mean that the data reported in literature should be disregarded, which shows – at present time – the poor 'yield' of the artificial procreation techniques carried out on 'non-penetrated' and cryoconserved ovocytes and – on the contrary – the improved performance (in final terms of 'babes in arms'), should the cryoconservation have been carried out in that phase defined the 'two pronuclei stage', or also by a certain 'pre-zygote' or ootide, which showed greater resistance with respect to the 'non-penetrated' ovocyte to processes of freezing – thawing.

Nonetheless this notion cannot affect the opinion that every ethical judgement expressed on embryo cryoconservation is also applied to the two pronuclei phase, collocat-ed in the 'necessitated' line of the taking place of the natural events without any alteration of continuity.

It must also be considered that – by virtue of the principle of continuity – considering that Act 40/2004 sets down that it is not admissible to produce a 'reserve' of morulated embryos (with 4-8 cells, frozen on the 2<sup>nd</sup> - 3<sup>rd</sup> day of development from the 'spermatic penetration') the fate of which is however uncertain, and in any case represents a strong stimulus for their use in research – the same considerations would be repropo-sed should a 'pool' of frozen '2P ovocytes' be set up, whatever name is given to them.

In conclusion, it must be considered that the solution to these dilemmas has to be dealt with through appropriate and intensified research on the cryoconservation of the 'non-pen-

etrated' ovocyte (whether this is ovulated or contained in sections and thin ovary fragments). The cryoconservation of this ovocyte can be granted on plausible medical grounds, moreover in well-defined cases.

It should be remembered that, since the news of a 'research programme' had begun to circulate, funded by government contributions to set up a national working group on this issue, and even though the question had not been formally debated in the NBC, the opinions gathered among the members were all positive ones, such as to be defined unanimous as long as 'non-penetrated' ovocytes, or ovary sections were concerned.

Today it still remains to encourage the search for this solution within the limits indicated above.

#### 4. Alternative bioethical evaluations

Those members of the NBC come to different bioethical evaluations who consider that, by means of the above described fertilisation process, a 'generational passage' is realised which in nature concerns a minority of cases owing to the complexity and delicate nature of the bimolecular interactions and biological events: the fertilizability index in couples of 25-30 is about 25-30% per cycle. The human species has a poor reproductive yield and the formation of a new 'biological entity', the embryo created by the parents, foresees a loss of 70-75%. The transition from the gametes to the embryo involves chronologically distinct and successive biological phases which present extensive functional and temporal overlapping which, even though constituting a *continuum*, are not however assimilable at the ontological level.

Scientific knowledge on embryo development has made great progress since the publication of the NBC's document '*Identity and statute of the human embryo*' (1996), above all owing to the greater resolution of research instruments, but the resulting picture is perhaps more complex and structured, revealing functional networks that are difficult to interpret in which the genomic contribution (the set of genes coming from the parents of the embryo) is progressively and continuously integrated with epigenetic maternal contributions present following conception and at the zygote stage. As could be foreseen, the interpretation of the biological data updated to 2005 has not however been useful for the formulation of shared ethical options.

The contrast of the two orientations in the interpretation of the biological phenomena relative to the first phases of development of the ovocyte – from the 'spermatic penetration' to the formation of the first two blastomeres – could seem like a simple academic disagreement if a different ethical approach did not correspond with it in relation to the operational choices that could be adopted for the protection of the embryo.

According to the NBC members in support of this different line of interpretation, the process of embryonic development in its first stages involves a complex network of events that is a lot less consequential than is commonly believed. In their opinion, the biological data show that every phase can entail alternative unforeseeable developments, even reversible in the first phases, with an unequal distribution of the competences and functions of the oocytes and spermatozoids, for which reason it would be really difficult to define the moment in which individual life begins.

Adopting an approach of extreme, even excessive precaution, some could reach the

point of not excluding (in a probabilistic sense) that such beginning corresponds to the moment in which the zygote is formed. It however remains somewhat problematic that this coincides with the meeting-penetration of the spermatozoid in the cytoplasm of the ovocyte and that from that moment on it is vital to protect the 'unity' that is formed. Such interpretation, which is obviously legitimate, is founded on the 'need' for the process from that meeting-penetration to continue without stopping, irreversibly and in a preordained way. The fact that an individual of our species is the result of the meeting of a spermatozoid and an ovocyte does not however authorise us to conclude that from such meeting a human being is necessarily born: scientific observation instead teaches us that the probability that this happens is rather low, as already stated, that the process is not even necessary, and that certainly in its initial stages there are a multiplicity of options to which are associated probabilities that we do not know.

It is even more important to highlight how the statement made by authoritative members of the NBC that the conceptus 'is one of us' cannot be acceptable to others: we should in fact agree on what of us we want to be present to 'make us individuals' and embryology could then give us the indications to establish the necessary conditions, but not for this reason sufficient ones. Biology in fact gives a mere description of the phenomena without giving them a hierarchy at the ontological and ethical level.

The data offered by biological research on embryo development are not adequate to clearly and authoritatively define what segment of the entire process can be assumed as crucial for the identification of the moment in which the new individual identity is made. In the NBC's document of 1996, '*Identity and statute of the human embryo*', the possibility was highlighted as controversial of being able to settle at a biological level the question of the beginning of the possession of an individual identity (person) by the embryo, and the *re-identification* criterion was proposed from a philosophical point of view, as considered particularly appropriate to establish the individual identity of the embryo: 'Until when is it possible to regress to find the point in which to position this individual identity? According to this criterion, the product of conception is recognised the statute of individual starting from the moment in which the capacity for subdivision into two or more embryos is irreversibly lost. The identification criterion is one that nonetheless expresses a sufficient but not necessary condition. This means that individual identity could exist even if adequate means of ascertaining it are lacking. Therefore, the ontological interpretation of biological data ends up by being influenced by the moral options of the interpreter, or rather by the way in which he consciously feels he should behave before the embryo right from its fertilisation'<sup>112</sup>.

The criteria that are each time indicated as being valid to support a certain assumption (continuity of development, appearance of a new genome, loss of totipotency by the embryo, implantation in the womb, appearance of nervous system etc.) have their legitimacy and rationality but are not a sufficient source to assume the beginning of human life with certainty.

It is useful to stress that such insufficiency is corroborated by the observation that the historical and social context greatly conditions the use of biological knowledge. Until recently, when social control was more strict and knowledge of the 'generational passage' insufficient, the phase considered decisive was that of copulation inside marriage. Today, with the possibility of controlling fertility making it independent of the sexual act and with the

---

<sup>112</sup> "Identity and statute of the human embryo" (1996), p.17.

increase of knowledge on embryo development, some consider that the decisive phase is the fertilisation, while others believe that this period must be moved into a successive phase, like the amphimixis (moment of the formation of the zygote), the moment in which the embryo is no longer dividable, the beginning of the implant, the 14<sup>th</sup> day from fertilisation (moment in which the absence of the nervous system is still considered certain), or also successive moments. From the scientific point of view there is no reason to privilege either of the phases and the choice with regard to this depends exclusively on different ethical options, insofar as the various possible 'interpretations' depend on the different value given to the different phases of human development.

In conclusion some members of the NBC consider that the interpretative line of events, maintained in paragraph 3 by those for whom the protection of the embryo must be absolute from conception and who share the ethical option of the non-admissibility of the cryoconservation of the 2PN ovocytes, derives from convictions and not only from biological reasons. The same members of the NBC, considering vice versa the rational impossibility of univocally establishing the beginning of human life, maintain that the cryoconservation of such ovocytes cannot be considered morally illicit.

Thus, these members hope for a modification of Act No. 40/2004 for the purposes of allowing the cryoconservation of at least 2PN ovocytes. Furthermore they also stress that the very formulation of the law lends itself to interpretations that could allow such practice even today. The 'conceptus' according to art. 1 is in fact protected by means of specific norms present in various points of the act where there is explicit reference to the 'embryo', or to an undoubtedly post-zygotic phase.

It must be added – even though it may be obvious – that personal use and not commercial use of the cryo-conserved 2PN ovocytes must be guaranteed, as defined by clear rules in the juridical and ethical criteria attaining to the balancing of the interests and rights of the subjects involved, the mother's being foremost.

## 5. Conclusions

Following extensive debate in working groups and during the plenary sessions, the Committee unanimously agreed on the *factual description of the events* concerning human fertilisation contained in this document in paragraph 1. On the other hand, despite great efforts made in this direction, no agreement was reached on the issue regarding the *ethical interpretation of those same events*, the description of which, as mentioned before, registered no dissent within the Committee. The second line of interpretation, summarised in paragraph 4, obtained the consensus of Professors:

Barni, Battaglia, Coghi, d'Avack, Flamigni, Gaddini, Guidoni, Neri, Piazza, Rescigno, Schiavone, Umani Ronchi.

The first of the two interpretations, illustrated above in paragraph 3, gained a greater consensus than the other, with the approval of Professors:

Amato, Belardinelli, Binetti, Bompiani, Borgia, Casini, D'Agostino, Dallapiccola, De Carli, Di Pietro, Eusebi, Federspil, Ferrari, Fiori, Iadecola, Isidori, Manni, Marini, Palazzani, Pistella, Possenti, Ricci, Sindoni, Santori, Scarpelli, Sgreccia, Silvestrini.

## GLOSSARY

**Allele:** Alternative form of a gene present in one or the other homologous chromosome.

**Amphimixis:** Reconstitution of a diploid chromosome complement.

**Haploid:** Referred to cell or individual in which the number of chromosomes characteristic of the species is halved, as one and one only couple of each chromosome is present. This condition is typical of the sex cells, egg cell and spermatozoid, and is indicated by  $n$ . The double structure,  $2n$ , is typical of the somatic cells.

**Egg cell:** Mature haploid female sex cell.

**Homologous Chromosome:** Single component of a pair of chromosomes, one of paternal origin and the other of maternal origin, generally with the same gene structure.

**Crossing-over:** Exchange of segments of homologous chromosomes and consequently of genes (more precisely 'alleles' – see).

**Oophorus cumulus:** Set of cells surrounding the egg cell.

**Polar globule:** A minute atrophic cell which is formed at the first and second meiotic division during the egg cell maturation. It contains a haploid nucleus.

**Gonocoric:** Referred to an individual that produces only one type of gametes, male or female. The term is used also to define a sexed reproduction system with separate sexes.

**Genetic or genomic imprinting:** Selective activation or non-activation of paternal or maternal genes that takes place during the maturation of the gametes or the first stages of development and is maintained in the somatic cells. For the genes involved only the allele transmitted by one of the parents is expressed, with consequences in the development and the manifestation of a number of hereditary diseases.

**Oocyte:** Female sex cell in the various stages of maturation to the formation of the egg cell, which joining the spermatozoid at fertilisation gives rise to the embryo.

**Ootide:** oocyte with two pronuclei.

**Perivitelline space:** Space between the cytoplasmic membrane of the egg cells and the pellucid zone.

**Zygote:** is the cell that is formed during amphimixis and possesses a chromosomal patrimony in metaphase.

**Pellucid zone:** Membrane surrounding the oocyte and covering the embryo in the first stages of development.

## PERSONAL REMARK SIGNED BY PROF CARLO FLAMIGNI

At least seven different theories<sup>113</sup> exist on the beginning of human life, all formulated by people belonging to the Roman Catholic Church and all very topical. The fact that one of these might be given priority by the Magisterium does not make the others less important: they are all in fact based on the same conceptual elaboration, which foresees a hypothesis of a philosophical type and a confirmation (or indication) of a biological nature. This is an inevitable convention in the presence of truths that are beyond our reach, which makes it necessary for each specific hypothesis to be given the same amount of verisimilitude. From my point of view it is above all common sense (in other cases it can be an act of faith, a philosophical lucubration or a personal interest) which indicates that of all the moments mentioned the one of the formation of a single genome should be preferred, according to the conclusions made by the embryologists whose names are to be found in the attachment.

I find not so much the fact that different opinions may exist rather peculiar, but the way in which their formulation came about. With regard to this I would like to stress that:

1) In many official documents, the Catholic Magisterium has stated that the moment of the beginning of human life is in the formation of the zygote. By way of example, I quote the document entitled 'Instructions on the respect for unborn life and the dignity of procreation: Replies to certain questions of the day', at the point in which it says: 'Thus the fruit of human generation from the first moment of its existence, that is that is to say from the moment the zygote has formed, demands the unconditional respect ...'.

And again: 'This teaching remains valid and is further confirmed, if confirmation were needed, by recent findings of human biological science which recognize that in the zygote\* resulting from fertilization the biological identity of a new human individual is already constituted'.

2) On page 568 of the above mentioned Instructions there is a footnote that defines the term 'zygote': 'The zygote is the cell produced when the nuclei of the two gametes have fused'. This is not the definitive version of the document (in the Latin version, which is the one that counts, this footnote changes, as we shall see), but it is however very important to understand the meaning of this note. In reality the definition is wrong, since in the human species there is no fusion of the pronuclei (they disappear), but the reference to amphimixis is more than evident. Having realised their error (a fact of which a number of details are known) the drafters remedied it by substituting the explanatory footnote with a new definition: 'The zygote is the cell produced when the nuclei of the two gametes have fused'. In all the debates on this question, that definition, even in its vagueness (*fusio duorum gametum* indicates a rather lengthy biological process, with no further details) it was considered useful to redefine amphimixis correctly this time.

3) In the documents on the ontological statute of the embryo that were presented in the past to the National Bioethics Committee, it was once again the word 'zygote' that was chosen to indicate the beginning of human life.

4) In order to avoid misunderstandings on the meaning of the word 'zygote', I quote

---

<sup>113</sup> The theory of the activated oocyte; the theory of the formation of a single genome; the hypothesis of the activation of the embryonic genome; the theory of the loss of cell totipotency and the capacity to form twins; the theory of the implant; the theory of the primitive embryonic line; the theory of the appearance of nerve cells; the hyalomorphic hypothesis.

the definition given by Adriano Bompiani: 'With regard to the beginning of the new being generically defined as 'conceptus', widespread opinion among biologists places this event in the fertilisation of the oocyte, a process that can be divided into various stages, but which takes place over a relatively short period of time and which however gives place to an event: the possession, in the entity that has been formed, of unique and unrepeatable information. To exactly fix the culminating moment within this process, mainstream opinion identifies the beginning of the new entity or being at this stage called zygote in the phase called amphimixis (or syngamy)'. (A.Bompiani: *Assisted Fertilisation and the ontological statute of the embryo*. In: *Fecondazione assistita - Una proposta di legge da discutere*. Edited by F.D. Busnelli A.R. Genazzani, E. Ripepe - CIC Edizioni Internazionali, Rome, 1997 - 19 - 32).

5) The new theory proposed by some members of the NBC presents, moreover, a number of biological incongruities. For example, the characteristics of this presumed new 'individual' adapt to the phase of conception that the embryologists define as that of the 'activated oocyte', in which the egg cell becomes impenetrable to the entry of sperm. In this case one can say that, continuing the fertilisation process, the genome that will establish itself cannot be different from the one produced by the fusion of the two protagonist gametes. In this phase the female gamete has not however reached the 'penetrated oocyte' stage (for which reason it is not yet one single cell, but adjacent and still separate cells) and has not yet expelled the 2<sup>nd</sup> polar globule.

6) It is evident that to abandon this theory in order to embrace a totally different one requires considerable effort. Hence the use – in my opinion extremely debatable – of ad hoc neologisms like 'bipronuclear zygote'.

7) The indifference is also peculiar with which well-known biologists and experts of the subject pass from one theory to another, often even forgetting that they have signed 'compromising' documents.

8) And lastly the recent tendency to involve biology is rather strange, after official documents had excluded it from the debate as being 'incapable'. It should be remembered that starting with Claude Bernard a great number of scientists ruled out that biology can intervene in the definition of the 'notion of life' and the beginning of human life.

## CONCLUSIVE DOCUMENT

(Conference: From the oocyte to the blastocyst: the generational passage in man - Rome, 28 September 2004)

The transition of the oocyte in the very first phases of a new human being is a non-instantaneous event which is associated with considerable fundamental biological changes within the oocyte.

Act No. 40 of 19 February 2004 grants the cryoconservation of this cell but expressly prohibits that of the embryo, with the exception of some particular circumstances that come under indispensable conditions. There is no reference, either in the law or in the guidelines (Ministerial Decree 21 of July 2004, Official Gazette No. 191 of 16 August 2004), to the other biological realities that follow one another during the course of this passage and therefore it is not clear if and when the oocyte that began it can be frozen. For the purposes of a better application of the present regulations, the biology experts of human reproduction, lecturers in the Italian faculties of medicine, committed to the training of future doctors and other healthcare workers, gave a technical contribution to the debate by means of a rigorous analysis of the knowledge on the oocyte-to-embryo transition in man, which are summarised as follows:

*The biological cycle of man is characterised by gonocoric sexual reproduction with fertilisation being the fundamental process by which the oocyte-to-embryo transition is realised and with it that generational passage which from 'parents' leads to 'children'.*

*Fertilisation is not an 'instantaneous' event and even considering it such only from strictly the cellular point of view, it consists in a process which:*

- *is triggered off by interactions at short intervals and of various nature between the spermatozoid and the cellular and acellular linings of the egg;*
- *continues with the fusion of the two gametes each coming from two parents of different sex, the woman supplying the 'oocyte' and the man supplying the 'spermatozoid';*
- *terminates, over a time varying from 16 to 30 hours, with the formation of the zygote.*

In the dynamics of the process a succession of imbricate events interacting among each other can be seen which, starting with the oocyte, lead to the successive appearance of different biological entities, all having features at the morphological, metabolic and genomic levels.

Among these entities appears the *oocyte with two pronuclei*, defined as '*ootide*' by some authors.

When the expulsion of the second polar globule has taken place, the new genomic structure can be identified in the two haploid genomes, even though these genomes must be still essentially considered genomes of the two parents even if contained in one single cytoplasm. Differently from what happens in other animal species, the pronuclei do not fuse but proceed separately in their functions and particularly in duplicating their DNA and in dissolving their shell to put their chromosomal structures in common on the same metaphysical plate.

This cell in metaphase is the *zygote*. Only in this phase in fact are the maternal and

paternal haploid chromosomal structures joined and coming together form the diploid chromosomal structure typical of the human species.

The creation of the new diploid genome represents the conclusive event of the fertilisation process. This precedes by a very short interval of time the beginning of the development that marks the taking place of the generational passage. This phase is followed by the first segmentation division with the appearance of a bi-cellular entity which is the first of a new unique and unrepeatable genome.

It must be stressed that this beginning does not activate the 'molecular personality' of the new being: the development continues for many hours still, in fact using a programme based on expression molecules of the genome of the two parents even if the maternal one is prevalent.

Lastly, it must be highlighted that, even in man, fertilisation as such is not indispensable for the generational passage and the activation of the development programme. *Parthenogenesis* can in fact take place in which the genome of the new human being derives completely from maternal chromosomes, and *androgenesis* where the genome is only paternal, although these processes do not lead to the birth of a new individual.

***IN CONCLUSION, the oocyte-to-embryo transition is the result of a succession of events that follow each other in time with broad functional and temporal overlapping. During this transition a peculiar event on which to base the criticality of the generational passage and therefore the beginning of a new human being, is represented by the constitution of the new diploid chromosomal structure and the successive start of the segmentation.***

As I have already stated, in reality this is also my personal conclusion even if my opinion on the beginning of human life is completely different.

If for practical reasons one is forced to state the point of greatest importance in the generational passage of man, this must certainly be indicated in the amphimixis and in the formation of the zygote.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**NOURISHMENT AND HYDRATION OF PATIENTS  
IN PERSISTENT VEGETATIVE STATE**

30<sup>th</sup> of September 2005



1. Recently, public opinion around the world has been profoundly shaken by the story of a woman who lived for fifteen years in a vegetative state and was left to die following the decision of a judge who authorised the husband's request (against her patients' wishes) to remove the nourishment tube from which the woman's life depended. Considering the considerable number of people who, also in Italy, are in a persistent vegetative state (PVS); also taking into account the controversy about considering or not the nourishment and hydration by nasogastric tube or percutaneous endoscopic gastronomy (PEG) as medical treatment and/or therapeutic obstinacy, the NBC believes that it is necessary to stress in this respect some fundamental principles of bioethics.

2. With the expression *persistent vegetative state* (once called *wakeful coma*) we indicate a clinical condition (deriving from a serious neurological impairment) characterised by an apparent state of wakefulness without consciousness, with eyes open, frequent aimless mastication movements, motor reflexes of the limbs limited to reflexes of retraction to nociceptive stimuli without purposeful movements. The patients in PVS sometimes smile for no apparent reason; the eyes and the head can rotate towards sounds and moving objects, without fixing the gaze. Vocalisation, if present, consists of incomprehensible sounds; there is spasticity, contractions, urinary and faecal incontinence. Cardiac and respiratory functions are preserved and the patient does not need the support of equipment. The gastrointestinal function is preserved, even though the patient is unable to take nourishment by mouth due to serious dysfunctions of the mastication and swallowing. If it is true that some terminally ill patients can become PVS patients, it is also true that people in a PVS are not always terminally ill patients (as they can survive for years if properly assisted). It is also wrong to associate the PVS condition to coma: the comatose state is in fact devoid of wakefulness, whilst people in a PVS, although they do not offer clear exterior signs of consciousness, alternate phases of sleep and wakefulness. The main bioethical problem is the *state of dependence from others*: these are people who, to survive, need the same things as any other human being (water, food, heating, cleanliness and movement), but who are not able to provide for them independently, needing to be helped, supported and looked after in all their functions, even the simplest ones. What must be strongly stressed is that people in a PVS do not generally need sophisticated, expensive and difficult to access technologies; what they need to live is care, intended not only in the sense of *therapy*, but also and mostly of *care*: they have the right to *be looked after*. In this sense we can say that people in a PVS require *assistance with a high and at times very high human content*, but a *low technological content*.

3. There is no doubt that the onset of PVS is a tragic event and even more tragic is the permanence (for a length of time that is difficult to predict) in such a state. But there is also no doubt that although PVS is definitely an extremely tragic pathological state, it does not in the least impair the dignity of the people affected and their full rights: it is therefore not possible to justify in any way not only the negation, but not even a weakening of their right to care, who they enjoy like any other human being. In fact we must not forget that it is not the quality of the pathology or the probability of recovery to justify the care: this finds its sufficient and exclusive reason in the need that the patient, as *weak subject*, has to be looked after and eventually undergo medical therapy. It is also common intuition, easy to argue bioethically, that the weaker the patient, the more is the ethical and legal duty to look

after him/her, which weighs on the healthcare system, on his/her family and on each single individual, who has the ability and opportunity. It is the opinion of the NBC that when the family is available to assist the patient in PVS at home, it is the duty of the institutions to support as much as possible the financial and care burdens.

4. To bioethically justify the basis and limitations of the right to care and the care towards people in PVS, we must therefore remember that *what must be guaranteed is basic sustenance*: nourishment and hydration, whether they are administered naturally or artificially. *Nourishment and hydration* must be considered *ethically* due acts (as well as deontologically and legally) as they are *indispensable to guarantee the basic physiological conditions for life* (guaranteeing survival, removing the symptoms of hunger and thirst, reducing the risks of infections due to nutritional deficiencies and immobility). Even when nourishment and hydration must be given by other people to PVS patients artificially, there are reasonable doubts whether such acts can be considered “medical procedures” or “medical treatments” as such, similarly to other vital support therapies, like, for example, mechanical ventilation. Water and food do not become, in fact, medical therapy only because they are administered artificially; this is a procedure that (although it undoubtedly requires a careful choice and preliminary evaluation by the doctor), apart from the small initial intervention, can be managed and controlled also by the patient’s family (as hospitalisation is not necessary). It is a procedure that, respecting minimal conditions (bathing, controlling posture), can be tolerated, managed at home by non-expert personnel appropriately trained (as demonstrated by the fact that *patients who are not in PVS* can be nourished in this way without it impeding a life of daily relationships). Care procedures do not become medical procedures only because they are carried out initially and periodically monitored by healthcare workers. The methods in which the elements necessary to sustain life (fluids, nutrients) are taken or administered is irrelevant from a bioethical point of view: naturally or artificially supplying (with the help of techniques that substitute natural ways) nourishment and hydration, eat or drink independently or thanks to others (in a surrogate manner, outside of the active participation of the individual) are not differentiating elements in the bioethical evaluation. The fact that nourishment is given through a tube or stoma, does not make water or food an artificial preparation (similarly to walking, which does not become artificial when the patient needs a prosthesis). Nor can we believe that water and food become medical or healthcare therapy only because another person supplies them. The problem is not the method of the act towards the patient, it is not how he/she is nourished or hydrated: nourishment and hydration are due acts because they are basic life supports, as they allow the individual to stay alive. Even though it was a medical treatment, the judgement on the appropriateness and suitability of such a treatment should depend only on the objective condition of the patient (namely, his/her effective clinical needs measured in risks and benefits) and not on the judgement of others about the quality of life, current and/or future.

5. If it is not very convincing to define the PEG a “medical procedure”, we should exclude even more the possibility that it will be generally considered as “therapeutic obstinacy”. The decision to not undertake or discontinue artificial nourishment and hydration is not governed by the principles regulating medical procedures (with reference to other life support systems): it is generally thought right to discontinue a medical procedure when it becomes persistence, namely, an insistence to obstinately postpone death at any cost

through technology, prolonging life beyond the limits of the possible (when the illness is serious and incurable, excluding with certainty that it could be reversed, when death is imminent and the prognosis terminal, therapies are disproportionate, onerous, expensive, ineffective and useless to improve the condition of the patient from a clinical point of view). As long as the organism is genuinely benefiting from artificial nourishment and hydration, they are forms of *primary and proportionate routine care* (effective, inexpensive financially, easy to access and practical, not requiring sophisticated equipment and being, in general, well tolerated). The discontinuation of such practices must be evaluated not like the rightful interruption of therapeutic obstinacy, but rather as a form, from a particularly cruel human and symbolic point of view, of “*abandonment*” of the patient: in fact it is not a coincidence that, as an act of coherence, the immediate euthanasia of the patient in PVS for whom the discontinuation of nourishment and hydration has been decided is required by many, in order to avoid that after a process that can last up to two weeks they end up “dying of hunger and thirst”.

6. There are instead no doubts on the ethical obligation to discontinue nourishment in the hypothesis that in the imminence of death the organism is no longer able to assimilate the substances provided: the only limit objectively recognisable to the ethical obligation to nourish the person in PVS is the organism’s ability to assimilate (therefore the possibility that the procedure achieves its aim because there is no positive reaction to the treatment) or a state of intolerance linked to food that is clinically verifiable.

7. We must therefore talk about the *human value* of the *care* of patients in PVS. If we generally feel that it is our duty to provide water and food to people who are not able to get it independently (children, the sick and the elderly), as a sign of a civilisation characterised by humanity and solidarity in recognising the duty to look after the weakest, in the same way we should believe that it is our duty to give food and fluids to patients in PVS, taking care of their physical needs and accompanying them emotively and psychologically, in their peculiar condition of vulnerability and fragility. This is an attitude that has a strong human, symbolic and social significance of care for others. We cannot reduce the decision to care/not care for, assist/not assist a patient in PVS to the cold utilitarian logic of balancing costs and benefits (considering the benefits to be limited in terms of recovery and the high costs of care), calculating the quality of life of others (and ours, seeing the sick as a “burden” for the family and society), limiting the considerations to convenience and opportunity and not also to the duty and responsibility of solidarity towards others.

8. In the context of this document it is appropriate to elaborate some considerations regarding the possibility that an individual, in drawing up *Advance Care Statements*, includes the request to discontinue nourishment and hydration, in anticipation of finding his/herself in a possible situation of PVS in his/her future. There is no doubt that formulating this request is absolutely legitimate, just as there is no doubt that a similar request cannot be completely generic, being very difficult to predict the specific way in which such particular events could come true in the future. The fundamental ethical criterion to assess the legitimacy of the content of *Advanced statements* identified by the NBC in a document formally dedicated to the *Advanced treatment statements* and approved on the 18<sup>th</sup> of December 2003. In it, at paragraph 6, the NBC has unanimously affirmed that in the

*Statements* “each individual has the right to express his or her wishes, including in advance, with respect to any therapeutic treatment or medical procedure about which they can legitimately express their current wishes”. It is therefore not to be doubted that when nourishment and hydration have an *extraordinary* character and their discontinuation has been legitimately requested by the patient in his/her *advanced statements*, the doctor could access this request (in the ways indicated by the NBC in the abovementioned document), even though this solution seems to preclude the great difficulty (psychological and human) mentioned above, of letting the patient die of starvation. The hypothesis – which in these pages is considered typical – in which nourishment and hydration are routine primary care rather than a medical procedure, is however different. According to NBC members subscribing to this document, the request in *advanced care statements* to discontinue this treatment, appears in fact like the request of *euthanasia by omission*, similar both ethically and legally to an intervention of *active euthanasia*, illegal in all respects.

9. In light of the previous considerations, the NBC conclusively confirms that:

- a) Human life must be considered a value that cannot be disposed of, regardless of the level of health, the perception of the quality of life, autonomy or ability to discern;
- b) Any distinction between lives worthy and unworthy to be lived is to be considered arbitrary, as dignity cannot be attributed, variably, on the basis of the conditions of existence;
- c) The hydration and nourishment of the patients in PVS must be ordinarily regarded as primary life support;
- d) Discontinuing the hydration and nourishment of patients in PVS is to be considered ethically and legally legitimate on the basis of objective parameters and when the hypothesis of a genuine therapeutic obstinacy is realised;
- e) The abovementioned discontinuation is to be considered ethically and legally unlawful every time it is carried out not on the basis of the real needs of the person concerned, but on the basis of the perception that others have of the patient’s quality of life.

*In the plenary meeting of the 30<sup>th</sup> of September 2005 this document was agreed upon by the following NBC members:*

Prof. Salvatore Amato, Prof. Sergio Belardinelli, Prof. Paola Binetti, Prof. Adriano Bompiani, Prof. Luisa Borgia, Dr. Carlo Casini, Prof. Francesco D’Agostino, Prof. Luigi De Carli, Prof. Luciano Eusebi, Prof. Giovanni Federspil, Prof. Angelo Fiori, Prof. Aldo Isidori, Prof. Corrado Manni, Prof. Luca Marini, Prof. Vittorio Mathieu, Prof. Laura Palazzani, Prof. Paola Ricci Sindoni, Prof. Giancarlo Umami Ronchi.

*The following NBC members voted against this document:*

Prof. Mauro Barni, Prof. Luisella Battaglia, Prof. Cinzia Caporale, Prof. Isabella Coghi, Prof. Lorenzo d’Avack, Prof. Carlo Flamigni, Dr. Laura Guidoni, Prof. Demetrio Neri.

Abstained from voting: Prof. Silvio Ferrari.

## PERSONAL REMARK

The undersigned, absent from the plenary meeting of the National Bioethics Committee on the 30<sup>th</sup> of September 2005, communicate their agreement with the document *Nourishment and Hydration of Patients in Persistent Vegetative State*.

Prof. Maria Luisa Di Pietro  
Dr. Gianfranco Iadecola  
Prof. Elio Sgreccia

## PERSONAL REMARK

The statement that characterises the NBC document, according to which the hydration and nourishment of patients in PVS should be regarded as a rightful primary “support” for the patient and not strictly as a medical treatment, expresses an ideological framework for the issue, respectable but completely unrelated to the clinical reality and the autonomy both of the patient (whose advance statement is ignored) and of the doctor, who is in this way deprived of his fundamental professional authority, which is to establish in science and conscience the moment when a therapy of even mere life support becomes futile and cruel persistence (condemned by ethical, deontological and scientific instance). On the other hand, the treatment in question is continuously characterised by medical assessments and choices based time after time on the specific condition of each patient and it develops through checks and prescription of specific and specialist medical expertise: which is reflected in every guideline, every clinical-scientific framework of PVS, to the point that repeating it is superfluous.

The document approved by the majority of the NBC is instead based on premises that are scientifically wrong and it is therefore incompatible with medical practice that is not dominated by ideology.

This does not mean that the diagnosis of PVS authorises in itself the abandonment of the patient and of every curative measure; but given the absolute “certainty” of no-recovery after no longer than a year (to be considered in any case with extreme prognostic care), it is the exclusive matter of a clinical-scientific evaluation supported, as it must be in the majority of developed countries, by guarantees and technical and temporal evidence, maybe to be indicatively established, the way it has already happened (peacefully) for the condition of the irreversible cessation of all encephalic functions, certifiable only in the convergence of the parameters and signs, based on science and endorsed by the law, so that they *allow* the discontinuation of every life support treatment.

Moreover, the same position of clarity can be found in the opinion expressed by a scientific commission purposefully created (1999) by the Ministry of Health, Prof. Veronesi.

Prof. Mario Barni

## NOTES

Regretting the fact that it has not been possible to pursue to the end the drafting of a single although not unified document, Prof. Mauro Barni, Prof. Luisella Battaglia, Prof. Cinzia Caporale, Prof. Isabella Maria Coghi, Prof. Lorenzo d'Avack, Prof. Renata De Benedetti Gaddini, Prof. Carlo Flamigni, Prof. Silvio Garattini, Prof. Laura Guidoni, Prof. Demetrio Neri, Prof. Alberto Piazza, Prof. Marco Lorenzo Scarpelli, Prof. Michele Schiavone, are in favour of discontinuing the hydration and nourishment of patients in PVS in some circumstances and with appropriate safeguards. The same Professors therefore declare their vote against the *Document*<sup>114</sup> approved by the majority of NBC members, explaining this choice in the following considerations.

1. Leaving aside the first three paragraphs of the *Document* which, appropriately modified during the discussion that took place in the plenary meeting of the 16<sup>th</sup> of September, can be endorsed as a description of the clinical framework called “vegetative state” (paragraph 2) and as introduction to the type of problems to tackle (paragraph 3), a first point of disagreement is the content of paragraphs 4-5-6 and 7, in particular with regards to the thesis according to which artificial nourishment and hydration cannot be considered medical treatments as such.

In this regard, it is necessary to stress that there is a tendency, constant and increasingly widespread in the national and international scientific community, in favour of the opposite thesis, that is, that artificial nourishment and hydration are in every way a medical treatment<sup>115</sup>, like other life support treatments, such as, for example, mechanical ventilation. Mechanical ventilation which, on the contrary, the *Document* believes inappropriate to mention as an element of comparison: almost as if mechanically supplying air to a patient who cannot breathe it in him/herself, is not just as “essential to ensure the basic physiological conditions for life”, as much as, according to the *Document*, supplying artificial nourishment and hydration.

These last ones are treatments that presume scientific knowledge and that only doctors can prescribe, only doctors can carry out by introducing a nasogastric tube or other even more complex methods, and only doctors can assess and eventually reorganise; this even if the mere execution can be carried out – as it happens for many other medical treatments – by nursing staff or in general those who assist the patient. In fact it is not “food and water” – as stated in the *Document* – that are supplied, but chemical components, solutions and preparations that imply technological procedures and scientific knowledge; and the methods to administer them are certainly not comparable to “providing water and food to people who are not able to get it independently (children, the sick and the elderly)” (paragraph 7). This highly evocative and emotionally engaging language, which the paragraphs in question are full of, is aimed at supporting the thesis of a “strong human, symbolic and social significance of care for others” (paragraph 7) demonstrated by the administration, even artificially, of “food and water”. However, again, it is incomprehensible – in the sense that the *Document* does not provide any reasons for this – why in the same context it is claimed

---

<sup>114</sup> Following, in the note titled: *Document*.

<sup>115</sup> See, finally, the Guidelines of the Italian Society for Parenteral and Enteral Nutrition (2002), with relative bibliography.

that “this value does not regard, for example, artificial respiration or dialysis”. In an ethics of taking care, the more or less technological nature of the treatments cannot be discriminatory: any medical or non-medical treatment, even the simplest one, can and should have the value of care for others.

2. In any case, although we maintain that if we consider the nature of this or that treatment we cannot ignore the opinion of the scientific community, I stress that the judgement on the bioethical appropriateness of these treatments depends only partially – or even not at all, as claimed by some of the writers – by considering them medical treatments, as to a certain extent the *Document* admits in the sentence that closes paragraph 4.

The solution of medical-legal problems could maybe depend on considering them as such, but the judgement of bioethical appropriateness certainly does not depend on it, and in any case not automatically, which – just like in any other treatment – must take into account other factors. Amongst these: the patient’s condition and the perception of his/her own life that the patient can manifest, in various forms, before entering PVS.

It is not about formulating judgements or agreeing with “the judgement of others” – as presented in the *Document* – on these patients’ “current and/or future quality of life”, but, on the contrary, it is about exploring the possibility of recreating the judgement that the patient would have formulated about his/her condition, or of verifying what preferences the patient has explicitly and clearly expressed in the form of advanced statements. The two different paths open, according to the bioethical principle we refer to: in Great Britain, for example, the aim is generally to establish if the permanence in that condition is in the patient’s “best interest”; whilst in the USA the respect of the patient’s autonomy is seen as the prevailing interest, even when he/she can no longer exercise it. These and other possible paths can be followed to find humanly acceptable solutions to these dramatic situations. The signatories of this note are hoping that the NBC reconsiders the issue, the analysis of which was already started in the previous mandate, as they are issues requiring much more in depth study.

3. We must also observe – with particular reference to paragraphs 5 and 6 – that artificial hydration and nourishment can almost never become a form of therapeutic obstinacy (although they can become simple persistence), not even in the cases, rare but conceivable, listed in paragraph 6.

With regards to this paragraph, we must however highlight that it is not realistic, or scientifically appropriate, to talk about an organism that “is no longer” able to assimilate the substances supplied (in this case the treatment, amongst other things, would be completely futile). It is on the other hand realistic to talk about an organism that has an increasingly reduced capacity to assimilate without it being possible in abstract to identify the threshold below which the ability to assimilate becomes insufficient and, therefore, the nutrients administered artificially do not achieve their biological goal to change, albeit in a more limited manner, the biohumoral parameters.

We therefore do not understand for which reason the discontinuation of these treatments in the case of patients in PVS<sup>116</sup> - which in any case have no awareness of being fed

---

<sup>116</sup> Which, for some of the signatories, can in any case happen only on the basis of an explicit expression of will by the patient through advanced statements.

and hydrated – would be “a form, particularly cruel from a human and symbolic point of view, of “abandonment” of the patient” (which, according to the same approved *Document*, would need, from those suggesting it, the coherence of asking also these patients’ euthanasia), whilst this “abandonment” according to the same *Document*, would not happen in the case of patients with a reduced or very reduced (but presumably never inexistent, at least as long as the patients are alive) capacity to assimilate, for whom the *Document* envisages the “dutifulness” of the discontinuation. And we also do not understand why the psychological and human difficulty of leaving a patient “to die of hunger and thirst”, is considered important in the case of patients in PVS and not also in the case of other type of serious patients with the same reduced capacity to assimilate: does it perhaps matter that in the first case the dying process may last for two weeks, whilst in the second case it may last “only” for a few days or a few hours?

Leaving aside the fact that what happens in reality is certainly not due to the harrowing images that the language used in the *Document* would lead us to think, if the problem is the psychological and human distress of those who treat the patients (if this is a valid reason), then – once the discontinuation of those treatments has been decided – in the terminal stage we could proceed, in one as in the other case, to sedation; in the second case obviously with the patient’s consent, if conscious.

There is therefore no need to call into question the issue of active euthanasia: in the framework of the ethical debate on the matter it is possible to argue in favour of the interruption of life support treatments (including artificial hydration and nourishment) without thereby accepting the hypothesis of a direct euthanasia<sup>117</sup>.

4. A further point of disagreement is the content of paragraph 8, relatively to the possibility of incorporating a request of not starting or discontinuing artificial hydration and nourishment in the Advanced care statements.

The Document *Advanced Care Statement*, approved unanimously by the NBC the 18<sup>th</sup> of December 2003, reads: “each individual has the right to express his or her wishes, including in advance, with respect to any therapeutic treatment or medical procedure about which they can legitimately express their current wishes”. In the opinion of the writers, from this follows the logic consequence that any treatment or intervention needs the person’s availability, regardless of whether ordinary or extraordinary, or whether it can be seen as therapeutic obstinacy or not, or – even more so, as artificial nourishment, is an intervention the termination of which causes effects that can be easily understood by the patient without any need for particular information or knowledge – whether it is “routine primary care”. We don’t see, in fact, how it is possible to argue that a conscious person refusing any of these interventions can be forced to suffer their administration. And with regards to the issue under discussion, it is important to recall that art. 51 of the Italian Code of Medical Deontology says: “When a person of sound mind voluntarily and consciously refuses to take nourishment, the doctor has the right to inform him/her of the consequences

---

<sup>117</sup> About this, see also paragraph 120 of the Charter for Health Care Workers of the Pontifical Council for Pastoral Assistance to Health Care Workers: “The administration of food and liquids, even artificially, is part of the normal treatment always due to the patient when this is not burdensome for him: their undue suspension could be real and properly so-called euthanasia”.

that this decision can have on his/her health conditions. If the person is aware of the possible consequences of his/her decision, the doctor *must not* force him/her *or take part in behaviours to compel* him/her to take artificial nourishment, but he/she must continue to assist him/her” (italics by the writers).

If therefore a person, in the full consciousness of his/her condition and of the consequences of his/her eventual refusal, is free to decide on any intervention offered, including artificial nourishment, then, under the principle mentioned above, it is not possible to take away from the same person the freedom of giving advanced statements to a similar end, and therefore also with regards to starting or not artificial hydration and nourishment, in case he/she should find him/herself in the condition, on the basis of medical knowledge and available protocols, of being diagnosed as being in a vegetative state.

5. With regards to the concluding considerations presented in paragraph 9, they obviously come from the content of the previous paragraphs and therefore they are not acceptable to the signatories of this note to the *Document*.

In conclusion, it seems however dutiful to observe that to reason bioethically about PVS, it is not strictly necessary to call into question the controversy on the value of human life, also because in this way the discussion moves to the level of the more complex and, often, abstract notions of the world and man, on which it is not the NBC’s task to take position. We should, if anything, try to reason about the object of the controversy, asking, for example, if, with regards to whether it is disposable or non-disposable, life can be considered as simple biological existence or as biography, as being alive or having a life, an existence.

Finally, the writers don’t believe that it is appropriate to recall the distinction between lives worthy or unworthy to be lived, because it is always true that people’s dignity does not depend on the conditions in which they find themselves: instead, it might be the conditions people find themselves in that are more or less worthy of the people. And, in this case, it is the writers’ belief – for some, always subordinating this decision to the consent explicitly expressed by the patient previously -, that discontinuing treatments that maintain undignified conditions is maybe to be seen as an extreme tribute to the dignity of the person.

Prof. Mauro Barni; Prof. Luisella Battaglia; Prof. Cinzia Caporale; Prof. Isabella Maria Coghi; Prof. Lorenzo d’Avack; Prof. Renata De Benedetti Gaddini; Prof. Carlo Flamigni; Prof. Silvio Garattini; Dr. Laura Guidoni; Prof. Demetrio Neri; Prof. Alberto Piazza; Dr. Marco Lorenzo Scarpelli; Prof. Michele Schiavone.

## PERSONAL REMARK

In full agreement with the principles and content of the document *Nourishment and Hydration of Patients in Persistent Vegetative State*, approved by the National Bioethical Committee in the Plenary meeting of the 30<sup>th</sup> of September 2005, we believe that it is appropriate to stress – in our capacity of doctors – that what was stated with regards to persistent vegetative state is also true for “permanent vegetative state”, about which the judgement of irreversibility has a character of probable prognosis and not absolute certainty, as occurrences of reversibility are known also after a considerable amount of time from the event that damaged the brain. Anyway, even in cases of “permanent vegetative state” it is still a human life that must be respected and protected, even more so because in conditions of extreme weakness.

Prof.ssa Paola Binetti; Prof. Adriano Bompiani; Prof. Bruno Dallapiccola; Prof.ssa Maria Luisa Di Pietro; Prof. Giovanni Federspil; Prof. Angelo Fiori; Prof. Aldo Isidori; Prof. Corrado Manni

## PERSONAL REMARK

After having read the document “Nourishment and Hydration of Patients in Persistent Vegetative State” in the text approved in the plenary meeting of the 30<sup>th</sup> of September 2005 (which I could not attend), I want to make known my full agreement with the conclusions formulated in paragraph 9, precisely as follows, as a personal reason:

- a) From a bioethical point of view, in Europe the person in PVS is not a *former person* (according to the principles formulated on the super-principle of autonomy), but is a person in the full sense, whose dignity must be protected guaranteeing, in line with the “Convention on Human Rights and Biomedicine” (art. 1) “without discrimination, respect for their integrity”;
- b) From a constitutional point of view, in Europe the person in PVS, as any other person, “has the right to life”, and consequently “to his physical and mental integrity” (European Union Charter of fundamental rights, articles II-62 and II-63);
- c) From a deontological point of view, in Italy “the doctor cannot abandon the incurable patient, but must continue to assist him/her even just to lessen the physical and psychological pain” (Code of medical deontology, art. 20), in view of “a medicine that takes care” (Ventafridda – De Conno, 1990), keeping in mind that if this is “the philosophy of palliative care” (*ibid.*), it must be even more so for the care of patients in PVS, who certainly cannot be considered incurable;
- d) From the point of view of terminology, there is no need to use a fashionable term (care) to highlight that the alternative between “medical procedure” and “assistance” here is a false problem: we can simply refer to Zingarelli to discover (or rediscover) that “care” means both “all medicines and remedies to treat an illness” as well as “the constant and solicitous interest in something or someone”.

Prof. Francesco Donato Busnelli



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**BIOETHICAL PROBLEMS CONCERNING THE USE OF ANIMALS  
IN ACTIVITIES LINKED TO HUMAN HEALTH AND WELL-BEING**

21<sup>st</sup> of October 2005



## PRESENTATION

Since its institution in 1990, the *National Bioethics Committee* has adopted the insight of the best bioethicists, according to which the sphere of bioethical reflection relates to whatever is *living in general* and does not only apply to the living *human being*. The Committee's constant attention to environmental bioethics and above all to bioethics *for animals and with animals* stems from this. Therefore, special attention should be given to three of the Committee's documents: *Animal testing and health of living beings* 17<sup>th</sup> April 1997, *Bioethics and veterinary science, animal well-being and human health* 30<sup>th</sup> November 2001, *Ritual slaughtering and animal suffering* 19<sup>th</sup> September 2003.

The theme of the document presented here, that of bioethical issues relating to *the use of animals in activities related to human health and well-being*, has prompted the attention of the members of the Committee since 2002: in the plenary session on September 19<sup>th</sup>, it was decided that a working group on the matter should be set up and its direction entrusted to Dr. Pasqualino Santori. This group was immediately joined by Profs. Salvatore Amato, Luisella Battaglia, Cinzia Caporale, Isabella Coghi e Renata Gaddini.

The work of the group has been particularly intense, as reflected both by the fact that from 2002 to 2005 it met eighteen times, and the large number of "external" experts, who have generously collaborated with the group. Allow me to name them one by one and thank them once again for their friendly alacrity: S. Del Papa (Zoo-prophylactic Experimental Institute of Abruzzo and Molise), G. Felicetti (Anti-Vivisection League), E. Natoli (ASL Roma D - Veterinary Hospital), F. Rametta (Psychotherapist, Scientific Director, Teacher and Supervisor of "Arethusa"), R. Marchesini (President of the SISC), A. Pugliese (University of Messina-Department of Veterinary Medical Sciences), M. Verga (Institute of Animal Science - Faculty of Veterinary Medicine-University of Milan), M. Minero (Istitute of Animal Science - Faculty of Veterinary Medicine-University of Milan), M. P. Onori (Equestrian Rehabilitation Centre Vittorio di Capua - Ca 'Granda Hospital in Milan), L. Valeri (Zoo-prophylactic Experimental Institute of Abruzzo and Molise), C. Weiss (Zoo-prophylactic Institute of Abruzzo and Molise), D. Salvi (International Academy for the study of communication with dogs), G. Pallante (Centre for Interdisciplinary Studies in Zoo-anthropology of Trento), A. Mannucci (Journalist), F. Allegrucci (Scientific Head of ANUNCS). Without their cooperation this text would not have been possible. After the work of the group was concluded, the document was distributed to all members of the Committee. Placed on the agenda and vigorously debated in the plenary session of 21<sup>st</sup> October 2005, it was finally approved unanimously. I am therefore very pleased to present it, not only to our institutional recipients, but to the widest audience of scientists, those operating in the legal, social, philosophical and bioethical context who follow of our work: I am convinced that they will agree to recognize that our text - further proof of the justified bioethical commitment that has always characterized our work - is marked by a distinct originality in imposition and approach, which will constructively raise awareness to bioethics and animal rights in our country.

*President of the Italian National Bioethics Committee*  
*Prof. Francesco D'Agostino*

## SUMMARY AND RECOMMENDATIONS

In this document the N.B.C. has taken into consideration, using the Anglo-Saxon term, widely in use, *Pet Therapy*, the different activities, that arouse the interest and hopes of the public and the medical community, conducted for the benefit of human beings and implemented with the use of animals.

Despite the remarkable diversity, the practices examined are characterized by two distinctive and common features:

- a) the pursuit of human health and well-being;
- b) the use of animals and the protection of their well-being.

These particular uses of animals, clearly different from the traditional ones had over the centuries, increase the need for thorough moral judgments involving not only the respect that is owed to every objectively “sentient being”, but also (and especially) the attempt to create a very special form of “therapeutic alliance”.

Four types of relationship between man and animal for the purpose of human well-being and health that present substantial differences in practical and organizational terms have been taken into consideration:

- a) cohabitation with an animal owned by a sick person in his or her own home or in a health care setting;
- b) the training and use of an animal to help a disabled person in his or her daily life;
- c) animal-assisted therapy;
- d) animal-assisted activities.

The bioethical problem concerns the assessment of the alleged benefits in their rapport with the nature of the relationship that is established with the animal. The latter must be guaranteed a persistent state of well-being and, if possible, the creation of a condition of actual benefit. Thoughtful definition of any risk to human health in the case of contact or proximity to a healthy animal as well as veterinary supervision is also hoped for.

Bioethical relevance is also given to the judgement on the use of these practices (some of which still in the working hypothesis stage) in relation to the costs, the alternatives, the demonstration of their actual effectiveness, the decision-sharing with the patient through the practice of informed consent.

It therefore calls for:

- a) research to be supported that is aimed at identifying the real benefits to human health and well-being of the practices involving animals (and among them the research to study neuro-physiological and cognitive parameters capable of interpreting their “language”) and this is true especially in the case of highly organized practices, such as the activities carried out with assistance animals, animal-assisted activities (AAA) and above all animal-assisted therapy (AAT);
- b) research to be supported that is aimed at identifying possible changes in animal well-being, in order not to expose the animals themselves to uses (regarding practices or work methods) that could cause conditions of discomfort for them. The absence of in-depth knowledge of the conditions for the employment of animals should be treated with a precautionary approach to exclude the possibility of stressful conditions;
- c) the non use of wild animals, as they are not accustomed to living with humans, or to life in a confined environment, and therefore inevitably subjected to a condition of discomfort;

- d) work to improve the quality of life for the animals involved using, wherever possible, and without prejudice to the result, animals taken from kennels, shelters or abandoned animals, appropriately selected and trained. It is considered necessary to consider the living conditions and well-being of the animal in all phases of the project and even after this has ended. It must be emphasized that for the protection of the animal there should always be guaranteed adequate public supervision;
  - e) guarantees for the possibility of maintaining a relationship with one's own pet in the case of admittance to a residential structure so as not to renounce to the care value of this affectionate relationship, both to avoid the danger of abandonment or removal. The opportunity for visits by animal, in the appropriate areas, for the patient admitted to a hospital facility should also be provided;
  - f) reliance on the dependability of the ethics committees for the evaluation of protocols and research projects and their implementation methods, where the involvement of animals in various activities different from those of their traditional use are foreseen;
  - g) use of so-called "gentle" training techniques, that respect the dignity and well-being of the animal as far as possible;
  - h) insistence on the need for physicians to pay the highest attention to these kinds of practices with regard to their possible effects and in particular to their significant psychological and existential nature. In this regard, it is also recommended not to suggest the general presence of an animal in a home environment without having realistically assessed the chances of a successful relationship with the patient and without having gained adequate knowledge on the animal and its needs.
  - i) in the use of animals, evaluation not only of the benefits but also of the risks that may concern allergies and infections (e.g. the risk of transmission of toxoplasmosis of the cat to a woman during pregnancy);
- Lastly, the NBC reiterates that *Pet Therapy* (in the form of AAT, that is, *animal-assisted therapy*) is at present in many of its applications a working hypothesis that is awaiting appropriate verification by means of scientific methodology and deserves public support only as regards projects research.

## INTRODUCTION

In the preparation of this document, the *National Bioethics Committee* has considered a particular area of the relationship between humans and the animal world, that of the various types of therapeutic or assistance relationships, that have as their purpose the promotion of the well-being and health of human beings. In particular, the Committee has examined so-called *Pet Therapy*, the training of *assistance animals* and, as relevant, cohabitation with a pet (in a health care setting or at home) by an individual who is particularly fragile from a psychological or physical point of view.

As illustrated by successive arguments, the now common and immediately understood name *Pet Therapy* was chosen to be used, despite the fact that the utilization of this terminology may lay open to criticism, because it does not distinguish between *animal-assisted activities* (A.A.A.) and *animal assisted therapy* (A.A.T.) that undoubtedly require differentiated analysis. It should be pointed out that *Pet Therapy* in the A.A.T. form, that is, *animal-assisted therapy*, is at present in many of its applications a working hypothesis that is awaiting verification by appropriate scientific methodologies and deserves public support only in research projects.

The document does not intend to provide a complete discussion of the matter in question, but rather wishes to emphasize some of the most important bioethical issues, suggesting also conditions and methods so that these practices may be confined in an ethically acceptable context even in the light of the moral significance acquired by animals. The “animal question” has taken on increasing importance over time in both the bioethical and bio-judicial context, as well as in public opinion. The need to address the moral dilemmas related to interspecific relationships is particularly important when new circumstances or new uses of animals are expected, as in the cases discussed here.

The *National Bioethics Committee*, as concerns issues regarding animals has already expressed its views in specific documents namely: *Animal testing and health of living beings* (1997), *Bioethics and veterinary science, animal well-being and human health* (2001), and *Ritual slaughtering and animal suffering* (2003).

In addressing this issue, as in previous cases, particular prominence has been given to man, as the user of the reviewed practices or as operator or professionally devoted researcher. We must recognize that from the beginning the main *raison d'être* of these practices is placed upon the benefits that man can gain in relation to his health and well-being.

One does not intend nor should one neglect the interests of the animal. Not only for the general and growing consideration due to sentient beings, but also as regards the same interests of humans in order that these practices are truly effective. Indeed it is from a genuine “therapeutic alliance”, namely from an intersubjective relationship, albeit inevitably an asymmetrical relationship, that man can derive the greatest therapeutic and existential advantage.

Animals have always played an important role in the history of human communities. At the dawn of civilization, it is likely that some human groups began a relationship in which the attempt was more or less to consciously manipulate, tame and then select for breeding (which has excluded them from natural selection) some animals with which it was possible to establish some form of communication. In this way the process of *domestication* began that has clearly involved a small number of species in relation to the many, *wild*, species

existing in nature and potentially more or less accessible so to create with some of them over time *tamed* relationships.

Domestication is a particularly complex biological phenomenon which according to some evidence could have initiated with the dog about 10-15 thousand years ago, or, according to other authors, several tens of thousands of years before then.

Living with pets has immediately taken on at the same time an instrumental dimension, of *exploitation* of animals by man, and a broadly relational and diversified dimension depending on era and dominant cultures. Among these utilities that man has enjoyed the benefits of there can also be included those to his well-being and health.

However, it is only in recent decades that many studies have focused on the existence of a causal link between some forms of cohabitation or common activities with animals and alleged physical or mental improvements in human subjects suffering from some disease (or general distress or needs). And it is only recently that extemporaneous and indeterminate practices have been systematized in actual intervention projects aimed at obtaining, as far as possible, measurable and repeatable benefits.

The articulation of these experiences, the scientific nature of which - should be emphasized - is ambiguous and still to be explored, it is briefly described below:

#### **Pet Therapy: A.A.A. and A.A.T.**

The name *Pet Therapy* has long been used in reference to activities involving animals or involving training programs in order to obtain specific functional animal behaviour to accomplish foreseen therapeutic or care targets.

#### **Animal-Assisted Activities**

Animal-Assisted Activities (A.A.A.) are aimed at improving the quality of life and general well-being of man. It is a question of recreational (or other) intervention carried out with animals that satisfy certain requirements these activities are directed at persons who live emotional or physical difficulties, or who find themselves in distressing conditions (hospitalization, stay in a nursing home, detention, etc.). Also included among the A.A.A., are activities of a pedagogical and educational value aimed at the very young, for example in schools or children's wards or in residential facilities for children with delinquent behaviour

Operators that manage the A.A.A. may be appropriately trained professionals, para-professionals and / or volunteers.

Normally, the activities are offered to numerous individuals contemporarily as they are not linked to actual clinical therapies subject to the conditions of the individual beneficiaries. Generally targets are not programmed for each intervention. Spontaneity and creativity are more prevalent in A.A.A. than in the A.A.T.

#### **Animal-Assisted Therapy**

The Animal-assisted therapy (A.A.T.) is intervention carried out with the aid of animals; it differs from A.A.A. as regards the objectives, methodology and evaluation

of the possible results found. In practice it is an activity focused on disability and aimed at achieving an improvement of the adaptive capabilities of the patient so as to make him reach, consistent with the pathology that he is affected by, the highest possible degree of development of motor (or, more generally physical), psychological and social potential.

A.A.T. acquired scientific dignity in 1961 through the work of the child psychiatrist Boris Levinson. Since then, numerous publications and conferences have examined the subject, but in general the studies carried out according to scientific criteria are few and the interest shown by the medical world has always been sporadic and limited (despite the fact that it is currently on the increase).

Assisted therapies are more complex, at least, in procedure and like all therapeutic treatments are based on a diagnosis made by the doctor and involve the determination of health objectives and a precise schedule of their administration.

In general, interventions have objectives that are specific predefined to improve the physical, social, emotional and / or cognitive functions (thinking and intellectual capabilities) that are calibrated to each patient. The objectives can be classified, for example, as *physical* (motor skills, balance, etc.), *educational* (language, memory, learning, etc.) *mental health* (attention, self-esteem, reduction of anxiety and the feeling of loneliness etc.) and *motivational* (involvement in community activities, ability to interact with others etc.). In any case, the aim of the treatment should be well defined, clear and achievable.

A.A.T. must be considered as co-therapy capable of stimulating progress in different functional areas (cognitive, motor, emotional, relational, etc.). This means that they simply support traditional and accredited rehabilitation therapies and are not able to replace them in any case.

A.A.T. are provided by a multidisciplinary team that may include from time to time and depending on the various cases professionals that both meet the needs related to human benefit (doctors, psychologists, therapists, etc..) and the methods of use of the animal (behaviourists, dog-drivers, etc.) as well as safeguarding the health and well-being of the animal (veterinarians, etc).

The team will evaluate the patient, establish whether the therapy with animals is appropriate or not, assess contraindications, set a therapeutic goal and develop an individualized treatment plan for that patient in that context.

Successively achievement or non-achievement of the objectives will be regularly reviewed.

From the above it can be deduced that therapy with animals can not be a rigid and invariable method, imposed on the patient using the same treatments for all patients and all pathologies.

The animal can provide valuable assistance as co-therapist increasing motivation and interest in treatment, reducing the symptoms of stress, increasing concentration and attention, waking emotions, stimulating senses and feelings, etc. All this potential, however, is to be used within an individualized project, aimed at achieving therapeutic goals that are clearly defined, developed and carried out by a multi-specialized team.

## Assistance Animals

Another condition, different from those previously mentioned, that we wanted to take into consideration in the analysis of the various possible uses of animals in activities related to human health and well-being, is that of assistance animals (usually dogs).

This kind of activity that is not believed to be part of the context of *Pet Therapy* requires very intense training that brings to mind many other jobs that dogs carry out for humans such as rescue under rubble, during an avalanche, or the search for drugs.

In this context, the psychological component of the relationship with the dog, while still being important, is overshadowed by the genuine material contribution given by the animal.

There are guide dogs for the blind, assistance dogs for persons with motor disabilities, dogs for the deaf, assistance dogs for people with epilepsy and it is likely that new useful forms of assistance will be found for humans in need.

The first specialized training was for guide dogs for the blind in Germany after the First World War.

If well trained and effectively coupled to the user, the aid to mobility that a guide dog can give the blind person is remarkable, and consists in pointing out the dangers and obstacles of a path and making a person more independent in his everyday life.

The assistance dogs for persons with motor disabilities have the task of helping people in everyday life who for various reasons, accidents or illnesses, have insufficient or reduced autonomy in movement and consists in teaching the dog innumerable tasks such as picking up objects, helping with movement, opening doors, etc.

While, generally, for assistance dogs specific breeds are chosen predictably the most suitable for the pursued aim, a good part of the dogs for deaf people come from kennels. This is possible because, unlike guide dogs and assistance dogs for persons with motor disabilities, the dogs for deaf people do not require a particular physical structure (for which careful selection is necessary) as they have the sole task of indicating sounds and noises.

As far as assistance dogs for people with epilepsy is concerned, this type of training is still the least known and least studied; it is based on the individual sensitivity of the dog and its link with the person, as well as the codified techniques of training.

In essence, these dogs, living with the person with epilepsy, learn to perceive the imminent seizure several minutes in advance. The possibility of diagnosing cancer (melanoma) using canine olfaction has also been recently hypothesized and studied.

Compared to the training techniques used for *Pet Therapy* the case of assistance animals is certainly special and significant; these animals, to be able to provide meaningful help to people with disabilities, must be subjected to particularly demanding training from an early age and for several months.

The methods used which, almost always, include the use of techniques that are considered “gentle” (based on awarding a prize and not on punishment, therefore enjoyed and even sought after by the animal); seem to some to substantially detach animals from their original ethological characteristics.

The boundaries of these uses (A.A.A., A.A.T., and assistance animals) are already currently quite large and it is possible that there will be a further expansion in the future especially in those cases where the customary therapy and care offer presently available in more traditional practices, provide only limited benefits.

### The relationship with one's own pet in a health facility

Lastly a further point to be considered is the matter relating to the possibility of not interrupting cohabitation with one's own pet should the owner-patient have to be transferred either temporarily or permanently to a hospital or care facility. Beyond the undoubted difficulties of a logistic nature that must be overcome to allow for this continuity, the benefit of maintaining the emotional relationship for the human patient is beyond doubt, as it is for the animal itself. The latter would, in addition, not run the risk of fortuitous accommodation or even abandonment (behaviour punished by law).

Current reference points are the studies showing benefits in humans from contact with pets, both in providing well-being and facilitating social contacts, and also in preventing and helping to control specific pathologies (cardiovascular, psychological problems etc.).

The present case has highlighted the need to safeguard the interests of other residents as regards to antropozoonosis, allergies and problems of a psychological nature.

Part of the difficulty of the health facility in the realization of these projects could be addressed by the realistic scaling of the significance of the health risks to human health that the relationship with a healthy animal that is subjected to veterinary controls may actually produce for in-patients. However, comparing the potential risks of antropozoonosis among other things to the certain psychological benefits for patients, a balance can be found in the practical management of the health facility.

### PURPOSE AND SCOPE OF THE DOCUMENT

The document aims to examine the general ethical lines of the relationship with animals used in activities related to health and human well-being without focusing in detail on the individual forms of uses (e.g. hippotherapy, etc).

It should however be borne in mind that for some of the illustrated activities (A.A.A., A.A.T., assistance animals) non-domestic animals such as dolphins, monkeys, etc. could sometimes be used.

It is therefore necessary to concentrate briefly on the complex problems of domestication. Although domestication always requires human intervention in at least three basic functions (protection, nutrition, breeding livestock), this intervention has produced, over time, a huge variety of symbiotic relationships that are loosely united by the elimination or reduction of aggression and by the seeking of proximity in variable degrees.

Between a pet par excellence such as the dog and a wild animal par excellence, we can identify many possible intermediate forms of interaction, which vary from animal to animal, culture to culture and from historical period to historical period. The document can not enter into the merits of such a complex issue, but it can not ignore that all these elements affect the bioethical evaluation of the examined practices. Most of the activities covered in the document concern a small number of animals, kept as pets (dogs, cats, horses). While for others there is the problem of the possible use of other species (e.g. dolphins).

In this case, the precautionary principle, understood as safeguarding human health and as protection of the specific animal, imposes to exclude from such practices both wild animals (even if tamed) and animals with an uncertain level of domestication so that even if

there are no obvious dangers to humans there are very likely negative consequences for the animal.

We should not think that there must necessarily be a conflict of interests between human beings that require a benefit to their health or well-being and the animals that contribute to providing it, we must indeed hope, as far as possible, to achieve mutual benefit.

It must however be taken into consideration that, for a kind of activity that is increasing and for which regulatory requirements are expected and future financing, the possibility is that, in the practical use of these techniques there may be a widening of the scope of these possible conflicts of interest. Any such conflict could be either at the expense of the interests of the animals in a perspective of improving human health and well-being, and also conversely, to the detriment of human health benefits in a perspective which exclusively safeguards the interests of animals.

In the accomplishment of bioethical analysis there has deliberately been taken into consideration the possible points of view of all those involved as well as their supposed interests.

In this perspective, we tried to bring out the critical points in order to evaluate them in a framework of values that are shared as much as possible and to give guidelines and recommendations.

In light of the importance taken on by the respect for animals in the Western world the point of view of animals, as far as it is possible to be presumed, was directly taken into account.

## THE INTERESTS OF ANIMALS

The practices taken into consideration in this document are intended, primarily, for the interests of human beings in states of distress or need. The human interest in obtaining the best possible state of health and well-being for individuals through the use of morally licit means is legitimate; including the methods that see the animal as a sort of therapeutic factor and / or as an active player in the actual therapies.

In these cases the interests of the animal, far from being neglected, have only an indirect value, but despite this they are not less important both ethically and legally.

When using animals for human purposes there is always together with “reification,” the strong likelihood of their “anthropomorphization”, which can lead to non-recognition or even neglect as regards their specific needs and the consequent emergence of increasingly difficult situations that in time, may constitute in actual fact forms of maltreatment.

According to a defined anthropological perspective human civilization was born and is still based on the domestication of plants and animals. Therefore, cohabitation with animals is to be considered a normal condition. However, not always has cohabitation coincided with respect, indeed, it has often resulted in some form of exploitation (animals as food, transportation, work tools, objects of leisure activities etc...). Even *Pet Therapy* etc. could be placed in the wake of this exploitation.

The animals used to assist children with physical or psychological problems, lonely elderly people, the sick, prisoners, etc., could experience states of major or minor distress, which could degenerate into stress and illness; they could suffer episodes of abuse and even sadism. They may also suffer simply because of the absence of a unique and stable emotional relationship with one or more human subjects.

We can not, in addition, overlook the risk that *Pet Therapy* is perceived as a mere recreational activity that meets the limited needs of persons in difficulty, indirectly contributing to reiteration of the mistaken, rhetoric, and intolerable idea, that *being with the animals* is for children for the *abnormal*, for people with problems.

These fears have been, moreover, already widely expressed in previous NBC documents, which emphasized the need to overcome the persistent influences of a perspective entirely focused on the anthropological model.

If it is impossible to make that leap of logic that consents to enter completely into the animal's perspective, in any case any ethical model must be able, at least to include the other in his existential horizon. In this document the "other" is, precisely, the animal condition in all those aspects that can be traced back (since we could talk of the dignity or integrity of the animal) to the notion of animal well-being.

Despite that studies in this field have been undertaken relatively recently they have provided the analytical, physiological, pathological and behavioural indicators that allow a certain degree of objectivity in judging, by a veterinarian. If the interest is to maintain and eventually increase the animal's state of well-being, it is necessary to identify any possible conditions that produce a direct benefit to the animal involved in A.A.A., A.A.T. or assistance.

First and foremost, it is a duty to ensure the animal has a permanent condition of life better than the one that it otherwise would have had and this applies even in times of non-use or after use. From this point of view, it would be beneficial, where feasible and with appropriate caution, to use animals in shelters that are generally in miserable conditions of life.

However, the use of wild animals and, in general, non-domestic species is to be excluded. There is strong perplexity, from the point of view of the protecting animal interests, regarding the use of dolphins, for the conditions of stress that these activities might entail. This stress is added to the already unnatural condition of captivity.

In any case, it is good practice and indeed a moral obligation to use so-called "gentle" training techniques, which are not violent.

It can be said that these are not practices which animals need fear most, as sick or mistreated animals would not be useful to the purpose, and also because, for those who organize *Pet Therapy*, etc., these animals are a real "asset" to be given the utmost care. It must be noted that when at any time this safety valve does not necessarily come into action there should be an interruption in activity to protect the weaker party, namely, the animal, regardless of the therapeutic feedback. Paradoxically, the very success of these therapies could reduce the attention for the animals to meet the growing demand for their services. Conversely, if these therapies should one day become less promising compared to the initial expectations, there is the problem of the fate of the animals involved in such activities until then.

For these reasons, therapeutic protocols must be defined that allow to obtain, at the same time, the scientific evidence relating to human pathologies and elements for assessment of possible cases of illness that may arise in animals.

In addition, resources should be found to provide the animal with a sufficient quality of life during and after its being used in therapeutic or assistance interventions.

Theoretically, the conditions for well-being could be met through an animal specifically "produced" for the purposes under consideration, defining the most appropriate

genetics by means of a selection of the breed or even by means of the creation of a breed or a mixture of breeds then to be nurtured and trained in conditions of maximum adaptability to the environment that it should frequent when used. However, this does not seem appropriate because if the “program” conditions should change it could cause serious situation concerning a lack of adaptive flexibility and therefore considerable distress.

Instead, certainly less problematic, from an ethical point of view, is the condition in which the animal finds itself should it be brought in to visit its owner in hospital or should it follow its owner who is permanently in a residential facility as an alternative to being ultimately separated.

## **TEAM WORK**

In Animal-Assisted Therapies and to a lesser extent in the case of Animal-Assisted Activities and the use of Assistance Animals the working group must necessarily be broad to include all the required professionals.

The maintaining of a dynamic balance between the interests of humans and animals in the management of care or therapeutic relationships requires the presence or at least the supervision of a number of professionals. These professionals must be able to understand the physical and behavioural conditions of animals in order to avoid distress and alterations in the relationship; in addition, in the interest of the human patient a condition of real effectiveness in relation to the intended purpose and also as regards possible alternative techniques must be clearly reached.

Both in the project phase and in the phase of application it is necessary to produce, albeit at different times and in different ways, the expertise needed for the treatment of the human patient (physicians, psychologists, therapists, etc.), to conduct the animal and provide for its needs (veterinarians, behaviourists, trainers and drivers) and lastly for the management of the relationship (psychologists, zoo-anthropologists etc.).

The interests of such a wide group of people could in turn affect the relationship between the human patient and the animal co-therapist. One can imagine the possible onset of a conflict of interest on the part of some or all elements of the team compared to animal well-being, as a result of the same “professionalization” of such activities and the need to ensure its performance over time even in economic and employment terms.

The acquisition of data of a scientific value as concerns both the benefits to humans as well as any possible inconvenience caused to animals would consent a better integration of expertise, and could limit the pressure related to the differences between the various ethics. Furthermore, the data once acquired:

- would reduce the area of scientific uncertainty of so-called gentle therapies of which A.A.T., as a co-therapy it seems in some ways closer;
- would facilitate the task of the team in correctly informing the patient following a correct informed consent procedure;- would make feasible the extension of the knowledge of such practices among physicians, particularly in the case of pathologies not otherwise treatable.

One should keep in mind that even if contact is always with healthy animals under veterinary supervision, it is important to identify any possible risk to human health.

The different ethical problems faced in this regard by the two “key figures” as part of the team is to be taken into consideration.

The doctor and the vet have two different tasks, although they aim at a common goal.

### **Ethical and deontological problems of the Vet**

The veterinary profession is historically responsible for the protection of animal health and well-being in a perspective mainly focused on human interests.

Only recently the increased attention for animals has led to a direct assessment of the interests of the animal that has become a fundamental element in bioethics to the point of limiting some traditional uses of animals.

In the cases dealt with in the document, the balance can often be implicit in the very nature of the activity that, as commonly said, can not be beneficial to human health and well-being if the animal involved is in discomfort.

It is the role of the veterinarian to supervise the entire process to ensure a state of persistent well-being for the animal. It is therefore the duty of the veterinarian to stop activities should this not occur.

In the case of an animal already owned that follows the owner-companion in a health facility or care setting, the task of the veterinarian will consist essentially in the creation of suitable conditions to ensure the health and well-being in new surroundings.

Instead, in the case of having to choose an animal to be accepted into the project, the veterinarian, in accordance with the team and availability, will have to identify the animal suited to adapt to the environment both from the point of view of health (antropozoonosis prevention etc.) and animal well-being.

Furthermore, in relation to the human-animal relationship, it would be desirable that vets acquire specific competence in this field to increase the value of the program and amplify the results and benefits.

### **Ethical and Deontological problems of the Doctor**

Each therapy, as such, should aim at improving the patient’s clinical situation, and should be verifiable and documented by the methods of clinical practice.

The prescribing physician must know the characteristics of the treatment, its true effectiveness, on which symptoms or pathologies it is effective and how this effect has been documented.

The doctor therefore needs to know how, when, and with whom this can occur.

The animal involved in the conducted therapy must also be known in order to focus specifically on care; using the animal that is most suitable for its physical or behavioural characteristics.

There must be the willingness to work together with the other specialists, who form the multidisciplinary team; this is an especially key element of A.A.T.

The doctor must be able to assess whether other therapies can lead to the same results with less cost.

A.A.T., due to the number of professionals involved, the cost of the animal, its care, its

preparation, its maintenance in optimal conditions, its limited use to avoid stress, may implicate specific financial costs.

This is of little importance when the NHS is going through a crisis and resources must be used with restraint and simplicity criteria

This is not insignificant at a moment when the NHS is going through a time of crisis and resources must be used according to the criteria of containment and essentiality.

## LEGAL PROFILES

### Lines of legislative policy and European regulations

Before examining the specific juridical rules on *Pet Therapy* we must quickly consider the slow cultural development by which animals have taken on increased legal importance, a sign of the attempt to find a different way of conceiving the relationship between humans and all other forms of life which has been expressed in the Universal Declaration of Animal Rights, proclaimed by UNESCO in 1978. In this sense, the new wording appears to be extremely significant in art. 20 of the German Constitution, approved June 21st 2002: “The State, taking into account its responsibilities towards future generations, protects the natural foundations of life [human] and animal through legislative power within the framework of constitutional order and, on the basis of law and right, through executive and judicial power”. Explicitly contemplating animals in the protection that is accorded to “the natural foundations of human life” (*die natürlichen Lebensgrundlagen*), tends to strengthen the jurisprudential development that began in Germany with the entry into force TierSchG of 17.02.1993, so called *Tierschutzgesetz*, and with the concise and evocative new condition of art. 90a Civil Code, which states that “... animals are not things”.

It should be noted that 11 of the 16 States of the German Federation explicitly contemplate, in their Constitution, the protection of animals. Some are even more poignant in the Grundgesetz itself for example, art. 59a of the Constitution of Saarland states that the “Tiere werden als Lebenwesen und Mitgeschöpfe geachtet und geschützt” (Animals must be respected and protected as elements of life and living creatures).

The first European country to include an explicit reference to animal issues in its constitutional text was Switzerland, in 1973, due to the amendment of art. 25 of the constitution (now art. 80 in the new Constitution of 1999). Particularly interesting is the Indian Constitution of 1950 which provides that, one of the *Fundamental Duties* is, “to protect and improve the natural environment including forests, lakes, rivers and wildlife and have compassion for living creatures” (article 51 A letter g).

It is within this perspective that the draft amendment to art. 9 of our Constitution should be seen, under which the republic should protect “the needs, welfare, of animals as sentient beings”.

Part II of the Treaty which establishes the future European Constitution, in the “Charter of Fundamental Rights”, expresses, however, a considerable contrast to the model indicated in the German Constitution, because it does not include animals in any way, even when governing the protection of the environment under the principle of sustainable development (article II-97). It only deals with it in Title III, on “Policies and internal actions”, recommending “in formulating and implementing the Union’s policies for agriculture, fish-

eries, transport, the internal market, research and technological development and Space “to take” full account of the requirements in the welfare of animals as sentient beings, while respecting the legislative or administrative provisions and customs of the Member States as regards, in particular to religious rites, cultural traditions and regional heritage” (III-121).

It seems more of a stylistic facade than a clause with a clear commitment to promote a different ethical sensitivity. Yet the European Community has acted on this issue with some important documents. In particular, the Council of Europe Convention for the Protection of Pet Animals, which was approved in Strasbourg on 13<sup>th</sup> November 1987 and the Protocol on protection and the welfare of animals, approved at the Conference in Amsterdam on June 16<sup>th</sup> 1997.

## Italian Legislation

### Direct normative references

In our country there is still no comprehensive legislation on this matter, although several bills are currently being examined. There is only a Decree of the President of the Council of Ministers February 28<sup>th</sup> 2003 (*Official Gazette. 4.3.2003 No 52*) which includes the agreement between the Ministry of Health, the regions and autonomous provinces of Trento and Bolzano on February 6<sup>th</sup> 2003 regarding the well-being of pet animals and *pet therapy* (*Official Gazette No. 51 of 03.03.2003*) in order to:

- a) ensure the well-being of animals,
- b) prevent reprehensible use, whether direct or indirect,
- c) consent to their identification through the use of special microchips
- d) use *pet therapy* for the treatment of the elderly and children throughout all the country.

We do not find in this provision, any definition of *Pet Therapy* neither is there any distinction between the different therapy options nor different pets. A little more analytical is the agreement between the State and regions in which it is stated that a pet, understood as being “any animal kept or intended to be kept by man for companionship and affection, or not for the aim of production or food, including those performing activities that are useful to humans, such as dogs for the disabled, animals for pet therapy, rehabilitation and those used in advertising. Wild animals are not considered companion animals” (article 2 a). The provision is limited to merely drawing a clear line between pets and wild animals, without considering the merits of the controversial question of the different possible levels of domestication. This solution is perhaps appropriate if we consider that any rigid typology is still controversial, however the overall picture is very confusing because it puts animals (any animal?) which man uses for companionship or affection on the same level, with those used in pet therapy or rehabilitation and, lastly, with those that appear in advertising. As we shall see in the next paragraph it may become extremely difficult to connect within the same ethical and regulatory structure such heterogeneous categories, held together more by human choice (often subjective and, at worst, arbitrary) than for objective reasons for the protection of animal well-being.

Lastly, the law of the Veneto Region of January 3<sup>rd</sup> 2005 No 3 should be remembered, which aims to “promote knowledge, study and the use of new support treatments and inte-

gration of clinical and therapeutic treatments such as smile therapy or gelotology and animal-assisted therapy or *Pet Therapy*” (art. 1).

### Indirect normative references

Recent amendments to the Penal Code introduced on the 20.07.2004 by Law No 189 play a significant role in the legal status of any form of activity with animals. In particular, art.544 ter prohibits the mistreatment of animals, punishing “anyone who, cruelly and unnecessarily, causes an injury to an animal or submits it to abuse, behaviour, labour or excessive work that is unbearable for its ethological characteristics...” This rule seems to impose a restricted interpretation of the already mentioned art. 2 (of the 'State-Regions Agreement for which we could conclude that there are animals, “wild animals”, whose use for any therapeutic or care therapy must always be considered as “unsustainable” a priori and apart from any firmly rooted traditions, on the basis of specific natural features. Therefore, the possibility to continue to sell as pets, and use in certain therapies, ferrets, gerbils and similar animals, as well as various types of reptiles such as iguanas, snakes, etc. would be debatable. There would also be some concern about the possibility of using dolphins.

The spread of the *Pet Therapy* opens, in short, a very wide space for ethical and legal reflection on the relationship between man and animal and on the meaning and limits of domestication: it would probably be appropriate to begin attempts to find a clear and precise dividing line between pets, animal companions, animals of affection, knowing that not always and not in all species the protection the characteristics of the animal and the protection of human health may be developed in the same way and reach the same forms of balance.

In light of this consideration the growing jurisprudential importance, concerning compensation for harm, the existential particularities and specificities of emotional relationships that develop with animals, must be kept in mind. This is a sign of a phenomenon that is no longer exclusively limited to the exclusively private sphere of property relations, but it takes on increasingly complex social implications for which a whole series of further legislative interventions have ensued. Law No. 281 of 14<sup>th</sup> August 1991 “Framework Law for pet animals and prevention of stray dogs”. The Legislative Decree of January 27<sup>th</sup> 1992, No. 116 regarding protection of animals used for experimental or other scientific purposes, and Law No. 413 of 12<sup>th</sup> October 1993, on conscientious objection to animal experimentation, to the extent that, as pointed out by the law of the Veneto Region, many of these therapies are still under study and in the experimental stage.

### THE INTERESTS OF SOCIETY AND THE PATIENT

The use of animals in activities related to human health and well-being seems to be an element of obvious interest if we consider the increasingly frequent legislative and regulatory interventions of certain regions. However, the lack of scientific data and perhaps the objective difficulty of its obtainment according to the canons of experimental medicine make the choice of health policy difficult. In fact, this choice can not ignore both the emer-

gence of some evidence that suggests possible positive prospects as well as the fact that only the diffusion and institutionalization of these practices will allow the acquisition of scientific data on their effectiveness, by setting the conditions to meet the needs of the sick in a targeted manner. The data would allow a better understanding of the uses of animals, allowing for an increase in their well-being.

The Institutions, therefore, have to consider a number of factors that are not easily correlated: the health and well-being of individual citizens, the health and well-being of animals, public health, the management allocation of resources, and the development of knowledge.

First and foremost, research protocols able to examine and compare all these factors would be highly welcome. Even assuming that these studies would give a positive result, in the sense of establishing the existence of objective benefits to health without any particular bias for animals, it should also be taken into account that this kind of therapy can be costly due to the large number of professionals required in the working group. The problem then comes down to the opportunity, faced with the increasing scarcity of financial resources, to allocate specific funds to *Pet Therapy*, etc. both in the form of reimbursement of the provided services by the National Health Service and also in the form of any other kind of incentive.

Even excluding the economic profile, a series of additional problems remain to be dealt with. Particular attention should be paid to the formation of informed consent, considering that these are widely practiced techniques, not only in our country, but they are not yet scientifically accredited and, in many cases, the decisions will be taken by parents or by whoever is legally responsible for a minor or a handicapped person.

Another problem concerns the structure of the team. It would be possible to reduce costs, relying on volunteers and organizing such practices on the basis of 'spontaneity' (with approximate, non-validated protocols that are not even in the process of being validated). The institutionalization of activities, with defined and validated protocols, and specific and recognized expertise, would result in a significant increase in expenditure. In the second case it would be easier to control the quality of the provided service, the guarantees of scientific correctness and the respect of animal well-being. Conversely, in the first case it is possible that the sphere of voluntarism - especially in a case like this where the benefits of such therapies are not yet certain - may guarantee the more experimental phase and diffusion.

Submitting the evaluation of protocols, especially if innovative, to independent Bioethics Committees, could be a solution to these problems.

## **A THERAPEUTIC ALLIANCE?**

### **Bioethical aspects of Pet Therapy**

The underlying bioethical presupposition of *Pet Therapy* is that between man and animal it is possible to establish a relationship modelled on that of interpersonal relations and therefore, as in every interaction, there is an exchange of feelings, affection, and emotions that mutually influence both subjects. From this stems the possibility of utilizing such an encounter in a therapeutic sense. This is, however, the challenge that *Pet*

*Therapy*, from a bioethical point of view, has to face: Is it possible to apply an interactive and communicative model to the interspecific relationship? If it is, under what conditions can this be done?

There is the need to develop a model that is respectful of the identity of both *partners* and that therefore takes utmost account of the element of *diversity* but also of inevitable *asymmetry*, in the relationship. A model, therefore, aimed at the protection of the dignity of both parties and that can also be practicable and satisfactory for all healthcare professionals.

To this purpose, we should, however, first clear the field of two objections that come from opposite sides: the animal rights activists, who are afraid that *Pet Therapy* reduces the animal to an object and consequently it is exploited and on the other hand traditional philosophers who are afraid that the animal will be raised to the status of a person, leading, therefore, to undue anthropomorphism.

The assumption on which *Pet Therapy* is based refers to a philosophical tradition that we could define as respect as opposed to that of *domination*, characterized by the overcoming of the vision of discontinuity between man and animal, to which the science of ethology has powerfully contributed.

The theory we propose to support is that *Pet Therapy* when successfully practiced is not exploitation, as argued by animal rights supporters, but it may even help to promote a *rehabilitation* of the figure of the animal. Similarly, *Pet Therapy* practiced properly does not result in undue anthropomorphism, according to the traditional philosophical objection, but it may even help to form a new 'culture of perception', in which animal diversity is recognized and accepted as a value and the <other> is maintained in his capacity as the subject.

In interspecific contemporary ethics, there is a wide range of approaches ranging from the theories of rights to utilitarianism, contractualism, and outlooks that focus on the issues of responsibility and care. Each of these perspectives present interesting elements that are worthy of in-depth study in relation to the different type of relationship with animals, traditionally distinguished as wild, pet, and livestock.

The recognition of the asymmetry of the human/animal relationship should lead to ethical conduct inspired by the paradigm of care - which involves a responsibility that does not propose the experience of reciprocity, as regards eminently weak subjects (see the NBC document "Animal well-being and human health").

As for the meaning of the animal as interlocutor, the communication between individuals of different species should foster an attitude of attention and respect for biodiversity. The human-animal relationship can promote ways of interaction that make us live this experience positively, as an opportunity for learning and enrichment.

Another characteristic element of interspecific communication seems to be its flexibility, its freedom from the constraints and rules typical of human relationships and, in particular, of verbal communication. This may allow freer expression of feelings and emotions, the spontaneous expression of anxieties and fears and thereby foster a better understanding of oneself. It has repeatedly been stressed that man does not feel judged by the animal interlocutor - and here the asymmetry turns out to be very functional - he is able to express himself without inhibition and release often unconscious tensions and fears.

In light of these general guidelines, bioethics must take into account the different modes of the human-animal relationship, particularly taking into account the variables that define

it and the factors that influence it (e.g. the type of animal chosen, the individual, his age, his sex, his medical condition, history, the living environment, the culture of origin, etc.) to prepare a series of strategies that make this relationship respectful of the identity of both partners, in order to optimize the possibilities of such an encounter.

Consider, to take only one example, the role that a culture of highly anthropocentric origin can have in such a relationship, oriented towards a rejection of an animal presence, that is identified with negativity, evil, and disorder or, conversely, a culture inspired by respect for the living world, that is tolerant and open to diversity, which sees in the animal a positive alterity, a companion or an essential reference point for man.

It is necessary to stress here the importance of an education to otherness precisely in order that the interspecific encounter does not become an instance of submission or appropriation nor should it be reduced to power play or trigger mechanisms of identification.

Certainly we come from a culture that has not sufficiently thematized *diversity*, especially as regards animals. The usual procedures have been those of reification (the diminishing of the animal as object, as machine) or those of anthropomorphism (the interpretation of the animal in human terms).

The rediscovery of the therapeutic role of animals – that seemed to have disappeared in the era of scientific medicine - can also be framed in the search for new models of medical bioethics, which refer to the paradigm of *Caring* and which give ample space to 'gentle' intervention, based on the interpersonal human/animal relationship in the treatment and prevention of disease. The shift in focus from the disease to the sick and from the sick to the person – perceived in his bio-psycho-historical entirety – can favour the study and the use of complementary therapies that attempt to provide a more integrated response to the needs of the sick and which, first and foremost, consider the disease not as an isolated event, but as a result of a combination of events related to biography, social environment and the individual's historical situation.

There is a strong appeal today to the humanization of medicine, the need to retrieve the essential ethical core of the medical profession. In the idea of 'therapeutic alliance' – a relationship based on trust – this refers to the willingness of the doctor to identify with the patient, his ability to listen and not just 'auscultate'.

In fact, the limiting of medical intervention to an objective examination, an exact diagnosis on a condition of the body or one of its parts and an eventual therapeutic prescription, may appear to be technically valid. It is, in fact, not only an insufficient response to the needs of the patient, but it constitutes an act that ignores the psycho-emotional basis of the state of health and illness. Such an insufficiency could result in reducing the actual patient from the suffering subject to the object of medical interest, with a limitation of the potential and effectiveness of the therapeutic relationship.

Conversely, a perception and non-reductive interpretation of the patient's wider needs and requests, favour a taking charge that is not limited purely to physical symptoms. It should be added that, in the area of 'malaise', small illnesses that have a social and psychological origin, the cultural and subjective way in which we live is apparent as a state of suffering that is defined as illness.

*Caring*, can however also be the most appropriate response even when faced with incurable and chronic diseases, for which there is no therapy or cure. Only a medicine that pursues as an objective not healing but the comprehensive well-being of incurable patients, can respond to their need to be listened to, protected and reassured.

In this context, the use of so-called gentle therapies, such as *Pet Therapy* can be in tune with the idea of a medicine of care (*Caring*) rather than healing.

If we can not expect animals to become 'healers' of our illnesses, what we might reasonably expect is that, thanks to their presence, and with the aid of appropriate conditions and strategies, it may be possible to establish a good relationship of care.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**ADOPTION FOR THE BIRTH OF CRYOPRESERVED AND RESIDUAL  
EMBRYOS OBTAINED BY MEDICALLY ASSISTED PROCREATION (MAP)**

18<sup>th</sup> of November 2005



## PRESENTATION

The *National Bioethics Committee* (NBC) expressed its opinion regarding *Medically Assisted Procreation* (MAP) a long time ago, in the 1994 document titled *NBC's Opinion on the Techniques of Medically Assisted Procreation*. It is a document in which all the doubts but also all the expectations raised by assisted procreation are discussed; an open text, *inconclusive* according to some of its critics, in which the most divergent opinions are presented to the reader in an essentially *aseptic* manner. Since then, the NBC has not tackled the issue again, as it had no reason to do so; there have not been truly new bioethical problems regarding this topic (except cloning reproduction, an issue to which the NBC has immediately dedicated its due attention). Also, the NBC has not found any reason to express its opinion again during the long years that have been necessary to the Italian Parliament to finally approve the first organic law on the matter, the Law No. 40/2004.

However, once this law was approved, the NBC immediately felt that one of its most significant provisions, which forbids the destruction of each single embryo produced by MAP, including those that are cryopreserved and abandoned, was significantly and in some way *incoherent*. This incoherence does not regard the stringent legal protection of embryonic life: this provision could be considered by some excessive and/or ethically questionable (not however by the person writing these lines), but without a doubt is not incoherent. The point, rather, is another; the law does not say anything about the future destiny of frozen and abandoned embryos, leaving us to assume at most that they should be preserved in their cryopreserved state until the moment of their natural extinction (a moment that, currently, science cannot predict).

We must therefore recognise that L.40 needs to be integrated on this point. If embryos are fully fledged human lives it is right to give them the chance to be born, even through that practice, for some objectively perturbing, that the NBC has called *Adoption for Birth* (AFB). The right to be born must prevail on any ethical and legal consideration against it, although they highlight the not small problems deriving from this solution.

The NBC started tackling the AFB issue since the November 2004 plenary meeting, due to a request by Prof. Luisella Battaglia, who committed the Committee, and in particular the working group already looking at issues of "Assisted Procreation", to reflect on the destiny of the so-called "supernumerary" embryos. In June 2005, the Committee decided to separate the issue of the AFB from that of the destiny of the embryos abandoned to scientific research: a topic close to ours, but conceptually different and on which the NBC has in any case decided to take position as soon as possible. The first draft of the document presented here was entrusted by the Committee to Dr. Carlo Casini; subsequently it was revised by me and further revised thanks to Prof. Lorenzo d'Avack's contribution and brought to the plenary meeting of the 18<sup>th</sup> of November 2005: in this occasion it was subjected to further revision work thanks particularly to interventions by Prof. Amato, Prof. Barni, Prof. Battaglia, Prof. Borgia, Prof. Caporale, Prof. Casini, Prof. Coghi, Prof. Dallapiccola, Prof. d'Avack, Prof. De Carli, Prof. Eusebi, Prof. Federspil, Prof. Fiori, Prof. Flamigni, Prof. Forleo, Prof. Garattini, Prof. Guidoni, Prof. Isidori, Prof. Manni, Prof. Marini, Prof. Mathieu, Prof. Neri, Prof. Scarpelli, Prof. Schiavone, Prof. Silvestrini and Prof. Umani Ronchi. Prof. Garaci and Pistella have asked to be represented, according to NBC regulations, respectively by Prof. Scaravelli and by Dr. Salberini. Prof. Flamigni, although he participated to the meeting, as we have just said, did not want to contribute to the work,

feeling that the overall formulation of the document is intrinsically incoherent and that in any case he cannot support it from a bioethical point of view. After ample discussion and after undergoing numerous amendments, the document was approved by all those present, with the only exception and vote against by Prof. Mauro Barni. Amongst the NBC members who did not participate to the meeting due to justifiable reasons, we must record the early approval of the bioethical substance of the document by Prof. Sergio Belardinelli, Prof. Paola Binetti, Prof. Laura Palazzani, Prof. Paola Ricci Sindoni.

The text of the document, approved by the NBC on the 18<sup>th</sup> of November 2005, is published with five personal remarks, some of which signed by more than one member. Some personal remarks are in total or partial disagreement, others however tend to better specify the reasons why the document deserves agreement. By reading these personal remarks we will be able to better appreciate the bioethical complexity of the issue and the sobriety characterising the text approved by the Committee.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## **ADOPTION FOR THE BIRTH OF CRYOPRESERVED AND RESIDUAL EMBRYOS OBTAINED BY MEDICALLY ASSISTED PROCREATION (MAP)**

1. The way in which extracorporeal MAP techniques have been applied until now in many countries in the world and also in Italy up to Law No. 40/2004 coming into force, determined the creation of a significant number of cryopreserved human embryos, for some of which the initial parental project is no longer possible, due to the refusal of the parents to bring the plan to fruition, or to the parents being untraceable – and in extreme cases, due to their being dead - or due to the mother being of an age, at which, objectively, it is no longer possible to avoid pregnancy risks. In addition, we recall attention to the fact that the current number of residual embryos, also after the approval of L. 40/2004, forbidding as a rule the cryopreservation process, can be increased, even though less so, by embryos cryopreserved due to circumstances beyond one's control, as they cannot be implanted in the woman during the same cycle and for which afterwards the parental project might no longer be possible (art. 14, subsection 3, Law No. 40/2004). The presence of these embryos, commonly called “abandoned”, “left-over”, “supernumerary” or “residual” (adjective, this last one, which will be adopted in these pages) is a relevant bioethical problem, because their paradoxical destiny, on first reflection, could only inevitably be that of those who, having been intentionally called to life, should die without ever being born.

2. The law in some countries includes the obligation, by the centres storing them, to destroy the residual cryopreserved embryos some years after their production. This solution highlights a further aspect of the bioethical issue raised here, because the destruction of these embryos happens by law, it becomes, namely, an administrative obligation, the justification of which is not explicitly clarified. Some stress the need to limit to a certain number of years the financial and organisational burden involved in maintaining them; others stress the risk of deterioration of the embryos due to their time in cryopreservation (this is, in any case, an argument that does not find any foundation in scientific literature, in which until today there is no evidence of loss of vitality in the embryos, even after many years in cryopreservation). In addition, those who have some bioethical doubts about some of the FIVET methods, observe that the elaboration of the techniques generating a large number of embryos and freezing a part on them – due to the hypothesis that the first or even following implantations in the uterus might not have a positive outcome -, namely, creating “spare” embryos for procreation purposes, implies in any case the previous approval of the hypothesis of abandoning them and therefore destroying them.

3. Another bioethical option, which has been largely accepted in the legislation of various countries, is that anticipating the possibility that residual embryos that have been definitely and without a doubt abandoned, and with their parents' consent, can be destined to scientific research, even when these practices require their destruction. Bioethicists took different positions with regards to this hypothesis. Some believe that, independently from the methods of procreation, from conception the embryo is an individual human life and consequently even the legitimate interests of scientific research cannot prevail on his/her “right to life”. Others, although they do not deny the human embryo protection and respect, believe instead that his/her abandonment can justify the use in research. Others believe that, where there is reasonable certainty that the embryo is unable to develop and

therefore is not suitable for implantation, the embryo's individual living cells can be used for research and therapy purposes<sup>118</sup>. The bioethical value of these different solutions will not be discussed in this document.

4. An adequate and reasonable bioethical solution must be measured against the complex problem of the status of the human embryo. With regards to this, we recall the 12/7/96 opinion by the Committee *Identity and Status of the Human Embryo*, where, even when there are differences of opinion, there is a common basis that considers the embryo a human life, deserving respect and protection from the beginning. This recognition is broadly confirmed in our legislation if we look at the way in which the Italian Constitutional Court interpreted the legalisation of abortion (*Law No. 194/78*), basing it on a situation of need and not on the negation of the human identity of the conceived (Cort. Cost. No. 27/1975 and stressed in the more recent decision by the Court, No. 35/97). It follows that, if the embryo must be considered a human life, to which the law must guarantee the most favourable conditions for development and birth, we must exclude behaviours that can be deemed discriminatory if referred to human individuals. The NBC moves from these premises, stressed by significant international and especially European documents, to believe that the embryo must be protected and safeguarded primarily to reach birth (which is the primary aim compared to others) and that therefore it is necessary to find legal tools suitable to achieve this possibility. This is in line with the abovementioned document by the NBC, *Identity and Status of the Human Embryo*, which had already taken into consideration the issue of cryopreserved abandoned embryos, highlighting the need to guarantee their chance of life and development and suggesting the solution of making them available to other couples and ensuring their implantation and birth. This solution is still today widely accepted and taken on board by the NBC, which refers to it with the expression *Adoption for Birth* (AFB).

5. The expression used has the merit, recalling the legitimising adoption and its discipline, to put first the values of solidarity, generosity and responsibility and irrevocability of the act that should characterise the behaviour of the parents or parent determined to give birth to a residual and abandoned embryo. However, the NBC recalls attention on the fact that, from an ethical and legal point of view, the two types of adoption present also profound differences. Most of all, the adopted minor has already suffered the trauma of abandonment and detachment from his/her natural family, being entrusted, most of the times, to a public institution or structure. A child who is already perfectly capable of suffering *now* both physically and psychologically. A trauma that must be healed – and it not always is – with love from the *new family*. This is the reason why adoption procedures follow strict legal protocols, full of verifications of the suitability of the adoptive parents in order to guarantee the correct psychological and physical development of the minor. With regards to the embryo's situation, there is an objective reduction of the risk of trauma, because we are not in the circumstances described above, but the embryo will be given birth by the uterus of the mother who wants him/her. The adopted child can say to have lived in the mother's *love*; the fact that an embryo is given birth means that the child will be able to say that she/he lived in the mother's *love* as well as *womb*. Not a small difference, also considering that con-

---

<sup>118</sup> The hypothesis of using embryos in research is in any case formally seen as illicit in Law No. 40/2004.

tinental legal systems base maternity on the biological fact of gestation and giving birth and that the science of child development believes that the growth in the maternal womb is very important for the personality of the future child. And from the maternal point of view, adoption for birth also meets a woman's profound motivation, which is to live the experience of pregnancy and birth, making the mother-child symbiosis a part of life that is rich of relevant and unique physical and psychological interrelations.

Therefore, the NBC is fully aware of the differences between this kind of procreation and that of the adoption of a child who has already been born, but it chooses to use the already mentioned expression *Adoption for Birth* (AFB) in order to better understand the spirit of solidarity and generosity that moves this kind of procreation, recommending that the legislator translates this solution in legal terms without giving the child a *ius singulare*, rules thought about for other situations and that necessarily could not neglect and underestimate the difficulties of the original family situation.

6. It seems right, in any case, to check the bioethical validity of the proposal, examining some criticisms that could be directed at it.

6.1. The most frequent is that which highlights the risk of indirectly legitimising heterologous MAP through AFB, a practice that Law No.40/2004 has explicitly declared illegal. This objection obviously does not touch those who believe that this type of procreation is morally justifiable. To those who believe it is morally unacceptable, we must stress that there is a considerable formal difference, bioethically consistent, between MAP and AFB.

In fact, whilst in heterologous MAP it is the fecundation that happens with the (genetic) contribution of a person external to the couple who wants to conceive, in AFB the intervention of the external person does not affect the fecundation, but it allows the continuation of the development of what happened with the fecundation. Therefore, it is a very early and involved external intervention, as, unlike post-natal adoption, it implies not only having the commitments of love and financial support towards the adopted, but also the biological availability of the woman who allows, through her body, the adopted embryo to reach birth: but, in any case, it is an intervention that does not affect the procreation project that led to the fecundation.

We also cannot talk about an overlap of AFB and surrogacy; if in fact in both hypotheses the pregnancy is carried out by a woman different from that whose oocyte has been fecundated, in AFB the woman carried out the pregnancy to have a maternal role and without her role being planned from the act of conception. The individual intention of those accessing these practices is also profoundly different: those who want to access heterologous MAP move primarily from the desire to have in any case a biological child; those ready to carry out AFB are rather moved by the desire to avoid for an embryonic human life to be frozen for an indeterminate time.

This difference can be denied by those who think that even just the phase of implantation of the embryos in the uterus of a woman, once fecundation has already happened, is wrong in itself, regardless of the aims and intentions of those who carry it out. Those who declare – even amongst those who have moral reservations towards MAP – the bioethical plausibility of AFB move instead from the premise that the defrosting of the embryo and his/her implantation in the uterus of a woman different from that who requested the fecundation of the oocyte, are abundantly justified by the fact that only in this way existing

embryos (otherwise destined to being frozen for an indeterminate time or, even worse, destroyed) can reach birth.

6.2. According to commonly accepted data, a percentage of about 30-35% of cryopreserved embryos dies in part when defrosted, in part is not biologically suitable for implantation. Therefore, some criticise AFB because it would expose residual embryos, frozen but alive, to the risk of death or not being used, in any case, for procreative purposes. We can answer this objection in two ways: a) applying the dual effect theory, that is, observing that the intention of those defrosting an embryo to give him/her a chance at AFB is evidently aimed at his/her birth and not death, although the possibility of failure or of the lack of realisation of it can be foreseen, as an unintentional effect of the procedure; b) observing that the freezing and the following defrosting are still provided as legitimate – although in exceptional cases – by Law No. 40/2004: if the argument was valid, we should paradoxically deny a woman's desire – impeded by an immediate implantation of the embryo – to have a subsequent implantation, thanks to the defrosting of her embryo frozen in a state of need and urgency.

6.3. According to a further suggestion, the AFB would be unacceptable, because it would cause a sort of therapeutic persistence towards the embryos. This could suggest the legitimacy of “letting the embryos die” after their defrosting, without recurring to their implantation into the uterus. But this implantation, which is the only way to allow the conceived to be born, certainly cannot be considered therapeutic persistence, unless it involves the use of disproportionate methods to pursue a life or, even better, to simulate a continuation of life that is already exhausted or in any case condemned to end in a very short time. Instead, nothing is more proportionate for the conceived than a uterus, the only “residence” that offers him/her the chance to survive and then be born.

6.4. It is not useful to observe that AFB will not in any case be able to allow a relevant number of embryos to be born, both for what has been said in paragraph 6.2, and for the probability of few AFB requests. In fact, we can easily answer that the chance of allowing even just one embryo to be born justifies the recourse to AFB and its aim is certainly not to increase the population, but to maximise the respect towards pre-natal human life.

7. We can, therefore, conclude by answering positively the bioethical question posed: it is ethically acceptable to suggest AFB to solve, at least in part, the bioethical problem of residual embryos, that is, definitely deprived of a parental project; and it is therefore, consequently just as ethically acceptable, and instead appropriate, to widely promote AFB and support couples or women who might request it.

In fact, if the higher value to justify AFB must be considered the *birth*, so that the alternative between being born and not being born must see the first alternative prevail on the second, it seems licit to the NBC that many of the limitations provided by the current law when choosing MAP or adoption should not be applied to this procedure. In other words, it is difficult to believe that the reasons for the prohibitions given by ethics and by the law with regards to the situations mentioned above, even though they can be understood, have the same value when the aim is to bring to life embryos who are formed and abandoned. Therefore, the NBC does not exclude the possibility of an *adoption for the monoparental birth* requested by the woman, only when the presence of both parents is not possible.

8. From a bioethical point of view it is appropriate to give further indications, which are implicit in the considerations already made:

8.1. the embryos' abandonment must be ascertained on the basis of rigorous criteria fixed by law;

8.2. the law should rigorously prevent any possibility of commercialisation or profit which could derive from AFB practices;

8.3. the identification of residual embryos to be destined to AFB should be carried out in line with the law with private procedures; privacy criteria should, also, be guaranteed to the embryo's biological parents and to the new parents accessing AFB;

8.4. in the eventual (even if not probable) hypothesis that the parents are against AFB, expressed when declaring their intentional renunciation to any future parental project, the abandonment should be equally recognised and consequently the "adoption" should be allowed. In fact, the human embryo cannot be considered as a property, which can be freely disposed of by the parents *against his/her interest*. It is for the same reason that an eventual request by the parents to proceed to the destruction of the embryo created instead of having him/her declared abandoned could not be accepted;

8.5. people who ask for the adoption should receive exhaustive information about the MAP medical procedure they intend to undergo, but especially about the legal effects of their decision;

8.6. once the implantation into the uterus has been achieved, in the case of an eventual birth, the child should have the full legal status of a legitimate or natural son/daughter.

9. In conclusion, the NBC formulates the following recommendations:

9.1. introducing in the regulation norms stating the legitimacy of AFB and its methods in favour of cryopreserved and objectively abandoned embryos;

9.2. that this abandonment is legally ascertained and qualified with rigorous criteria;

9.3. that the law formulates appropriate criteria for the identification of the couples or in any case of the women offering themselves to AFB;

9.4. that AFB practice is guaranteed against any form of commercialisation or profit;

9.5. that the child born from AFB has the same legal status given in general for born by MAP.

## PERSONAL REMARKS

1) Personal remark by Prof. Carlo Casini, Prof. Salvatore Amato, Prof. Sergio Belardinelli, Prof. Paola Binetti, Prof. Luisa Borgia, Prof. Bruno Dallapiccola, Prof. Giuseppe Del Barone, Prof. Luciano Eusebi, Prof. Giovanni Federspil, Prof. Angelo Fiori, Prof. Luca Marini, Prof. Laura Palazzani, Prof. Vittorio Possenti, Prof. Paola Ricci Sindoni

We agree with the document “Adoption for Birth” (AFB) of the cryopreserved and residual embryos deriving from MAP, but we intervene to reinforce the motivation and integrate it with some logical deductions.

Very rightly, in the research of the bioethical foundation of AFB the document at n. 4 confirms the recognition of the “human identity of the conceived” and the consequent “value of birth, primary compared to other values”. More precisely, the recalled opinion on the “Identity and Status of the Human Embryo” of the 12.07.96 concluded as follows: *“The Committee unanimously arrived at recognising the moral duty to treat the human embryo, since conception, according to the same criteria of respect and protection which must be adopted towards human beings, to whom we commonly attribute the characteristic of person”*. More recently, on the 11.4.03, the NBC declared “supernumerary” embryos “fully fledged human lives” and stated *“the moral duty to always respect them and protect them in their right to life independently from the methods with which they have been procreated and independently from the fact that some of them can be qualified, with a questionable expression because it is devoid of ontological meaning, supernumerary”*. From this premise logically derives the desirability for AFB. The use of the word “adoption”, despite the difference in the adoption of minors already been born highlighted in n. 5 of the document, states that AFB is the extreme remedy for the abandonment of the embryo: the procedure is aimed at saving the life of the conceived and offer him/her a family rather than satisfy the adults’ desire to have a child.

The consequence of the bioethical desirability for AFB is the bioethical non-desirability of techniques that generate a number of embryos higher than that immediately implantable in the maternal womb, because the supernumerary ones have an insecure destiny from the beginning. The systematic freezing, as ordinary practice rather than as exceptional remedy in the case of difficulties in the implantation into the uterus previously unforeseen (in the cases described in art. 14/3 of Law No. 40/2004 and also considered in the relative guidelines) implies the previous acceptance of their death because of the defrosting or of their abandonment and consequent destruction. It is not reasonable to have remedies for something bad if we don’t try to avoid it in the first place.

Actually, the bioethical problem of the destiny of “abandoned” embryos in Italy only involves those created before the coming into force of Law No. 40/2004. In fact, the current law forbids the creation of “spare” embryos. Therefore, AFB is a transient and exceptional remedy. True is that, even though Law 40/2004 is in force, “residual” embryos can be created, in two hypothesis: that already recalled in art. 14/3 and in the case of violation of the said law. However, these are still exceptional hypothesis, in which AFB preserves its character of temporary remedy in view of the protection of human life. Only the nature of exceptional and/or transient intervention makes AFB bioethically acceptable. The general prohibition to produce supernumerary embryos and freeze them is its logical and ethical prem-

ise. If the supernumerary production of embryos was allowed, AFB would become the permanent surreptitious tool not to save the life of the conceived, but to overcome the eventual prohibition of heterologous procreation and to violate the limitations eventually established to access it. In fact, the nature of extreme “remedy” of AFB allows us to believe that the directives limiting the access to MAP are not insurmountable.

Therefore, we share also the statement found at the end of n. 7 of the document discussed here, according to which we must accept “the possibility of an *adoption for the monoparental birth* requested by the woman, only when the presence of both parents is not possible”. In fact, this is a rule deduced from the regulations on the adoption of minors: we must offer the child the best, that is, female and male parents consolidated by a stable bond (that the adoption law requires to be marriage) but, in the exceptional case in which an adoptable minor does not find a couple ready to welcome him/her, that limit is not valid anymore, in the higher interest of the child. In the embryo’s case, the interest of the conceived to develop and grow in a stable family with a father and a mother is evident, but it is just as evident that his/her right to life has even greater weight. We must however strongly stress the condition that there should be no couple available to welcome the conceived and the analogy with the adoption of minors suggests the preference for married couples compared to unmarried ones.

## **2) Personal remark by Prof. Luciano Eusebi**

Prof. Eusebi observes, with regards to point 7 of the document, that we should consider the hypothesis, in analogy to the rules in force for minors, in which the request of AFB comes from a woman who has a family tie with the woman who (because of death or other causes) could not carry on with the implantation of the embryos.

## **3) Personal remark by Prof. Carlo Flamigni**

The document on the “adoption” of frozen and abandoned embryos cannot be agreed upon for different reasons.

First of all, it dogmatically and “definitively” states that the embryo is a person, individual, “one of us”, a concept that cannot certainly be considered unique or shared.

The implantation into the uterus of these embryos is therefore foreseen only in order to save the poor “embryo person”; those who would have taken into consideration a donation of abandoned embryos, for the benefit of couples who cannot have children, were in effect stopped from participating to the discussion.

If we exclude that the embryo is a person, it is no longer possible to talk about adoption, we must use different terms, like “donation”.

From the beginning of the plenary meeting it was clear that changing this word, “adoption”, would have involved the withdrawal of the document. It is evident that, under these conditions, it made no sense participating in the discussion.

With regards to the second point, I simply quote the recent work by Stefano Rodotà, in the part in which he states that the woman, in this way “is considered only a container, to be used to achieve an aim that is socially relevant” and that, as a consequence, “the

woman's body is considered a public place that can be owned by the legislator, who regulates it as he pleases". In this way the opportunity offered, for example to a single woman, is paid by damaging her dignity and by blackmail.

Therefore, not having taken part to the discussion, I could not highlight certain technical shortcomings in the document.

Only as an example, my personal experience on embryo donation taught me that the difficulties are often insurmountable. Many couples who abandon their embryos do not want to be involved with them anymore, refuse to come back to the centres and do not accept to carry out checks; without their collaboration it is impossible to give acceptable guarantee about the biological conditions of the embryos and on the lack of risks for the women who are available for implantation.

Finally, I believe that it is indispensable to express a critical judgement on the NBC's choices, which for some time have excluded any possible form of mediation in the drafting of the documents.

To entrust the expression of a contradictory opinion to personal remarks like this, at least according to my personal point of view, represents a mortification of the positions of the minority: it should be clear by now that no-one reads the personal remarks and that the documents of the majority end up expressing, for almost all readers, the only position of the Committee.

#### **4) Personal remark by Prof. Luisella Battaglia, Prof. Cinzia Caporale, Prof. Isabella Coghi, Prof. Silvio Garattini, Prof. Laura Guidoni, Prof. Demetrio Neri, Prof. Alberto Piazza, Prof. Marco Scarpelli, Prof. Michele Schiavone**

In sharing the recommendation (paragraph 9) and part of the content (paragraphs 1, 2 and 4) of the document *Adoption for the birth of cryopreserved and residual embryos obtained by medically assisted procreation (MAP)*, approved by the National Bioethics Committee in the plenary meeting of the 18<sup>th</sup> of November 2005, we believe that it is appropriate to highlight what follows, for personal reasons:

1. With regards to paragraph 5, we feel that the arguments in support of the fact that legitimate adoption and the so-called *adoption for birth* (AFB) are profoundly different, can be easily agreed upon and are very important. For these differences, moreover, the NBC recommends the legislator to formulate regulations that are different and inspired by other reflections. In addition, we highlight how "to put first the values of solidarity, generosity and responsibility and irrevocability of the act", which according to the document characterises the behaviour of the "parents or parent determined to give birth to a residual and abandoned embryo", could be attributed, in a totally equivalent manner, to those who donate residual embryos for birth, as they act with the same spirit of solidarity, generosity and responsibility, and irrevocably. For these reasons we disagree with the NBC's decision to use the expression "adoption for birth" and we agree that the practice could be better and more appropriately described with the expression "donation for birth".

2. With regards to paragraph 6 (6.1), as well as agreeing with those who believe that heterologous MAP is morally justifiable, we believe weak the arguments according to which there is a "considerable *formal* difference, bioethically consistent, between MAP and AFB". In fact it is true that in the donation for birth "the intervention of the external per-

son does not affect the fecundation” and that “it is an intervention that does not affect the procreation project that led to the fecundation”. However, bioethical consistency cannot be found exclusively in formal aspects, but it must take into account the considerable fact that the practice’s outcome in effect is a double heterologous MAP, considered – in this as in other cases – morally justifiable. And indeed, along with the chance to be born given to residual embryos, it is the possibility of satisfying the “individual intention” to “have in any case a biological child” (although not genetic) to convince the writer to adhere to the document.

3. With regards to paragraph 7, we stress that the ethical acceptability of donation for birth does not end in the resolution “at least in part, the bioethical problem of residual embryos, that is, definitely deprived of a parental project”, but that this acceptability is just as well justified by the chances that the practice would open – as Law 40/2004 is in force –, for those requesting to have a “biological” child through pregnancy.

4. With regards to paragraph 8 (8.4), considering the difference of opinion in society about the ontological status of the human embryo, and in any case believing it is not appropriate for the State to interfere in very private and morally onerous issues like the donation for birth of embryos generated by those who have the right to take this decision, we believe that the donation for birth should remain confined to the free availability of the parents, expressed by explicit and informed consent. This would highlight the sphere of solidarity and generosity implicit in the choice to donate and the sense of responsibility inherent in the act – responsibility that however can express itself only if accompanied by the freedom of choice –, and it would avoid raising a dangerous conflict between the Authority and the citizens, a conflict that could probably lead to attempts of evasion and secrecy.

5. With regards to paragraph 3, although we accept the decision to not tackle in the document the issue of the eventual donation for research purposes, we believe that this alternative is strictly and intrinsically linked to the donation for birth and that it is a practice that deserves the same moral consideration. We therefore hope to discuss it as soon as possible.

6. With regards to the recommendations, which we agree with, we stress the need for the legislator to integrate them with precise predictions about the security and the appropriate clinical guarantees for those who ask for the donation of embryos for birth.

##### **5) Personal remark by Prof. Adriano Bompiani, Prof. Maria Luisa Di Pietro, Prof. Elio Sgreccia**

“With this personal remark we express our *abstention from vote* because we believe that the debate on the issue of the AFB has not yet given sufficient elements for an adequate ethical evaluation. In addition, although it has the best intentions, which coincides with our vision and our commitment, the solution presented by the document approved in the plenary meeting appears theoretical and imperfect and it does not fit in a context of real protection of life of all conceived embryos”.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**ASSISTANCE TO PREGNANT WOMEN  
AND POST-PARTUM DEPRESSION**

16<sup>th</sup> of December 2005



## PRESENTATION

In the early summer of the year 2002, in the wake of the dramatic news stories, which had deeply perturbed Italian public opinion, the *National Bioethics Committee* decided to deal with and examine in depth the complex issue of *post-partum* depression, in order to remain faithful to the commitment to continue to promote two bioethical principles that have always been precious to the Committee: namely, recognition of the equal importance of mental health and physical health (this principle had been recognized and shared by the Committee from its very first documents) and the very special bioethical attention that is to be given to women in all the circumstances in which, unfortunately, (due to physical, psychological or social reasons) she may manifest her identity as a *weak subject*. Inspiration regarding reflection on the issue was provided by Prof. Renata Gaddini, who was unanimously asked to develop the first guidelines on this topic. Moreover, at the plenary session on September 19th 2002, there was a lively discussion concerning the advisability of prefacing the discussion on *post-partum* depression with – what many members of the Committee considered as equally important and some even logically considered as a priority – a reflection on *assistance to pregnant women*, as being the central bioethical theme, also in view of an appropriate *prevention* of depression. It was therefore decided on in that plenary session to give the topic and the consequent task of the Committee the title that it has definitively adopted since then and Professor Luciano Eusebi - one of the most lucid supporters of the opportunity to join together the reflection on assistance to pregnant women and that on *post-partum* depression - was invited, together with Professor Gaddini, to preside over the newly established working group. Profs. Battaglia, Binetti, Coghi, Forleo, Flaminghi, immediately expressed their desire to participate in the work of the group; subsequently, they were joined by other colleagues, namely, Profs. Bompiani, Borgia, Caporale, Casini, Di Pietro, Guidoni, Palazzani.

The working group held its first meeting November 21<sup>st</sup> 2002, after a subsequent meeting in December of that year, it met five times in 2003, three times in 2004 and four more times in 2005. The group meetings have always been very intense and lively, also due to the fact that there were, from the very beginning, two different lines of reasoning on development of the topic within the group: one that interpreted the issue of assistance to pregnant women as to be connected *exclusively* to the risk of *post-partum* depression, and the other that aimed instead at extending in a complete way the subject of assistance to pregnant women, even in terms of prevention of abortion (according to the explicit provisions of Article. 5 of Law 194 / 1978) and therefore independently from strictly limiting this subject to depression. Very authoritative opinions in the group came forward, for instance, that of Professor Carlo Flamigni, who was contrary to the second option and this stance was largely shared by Prof Gaddini herself. However this line of reasoning remained a minority view within the working group, as indeed it remained a minority when it was repropounded by the writer in the plenary session, which instead confirmed with an overwhelming majority the opportunity to hold together the “two souls” of the document, provided, however, that they were examined in two distinct sections, coordinated among themselves, but also easily isolated from each other.

All the members of the group collaborated in the drawing up of the draft document, Prof. Eusebi revised it several times, demonstrating his great willingness and patience; Prof. Gaddini prepared for publication the pages that are of particular psychological and

psychoanalytical importance; Prof. Coghi effectively revised and supplemented the document, particularly as regards the second part; our special gratitude goes to Prof. Cinzia Caporale, who worked hard to obtain as much convergence as *possible* on the text: proof of the success of her work is given by the very small number of Committee members who could not identify with the pages we are now taking to press.

The draft document prepared by the working group was received by the Committee which met in plenary session on the 15<sup>th</sup> of July 2005. It took another five sessions (16<sup>th</sup> of September, 30<sup>th</sup> of September, 21<sup>st</sup> of October 18<sup>th</sup> of November and 16<sup>th</sup> of December) to complete in-depth discuss –and in some points to radically revise - the draft prepared by the working group. A member of the Committee, Professor Carlo Flamigni, while participating in four of the six plenary sessions dedicated to the subject (more precisely to that the 15<sup>th</sup> of July, 30<sup>th</sup> of September, 21<sup>st</sup> of October and 18<sup>th</sup> of November 2005), stated his abstention from work on this subject, as he did not agree with the structural layout of the document, [his presence (documented in the minutes) is hereby officially confirmed, seeing as unfortunately a major daily newspaper published a completely unfounded statement, according to which, Prof. Flamigni *had not been informed* or even *notified of what was on the work agenda* of the Committee]; similar doubts were also expressed more than once even by Prof. Mauro Barni.

At the session of the 21<sup>st</sup> of October 2005 the Committee approved the first part of the document. At the session of the 16<sup>th</sup> of December 2005, the Committee also approved the second part of the document and carried out a further vote on the document as a whole. Professors. Forleo, Garattini and Schiavone abstained in the voting. Prof. Mauro Barni voted against.

The writer hopes, disagreements aside, which are objectively deemed marginal, that this work evinces the high commitment to bioethics that distinguishes the NBC.

*President of the Italian National Bioethics Committee*  
*Prof. Francesco D'Agostino*

## INTRODUCTION

1. In a previous document entitled “Pregnancy and childbirth from the bioethical standpoint,” the NBC highlighted the bioethical issues related to such *vital states* as mother and child, considering them not only worth of the protection relating to health and life, but also of appropriate protection with regard to the psychological and social aspects.

On this basis, the NBC intends, to consider, through this text, the assistance requirements in favor of women in reference to - within the framework of existing legislation - the stages of pregnancy and the *post-partum* stage, emphasizing the bioethical significance involved, in relation to such requirements, in the concreteness of the social and institutional response: that is, even in light of the renewed social interest, perceived for similar stages of life and their relative problems<sup>119</sup>.

Particular attention, even on the invitation of the Minister of Health, is dedicated to the subject of mental illness that can occur in the mother, sometimes markedly, during the puerperium, through events ranging from mood changes, to the *blues*, post-partum depression, as far as puerperal psychosis. These are events which, because of the peculiarities of the bond that develops between mother and child through pregnancy, can also have a direct fallout on the life of the latter, as well as, serious tensions as regards the interaction between mother and newborn.

The unitarian approach to the multiple profiles which, for a woman, may be adopted by the assistance linked to the sequence-pregnancy-childbirth-puerperium is proposed therefore to encourage deeper reflection on the overall significance of such a condition – unique in its characteristics – on a woman’s life as well as on each human being, so as to help protect it from possible traumatic consequences.

2. Pregnancy constitutes one of the most challenging tests for a woman, given the biological commitment and psychic elaboration that is involved in the event, despite its being confined within defined chronological limits. It also constitutes a test as regards the couple’s life project, as its natural maturational evolution.

It is an event which, although it occurs within a precise time, starts from very far off, summing up in itself the incidence of various components, such as the two partners’ families of origin, their biological and psychological history, the socio-cultural environment in which they grew up: this event, therefore, takes on a particular complexity and uniqueness, that conduct to many possible fragile points.

Everything in pregnancy occurs through visible changes, not comparable in scope, to those that characterize other periods of transition in a female’s life, such as, for example, adolescence and menopause, which unfold over a longer period of time. From a biological point of view the body becomes a laboratory that is activated in an exceptional way to ensure the development of new individual, to carry out a series of adjustments to new needs, to create, among other things, the physical space needed for pregnancy itself, through an extremely important transformation of the body.

This intense biological work is matched by a very challenging psychic mobilization, that

---

<sup>119</sup> Consider, among other things, how our country is representative in Europe, of the lowest rates of birth and for the most advanced average age (30 years) at first birth.

has to face up to the new reality, but also deal with the reappearance of past conflicts, in a situation of increased permeability between the somatic sphere and the mind, with reverberations and mutual interference between these levels.

The personal structure of the woman is therefore involved at all levels in the experience of pregnancy: on a biological and physical and physiological level, on a psychological and psychodynamic level, but also on a relational and spiritual one.

Pregnancy, in fact, affects all of the relationships experienced by the mother: on the one she has with itself and with her partner, but also on those relating to family, friendships, work; and what is more, above all, it affects the relationship with the child that the mother has *inside*, and not just *in front of* her: the - only - case in which an individual contains within itself another individual; therefore, it is a condition worthy of extra-special attention and support from society, even as the prototype of every intimate relationship or of care.

Pregnancy, due to these aspects, directs to what *goes beyond* sight, touch, and emotional feeling, that is to say, a reality (which could be defined as *mysterical*) that can not be fully possessed, confined or dominated.

Approaching pregnancy, therefore, requires a global approach that takes into account as much as possible the different aspects at stake in order to be able to identify the area for “assistance to the woman” that will experience, is experiencing or has just experienced pregnancy.

Therefore, pregnancy and along with it the puerperium and lactation constitute a sequence of events that are from their very beginning biological, psychological, and relational. Now, while the biological events have for the most part a predictable and relatively homogeneous sequence, psychological and relational events are part of the existential vicissitudes of the person involved, and take shape in this way according to very extensive variability.

In this context, it is usual to consider pregnancy, especially the first pregnancy and pregnancy in its early stages, as a moment of crisis, to refer to the collective changes that occur in conjunction with some nodal events of life. Under the influence of biological and psychological facts that are themselves complementary and interactive, during pregnancy, substantial transformations occur as regards the factors structuring the organization of personality. Pregnancy, therefore, is a critical stage of life, in which psychological development is called on, to some extent, to change direction, which implies a sort of recovery of individual growth: it is, consequently, a phase rich in incalculable evolutionary potential, but which at the same time is open to risks that should not be underestimated.

It is hoped that due psychological attention is also given to these changes, to avoid only hearing about clinically manifest psychiatric disorders and disorders which have already caused serious consequences.

When certain characteristics of personality are present, they can in fact determine such imbalances as regards pregnancy that the above-mentioned crisis profiles take on psychopathological aspects, sometimes with frankly psychotic outcomes, as far as the configurability of so-called puerperal psychosis.

Faced with the need to prevent such phenomena there does not, however, seem to be any benefit, from the tendency which sometimes assumes the contours of a genuine cultural solicitation, towards an exclusively medical approach to pregnancy and motherhood. A similar reductionist perspective, on the other hand, impoverishes the very experience of motherhood and, thus, the woman experiencing it. Even the language betrays this way of

thinking, not surprisingly, there is more reference to pregnancy than there is to maternity, to diagnostic protocols to be followed in a binding iter rather than human growth related to, and so on.

There is the tendency to ignore, in this way, the psychological support of the mother and the couple during pregnancy, limiting it only to cases in which the failure now appear obvious.

3. From these premises, the NBC has elaborated two distinct reflections, proposed later in the document: one refers to the assistance to which every woman has a right to during pregnancy, based on an analysis of the problems emerging in the different stages of pregnancy and the training of the young in parenthood, and the other is oriented to analyze, on the basis of a more specific psychological approach, the reasons, the prospects for prevention and treatment options of the various *post-partum* diseases.

## ASSISTANCE TO PREGNANT WOMEN

1. The issues related to early stages of pregnancy - The start of pregnancy for the woman opens a time of great emotional tension: on the psychodynamic level it includes processes of maturation towards the achievement of the new role, which recreates the experience of relationship with her mother and causes a re-elaboration, and regression processes, because each new reality causes anxiety and induces to seek reassurance in the way experienced in the past.

The first few weeks are often marked by ambivalent feelings of satisfaction with the child's existence, but also of fear of it, granted that the child imposes itself through the laws of its growth. In this respect, the ambivalence can result in such a widespread malaise as to be considered physiological

During pregnancy, similar ambivalence evolves more clearly with the recognition of the child, giving rise to the assumption of the maternal role. Not always, however, without difficulty: difficulties which would benefit from the availability of psychological support, which should eventually be accessible even to the father.

The stage, under examination, of pregnancy can be described within some time limits and certain generally recognized characteristics:

- a) that it begins at the moment of realization of awareness of pregnancy and, therefore, motherhood taking place;
- b) the existence of an intrapsychic conflict – related to having to make room in the body, mind, and in one's life for a child that exists, is growing, and imposes its own pace, needs, and the laws of its development – together with instances of acceptance, always present in the inner structure of female personality, and instances, found in every individual, of non-acceptance and immediate self-affirmation;
- c) its being characterized, therefore, as a phase of transition from ambivalence to inner acceptance of pregnancy, which in this way, psychologically, is taken up by the woman: through the organizing of the mother-child relationship in the coordination of respective identity and needs, the strengthening or the structuring of the couple's relationship faced with the reality of the child, the course of affirmation of her role by the mother herself, accompanied by the recognition of that role by society.

In the case of obstacles and / or emotional difficulties, assistance to the woman during the internalization of pregnancy, therefore, assume the contours of support to the natural evolution.

The problem that involves the voluntary interruption of pregnancy should also be considered in this framework, its ability (de facto or within legally defined limits) changes in many cases the basic psychological dynamics related to the first stage of gestation: for many women, as seems broadly widespread, this stage, is, in fact, consequently to be seen as the time in which willingness or unwillingness to continue the pregnancy is decided.

We find ourselves faced with different aspects of the first stage under review, which should be reflected in the corresponding forms of assistance to the woman.

It follows that material and psychological assistance, empathetic expression of a willingness to support intended to promote a calm approach to gestation, will have to operate for the benefit of every woman who is pregnant, and should not be limited only to situations, or the period of time, where the woman has already been placed in a perspective for its continuation.

It therefore seems necessary to reflect on the activities of counsellors, social workers, hospital obstetric and gynecological services and, in general, physicians who encounter the woman when she realizes she is pregnant. The establishment of the psychological interview and the interview for assistance can not neglect to emphasize the value of *favourable reception* (for the woman, for her child, for the father, for society), showing a positive stance to it.

2. Attention to difficulties – Particular attention should be devoted to analyzing and contrasting the many difficulties that today often seem to hinder the desire to become pregnant, or the opportunity to live the experience in a serene way.

These are among the many issues that seem significant:

- a) beyond the situations of conflict, is the transition itself from being a “couple” to being a “parental couple” and “family” which is often now seen as problematic: in many cases the individuals in the relationship appear to limit this horizon, at least for a long period, to being only a couple, showing poor motivation to identifying with the parental aspect;
- b) to act as people who contribute to the building of a civil society in the same roles that are accessible to men is an arduous experience for many women and they however, at some time, find fulfillment in motherhood as a potential expression typical of their identity;
- c) there comes into play, as well as the existential conditions of women, the difficulties of daily life that according to the model characterize, in our time, social relations (economic difficulties, concerning the preservation of a certain standard of living, work, management of schedules and time in general, lack of family support services or sufficiently numerous support services that are sufficiently available to respond to actual needs);
- d) the aspect of competition takes on a role that can not be overlooked, in an age group that is the most important for professional inclusion, also, to be considered are the problems relating to the guarantee for maintaining employment; nor can one ignore areas of circumvention of the very rules to ensure the freedom of workers to undertake a pregnancy.

In this framework, however, it turns out to be important for a positive attitude to preg-

nancy to help the woman's development of a mental space for the child, to open up to the possibility to take an active role towards the prospect of pregnancy or to an ongoing pregnancy and the associated imagined plans: a space which is limited, especially, by conflicts with the partner, the family of origin or with personal life projects, by not enough support for *single* mothers, etc.. (whereas constraints arising from practical situations of an economic or logistical nature appear to have a weaker influence).

The need for special training for gynecologists and health professionals, to enable them to understand the various ways in which women face the prospect or reality of a pregnancy emerges from all this. Similar training should be oriented to detecting the possible conflicts with regard to pregnancy, giving ample space to the capacity to listen and to the finding of the conditions for the existence of the mental space for the child.

3. Investigations on the health of the fetus - Another aspect that should be carefully considered with regard to assistance to pregnant women is the availability and a major use of means designed to monitor fetal development and detection of genetic features.

In the perspective of this Document it should be particularly noted, in this context, that research, particularly genetic research, so full of psychological and ethical implications must always be preceded and followed, as also provided in several guidelines, by counselling by a geneticist, obstetrician and pediatrician (while it appears that in 2002 only 20% of the tests were accompanied by genetic counselling). Some reservations regarding the qualitative aspect seem inevitable (consider that only 25% of the Italian Centres have a quality certification).

The danger is that prenatal diagnosis is understood as a business, especially in the context of availability of the test without medical supervision, and does not take due account of the basic problematic issues from the ethical and medical point of view (in particular, of the appropriate use of safe and effective genetic testing to be carried out in laboratories with high standards of quality) and the psychological point of view.

The presence of the geneticist is essential to give adequate information before and after the test, taking particular note that in many cases there may be only probabilistic answers (among other things also limited by the incidence of false positives and false negatives) or that can not provide certainty with regard to the range of severity that a disease may present. It should be noted, in this sense, that the risk of spreading a genetic-technological mentality - a cultural drift - which attributes to genetic data an all-encompassing deterministic role and promotes a social attitude of rejection of the subjects that are considered abnormal, presenting fetal disease as intollerable.

Mostly, the results of these investigations are not mentioned so far, despite being ethically indispensable, as part of a dialogue in which to prepare and facilitate the processing of any bad news and suffering resulting from it. Indeed, it is sometimes considered a mere solicitation for investigation, dependent on considerations of supposed medical self-defense.

The already reported significance of psychological assistance to pregnancy, which contributes to a responsible attitude, therefore, assumes special profiles with regard to the finding of a negative genetic data concerning the fetus, in order to avoid a certain kind of automaticity between specific results of genetic testing and abortion outcomes.

The woman and the couple, in particular, are entitled to know with precision, as part of prenatal diagnostic feedback, not only the clinical data acquired objectively, but also their meaning and also to have adequate information about the resources available as to the

favourable reception, education and care of a child with problems identified during pregnancy, as well as being able to count on constant and enduring institutional and human solidarity, this latter requirement, often disregarded.

4. Educational profiles - In addition, there is a call for further attention concerning the formation and guidance of young people in relation to pregnancy.

In particular it should be noted, among the many possible considerations, that there are very common patterns of sexual behavior characterized by a basic common denominator, represented by the a priori separation between sexuality and the prospective of procreation, or more generally between a couple's life and parenthood.

What often appears absent is the formation for the taking of future responsibility represented by the generation and to a responsible generation. The sense of personal responsibility to which many young people, in this regard, are educated, does not go beyond the level of protection against infection and risk of pregnancy by means of mechanical or chemical contraception.

However, it would be a serious impoverishment to deprive young people of reflection on the opening up to the generation of life, which is the premise of sexuality, as well as information on the recognition of fertility. Consequently, it appears, fundamental to extend the perception of the sense of responsibility of young people with regard to the possible determination of the life of a new individual. Therefore, it can not be satisfactory to have sex education without education to the generation of life.

It would be superficial, for example, to address the problem of underage pregnancies in girls as a problem related to the mere information on contraceptives. Nor would it be satisfying to merely propose support for the possibility of an ongoing pregnancy.

Often young people are encouraged to think, in the case of an early pregnancy, that the solution lies in the non involvement of parents and to pretend that "later", after the interruption of the pregnancy, everything will be like before; rarely are they helped to analyze the psychological burden of entry to life marked the experience of an abortion.

Of course, it is necessary to reflect on the educational reality of the young woman and young man, from the time of adolescence: it is then, in fact, that the possibility of clear, objective and involving information on pregnancy and its physical and emotional profiles, prenatal development of the child, the human significance of motherhood and fatherhood begins.

Another aspect concerns the importance of formation for favourable reception, designed to avoid the problems linked to the prospect, through having a child, of merely realizing the psychological needs of parents or their too specific expectations. In such a context, in fact, only at first sight this could create a kind of "strengthened", granted that any motivation other than that in reference to the very existence of the child itself may make the parents more insecure as regards the difficulties that may arise in future. Although today children are often born in the context of highly motivated choices made in relation to the experiences of the parents, neglect and violence against children does not seem, moreover, significantly on the decrease.

5. Assistance to women faced with the hypothesis of termination of pregnancy - As regards, in particular, assistance to women considering a possible termination of pregnancy it should be noted, first of all, that this hypothesis comes during the stage of ambivalence described above and is therefore refers to a context of particular emotional fragility.

It appears on the other hand, that if the process started at conception is interrupted, albeit voluntarily or even spontaneously, the abovementioned ambivalence there is a lack of constructive elaboration, and the possibility of the production of destabilizing effects.

Pregnancy is not just a physical fact and the relationship with the child is not just physical: in fact, mourning the loss of a child requires elaboration, because the child remains intrapsychically. To confine the pregnancy to a woman's *body* and ignore the intensity of interior involvement which it implies (it is significant we refer to the *desire for pregnancy* and *maternity*), thus forgetting the complexity of the psychodynamics of pregnancy, is likely to induce the woman operation to devalue or deny the emotional and relational reality that she is experiencing.

In addition to the problems inherent to the context of a woman's life, it is therefore necessary to consider, from the point of view of psychological assistance, precisely the relationship of the woman with the reality of pregnancy: evading the issue would mean to not consider the role that it assumes, for the woman herself, the *content* of the decision referred to the possibility of abortion.

Abortion has an objective significance that goes beyond individual "experience" and, therefore, the reality represented by the existence of the unborn child can not be anything less than consistent in the interview.

Working on the inner "experience" of the woman in relation to an unexpected or unwanted pregnancy is especially important when the couple's relationship is problematic. The woman who feels alone when faced with maternity experiences insecurity regarding her abilities, along with the fear of not being able to manage the situation independently. The anguish of not being able to cope psychologically with the unfavorable environment may prevail over the inner perception of positivity. And this is precisely the moment at which the option of an abortion can occur, this involves, as well as the life of the child, also that of the woman by inhibiting the realization of positive aspects of her identity.

When those to whom the woman turns to for support, even indirectly, do in actual fact, give a negative opinion ("you can't cope"), this assessment could become a very insidious message for the image that the woman structures within herself as regards to her own individual resources: in the research on post-abortion the woman manifests in many cases an increase of contempt, not only in relation to any feelings of guilt, but also in relation to self-judgment ("you weren't able to cope").

The assumption of the principle that pregnancy is a condition that requires specific forms of assistance in favor of women, given the human value of gestation and the commitment that it requires from the expectant mother, is a universally shared fact and is expressed in various legislative texts, including the Law 194/1978, whose title first of all makes reference to the *social protection of maternity*.

In particular, the provisions of art. 5 of that law, which focus on the concept of assistance to be offered to women when they enter the interview, as provided by the aforementioned legislation, should have constituted the unanimously shared social and legal approach to the problem of abortion, but their implementation - according to widely shared opinion - has remained insufficient.

Such provisions, aimed to "*remove the causes that lead [the woman] to the interruption of pregnancy*", move in the direction of a commitment of the socio-sanitary services both to the interests of the woman, and to the interests of the unborn and express, in an case, the *non-indifference* of the legal system as regards the prospect of an interruption of

pregnancy. In this way, they fulfill the preventive aim prior to abortion, according to the will expressed by the legislature, through dialogue and assistance (in this regard, special attention is now paid to immigrant women, especially if their presence in Italy is illegal).

It is a direction that must be pursued even if the interview is performed by a doctor (making available to him, among other things, appropriate training and methodological guidance), in order to not miss, even in that case, the opportunities arising from orientation to dialogue and assistance, according to the instructions of the legislation at issue.

It is, in short, a fundamental reevaluation of a shared commitment to supporting women in pregnancy, so as to make clear in the context of social and public institutions the existence of a positive climate, a sympathetic approach and solidarity to the ongoing pregnancy, the climate the perceptibility of such a climate often seems rare; and therefore to counteract the effects of discouraging or even blaming the woman who, is preparing to face a pregnancy that is in any way problematic, undertakes a series of responsibilities personally and indirectly for society.

In the same sense, the often asserted logic must be overcome which perceives pregnancy as a sort of intrinsic conflict between the interests of the woman and those of the unborn child: taking into account, among other things, the impact that an interruption of a pregnancy could have in future on the woman, as attested by many post-abortive experiences.

The implementation of the stated provisions responds moreover, to the legislative choice to request, in the case of possible voluntary interruption of pregnancy, for the woman to relate to the facilities or persons specified by the legal system<sup>120</sup>.

In this context, serious planning of the way in which the interview, requested Law 194/1978, is conducted with the woman seems important, particularly as regards the not strictly medical aspects. In particular, in the interview, it would be necessary to distinguish, a first phase that has the objective of providing social and psychological assistance, which should not coincide with the phase in which it is possible to issue the document as provided by art. 5, last paragraph, and it should involve more than health care expertise (the delivery of the aforementioned document not yet being involved, participation in this phase does not present problems related to conscientious objection). Assistance of a social nature should, among other things, make readily available to women all the contacts necessary to resolve material problems (of residence, employment, etc.).

Similar needs of assistance, support and reflection from the ethical point of view in the presence of the relevant factors pursuant to Art. 6 l. No 194/1978, in the ninetieth day of gestation and when there is a possibility of independent life of the fetus, although in this case the *interview* is not expressly required by law. Moreover, the need even in this context, for those requirements to be met through a phase, that although it is called an *interview*, seems to follow the general principle that any medical intervention must be conducted on the basis of adequate information relating to the concrete situation.

It would not be acceptable, both with respect to women's rights, and respect for the dignity of people with deformities or abnormalities, in the most frequent hypothesis as mentioned in art. 6 – when there is a serious danger to the mental health of the woman in the

---

<sup>120</sup> It would not be constitutionally permissible for the problems concerning the termination of pregnancy that it could be dealt with under “a regime of total freedom on the part of the individual pregnant woman” (Constitutional Court. No 35/1997).

event of continuation of pregnancy with reference to “significant anomalies or malformations” of the fetus - consider the social reaction to recourse to interruption of pregnancy that is taken for granted.

The need for psychological assistance to the woman encompasses, of course, also the case in which termination of pregnancy has been carried out: if, in fact, it is true, that miscarriage requires elaboration of the mourning for the loss, it is all the more reason for necessary psychological support in the case of voluntary interruption of pregnancy.

6. The role of social policies – The bioethical importance of which must also be reiterated, for assistance to pregnant women, social policies in support of motherhood, especially with regard to the protection of families<sup>121</sup>, single mothers, and lack of adequate financial resources as well as mothers of any job title, early childhood services, to recognition of support from parents for the maintenance and education of children.

These factors are, in fact, fundamental preconditions for an effective recognition of the social value of motherhood and of parenting in general.

Particular attention must be paid to the protection of pregnant women immigrant who have immigrated illegally.

Assistance to pregnant women, therefore, requires different and complementary profiles of intervention, which encompass educational, psychological, health and social dimensions.

The confinement of a woman in solitude, whether material or moral, faced with the commitment of motherhood constitutes a radical breach of the same human dignity of that woman and her child, and at the same time represents the failure of the fundamental bonds of solidarity for civil life.

## BIOETHICAL ASPECTS OF POST-PARTUM DEPRESSION

1. Childbirth and the puerperium – Before directly considering variations in mood that occur in the post-partum<sup>122</sup>, but that may be present even in pregnancy and be prolonged to the postnatal period, it seems appropriate to mention the significance of the intercurrent stages between pregnancy, childbirth and the puerperium for a woman.

Childbirth is a caesura, a point of no return between a before and an after. Surpassing the biological separation of the boundary, though expected, imposes itself in all its concrete-

---

<sup>121</sup> Public investment for the family with respect to social spending in our country is much lower (4.2%) compared to that of other large European countries.

<sup>122</sup> The term postpartum in this document is not intended in the strictly obstetrical sense as that period - according to the Italian regulatory classification - which includes 2 hours after expulsion or extraction of the placenta. It is understood in the broadest sense, as the period of existential experience succeeding childbirth (meaning consistently endorsed by international literature), the duration of this period is difficult to define. The puerperium is classified, however, as a period of time beginning after the expulsion of the placenta (and thus also including the 2 hours of “postpartum” as by regulation) and ends with the resumption of cyclic ovarian activity. Conventionally, puerperium is assigned a period of 6-8 weeks because in that range there is usually a complete regression of the majority of the changes in pregnancy involving the various organs and systems. If the woman is breast feeding, during puerperium the activation of the breast function occurs (see Pescetto et al., *Manual of Gynecology and Obstetrics*, SEU, Rome 1989, p. 1063 ff.).

ness and marks the transition, the end of pregnancy, and the new dimension of motherhood. The biological separation is a real critical point, which involves the breaking away from a previous state, and implies the formation of a new stance of the person in all its multiple aspects.

The path which leads from pregnancy to the new phase of the relationship between mother and child recognizes in accordance with the established psycho-analytical interpretation, some of the most significant points:

- the sensation of suffering, almost of shock at what is being lost, in other words, the loss of a part of oneself, one's own body, identified with her inner self on the part of women despite the awareness of the existence of the fetus;
- the opening to the new that is acquired: the breaking away of the above-mentioned biological unit finds its match in psychological terms in the transition from the imagined child to the real child that can be touched and seen, with the possible disappointment in the perception of this divergence;
- The mother's need to manage the empty space that has been created and her attempts to fill it, with equal satisfaction.

All this is possible only thanks to a "regression" that is in some way driven by the baby, so the mother and the infant form a whole. Winnicott speaks of this particular state of fusion as a true *psychiatric state* very particular to the mother, a "normal illness", the so-called "*primary maternal preoccupation*", in which the mother can develop an instinctive understanding of the needs of the newborn, even without signals. This identification of the mother with the baby and the inherent regression permit the filling of the void created after delivery, fostering a sense of continuity with the intrauterine life. Gradually, the mother and the infant overcome the sense of separation caused by childbirth, and permit the baby itself to move from absolute dependence to relative dependence<sup>123</sup>.

For its part the baby, that has not yet achieved a sense of integration, searches for a reality that includes it and that makes the baby feel more than just a voice or something that is perceived with the senses, and gives it a sense of continuity. The smell of the mother, the baby's pace, posture, way of moving and communicating only with the body, contribute in some way to restore it with a sense of continuity, that has been lost with the caesura of birth (Bion, 1979). What ordinarily permits the baby to re-establish the lost continuity with the resection of the umbilical cord is the mother's breast, and in particular the nipple that works almost like a second umbilical cord.

In the puerperium the mother often feels a sense of having "finally emptied" and at the same time, they have lost important parts of themselves. Only through a gradual process of developing these feelings, and not without alternation between moments of confidence and depression, does she usually put into action the natural transition to her new status as a mother. The completion of this psychological journey can be modulated, however, according to different paces, the characteristics of the woman, the couple, and the environmental context.

In light of these considerations, the best way to encourage the unfolding of the first rapport after birth between mother and child seems to be not to remove the infant from the

---

<sup>123</sup> The transition from absolute dependence to a real interdependence, able to ensure to both "active adaptation to needs" is however a long and tortuous transition, and includes the puerperium.

mother except for a short time since, in so doing it allows both to be reassured, to adapt to one another and favours the eventual establishment of breastfeeding.

After delivery, through varying moods one moment confident and promising, and the next negative, the woman encounters the new condition of the child and the recognition of it in this new condition takes place by degrees, after months of the most varied fantasies.

2. Post-partum pathologies – The transition from childbirth to puerperium can occur normally, but there are also situations where adaptation to the new condition of the mother proves difficult, so as to determine states of suffering and even anxiety, as far as decidedly pathological conditions.

The relevance of the situations founded in the *post-partum* is not limited to the distress and suffering of the mother but has a direct effect on the newborn child and the family. There are numerous studies showing that the infant at birth reflects, almost as in a mirror (“mirror neurons”), the mood of the mother, creating a short circuit with it that determines not only their mutual relationship, but that will also have an impact on the future relationship with the outside world.

The variations that may occur in the ways of adaptation to the new condition as a mother have provided a wide range of situations that differ in intensity and severity of mood disorders. It is difficult to give a specific order to clinical material that appears by its very nature extremely confusing due to the infinite and much discussed limits that the “organic” disease has both on the extreme polymorphism and variability of the psychiatric framework.

It seems appropriate at this point, to define the boundaries in which such complex psychological and existential situations must be considered.

These are situations that can blend into one another as in a *continuum*, but for nosographic simplification are shown in growing as “*maternal blues*”, *post-partum* depression, puerperal psychosis.

“*Maternal blues*” (a term used internationally to indicate a mild postnatal depression in puerperium) is a transient mood disturbance that occurs in the early days of *post-partum* with a peak between the third and fifth day, with remission generally, around the tenth day, or more rarely a few weeks. It affects 50% of women (40-80%). Its persistence for longer, which occurs in a small percentage of cases, and the intensity of mood alteration suggest reconsideration of the diagnosis as it may be an indication of the evolution towards a form of depression. The apparent banality of the disease should not lead us to overlook this discomfort that is of a limited extent, also for the possible repercussions on the newborn child which have been mentioned.

The post-partum depression (PPD) which is part of a clinical picture of medium severity is considered the most common post-partum pathology. It occurs in approximately 10% of births, and is more common in adolescent mothers, but it can last from a few weeks to a few months, since one of its features is an evolution that tends to chronicity. If unrecognized and untreated it can continue even after a year of onset and extend indefinitely in terms of the negative impact on the child. Recurrence it is very frequent (1:3) in a subsequent pregnancy. Clinically the depressive symptoms are evident: loss of interest in normally pleasurable activities, psychomotor agitation, difficulty in addressing the more mundane events, uneasiness in dealing with interpersonal relationships, distress associated with fatigue, anorexia, weight loss, insomnia, feelings of guilt and above all inadequacy in the maternal

role, with an excessive anxiety regarding the baby's health. In addition to melancholic depression, there are also those that are not mental that barricade themselves behind a "pragmatic system" by which the interaction with the child may also be excessive but it is devitalized and lifeless.

The most worrying situation is represented by the *post-partum psychosis*, which, however, occurs in a much more limited number of cases: 2-3 cases per thousand births. It can develop in the early days of the puerperium, usually in the first weeks after birth but even after a few months. A woman in the first month after birth runs the highest risk of her entire life to be admitted to a psychiatric facility (Asch, 1992).

Approximately 70-80% of *post-partum psychosis* occurs in women who are prone to bi-polar illness (manic-depressive illness). The remaining 20-30% of the psychosis is manifest in women who are already ill before the birth, and they become unbalanced with the birth of the child.

*Post-partum psychosis* is often the first manifestation of a bipolar episode of the young woman and like all bipolar disease can last months and even years, unless appropriate assistance is obtained.

Peculiar clinical features are the surprising suddenness with which delirium occurs, the extreme polymorphism of delusional themes, the intensity of affective reactions and the inevitable confusion that reveals an acute process of deconstruction, of various degrees. The delirious productions generally develop on particular and recurring topics, such as the denial of marriage, childbirth, motherhood, the very existence of the child. It is often only during hospitalization that knowledge of the previous organization of personality is gained, through the accurate medical history (not only of the patient but also family members), which takes into account the prior history, both with regard to external events, both also to those of the inner world.

If the psychosis begins quietly, and is pertains significantly to depression, the mother may complain of insomnia and anxiety increased as a preliminary signs, but what inexorably increases is her anxiety concerning her *inability to care for the child*, especially as concerns breastfeeding. She fears that the child may die; she may drop it, or not know how to feed it, etc. A specific phenomenon is the transferral to the newborn child by the mother of her own depressive characteristics and her suicidal impulses. Feelings and thoughts like: "I'm useless, I'm evil" are transferred to the newborn baby. Instead of believing she herself is bad, or even the incarnation of evil, the maniacal fantasy can be projected onto the child, who becomes the object of disillusionment. When the new mother perceives the child as the quintessential "evil" like a serpent or the devil (see the movie and book, *Rosemary's Baby*), this is a moment of extreme danger. Suicidal impulses and / or infanticide often occur at this point: the mother can kill herself; sometimes she kills the child, and sometimes both herself and the child, jumping out of a window with the baby in her arms.

When the post-partum psychosis has maniac characteristics as opposed to those of depression, the woman usually manifests the typical signs of mania: euphoric excitement, excitation, grandiosity, hyperactivity, etc.

In extreme cases, infanticide occurs. The horrifying events of infanticide, often accompanied by the mother's suicide, are not always examined in depth or understood in regards to their tragic dynamics. Public opinion has largely polarized on the rise, touted by the media, of the number of trials for infanticide.

The issue has become a subject of study especially since the problem of abuse against

children is seen as a social problem of the highest order. It is amazing how little information there is on the morbid condition of infanticide, despite its being known for some time along with its extreme gravity. This lack of information is probably due to the social unacceptability of such a crime and the complex interweaving that for sentimental reasons are often employed as a cover up of the protagonist. It is therefore very difficult to have reliable facts, since, in all probability, some cases remain unknown.

According to different legislations there are various definitions of infanticide and neonaticide. According to Italian law infanticide is recognized as a particular situation, the same way as happens in almost every country in the world. Infanticide is considered the situation in which “the mother causes the death of his newborn immediately after birth, or the fetus during labor, when the fact is determined by material and moral conditions of neglect related to childbirth...” (CP Art. 578) whereas it is considered “murder” when the child is suppressed at any age, the same way as other homicides. Other laws provide instead a distinction between “neonaticide” (within the first 24 hours) and “infanticide” (within the first year of life).

The Italian data on infanticide denounce a progression over time (from 12 cases in 1998 to 63 in 2001: C. Petrignani, 2002). According to data from the United Kingdom the cases of suppression within the first year of life are between 30-40 per year, of which one quarter are neonaticides.

A comprehensive and reliable overview on infanticide carried out by Resnick (1970) although dated, suggests that in England, each year, these are much more numerous. An estimate of the frequency of infanticide caused by *post-partum* psychosis in the United States suggests an annual rate of 400-500 cases.

Literature demonstrates that neonaticide is more related to contingent factors (first child, socio-economic difficulties, the woman being a single parent or immigrant), and infanticide (in the Anglo-Saxon sense) would refer mainly to a psychiatric disorder.

Among the alarming manifestations of *post-partum* depression the suicide attempts of the mother (in the psychological profile), in which, however, the child is made the object should be considered. The genesis of all this is a fantasy (conscious or unconscious) that the child is suffering and will suffer all kinds of evil, from which only death can save him. The unconscious dynamics of filicide, in this case, involves the projection of the self or at least a part of the self on the child. The death of the child implicates, in the light of this unconscious fantasy, the only way to eliminate terror and at the same time to get rid of what generates it.

3. Legal consequences with regard to imputability – On the basis of the considerations above it should be highlighted that the legal significance of the psychotic and psychopathological factors considered here must be recognized, especially with regard to criminal profile. These factors are in fact more readily classifiable among those that surely implicate the exclusion of imputability, granted that the women we are discussing undoubtedly have a radical anomaly regarding the representation of reality and the formation of will, together with the lack of motivation for the latter through regulation.

It should be stressed that the seriousness of the damaging event that is possibly committed (consummated or attempted neonaticide or infanticide) can not affect in any way, the legal recognition of state of non-accountability, when these factors subsist.

This recognition allows the woman concerned to express her problems frankly, inter

alia, both before and after the possible committal of any criminal acts: which is to the benefit of effective prevention.

4. Etiopathogenetic factors of depression and postpartum psychosis – The pathogenetic interpretation of the scenarios that we have described is still not clearly defined. There are, in this regard, “psychogenic” hypothesis alongside others that are “neurogenic”: the first rather inclined to exploit the related deep psychodynamic messages even as concerns the “lived” experiential factor, while the second is focused on the influence of genetic-constitutional factors, and however of an organic “predisposition” in a broad sense.

First of all, we need to recall the importance of the role they had in the description of the symptoms, and of the results of passed Schools directly or more broadly related to psychoanalysis (in the appendix to this document the pathogenetic interpretations provided by some of these Schools on the subject in question will be presented - albeit briefly).

One wonders, however, if it still makes sense to propose similar dichotomies faced with the close relationship between *psyche soma* and that are increasingly being documented by the neurosciences.

The uncertainties in the cataloging of nosographic *post-partum* mental health problems testify the complexity of interpretation of this subject. It is debated whether *post-partum* depression and psychosis (which according to the authors of Anglo-Saxon Minor and Major Depression correspond to the DSM IV - *Diagnostic and Statistical Manual of Mental Disorders*) should be considered specific pathologies to the period after childbirth or even during pregnancy: in other words, whether they should be seen as significantly associated with the event of childbirth or with the general chapter of mental illness. According to the DSM IV, the condition under examination comes under the chapter on psychosis (with the specification of “onset of psychosis in the *post-partum*”), since the general risk factors are considered prevalent to the specific incidence of childbirth.

The French school tends instead to give independent nosographic dignity to the psychosis of pregnancy and puerperium, meaning inclusively in the title “all the psychiatric accidents that are related with pregnancy, puerperium, and lactation”: therefore, it becomes possible to give unity to material that would be confused in the maze of the various nosographic categories and emphasize a more precise causal connection between events.

The various attempts to highlight specific etiological factors of depression and *post-partum* psychosis have not obtained general consensus. The multifactorial genesis behind similar changes in mood, because of the intricacy of biological, psychological and socio-cultural factors, allows, therefore, only interpretive hypotheses that favor one model rather than another.

The endocrine component has variously been called into question, for the spectacle of the hormonal change that occurs after childbirth (in all women there is a sharp fall of hormones at the end of the gravidic process - estrogen and progesterone in particular - or related to it, such as cortisol) and analogously with other situations of a woman’s life (menopause, premenstrual syndrome) that are associated with abrupt hormonal changes and mood changes that are connected at least chronologically. However, in the face of such an endocrine situation, common to all pregnancies, there is in the puerperium a statistically modest mood changes.

In recent years, the data in literature has emphasized the effects of estrogen on brain structures and functions such as, among others, cognitive capacity, memory and mood.

Such effects involve both the nerve cells, and the various neurotransmitter systems and their receptors. Estrogen, in particular, increases the *turn-over* of dopamine and dopaminergic receptors, as well as carrying on an active reductive effect on serotonergic and beta adrenergic receptors. Despite the existence of this evidence, there has not, however, been any experimental link found between estrogen and *post-partum* depression or psychosis. In addition, in this way, there is no explanation of late-onset cases, when the hormonal situation is being restored or has been normalized. Similar considerations can be made regarding progesterone, prolactin and cortisol, since in cases of depression and *post-partum* psychosis conflicting values of these have been found.

Among the potentially relevant biological factors the genetic ones should be considered, in terms of a predisposition to depression or more serious psychiatric conditions: in this regard valuable indicators can be found in personal and family history. It is known that the genome expresses the genetic potential, which, however, soon becomes, in relation to the environment, epigenetic individuality, that is, an organization of innate and acquired elements so that the same predisposition, which still remains however a certain risk factor, may be followed by different outcomes.

The etiopathogenesis diathesis-stress model involves interaction and the causal and systemic circularity between predisposition and stressful events, including environmental and behavioral ones.

Also with regard to biological factors, literature has found a place for the interpretation of depression in general as a “dysregulation” of serotonin neurotransmitters and other pyrogenic amines such as nor-epinephrine, epinephrine, and dopamine. The role of these factors has in fact been studied also in relation to depression and post-partum psychosis, with however not consonant results.

The importance of psychogenic factors in the DPP finds broad consensus in the literature and the premises previously set out on the psychodynamic commitment that the phenomenon of pregnancy can involve and the doctor’s experience.

In this still uncertain framework of interpretation, research, that in many cases demonstrate a correlation between pre-and post-natal depression, should however be highlighted.

A similar correlation is found between *pre*-and *post-partum* states of anxiety. This confirms the “stability” of individual psychological behavior, despite the large mood, emotional and social variations experienced during pregnancy and *post-partum* (Llewellyn et al., 1997, O’Hara and Swain, 1996; HERON et al., 2004). There are, however, only reports of onset of depression in the *post-partum*, that is, not preceded by symptoms of depression during pregnancy (Da Costa et al. 2000; Josefsoon et al., 2001, etc.).

Taking into account these assumptions, the complex process that leads to the birth of a child must deal with multiple factors: genetic and epigenetic heritage acquired through destiny, the relationship with the family of origin, the events of life and the way in which they are experienced by individuals, the structure of formed personality, the atmosphere of the couple, the attitude to becoming a mother, the very experience of childbirth and, last but not least, socio-economic conditions.

5. Identification of risk factors and prevention of the mental pathologies of post-partum – The goal of prevention, associated to the early identification of risk factors, constitutes, with regard to the subject in question, the topic of most interest bioethically and the

primary goal to be pursued, both in the very course of pregnancy and, in any case through the timely diagnosis of the first suspicious events of discomfort in puerperium.

The problem is being addressed clinically through the usual classical clinical order paths, for which the collection of anamnesis, the use of guidelines, and the experience of the physician take on fundamental importance.

Much space has been recently attributed to the search for predictive factors, to an approach that is generally based on semi-structured clinical interviews, the use of different tests on self-assessment questionnaires, all administered during pregnancy and after childbirth, in some cases up to one year after childbirth itself<sup>124</sup>. One of the aims would be to establish a reference platform to evaluate apart from the risk even the effectiveness of various therapies.

Even in Italy there are under study projects on depression and *post-partum* psychosis at universities (Pisa and Naples) and in Emilia Romagna. Abroad, we can cite, among others, research centers active in Geneva, Heidelberg and Cambridge.

A study by the *Canadian Task Force on Preventive Health Care* in 2003, faced with the wide range of tests available and the lack of reliability that they offer, especially in cases of medium severity, advises the doctor concerned to choose the method that best suits his personal preferences, the type of the population investigated and the practicality of the *setting*. These types of screening, therefore, are still considered as a working hypothesis.

The *American College of Obstetricians and Gynecologists* recommends that doctors are always alert to symptoms of depression and during case history to gather information about possible psychosocial stress, as well as a possible family history of depression.

6. Therapeutic profiles of post-partum pathologies –The difficulties in formulating a diagnosis of DPP automatically fall on the choice of treatment to be implemented.

In a recent review of the literature in English from 1990 to 2003 (E. Cindy-Lee And Dennis D. Stewart 2004) therapy on the outcome of depression and *post-partum* psychosis, these are related to 'organic' and 'non-organic' interventions, which indicates once again the basic dichotomy that exists in the interpretation of the issue in question.

The disease is considered with respect to the minor disorder (depression) and major disorder (psychosis), as the "maternal blues" effectively making use of care by the father of the unborn child and / or a "good mother figure" that looks after the mother.

The available studies, given their methodological characteristics and number are not however able to provide reliable and unique therapeutic indications: a brief account is therefore provided only for the sake of completeness.

---

<sup>124</sup> Diagnostic interviews generally follow the standard criteria of the DSM IV, which is a very useful tool to communicate unequivocally within the scientific community. The distinction between Major and Minor Depression is based on the DSM IV results, and corresponds, as noted, to the distinction between 'psychosis' and *post-partum* 'depression' (it is the major depression easiest to identify through the various screening tools). Most widely used among the tests is the *Edinburgh Postnatal Depression Scale* (EPDS), especially to follow the results of treatment over a period of time; there are also proposed several types of tests and self-assessment questionnaires, which take into consideration various aspects including the spectrum of mood, obsessive-compulsive spectrum, the so-called "Work and Social Adjustment Scale", the STAI (*State-Trait Anxiety Inventory*). There have also been attempts to assess the predictive accuracy of the different types of screening.

a) Pharmacological treatments

As regards pharmacological treatment with antidepressants, literature is full of controlled *trials* on the effectiveness of this on depression in general, however, specific studies related to the DPP are noticeably lacking.

In the last decade selective serotonin *reuptake* inhibitors have been used as initial attack (SSRIs fluoxetine type, instead of tricyclic antidepressants) because they are freer from side effects and have a wide margin of safety for nursing mothers.

Apart from the fact that some of the studies considered as valid according to the selection criteria adopted in the meta-analysis combine at the same time from one to six *counselling* sessions with good results, the same overall conclusions drawn in the literature on the quality of acquired data and on deducible practical recommendations state that there is insufficient evidence to infer reliable therapeutic indications.

There is also work on two hormonal treatments related to the administration of estrogen. In the first, however, the evaluated patients are very depressed, 47% of which were taking antidepressants. The results indicate an improvement in the early stages of treatment, but the findings suggest to expand the research to less depressed patients without other pharmacological interference and to seek to establish, through basic research, the role played by estrogen in the DPP.

b) Psycho-therapeutic treatment

21 studies were examined, including interpersonal psychotherapy, cognitive behavioral therapy, psycho-social interventions (support therapy, non-directive *counselling* also defined as a “listening examination”), and “mother-child” therapy.

Interpersonal therapy has achieved significant results in treated patients compared with controls. It is recommended, however, to wait long *follow-up* periods to compare the efficacy in relation to pharmacologist and psycho-social treatments and to make use of personnel with a good level of training on the subject.

The cognitive-behavioral therapy, very widespread in English-speaking countries, is documented in six studies, but all have methodological limitations, represented, for example, by the low numbers, or lack of control group. The lack of inclusion of such therapy in the treatment programs of the DPP must also be considered in the conclusions regarding evidence. Its potential role is supported by reference to the effectiveness of the cognitive-behavioral approach to depression in general. Also raised are the problems of the considerable time required for implementation and the related cost elements conditioning *compliance*.

Among the psycho-social interventions there has been attributed to “supportive therapy” a potential beneficial effect under certain conditions, especially in cases of moderate severity, however, the methodological weaknesses of the research makes the results ambiguous.

Also being tested is also a supportive therapy via telephone, through a large randomized trial.

Other approaches, as reported by some *trials*, include non-directive *counselling* and “Mother-child” therapy. These are interventions that may be a secondary option in the treatment of DPP in situations of medium or moderate depression. Once again, however, the methodological weaknesses of the *trials* make the results non-unique.

c) Other approaches

One work describes intervention involving sleep deprivation according to certain chronological criteria: the mechanism could restore good quality to sleep and re-establish the circadian rhythms which underlie this. The same *trial* calls, however, to further develop the research.

Electroconvulsive therapy also appears to have been taken into consideration, compared to cases with acute risk of suicide or psychosis resistant to the common therapeutic approach. The information is limited only to the cases examined, which are few.

A profile, which however, has received too little attention is the one concerning the role of the father of the unborn child, he can undoubtedly be a good source of emotional and practical support, as well as a valuable *trait d'union* between the woman and the other members of the family.

The need for support in the puerperium is now so great as to see activated various means of assistance, by setting up centers at the Departments of mother and child, at family planning clinics or by free associations such as the Italian Parents Movement, as well as research aimed at the various university centers aimed at the care of women with depressive disorders in the puerperium and the parallel observation of the child, given the impact that these disorders can cause. Details of these are readily available online.

In England prevention has become systematic and has become part of the measures required in all hospitals that are part of the National Health Service, with the establishment of the “*Perinatal Mental Health Team*”.

The availability of social support should be part of the institutional tasks, possibly with an external support at home for the care of the child.

In conclusion: the difficulties encountered in establishing the correct diagnosis - much less concrete than in other areas, especially in cases of medium severity - give an account of the uncertainties that arise in dealing with the question of therapeutic conduct. The constant reminder of the need to set up new studies that might lead to comparable data is testimony of the current state of provisional of each behavioral pattern.

The multiplicity of etiologic factors makes the event of unambiguous action unlikely: it must be noted that, as the causes are multifactorial, so are the treatment needs, only an approach which takes account of biological, psychological, and social factors and knows how to use one therapy or the other, alone or in combined treatments, can give successful outcomes, that should be considered, even if temporarily indecisive in terms of evidence.

7. Summary and Conclusions from the bioethical standpoint – The potential and real gravity of the syndrome of depression during pregnancy and especially *post-partum* calls into question the responsibility of care, in the broadest sense of the expression, which has already directed to every woman during the course of a normal pregnancy.

According to the majority of authors (see, for example, Kumar and Robson, 1984; O'Hara et al., 1984, Watson et al., 1984, Campbell et al., 1992, O'Hara and Swain, 1996; Bernazzani et al. 1997; Discard-Veltem et al. 1998; Da Costa et al., 2000; Beck, 2001; Logson and Usui 2001; Verkerk et al. 2004; Mac Mahon et al., 2005), the search for “risk factors” at the onset of *post-partum* depression is necessary in the course of prenatal care, on the basis of the following factors: family history of *post-partum* depression, a history of

psychopathology, conflictual relationships with parents during childhood, bad marital relationships, low self-esteem, a low socio-economic level, absent or inadequate social support, stressful life events, and unplanned pregnancy.

However, an evaluation, during pregnancy, of the specific importance of the individual case of each of the factors mentioned, and of the “intensity” of risk is currently problematic: while some authors (e.g. Cooper et al. 1996; Nielsen Forman et al. 2000; Verkerk et al., 2003) believe possible the identification of individuals who will present a higher probability of depressive episodes in the first three months of the puerperium, other authors do not consider the utilized tests appropriate for the required purpose, or consider the observations made still insufficient.

In any case, the detected presence of ‘risk factors’ directs to closer monitoring and possibly towards adoption of appropriate pharmacological and psychological therapy.

Assistance to women during pregnancy, childbirth and puerperium, is a priority for the value of what is at stake. The interplay between the biological and psychological dimension which involves the mother, child and their mutual relations is so close and full of immediate and future consequences, especially for the newborn child, that it deserves special attention both in terms of research on an operational level, in order to effectively have an impact on this fundamental life process. If this assumption has a general value for apparently normal situations, it is even more important in cases where there is a particular weakness, which exposes to the risk of psychiatric disorders.

The extensive literature based on the mother-child observation with the various methods available today clearly points out the possibility that the mental suffering of the mother has an impact on newborn child, whether overt or implicit. It is not necessary to recall the most challenging cases of the *post-partum* pathology: the anguish of the mother, both psychological and physical, the sense of loneliness when many mothers feel submersed, often connected to really being left alone, which can alter the flow of communication between mother and child by depriving the baby of the affectionate atmosphere favourable to its harmonious development.

The characteristics of “good care” conditions effective at least to reduce risk conditions or immediately prevent the worsening of them can be specified as follows:

- Assistance to women who are experiencing such fundamental situations requires the specific training of those who, having various skills, are involved in the health care itself. Frequent comparison among the figures involved in this sector that have a common basic formation and who are attentive to everything that is newly added to their discipline and is validly attached to health policy.
- It is necessary to create the conditions for a good relationship between those treating the woman, the woman herself and the father of the unborn child: the relationship should go beyond “good clinical practice” and provide the ability to listen and a refined sensibility to discern the states of ‘mind and perceive risk situations. In addition to the theoretical training that should be provided to this effect in the schools of specialization for Obstetrics, there should also be ‘training’ in real clinics in interdisciplinary working groups (such as Balint, for example) that are open even to non-medical health personnel, in order to compare and discuss the methods of approach that are most useful and effective in prevention, “cure” and “care”.
- It would be desirable to have continuous and proper prenatal care, preferably with the same *equipe* or with a homogeneous *equipe*, based on trust, in a sort of “therapeutic

alliance” not only to evaluate the organic parameters but also to understand, give answers to many questions, and offer advice.

- There should also be a good preparation for childbirth and the woman’s introduction to the environment where she will give birth (an issue already addressed in the NBC document *Pregnancy and childbirth from the bioethical standpoint* April 17<sup>th</sup> 1998).
- The request for a psychiatric consultation should take place when there is the need for wider experience to understand the clinical case. There could also be provided alternatively, especially in public health care, a “routine” consultation with a psychiatrist towards the end of the pregnancy, thereby mitigating the possible negative connotations that this proposal may have for some.

The current reality of hospital discharge quickly after childbirth reduces significantly the time of contact between the mother and the nursing staff, who are the most suitable for their physical proximity to perceive “something wrong” and to allow the mother in a confidential environment to give voice to her state of mind: boredom, bad mood, lack of pleasure interacting with the baby and so on. The woman giving birth often finds herself so quickly alone at home with the father of the newborn child, or even without him, having to manage the care of the child with a thousand doubts and uncertainties, and without a moment to rest to calmly live this new experience. The awareness of the father of the unborn child and the family as a natural support, at least in the first phase, is to be sought and in special cases, external home support through the social care services should be provided.

In this regard the family should be made aware of the situation and, especially, the father, calling him to his responsibilities and moral and legal obligations as well as to the importance of his involvement in both the period of gestation and *post-partum*. Great help can be provided by the Centers which have previously been referred to.

The culture of childbirth, given its profound bioethical and social value, should pervade the whole of society and consequently the public health service. DPP represents an important aspect of the many difficulties which “coming into the world” puts forward and it underlines how the only way to deal with them is collectively, that is to say by focusing on the value of the human being, related to each component of the family<sup>125</sup>.

---

<sup>125</sup> As part of investigations for the preparation of this text on *post-partum* pathologies, the *National Institute of Mental Health* (Washington DC) has been consulted, among others, and specifically Karen S. Babich, *Director, Office of Global Mental Health*, with a request to transfer the contents of the latest research on the subject of DPP. The reply expressed regret at the scarcity of available research.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**BIOETHICS AND THE RIGHTS OF THE ELDERLY**

20<sup>th</sup> of January 2006



## PREMISE

With regards to how we see old age, there is a sort of hermeneutic abyss between us and those who belong to previous generations, which is very difficult to overcome. In fact it is no longer possible today to consider the condition of the elderly by bringing together – according to another classic paradigm – the ontological and biological perspectives: it is no longer possible, in other words, to define what is old age analysing it from a reductionist point of view, starting for example from the loss of the ability to reproduce or from the “slowing down” of the intellectual activity or from the loss or the constant and irreversible weakening of any other specific physical-biological function. It is by now a consolidated point of view that “old age is the expression of a biology in an environment”, according to Andreoli’s expression, and that the environment is a meta-biological concept, in which psychological, political, social, historical-cultural dynamics interact.

Demography has explained how modernity has profoundly changed the structure of the population in modern societies, de-structuring the characteristic pyramidal form that characterised the relationship between generations for millennia and consequently radically changing our perception of the physicality of being elderly. It has changed with such speed that it has not allowed language to catch up: as acutely observed by Norberto Bobbio “nothing proves that a phenomenon is new better than realising that there are no words to describe it: even in official documents, *tres ages follows ages*”, the young old, the new demographic category of those between sixty-five and seventy-five, is followed by the oldest old, who are older than seventy-five. The number of studies, which has been increasing in the last decades – as well as, more in general, the widespread experience we have all witnessed – convinced us that the paradigm of the elderly as victims of a progressive and inexorable psycho-physical decay, which annihilated his/her individual life and his/her social function, is unfounded. In other words, Terenzio’s motto: *Senectus ipsa morbus*, has become absolutely obsolete. “Growing old – wrote John Eccles – is a relative concept. The so-called senescence is a process due to the slowing down or the reduction of intellectual possibilities, caused by a decrease in the ability to learn, memorise and create. But because it is defined in this way, there is no typical time when it appears”.

Consequently, stereotypes deeply-rooted in the collective consciousness have collapsed or are in any case destined to be remodelled. The stereotype of the specific admiration due to senile wisdom, which would qualify it especially for political activity and the loss of which, still within the stereotype, is lamented by every generation, has collapsed. Envy for the once very rare event of longevity loses meaning, following the incredible increase in the average life span. The traditional irritation with the despotic, pretentious, arrogant and un-punishable old age, destined to be laughed at and chastised and that provided so much literary material, from ancient times until the 1800s, to poets, dramatists and opera writers, loses bitterness and acquires new connotations of goodness; but symmetrically also loses strength the tenderness towards a mild old age, with an almost return to infancy, portrayed in fables and myths (Filemone and Bauci). The stereotype of the atrocity of old age also collapses, an old age that can be compared to a decayed house, believed to be so detestable to make us hope for an early death (remember the classic saying *Those who die young are dear to the gods*, a theme we still

find in the young Leopardi, who hopes never to cross the threshold of old age); the fantastical illusions to find a way to eternal youth lose incisiveness and become vulgar in the collective consciousness, illusions that are more prosaically but also more concretely substitutes by the legitimate desire to have a healthy, efficient, socially guaranteed, sexually active old age.

Essentially, old age appears today as any other age of life, characterised (like any other age) by particular fragilities – and for this reason deserving owed and specific hygienic, biomedical and social attention –, but certainly not as an age when necessarily, because of an inscrutable will of nature, the right to health, as a fundamental human right not only to therapy, but in the broader sense of care, weakens.

Bioethical reflection has, from this point of view, infinite fields of action, especially socially. It must condemn all forms of violence, mostly underhand and indirect, inflicted on the elderly. It must condemn as a myth the idea that their psycho-physical decline is unavoidable and progressive; and it must condemn it as a dangerous myth, because it is in large part the reason for the discomfort – social, political, psychological – which often the elderly find themselves in, victims of dynamics of marginalisation that are intolerable from every point of view.

If bioethics is victorious in this battle (but really this is not a battle that can be won once and for all, because it is destined to reoccur every generation), it should not for this reason feel that its task is done. It should still fight a further battle, infinitely more complex: which has as its object not biology, but the ontology of the condition of old age as such. In fact, regardless of how much we dutifully and efficiently state the rights of the elderly and regardless of how much medicine can efficiently work to actually give them a biological support in exercising their rights, the problem of facing the biggest obstacle remains, as Romano Guardini wrote: “the secret hostility that growing life has for declining life”; we still have to face that widespread feeling of deprecation towards the elderly, which we rarely have the courage to take fully into consideration and that is rooted in the idea that it is unnatural for man to grow old and which is shown on the faces of the elderly, and it creates, in those who are not yet elderly, a profound anxiety, which is generally removed and hidden, but that even more often leads to feelings of aggression. If the task of promoting the defence of elderly life in its material dimension requires that bioethics, medicine and social politics work together, the task of taking seriously the very difficult dialectic between old age and the previous phases of life belongs probably exclusively to bioethics, as ethics of life. And we cannot say that bioethics, generally speaking, has the tools to carry it out.

With this awareness, the National Bioethics Committee in the plenary meeting of the 19th of September 2002 decided to start a working group, dedicating it to the Bioethics of the rights of the elderly. The interdisciplinary character of the research and the reflection on this topic led to nominating three different coordinators for the group, Profs. Adriano Bompiani, Luisella Battaglia and Annalisa Silvestro. Numerous colleagues were soon part of the group, amongst which Paola Binetti, Isabella Coghi, Carlo Flamigni, Romano Forleo, Laura Palazzani, Elio Sgreccia, Giancarlo Umamo Ronchi. The first draft of the text was created through many and lively meetings; once the preliminary work was finished, the draft of the document was finally brought to the attention of the Committee in the plenary meeting of the 28th of January 2005 and in this occasion it was decided to entrust a further revision of the text to Prof. Cinzia Caporale,

in order to better structure and coordinate its different parts. The text that is now printed was then finally approved in the meeting of the 20th of January 2006: offering it to the public, the NBC is aware of the limits of its reflection, but at the same time rightly proud of having, with such commitment, brought this delicate and essential issue to the attention of Italian bioethics.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## INTRODUCTION

The National Bioethics Committee presents to public opinion some reflections regarding the condition of the elderly in current society, inviting the public to consider more openly the dignity and the rights due to the people who are going through this particular phase of human life.

The Committee wants first of all to stress that a bioethics for the elderly is now absolutely necessary, as it is susceptible to involve different subjects (individuals, families, institutions, voluntary associations, etc.) and to be able to support a broad reflection on an urgent social issue that must be tackled from different perspectives: medical-healthcare, psycho-social, ethico-legal and finally anthropological, both with the interested people and the public.

The discussion about these topics has reached – both nationally and internationally – a very broad dimension for a variety of contributions, many of which of a very good quality. The NBC, even taking into account the main lines of thought that have emerged, did not however intend to attempt a synthesis of them, or to carry out a detailed analysis of the available literature. Neither did the NBC intend to linger on the financial issues that in many cases burden the person who has stopped working, or on the strictly political-administrative issues (although recognising that they are very important in the life of the individual), or debate the “classification” of old age with regards to the temporal limits and the denominations that have been suggested for the different classes (e.g. elderly, aging, long-lived, senior, etc.).

Including in the notion of old age that continuum of problems that happen after the end of professional work and in any case conventionally fixed at 65 years, with the present Document the NBC wants to stress with bioethical arguments the duty to adopt behaviours that – universally adopted – could contribute to reinforce the concept of the dignity of the elderly and support respect for the rights due to them.

### The demographic issue

There is a widespread awareness of the importance of the phenomenon of the progressive increase of the average life-span for a balanced social set-up. A phenomenon that has grown in the second half of the 20th century, in particular in all the Countries with a high standard of living and sufficient alphabetisation and healthcare organisation, which is referred to as an element of “danger” for the foundations of the social protection system in many treaties.

Less widespread, at least in some countries, seems instead to be the awareness that the ageing of the population – intended as the global index of the social balance between the different classes of age – is influenced not only by the shift of mortality to an increasingly older age, but also by the decrease in fertility. As known, the ageing of the population and the decrease of fertility represent an inversely proportional phenomenon in many European countries, but that is particularly strong in Italy, where it is happening very rapidly.

Without entering here into a discussion about the ways in which the phenomenon can be tackled, the NBC cannot avoid suggesting that demographic phenomena should be brought to the public attention in the right manner. This approach, in any case always

respectful of the choices that each individual makes when procreating, must not be intended as the mere expression of a utilitarian ethics promoted by public authority to re-balance public welfare, but it should have the meaning of “solidarity between generations”, that the NBC considers to be an essential ethical principle in the topic under examination.

In synthesis, in Italy in the last 50 years the over 65s have increased by about 150%, comprising in 2003 of almost 20% of the overall population. The growth is widespread everywhere in our country, even though there are considerable territorial differences: Liguria has the record for the highest number of elderly people (24.4% of the population); Umbria follows with 22% and Emilia Romagna with 21.9%. The lowest percentage belongs to Campania with 14.2%.

In our country as well, there are more women than men (in Italy there are 93.8 men for every 100 women). This gender difference, consolidated in the last decade for those over 75, is due to the progressive aging of the population and to women’s longer life-span. In fact, although more males than females are born, men are affected by a higher mortality from a younger age, which means that in the overall population there are more women. The advantage of the female gender in terms of years lived is probably linked also to being less exposed to the risks of work and to profound differences in lifestyles: alcohol abuse is still mostly a male issue, whilst with regards to tobacco consumption young females are growing more than proportionally in number.

The aforementioned demographic variations have profoundly transformed the family, which is today often multigenerational and tends to “stretch” for the considerable reduction in brothers, sisters and cousins. The members rarely remain united in the original house where, more and more frequently, only one person lives, generally an elderly woman, due to the higher longevity of women. “Single-person” families, where there’s no cohabitation with others, are almost one in four and in considerable increase compared to the past decade.

Because of its record in longevity, which unfortunately goes hand in hand with an increase in the dependency from the infrastructures<sup>126</sup>, Italy could be a “laboratory” for other countries by proposing and trialling programmes and interventions directed to the social enhancement of the elderly who are self-sufficient elderly, but also to the prevention and care of the needs of the elderly who are not self-sufficient.

### The epidemiological point of view

Together with the ageing of the population, we are seeing radical epidemiological changes, which interest first of all medicine and – more closely – healthcare and the different allocation of financial resources.

These epidemiological changes can be summarised as follows:

- The constant forward shift of mortality coincides with the progressive prevalence of chronic-degenerative diseases (cardio-vascular pathologies, tumours, diabetes, osteoporosis, dementia) compared to infective diseases which on the contrary dominated until the first half of the 20th century.

---

<sup>126</sup> The “index of the elderly’s dependency from the infrastructures” is the relationship between people of working age (15-64 years) and those of pensionable age (65 and beyond).

- The prevalence of chronic-degenerative pathologies goes together with other two typical aspects of the aging of the population: the increase in age – linked to co-morbidity and polyopathologies, and disability, measured as common activities of daily life – namely, being self-sufficient in controlling the sphincters, washing and dressing themselves, moving within the house, feeding and taking care of themselves.
- The increase in age – linked to co-morbidity and disability is not however such to lead to a poor state of health for all elderly people: even amongst the over 80s, there is always a percentage of individuals – from 5% to over 20% - that does not have any illnesses and is perfectly self-sufficient.

From a medical point of view, old age is interpreted as that period of life when the probability of having to recur to medical treatments and therapies is higher.

This probability is certainly minimal in the age following – normally – pensionable age (in OCDE countries, about 65 years), whilst it becomes generally more relevant with the passing of time (from the concept of senior to elderly, etc.).

According to the most important conclusions to draw from the demographic-epidemiological data gathered so far, the NBC believes it possible to share these principles:

- Effective prevention is still “possible” also for very elderly people, as long as they are properly looked after by expert geriatric teams.
- The combination of co-morbidity and disability expresses the concept of “fragility” in old age, and it requires the intervention of workers with different professional specialisations and specific training.
- The fragile and disabled elderly needs an integrated system of services able to ensure continued assistance.

Whilst these principles apply to the ethics of the rights of the single elderly person, in parallel the demographic evolution described has invested public ethics, for which old age is examined in the perspective of legal regulations and, more precisely, of justice in the distribution especially of the medical-healthcare resources in a certain social context, in which the seen rapid increment of the elderly population and the corresponding increase in the cost of healthcare force us to establish criteria to fairly allocate limited resources. In this way started a debate on the essential characters of a healthcare system to be considered “fair”, a judgement that is given without contrasts in relation to the main ethico-political traditions (personalism, utilitarianism, liberalism, contractualism, communitarianism, etc.) found in society.

### The “self-sufficient” elderly

Before examining more directly the bioethical issues arising from the fragility of dependency, the NBC believed appropriate to focus on considering also some aspects of the “physiology” of aging, intended from a point of view not only of physical changes, but of the “experience of old age” most people have.

This process of “being aware” of our existence as an elderly person and of the possible changes as such, is unavoidable for those who advance in age, and is present both in the condition of “self-sufficiency” and “dependency”. It is however influenced by these states, it is felt differently by each individual, and it is in any case linked to a multiplicity of factors, partly “innate” and partly “environmental”.

For some time we have tried to identify “physiological” aging, offering an anthropological judgement valid for the conditions of self-sufficiency. However, in literature it seems evident that we cannot give a uniform judgement of it.

The NBC recognises that in the anthropological context we can define as optimistic comes forward in all its strength of millennia, expressed in the different cultures, the image of old age as the bringer of wisdom. A notion that is at the basis of gerontocracy in many societies that developed in the course of the centuries. This role, certainly today very weakened in western technological societies, is however not completely suppressed. Actually, many state that the elderly’s task to be wise is even more urgent in a society in which technological development risks of compromising human values.

On the other hand, in the widespread inclination towards a pessimistic judgement of aging, there’s an insistence in highlighting that senescence brings closer the perception of death, limits the display of physical and psychological potentialities as well as the harmonious relationship with the environment, emphasises any fragility and weakness with regards to health which, although they cannot yet be called illnesses, are the source of obstacles to better exercise any vital functions. The pessimistic judgement sees in old age a socially disagreeable condition, as it is linked to being “ill”, which very often society attributes to the elderly, and is in any case a source of “discrimination” with regards to exercising the ability to decide that can still be carried out by the elderly in society.

The NBC believes that each of the points of view is “authentic” in relation to the context in which each observer has experienced it. Visual perspectives that force us to make appropriate distinctions in formulating judgements regarding the age group under consideration, the state of health and especially the lifestyle. However, it is certain that biological life and psychological life happen in close and essential vicinity with the environment and that the lack of environmental stimuli (visual, auditory, of movement, etc.) reduces the brain’s ability to adapt at any age (as it can also be documented with an ECG).

From these considerations comes the suggestion – shared by the NBC – that in old age it is important to maintain a “job” able to stimulate interest and the senses, carry out physical exercise to consolidate motor skills, and develop a relationship with the environment that is “gratifying” for the individual (this corresponds to the so-called “active aging”).

We must also react to the progressive loss of “self-esteem” that generally happens with the loss of a work life or the loss of the primary role within the family and the rise of financial problems, and which leads the elderly to voluntary isolation and passivity. Literature validates the fact that the elderly who live alone, without family stimuli or in hospital, goes through this involution more. To tackle this phenomenon it would be useful to support the development of interests and occupations parallel to work, in order to widen the elderly’s cultural horizons and their socialisation.

The studies of religious philosophy – finally – confirm in the current elderly population the frequent presence of a spirituality open to religious faith. This factor is able to give hope and creative optimism in the elderly. Often it stimulates the solidarity towards other elderly people and it contributes to the cohesion within the family and in the community. Respecting each individual conscience and the right to religious freedom, where this need is felt, it must be welcomed and supported, as faith, together with spirituality, are essential dimensions of the human spirit.

### The elderly who are not self-sufficient

The NBC has considered, with particular attention, the “moral” situation of the elderly who are not self-sufficient, also called “dependant”.

This is the state of those who – for reasons linked to the lack or loss of physical, psychological or intellectual autonomy –, need considerable assistance and/or help in order to carry out coherent actions in their life. Today, for the elderly, the following expression completes the definition: “in elderly people, dependency can equally be caused or aggravated by the absence of social integration, relationships of solidarity and sufficient financial resources”<sup>127</sup>. There are many bioethical problems that come from this context and some are of considerable interest:

a) Dependency and the measure of the quality of life

The problem has two aspects: subjective and objective. Both pose issues of definition and measurement. The quality of life could be defined “the satisfaction life gives, the individual well-being, physical, the ability to adapt to concrete situations (subjective assessment). The objective criterion, however, consists of measuring, according to a variety of scales and indexes that explore the absolute or relative dimension of a person’s satisfaction, comparing his/her actual situation to the ideal situation in different spheres. We can ask ourselves if some of these investigations, carried out sometimes without much regard for the dignity of the elderly and the respect due to them, correspond to bioethical criteria regulating the research on man. The definition of quality of life is complex when facing dementia, where – in the investigations – there’s no effective consent of the person. Welfare criteria that prevail in literature – and that indicatively are today widely accepted – seem to want to add quality to the remaining years rather than add years to a life without quality.

b) The bioethical principles that must be applied also to the condition of dependency of the elderly are:

- respect for the elderly’s moral autonomy;
- integrity of the person, with “beneficial” attitudes and rejecting every expression of “maleficence”.

From these two principles derive first of all the applications exemplified in articles 11, 15 and 23 of the Social European Charter of the Council of Europe (2000 edition) for dependant people, namely: right to the protection of health; rights of the handicapped – and many non-self-sufficient elderly people are – to enjoy their residual self-sufficiency, an adequate social integration and participation to the life of the community; the right of the elderly to social protection.

c) Strategies of assistance

These rights suggest five principles useful as the basis of the strategies of assistance:

---

<sup>127</sup> Specialists of the European Group of Social Cohesion CDCS of the Council of Europe, 2002.

- We must respect (as much as possible) the preferences of those who are dependent in order to encourage their sense of autonomy and well-being.
- Support services must be multidisciplinary and solutions that include care in the home should be preferred.
- The offer of services given must focus on the needs of the individual person.<sup>128</sup>  
It's important to ensure the equality of access to services that must be shared within the territory proportionally to the density of the population and made easy to access.

d) The respect for the integrity of the elderly and the non-maleficence

The NBC also considered bioethical issues regarding the respect of the physical and moral integrity of the elderly, focusing its attention on mistreatment, abuse and abandonment, including violence. With regards to this, we must stress how containment can become maleficence towards the elderly, intended as mechanical or pharmacological limitation of an individual's capability of free movement. This containment is absolutely wrong when it is applied without a more than justifiable reason and only for the purpose of protecting the person's well-being. The same identical judgement is valid for an unjustified isolation.

We must also highlight the changed public conscience, also in our country, towards the problem that is historically and seriously emerging from the protection of the weaker subjects – amongst whom, obviously, the elderly, especially those affected by pathologies -, a change that has led to a new way of reading articles 2 and 3 of the constitution, clarifying the meaning of some fundamental values (dignity, equality, freedom, physical, psychological, relational and spiritual integrity). A renewed respect for the human being, for his/her autonomy and his/her legitimate expectations, has been emphasised also in international and European Community documents. We can mention the Ajax Convention of the 13th of January 2000, which recommends the protection of weaker subjects and indicates, amongst the tools to use, the possibility of the individual to provide a mandate to act, given both through a contract and a unilateral act, for the future and eventual hypothesis of the onset of a state of incapacitation or limited capacity. In addition, the European Union's Charter of Fundamental Rights (2000), which in article 25, "The rights of the Elderly", recognises their right to "have a dignified and independent life and participate to the social and cultural life"<sup>129</sup>.

Expressions that have been a primary point of reference for our legislator in deciding to issue law number 6 of the 9th of January 2004, which instituted the "support administration" and that represents a break from the previous and consolidated rigid and ancient cultural schemes with regards to the protection of fragile individuals. In fact, it is a law that intends to "support" all those who cannot, even temporarily, look after their interests and express the principle that the "support" of the care of the person and his/her interests is not

<sup>128</sup> In this sense, it is useful to assess these needs accurately: see the "multidisciplinary nucleus of assessment", anticipated in Italy in the "Progetto obiettivo anziani", positively operating in some places.

<sup>129</sup> We can also remember that with regards to provisions about the fostering of minors when a family is in crisis, it has been recently dictated by the legislator that the minor has the right to "maintain significant relationships" with their relatives. A regulation anticipated in the law that, for some time already, recognised and regulated the chance to meet and see grandparents, believing in family tradition ties, of which the oldest representatives are a fundamental point of reference for a correct psycho-physical development of the minors (Cassation number 9606/1998; number 1115/1981).

limited to the financial sphere, but also takes into account the needs and aspirations of the man, including every activity significant to social life. An institution that has allowed, in cases like that of progressive dementia, to leave to residual legal solutions the deprivation of civil rights and disablement that, perceived by the community as “social death”, are “excluding” events in the social context, far from supporting and promoting the individual.

### Voluntary work and “looking after” the elderly

The NBC highlights the importance of the development of a network of voluntary associations and/or non-profit-making cooperatives, which show society’s focus towards the problem of caring for both elderly who are self-sufficient but lonely and without the support of a family, or non-self-sufficient. Obviously, we must stress that these initiatives must not and cannot substitute the duties of public institutions, but maybe should integrate their action. The expression of a “friendly” section of society is also the voluntary work that looks after the elderly by simply managing the “presence” and the “company”, when the elderly is confined (especially because of age or slow chronic illnesses) at home. Voluntary work offers empathy, for example by reading, talking, substituting for a few hours a family member who is necessarily occupied elsewhere, carrying out small household chores. The positive “moral significance” for those receiving, but also those offering, this sharing of experiences seems evident.

### The rehabilitation

Rehabilitation must be intended not only as a set of techniques and methodologies, but also as a philosophy of interventions intended to give back to the person his/her previous functional and environmental state, or, alternatively, to maintain or maximise his/her remaining functions<sup>130</sup>. Therefore, the ethical contents of it are high: it is a philosophy of intervention that is antagonistic to disability and the passive acceptance of it. A moral tension will have to support the individual to rehabilitate and the personnel, to overcome physical and psychological barriers, to compensate that margin of disability and handicap that remains insurmountable, to develop new potentialities in the person as a whole.

---

<sup>130</sup> Williams, 1985.

## PART ONE: BIOETHICS AND SENESCENCE

### 1. Old age between philosophical reflection and bioethical investigation

In the current bioethical debate, the issue of aging is mostly considered from two points of view: a medical point of view (old age is interpreted as that period in life when the probability of having to recur to medical therapies and treatments is higher) and a public ethics point of view (old age is examined in the perspective of the regulation theories of justice and, more precisely, of the equity in the distribution of the medical-healthcare resources available in a certain social context).

The two points of view, however important and full of problems, seem however of limited import as they offer a partial – if not reductive - understanding of the experience of aging. In fact, as well as overlooking the psychological and socio-cultural aspects relative to the significance of old age in contemporary society and the issue of the relationship – especially the communication – between generations, in the profoundly changed contexts of family and society, do not properly tackle the crucial problem of the meaning of old age in the life of the individual and the collective existence.

Aging today is a phenomenon that has peculiar characteristics at least from three points of view<sup>131</sup>:

- a. The quantitative dimension (we talk about a structure of the population that, in perspective, could even be dominated by the elderly);
- b. The prolonging of life and the parallel increase in the lack of autonomy (or no self-sufficiency), which causes situations of dependency that require increasing healthcare interventions.
- c. The different way of organising and living free time in comparison to work, forming a family, as well as a new system of rights and duties that considerably influence the cultural change.

It is, therefore, a structural phenomenon that corresponds to a problem this industrial society is going through, and that signals a big social change, relative to our model of development and to the rules of living together.

*As I approve of a youth that has something of the old man in him, so I am no less pleased with an old man that has something of the youth; he that follows this rule may be old in body but can never be so in mind.*

Cicero, *De Senectute*

Unfortunately aging even today is not active, the way it could (and should) be: marginalisation, exclusion, isolation but also frauds, aggression, abuses, threaten to make it a dangerous age. Our culture does not give old age a good image: if anything, it suggests the idea that it is possible to stay young forever. Even the messages we get from some spheres of scientific research tend to convince us that aging can be fought, making us hope that it will not exist or that it will affect only others, those we see as old. From this, the need of a reflection

---

<sup>131</sup> R. Scortegagna, *Invecchiare*, Il Mulino, Bologna 1999.

that, as well as showing how aging involves all of us directly, invites us to discover its contents, know its ways – both to understand other people’s old age and accept ours.

### 1.1. *The conspiracy of silence*<sup>132</sup>

Recognising the process of aging, in its authentic reality, understanding it in its characteristics and fluctuation is the condition necessary to fully own it. On the contrary, in modern society aging tends to become a sort of taboo, a forbidden topic, as if it didn’t exist. But against the incurable disease of aging neither the exorcisms of analytical reason nor the processes of collective removal are effective.

The category of “other” could be adopted to characterise the condition of the elderly as perceived – and often treated – in society. Namely, adults tend to see in the elderly not another person like them but an “other”. An “other” whose image can be sublimated or degraded but that is in any case outside of the human.

The situation of the elderly can be seen from this particular point of view: although they are, like any individual, an autonomous freedom, they discover and choose in a society that forces them into the role of “other”. The drama of the elderly consists in the conflict between the fundamental claim of every individual to be essential and the needs of a situation that makes him/her inessential. Given this condition, how can he/she claim his/her full humanity and gain that minimum that is necessary to lead a life deserving of this name?

According to de Beauvoir, we push this ostracism so far that we even force it on ourselves, refusing to recognise we will be old.

*Of all realities, old age is perhaps the one of which we retain a purely abstract notion for the longest time”, Proust rightly said. All men are mortal, that we admit. But that many will become old, almost no-one thinks about as a metamorphosis.*

Simone de Beauvoir, *La Vieillesse*

But how does discovering old age happen? According to Goethe “age catches us by surprise”. Each of us is, for him/herself, the only individual, and often we are surprised when the common fate becomes ours as we face illnesses, misfortunes, deaths. Old age is a destiny and when it comes into our life it leaves us shocked: that the universal passage of time leads to a personal metamorphosis is disconcerting. But old age is particularly difficult to accept because we have always considered it as alien: would I therefore become someone else whilst still remaining myself? In effect, we consider with more clarity death than old age. Death is part, in fact, of our immediate possibilities, threatens us at any age, we happen to brush with it, often we are afraid of it, whilst we don’t get old in an instant. Young or fully mature, we don’t think we are already inhabited by our future old age, which is separated from us from such a long time that in our eyes it becomes confused with eternity: a faraway event that seems unreal. At twenty, at forty, thinking about being old is the same as thinking about being someone else and there’s something frightening about any metamorphosis.

But old age is also different from illness, with whom is at times confused (*senectus ipsa morbus*): this in fact tells us of its presence and the organism defends us against it. Illness

---

<sup>132</sup> Cf. Simone de Beauvoir (1908-1986) in *La Vieillesse*, the book that maybe more than all others broke the “conspiracy of silence” on old age (Editions Gallimard, Paris 1971).

in addition exists more evidently for the individual who suffers it than for those who surround him/her and often don't realise its importance.

Old age, instead, appears to others more clearly than to the individual: it is a new state of biological balance and, if adapting happens without shocks, the individual does not realise he/she is getting old. Artificial things, habits, allow the attenuation, for a long time, of psychomotor deficiencies; indispositions due to senescence can be just about perceived and kept quiet: we must have an awareness of our age to decipher them in our body. Many want to believe they are young at all costs, preferring to think they are in bad health rather than old. Others find it easy to define themselves as prematurely old, seeing in old age a sort of alibi; others, without accepting old age, prefer it however to illnesses that scare them and would force them to take countermeasures.

Therefore, how does the discovery and the acceptance of old age happen? The revelation of the other who is in us, of our new image, comes in fact from the outside, from those who look at us.

### *1.2. The identification crisis and the pursue of meanings*

In our old age we have an identification crisis: our image is at stake. We try and represent who we are through the way others see us. There are times when this is enough to reassure us of our identity – this is the case with children who feel loved and are satisfied of that reflection of themselves which they discover through the words and behaviours of their family and to which they conform, accepting it as their own. At the beginning of adolescence, that image shatters and a similar wavering also happens at the beginning of old age. In both cases, we talk about an identification crisis even though there are great differences: the adolescent is aware of going through a transition, his/her body changes and this embarrasses him/her; the elderly individual feels old through others, without having felt serious changes: inside, he/she does not agree with the label given to him/her, and ends up being unsure of who he/she is.

In this new condition, whether we like it or not, we end up giving in to the point of view of others, but this is never easy.

There is in fact a discrepancy between the situation we live and experience inside and the objective form that it has for others but that escapes us. In our society, the elderly person is designed as such by habit, by the behaviour of others, by vocabulary: he/she has to accept this reality. There is an infinity of ways to do this, but no-one will allow me to agree with the reality that I accept. To avoid old age becoming a comedic parody of our previous existence, there is only one solution, namely, to continue to pursue aims that give meaning to our life: dedication to other people, the collective, a cause, social or political, intellectual or creative work.

Contrary to what is sometimes suggested by moralists – who preach the serene acceptance of the evils science and technology cannot eliminate – we should maintain into old age passions that are strong enough to stop us from falling back on ourselves. Life, in fact, has value as long as we give value to the life of others, through love, friendship, indignation, compassion. We retain, then, some reasons to act and talk. The condition of old age seems to suggest a reconsideration of the relationships between men. If culture was not an inert knowledge, acquired once and then forgotten, if it was living, every individual would have a hold on his/her environment able to realise and renovate itself during the years and he/she

would be an active and useful citizen at any age. If the individual was not atomised since infancy, closed and isolated amongst other atoms, if he/she participated to the collective life, as daily and essential as their own, he/she would not know the exile of old age.

And how should a society be, for a man to remain as such even in his old age? The answer is simple: it would be necessary for him to have always been treated as a man. It is in front of old age, in fact, that society takes away its mask: the way in which it treats its inactive members tells a lot about it and how much emphasis it places on the mere productive function of individuals.

On the other hand, the elderly can also become accomplices in an oppressive culture of having to be, which is assigned to them by authority. In exchange for the protection it offers, they can be pleased with the role of “other” and trade their freedom, their individuality for that protection, which is actually more apparent than real. We know, in fact, that every individual, as well as the need to be known as an individual – which is an ethical need – has in him/herself the temptation to escape his/her freedom, to transform into an object. It is a fatal journey but it is also an easy journey: in fact, in this way we avoid the anguish and the tension of an existence lived authentically.

It is not, in fact, only society but our subconscious that defines the elderly as “other”. Whilst in the first case the process of deconstruction of what is “other” regards the social (the images, myths, stereotypes that surround old age), in the second, our subconscious is involved and this process appears, therefore, more complex because the taboo involves us. On the other hand, we can see a collusion between society’s myth of youth and our subconscious.

In front of the image of our future that the elderly propose, we remain incredulous, a voice inside of us murmurs absurdly that this won’t happen to us, that we won’t be ourselves anymore when this will happen. Old age is something that only regards others.

And this way we can understand how society is able to stop us from recognising ourselves as elderly. To see in old people not “others” but people like us, in order to no longer be indifferent to the destiny of someone we feel as far, alien, separate but is instead close, familiar, near, it is necessary what we could call a perspective identification, the recognition, that is, of our identity before that time in our life.

Individual aging is part of the human adventure that raises the fundamental questions of existence: confronted by its limitations, the elderly person reinterprets his/her presence in the world. In this story he/she is not isolated but remains strictly in line with the cultural, social and family group to which he/she is connected. In fact, each society attributes, implicitly or explicitly, a role to their elderly and it organises responses to the needs of the weakest, in particular of the non-self-sufficient “great old”.

Also in light of these comments, we can be surprised about the little interest towards the problems of the elderly in ethical debates, which certainly do not ignore the data relative to the so-called “weakest subjects”, however, the issues linked to old age (socio-family isolation, lack of financial resources, dependency) are rarely the object of an in depth reflection. Old age still remains a marginal issue in our western society despite medical progress putting in a new context the experience of aging and the approach to death.

In the West the most important things, functionality and usefulness, make us age really badly. In fact, we don’t age only because of biological decline but, as we have seen, also and especially for cultural reasons and precisely for the idea that our culture has of old age. On the other hand, the discussion about the meaning of old age cannot be purely theoretic.

Each of us is confronted with the reality of a possible event, for him/herself, his/her parents and friends: the questions to ask presuppose a personal investigation in relation to the issue of being “other”. It is, at the same time, about recognising the “other” as him/herself and respect, beyond what is expressed, the secret of his/her complex individuality. In situations of dependency, all those involved (and there are many, from the children to their families to the institutions and political authorities) must appeal to their ideas of person and respect for his/her dignity. Each person is in this way called to justify his/her interpretation of the notion of solidarity, progress, the idea of its power on life.

## 2. From care to taking care, to self-care

If it is undoubtedly true that the issue of aging is closely linked to other very important bioethical issues (the end of life, the right to health, therapeutic persistence, etc.), it however needs to be examined in itself as a phenomenon that presents a specificity and characteristics that must be put through a rigorous philosophical analysis.

In particular, the issue of the value of old age cannot be examined assuming as the model of reference only health. Health, even intended as full psycho-physical vigour, does not seem an adequate measure to search for the possible meaning of the condition of old age and, in general, of the various phases of life. This is fitting for old age, where we consider the increasing frequency, with the passing of years, of the condition in between full health and full-blown illness, which does not take away value from the dignity of the elderly.

If we had to compare old age to illness, we should maybe choose a condition of “normality” in the life of a man as the only parameter to define health. This cannot happen because each human age has its “normality”: there are, in other words, many normalities in relation to the different ages (infancy, adolescence, maturity, etc.). In this sense, old age is not the “loss of normality”, but is in itself a normal condition, connoted in a specific way at all levels – physical, psychological, social. Too often however, according to a perspective that can be seen in Western cultural models, illness itself can be used as an instrument to mask old age: as illness can be cured, it is legitimate to hope to get better; if this then doesn’t happen, it is the fault of the inabilities of medical sciences, never old age. It is a kind of idea that stops us from fully recognising old age, however, with the scientific paradigm according to which, sooner or later, we’ll find a solution to the illness. It can then happen that we give up taking care of aging, in its globalism and its dimensions, to chase hypothetical treatments, with the consequence, sometimes, that the choice of the programme of care loses the reference to the elderly’s quality of life.

As Daniel Callahan, one of the scholars of bioethics more involved in this topic, wrote: “The search for the meaning of health and the search for health do not walk hand in hand”<sup>133</sup>. Modern medicine’s temptation to put forward its ways to judge in terms of health in order to determine the global value of people’s lives, does not take into account the com-

---

<sup>133</sup> By Callahan, see in particular: *Setting Limits*, Simon & Schuster, New York 1987; *What Kind of Life?*, ibid. 1993; *The Troubled Dream of Life*, ibid. 1993.; *La medicina impossibile. Le utopie e gli errori della medicina moderna*, it. tr., Baldini & Castoldi, Milan 2000.

plexity of this value that appears – in its essential traits – rather linked to time and the relationships that exist between the past, the present and the future.

The improvement of the conditions of life (more availability of resources, better diet and personal care, more secure home hygiene) and therefore of the hygienic-healthcare conditions of our life (disappearance of the great epidemics, better care of the environment, etc.) must be attributed to the technico-scientific progress. On the one hand, the results of scientific and technological research, especially in the medical and biological field, allow us to tackle in increasingly more effective ways many illnesses, with interventions and treatments that were once unimaginable, on the other, the changes in the field of the organisation of work and the economy (deriving from the applications of scientific research and technological development) allow us to reduce our effort and the reduction of the time we spend working.

We ask, in light of these issues (increase in the average life expectancy, corresponding growth of the medical needs, relative increase of healthcare expenses) regarding medical practices and their aims, in the framework of a challenge for the self-understanding of medicine. One of the main problems is how to reformulate its relationship with health and sickness. According to Callahan, we must give more importance to achieving a good quality of life than to fighting illness, putting into question again some traditional attitudes towards death and life (those, for example, for which medicine opposes death by strenuously defending life).

In this way, we support a change in our healthcare system, aimed at the cure rather than the care – a sort of revolution in our way of thinking and our habits. Instead of a system aimed at increasing life expectancy, we should elaborate a philosophy of medicine and a type of healthcare assistance able to identify a better balance between curative and aggressive (technological) medicine and the most patient one of taking care.

With regards specifically to the elderly, this philosophy should recognise that they need interventions aimed not at prolonging life at all costs, but to avoid premature death and to guarantee a qualitatively good existence within the said limits.

In the view of aging as a “race against death” there’s the attempt to hide death, in which we see, in any case, the sign of defeat. For this, there are specific places to welcome the dying, quickly taking them away from the community of the living, or they are relegated in hospital wards or hospices. It is here that aging questions culture, ethics, social organisation, politics: the answer must not be looked for within the debate on euthanasia but in the system of individual rights, in the framework of a bioethics of caring, that takes on the defence of the rights of the weakest subjects.

Today we have a medicine that is reluctant to accept our common destiny, which is old age, decline, death. In this sense, the anti-aging movement and highly technological medicine are allies as each confirms the prejudices of the other: one in minimising the general characteristics of old age, the other in tending to fix the individual bodies deteriorated by their mortality. There is no limit, says Callahan in this regard, to the possibility of spending money to fight against the inevitable biological decline and the inevitable death, which are inherent to old age.

Callahan comments that it is the predisposition we have towards technological medicine that requires the investment of disproportionate amounts of healthcare resources.

On the contrary, a philosophy of medicine aimed at the bioethical principle of taking care and focused on defending the quality of life can better put the individuality of the per-

son in a context of more social interdependence and of careful acceptance of our mortality. The priority of this kind of medicine will not be to infinitely lengthen life but to use our resources to make sure that old age is a time of conclusion and enrichment, putting in first place nursing assistance, wide social services in order to help the elderly who are chronically ill and their families.

It is maybe superfluous to stress that we propose not to eliminate technological curative medicine but only to put it in the right perspective, making it less important in the future, highlighting new priorities.

People, we have said, have the right to “getting old living”, enjoying, that is, a quality of life that corresponds to the highest possible level of wellbeing. But it is necessary, with regards to this, to point out the absence of an adequate reflection about the issue of the minimum parameters of quality of life to protect for the elderly, as opposed to, once again, of scientific research, clinical trials and, sometimes, therapeutic persistence. This same predisposition towards curative medicine risks of depriving old age of meaning.

### *2.1. The balance of competences for the elderly*

Old age is characterised on the one hand by an increase in illness, inability, dysfunctions, but on the other hand we should also consider the rise in unpredictable intellectual and emotive resources, which give it new boundaries and perspectives. The lack of agreement on the concept of aging makes it difficult to collect reliable data on this issue, even if everyone agrees that it cannot coincide with merely chronological criteria.

The elderly’s level of social dependency is currently becoming the parameter of reference to predict and calculate the type of resources they will need at a certain time, in order to organise in the proper manner the necessary resources. Old age is not identified so much with age, as with the level of social autonomy, which contextually measures how the individual is able to take care of him/herself and possibly of others around him/her – often it’s an elderly couple – how he/she is able to tackle and resolve his/her own problems, using the resources usually available in the socio-healthcare system, and thirdly what is his/her social network: the number of active relationships, their efficiency and their mutuality<sup>134</sup>. For some years already, at the socio-healthcare level, there is a tendency to see the elderly in a perspective of self-care, going through a permanent project of training, so that the individual re-learns to manage his/her resources taking into account, rather than the inevitable limitations, the available personal resources or social network resources<sup>135</sup>.

If the reference to social autonomy and the ability to face daily experiences is made more explicit, the process of aging is less likely to be tackled by medicine and to be identified with psycho-physical discomfort, even though obviously these data are important in changing the way the elderly see themselves, their personal safety and their perception of the social network. If we accept that old age can be expressed especially through the consumption of healthcare resources in a certain amount of time, because it is not identified with shared criteria, like the healthcare needs seen through hospital admissions, day hospi-

---

<sup>134</sup> D. Demetrio, *L'età adulta. Teorie dell'identità e pedagogie dello sviluppo*. La Nuova Italia scientifica, Rome 1990.

<sup>135</sup> W.A. Mc Intosh et al., *Social support, stressful events, strain, dietary intake and the elderly*, Medical Care, 1989, 27 (2), pp.140-153.

tals, surgeries and instrumental diagnostic. These are necessary but insufficient data to describe the new boundaries of old age, not always fitting to start an effective action of prevention, or guarantee a better quality of life and limit the emerging costs.

It has authoritatively been said that the level of civilisation of a society is measured by the degree of care and protection towards the weakest individuals in the community. Given, however, that old age seems to always be a polychrome galaxy to the point of being able to refer to old ages in the plural, we must certainly overcome the stereotype of the elderly “alone” as a problem, in order to increasingly see the old person as a “resource”<sup>136</sup>, whatever his/her psycho-physical state. This, therefore, overturns the social perspective towards the elderly also from a religious-spiritual point of view and the point of view of values.

We can therefore talk about a society that grows in civic maturity not only when it safeguards and protects, but when it promotes the person and frees his/her resources, at any time in his/her life. Operatively, this goes through the necessary organisation of services, civic administration, “adequate” housing for the man in his totality.

For the elderly person, therefore, the solution is not so much and only to increment the socio-healthcare services, but to promote what has been defined as Active Aging<sup>137</sup>. Old age is an age that – if “educated” – can still be active and creative according to each person’s ability in each single phase of their life.

Moreover, a highly civilised society puts into place pedagogic strategies to prepare for the condition of old age (the so-called geragogy). What we want to state, instead, is that the human being, with his/her rights and duties, has a dignity and a richness that must be promoted in each phase of his/her existence. The elderly must be always considered as subjects participating to the construction of society, according to each individual’s capabilities. In this sense, then a mature society is called to not overlook individuals when they become old but to promote their resources of culture, ability to pass on values and experiences, individual current capabilities of spirituality and religious thought: we can in this sense fully realise the notion of Active Aging.

### 2.1.1. Healthcare centres for the elderly

The creation of Healthcare centres for the elderly has allowed a better integration of rehabilitative-welfare interventions, unifying them in a single context in which they are more easily accessible for the elderly and their families, and it has allowed us to experiment some positive actions to improve their health, through a series of socio-psycho-pedagogic interventions, starting for each elderly person from assessing his/her competences. This assessment has the objective to let someone know his/her competences better, clarifying

---

<sup>136</sup> Cfr. Antico, E. Sgreccia, *Anzianità creativa*; G. Baldassarre, *Da fardello a ricchezza. L'anzianità del nuovo millennio*, Edizioni dal Sud, Modugno (BA) 1999; L. Baracco, *Una vita lunga e serena*, Casale Monferrato (AL), Piemme, 1999; M. Cesa-Bianchi, *Giovani per sempre? L'arte di invecchiare*, Editori Laterza, Bari 1998; Vissani, Salvi, *La donna marchigiana*; De Rose, Sacchini (a cura di), *L'età in gioco. Anziani in Calabria tra vecchie e nuove identità*. Soveria Mannelli, Rubbettino 2002.

<sup>137</sup> With the term Active Aging we intend an active, creative old age, shaped – as much as possible by the individual subjective and objective situation – by the will and involvement of the elderly in different activities. With regards to this issue, see Antico, E. Sgreccia (ed.), *Anzianità creativa*; L. Antico, *Gerotrascendenza e vecchiaia attiva*, in Petrini, Caretta, Antico, Bernabei, *L'assistenza alla persona anziana. Aspetti teologici, etici, clinici, assistenziali, pastorali*, CEPSAG-UCSC, Roma 1993, vol. I, pp.11-22; K. Avlund *et al.*, *Active life in old age. Combining measures of functional ability and social participation*, Dan. Med. Bull., 1999, 46 (4), pp. 345-349.

them in relation to a new personal or professional project, highlighting the means and phases necessary to realise it. The main characteristics of this assessment come from a synthesis of known procedures that associate a psychological analysis of the competences to an active pedagogic dimension. The most important means to carry out this type of assessment are a personalised empathic listening and careful observation, during a suitably long time, to verify the concrete ways in which different situations are tackled and managed. This is a journey that includes theoretical, methodological and operative aspects to go through together with the elderly. The perceived quality of life is linked to his/her history, and it also changes the way in which he/she responds to new situations, without someone making decisions, deciding the time scale of events, characterising the solutions he/she slowly arrives to<sup>138</sup>. The problems of the elderly, like anyone's, at whatever age, must be tackled with an integrated approach to guarantee the necessary level of socio-welfare quality. We cannot reduce the perception a person has of him/herself to his/her perception of his/her illness, or poverty, forgetting the cultural and professional experience he/she has had for a number of decades. Many WHO documents often highlight how the fundamental objective is to make the total life expectancy coincide with the expectation of an active life: adding life to the years is more important than adding years to life.

Currently, in the most advanced structures dedicated to the elderly, a multi-dimensional evaluation of their care-needs is carried out by using a range of tests that explore the functional and environmental issues not included in ordinary objective examinations. It is a more thorough approach, but still focused on the needs of care. To change the approach to the elderly by avoiding introducing medications and implementing instead the focus on their abilities and the energy actually available requires a project that anticipates:

- a different anthropological basis for the definition of old age,
- a new psycho-pedagogic competence to identify the active resources on which to intervene,
- a socio-healthcare network adequately motivated and competent.

To tackle this new challenge that, although it can also involve a reduction in costs for the National Healthcare Service, must be taken on mostly for the improvement in the elderly's quality of life, the hypothesis that monitoring their health cannot be done only with the traditional clinical approach has been formulated. There will always be cases where the level of disability requires an uninterrupted intervention for their physical rehabilitation, as a consequence of cardio-vascular, neurological or post-traumatic pathologies. But even then the best recuperation happens by integrating the psycho-motor field (never only motor), with that focused on a personalised project to strengthen the learning abilities, after carrying out an evaluation of their competences. The professionals involved in this process are very varied and include the geriatrician, psychiatrist, but also the nurse, the physiotherapist, the speech therapist, the psychologist, the educator, etc. With all of their contribution a port-folio is created<sup>139</sup>, which is something simpler than a medical record, in which

---

<sup>138</sup> N.P. Roos, E. Shapiro, L.L. Roos, *Aging and the demand of health Services, which aged and whose demand?* Gerontologist, 1984, 24, pp. 31-36.

<sup>139</sup> The port-folio is an instrument that in the last few years is becoming increasingly interesting, because it allows us to overcome the quantitative reductionism of an assessment and it opens towards a qualitative description of what the subject has done and learnt to do. And at the same time it is a memory of the things done and a project

are collected, in an organised but often fragmented manner, the clinical data regarding the elderly: it is the description that suggests the assessment of their active competences<sup>140</sup>.

To define what the assessment of competences is however, it's not easy. The assessment of competences must allow the elderly to take into consideration all their professional activities to explain their personal and professional experiences: finding and evaluating their acquisitions linked to work, training and social life; better identifying their knowledge, competences and habits; discovering their unexplored potential; collecting and structuring the elements that allow them to elaborate a personal and professional project, better managing their personal resources; organising their personal and family priorities, better use their resources in negotiating their needs with external interlocutors. The assessment of competences is found in the boundary between a retrospective dimension: the important moments of their professional activity and socio-family life, to rediscover the acquired competences, centres of interests and the reasons of a perspective dimension, which allows them to realistically formulate new choices, making the right decisions.

In the assessment of competences, the diagnostic-evaluative moment is seen as educational, as it expresses openness towards a new phase of life, with characteristics partly equal and partly different from the previous ones, but in any case it is still our life. The assessment of competences, whilst giving back to the elderly an awareness of their capabilities, reminds them of the urgency to adapt them to new situations and probably also the need to gain new ones. In other words, it looks at old age in terms of a new learning phase, with its own peculiar physio-pedagogic approach, that goes beyond the confines of involving medicine (even though often necessary).

The slogan, which characterises this approach, is to remember that we need to learn to age to realise interesting things and maybe never done or done so far in a different way. The technico-methodological directive of reference therefore moves away from a strictly diagnostic notion and it turns in a new opportunity to learn, which involves the individual actively. In this way it becomes possible to think of re-evaluating the social involvement of the elderly in society, both with regards to family as a wider social network<sup>141</sup>.

The basic objectives of an assessment of competences therefore are:

Support the critical reconstruction of their professional past, to highlight abilities and

---

of things to do, so that it contextually explains the results achieved and the processes started. It is also important for the elderly, because whilst from a certain point of view it represents their overall history, on the other it explains their current interests, as well as their difficulties, and it changes both in a rehabilitative project. As a product it includes the things done, with the relative objective evaluations. As a process it expresses the things to do, with the subjective evaluation of the motivations and the difficulties. It therefore belongs to the sphere of the meanings that the elderly wants to achieve, intentionally calling into play strategies of change. In the portfolio there are different types of documentation: personal history, with the knowledge and the awareness of our resources; the results of all the tests carried out, to investigate particular aspects; the type of commitment with the Centre; the plan of activities anticipated for the future, with the relative people responsible; the references to the medical records held by the Centre. The portfolio is the frequent object of discussion with the elderly, which contributes to their renewal, with regards to their personal history, and it continuously revises progress and difficulties with the operators, to redress the aim.

<sup>140</sup> A. Di Fabio, *Bilancio di competenze e orientamento formativo, Il contributo psicologico*. Giunti, Firenze 2002.

<sup>141</sup> F. Boschi, A. Di Fabio, *Apprendimento e nuove dimensioni della mente*. Continuità e scuola, November-December 1997, pp.72-85.

competences that can be used within other contexts; Facilitate the identification of the individual's values, preferences, interests and motivations;

Help them to elaborate a personal and social project, eventually also with professional aspects, to negotiate the possibilities of expression and realisation of the individual.

The assessment represents for the elderly the opportunity to verify their ability to transfer the wealth of experiences and competences accumulated previously to the new situation, making the necessary changes and therefore strengthening their ability to modify in their favour the situations of change.

### 2.1.2. The different phases of the assessment of competences

The intervention on the Assessment of competences is structurally a team effort, in which the role of psychologist, who can be the trainer to strengthen in the individual the perception of his/her own self-efficacy<sup>142</sup>, has the contribution of new Educators. They have to be able to elaborate with the elderly a project-development aimed at strengthening their capabilities, which go from the guarantee of the minimum levels of autonomy to higher profiles of commitment. The objective is to reach a project that reduces the gap between the plane of aspirations and the fear of our own inability to get there, to identify a way to realistically see the strategies necessary to realise what we need<sup>143</sup>. The educator in this phase uses both teaching-training techniques, and counselling strategies<sup>144</sup>, to achieve a positive perception of self. The terms ability, aptitude, qualification and competence are not synonyms, even though they are partially included one into the other. Usually a competent person is able to face complex situations and resolve his/her problems using his know-how flexibly. It requires a certain dose of creativity to be able to transfer their own abilities in situations that are not always foreseeable beforehand, even when lacking the usual resources used in similar situations. Studies on the elderly's learning abilities show in these two aspects the most problems: the transfer of the abilities they have in fields that are slightly different from those who belong to the boundaries of daily life and the application to known contexts of consolidated, but reduced, abilities. The relationships between the elderly with themselves and their context are still at play: social-family, technico-organisational, etc. To teach and to learn again to manage him/herself and the circumstances is the objective of this new approach. It is a dynamic assessment aimed positively, which includes also the possibility to teach the elderly how to use new technical and behavioural strategies, overcoming the levels or anxiety linked to change<sup>145</sup>.

---

<sup>142</sup> A. Bandura, Self-efficacy mechanism in human agency, *American Psychologist*, 1982, 37, pp.122-147.

<sup>143</sup> L. Arcuri, *Il Sé come soggetto e oggetto della cognizione sociale*, Laterza, Bari 2000.

<sup>144</sup> A. Di Fabio, *Counseling. Dalla teoria alla applicazione*, Giunti, Firenze 1999.

<sup>145</sup> An experience of this type was carried out recently with one hundred elderly people, who frequented in Rome some social rather than healthcare centres dedicated to them. The work was tackled in three phases: (a) a welcome, explorative phase, to verify the availability to accept the new approach; (b) a phase of analysis, based on a careful exploration of the personal resources of the individual to reinforce the sense of self-efficacy, and carried out with a personalised help in order to investigate the reasons, the professional and personal interests, identify the competences and aptitudes, evaluate the personal knowledge and the possibilities that can actually happen; (c) a final discussion, for a positive restitution to the individual of the data found, with a profile of current competences that can be used, aimed at supporting their level of autonomy, also with new forms of guided learning. In the final synthesis the individual carries out a reflection on his/her competences not only to increase his/her self-esteem and relative safety, but to also show to others the competences acquired during his/her life, offering mem-

The training of workers in this field is not easy or obvious. It is not about observing or assessing objectively, but being with the subjects and accompanying him/her in the effort to clarify what are the things he/she would like but can't do, discreetly suggesting alternative ways, without substituting ourselves to him/her. It is important to stimulate the elderly to exercise a strong self-attention to grasp the right associative connections between perceived competences and tasks to carry out. Rather than an expertise, it is a structuring help, strongly interactive and linked to a pedagogy of appropriation. What is decisive is to interpret old age not so much in terms of loss of ability as in terms of permanent training, with particular categories, both from the point of view of methodology and assessment<sup>146</sup>.

The emergency elderly is still a novelty in our socio-healthcare context and it is not easy to overturn the medical approach, almost the only one until now, in favour of a psycho-educational approach, in which the focus is not the lack of competences, which makes the elderly more or less explicitly dependent, but their potential self-care. The worker's intervention in this logic must have a different aim, based on recognising the experiences of the elderly, who become a privileged source of common reflection<sup>147</sup>. Talking is not only venting and sometimes looking for comfort, but the moment of active remembrance of positive experiences. The retrospective approach aims at identifying episodes of the individual's life, when he/she had responsibility and was able to tackle it<sup>148</sup>. They are the most important strategies to re-elaborate and apply them to the present. It's not so much the facts in themselves that are important, but the perception of events, according to a technique that integrates the subjective and the objective point of view and allows the more in depth exploration the relationship of the elderly with themselves, or, as it has been perceptively said, with their ghost. Through his/her memory the subject reveals to the educator a very interesting space in which the possibility arises of highlighting the competences he/she once had, to interpret them and give them back to the subject, as a reassuring moment of what he/she is still able to do today.

To rethink old age in terms of permanent training requires also the identification of tools with which to take into account its process of adaptation to new events that mature both in the changes in exterior circumstances and in the different psycho-physical resources available.

The history of this formative stage for the elderly, the last in their lives, represents also the spiral of an educational circle that started many years before, and that found its efficacy when it began to link objectives, intended as specific needs, with adequate contents and appropriate didactic methodologies, to end with a coherent evaluation of the needs initially highlighted and the results achieved<sup>149</sup>. The elderly has the right to learn to be old as well

---

ories a more concrete and credible substrata of experience. The method has its strong points in a series of factors that can be summarised as follows: the elderly explicitly show their will to participate, giving their consent; the working method is chosen with them, starting with a self-analysis assisted by an expert; there are the premises for an evolution of the image of the elderly, directing it positively; the data collected belong to the elderly and cannot be communicated to others without their consent. To evaluate experience, the following elements have been identified: the psychological effects on the elderly; the social effect of experience; the effects on the training of the operators; the defence of financial autonomy, intended in itself as a form of self-care, allows us to limit the costs, also in terms of consumption of healthcare resources.

<sup>146</sup> P. Gilbert, Schmidt, *Evaluation des compétences et situations de gestion*, Economica, Paris 1999.

<sup>147</sup> J. Bruner, *La ricerca del significato*, Bollati-Boringhieri, Torino 1992.

<sup>148</sup> A. H. Maslow, *Motivazione e personalità*, Armando, Roma 1973.

<sup>149</sup> D. Demetrio, *Raccontarsi. L'autobiografia come cura di sé*. Raffaello Cortina Editore, Milan 1996.

and this right involved the obligation for someone to teach him/her, without necessarily seeing his/her limitations as an illness.

The acquisition of new competences, with the relative awareness, improves the image of self and reinforces self-esteem and confidence. It therefore becomes easier to maintain an internal control, as feeling masters of our own lives make it easier to overcome the limits of a stereotypical view of old age, which centres on the diagnosis of the limitations and only advocates medical interventions.

Becoming aware of ourselves and our image in connection with the external environment can present difficulties at any age and it is important for it to happen in the context of an empathic relationship, capable of guaranteeing welcome and support to the management of critical incidents, in which the perception of self is full of negativity<sup>150</sup>. The concept of care assumes from this point of view a particular value and it touches the most intimate aspects of our emotive life, loneliness, abandonment, if it finds in the other someone ready to listen to our problems. It is difficult to say at this point whose task it is: the geriatrician, or the nurse, the psychologist or the educator. It touches all the team in its united structure, even if it is delegated to the individual most capable of establishing a significant relationship with the elderly, overcoming the risk of group anonymity, in which anyone is fine, because no-one has expressed a real option for the individual.

What is necessary to stress is that, in the assessment of the elderly's competences, as well as the cultural and technico-scientific aspects, we must also explore the relational ones and the values. It is worth focusing on these last ones, because they represent the humus on which the elderly keep re-elaborating their personal history and judges it. It is difficult, that is, to positively interact with an elderly person if we don't know his/her values.

### **3. Old age: intergenerational communication and cultural, spiritual/religious aspects and values**

#### ***3.1. Intergenerational communication***

What is the meaning of growing old as part of the vital cycle and in the framework of our individual biography? One of the facets more deserving of reflection is that of intergenerational communication, to be fundamentally intended as an exchange of meanings appropriate to the different phases of life and as a search for shared values in the various phases of existence. The cultural (namely, the lack of a network of shared meanings regarding the fundamental aspects of living: birth, procreation, death) and social (the current life conditions are such to make authentic forms of communication increasingly difficult) causes have been mentioned more than once – with regards to the inability of contemporary society to find this communicative sense of being alive, especially when life conditions are not optimal.

To support this process – that can be found in terms of creative ageing – could be useful to face our perception of old age through an historical and anthropological journey to help re-discover the images of the different societies and historical times, and that allow us to find the web of the symbolic meanings linked to old age – men and women. This journey

---

<sup>150</sup> C. Dweck, E.L. Leggette, *A social-cognitive approach to motivation and personality*, *Psychological Review*, 1988, 95, pp.256-273.

seems important to re-build a relationship between generations that connects yesterday's world to today's world and its challenges. In this framework the concept of generativity – as characteristic of adult age - elaborated by Erik H. Erikson seems particularly important. As stated by Erikson, the adult who takes care of the following generations, takes on him/herself the generational task of giving strength to those coming after him/her. This concept brings us back, amongst other things, to the crucial relationship of the elderly with time. To overcome egocentrism and open ourselves to others means, in fact, coming out of the present and projecting ourselves into the future, going beyond the simple consumption of existence to create something new: more mature conditions of existence and more profound links with life.

Erikson's is a tentative attempt at giving meaning to the entire circle of life through the idea of a journey, a journey open and never completely finished, which takes shape in different phases and roles with a strong emphasis on the values of exchange and mutuality. In adult age, the crisis of development is marked by two antagonistic forces: generativity against stagnation. The conflict knows alternate phases and the individual's psychological balance is, therefore, unstable. This is, however, a normal stage of growth for which the individual must be pushed to make the sane forces prevail and resist the pathogenic stimuli.

But what is actually meant by generativity? It can be defined as the individual's predisposition to conceive individuals, products, ideas; enrich our personality and guide those who are growing. And, therefore, an ability that encompasses a wide scope of activities, projects and intentions, as it concerns not only the ability to have children or show the capabilities we have in various fields, but also the tendency to follow the rise of the young to an adult life. Generativity does not come, therefore, automatically from being parents, but is without a doubt a sign of profound psycho-sexual and psycho-social maturity we can see in adults when personal constructive forces prevail within them.

The stagnation, in which Erikson finds the pathological centre of adult life, is, on the contrary, a weakening of the tendencies that make the individual a productive and creative being, a regression to an unnatural intimacy accompanied by a widespread dissatisfaction, by a self-deprecation often induced by psychophysical deficiencies which cause anxiety.

From the antinomy between generativity and stagnation derives the virtue of care, a term that indicates a type of commitment and consideration that is continuously expanding, where the positive forces of the previous age can be found. It expresses the instinctive impulse to love, stroke anyone who, in a state of abandonment, shows his/her desperation.

As we can see, caring assumes a central importance in inter-human relationships, seen as the essence of the first and last phases of life: it gives life a sense of cycle, the meaning of returning.

Erikson warns us that he lists the stages of life starting with the last one, that of old age, to verify what meaning can have a look through the whole life cycle in the global context of its journey. He also re-affirms his conviction that, after having completed the inter-connection between all the stages, it is possible to start from any one of them to arrive to the others within the map that expresses their meanings and position. In this framework, we stress that adult age is the link between the life cycle of the individual and that of the generations.

An objective difficulty of the transition phase we are going through, which goes from the elite of the elderly to the mass of the aged, is that of the relationship between the change

in the social conditions and the persistence of cultural images. And however the elderly can and must preserve an important generative function: in old age, in fact, according to Erikson, all the qualities of the past are enriched with new values. Therefore, great importance has the generative stage of the adult age that precedes old age even though, it must be remembered, in an epigenetic framework, the after only means the subsequent version of a previous level, not its loss.

Generativity includes in itself the characters of procreation, productivity and creativity, the ability, therefore, not only to create new individuals but also a sort of self-generative power relative to a further development of identity.

Erikson insists on the attitude of care that the elderly can have towards those he loves, an attitude that can keep and reinforce his/her identity as well as open him/her up to the relationship with other generations. It is a very interesting aspect and, generally, scarcely taken into account in the reflection on senescence as, when we talk about the elderly, especially the subjective dimension of self-care, of the preoccupation for our own destiny, is stressed.

Erikson has no doubts: the role of old age has to be re-considered and revised in light of the fact that the last stage of life assumes a big relevance for the first: in the most vital cultures, children mature mentally thanks to the relationship they have with the elderly. We will therefore have to reflect for a long time on the importance that it will have, and must have in the future, this relationship when a mature old age will hold experience which is susceptible of being learnt according to a “creative ageing”. The changes induced by time – amongst which the increase in life expectancy – require, in fact, new and more profound re-ritualization, able to ensure a more significant interchange between the beginning and the end of life, a more defined synthesis of the stages.

Erikson denounces the current disorganisation of family life as the cause that largely contributes to the loss, in old age, of that little vital involvement that is necessary to feel really alive. The lack of this involvement seems to him to be the nostalgic theme hidden in the apparent symptoms that push the elderly to recur to psychotherapy, the most common reason of their desperation, due to a prolonged sense of stagnation.

There is nothing natural, warns Erikson, in the loneliness of the elderly: it's not in their nature to give up the encounter with others, the exchange. On the contrary, they fully belong to the community, and with all the wealth of their personal history, it appears as one of the strongest needs of this stage of life. The isolation of the elderly is not, therefore, inevitable, as it is not the result of their inclination but of prejudice and cultural and social barriers, which we must commit to remove.

It's up to all of us – the problem of the elderly is not just their problem – to trace the project of a new culture, made of laws but also behaviours, that is able to see in ageing that moment in life when fuse and acquire meaning all the themes of what we have lived, learnt, suffered – like in a symphony or a tale that, with its enormous load of wisdom, could be a precious link between generations.

### *3.2. Spirituality and religion in senescence*

The condition of old age can be investigated in various fields – think, for example, of the state of health and the socio-healthcare services or the activities (work and fun) – even relatively to factors that play a role not less relevant in determining the concrete situation

of a personal life<sup>151</sup>. We talk, namely, of elements that are “immaterial” but strongly influence the “materiality” of daily life, like: interpersonal relationships, spirituality (the meaning of life, death and transcendence) and religion with its load of attitudes and cultural practices, the sphere of personal and social values, the formation and promotion of the person also in old age, his/her creativity (Active Aging), also mentioning the preparation of the new generations to old age (geragogy)<sup>152</sup>.

Independently from the general philosophical notion according to which each of us considers life as a whole, the spiritual and religious dimension represents an element which is really difficult to ignore when we discuss man. And although this dimension recalls very wide and often heterogeneous semantic connotations, it is still unquestionable that spirituality and religion constitute a privileged horizon through which the person, and in particular the elderly person, can better understand a hurried and superficial daily life<sup>153</sup>.

Therefore, the religiosity of the elderly represents a very interesting field of investigation – although it has been explored less than other fields in specialised literature – because

---

<sup>151</sup> Also in sectors that cannot be immediately referred to a religious/spiritual dimension, like biomedicine, said dimension find a relevant space. An investigation (of the 14.1.2005) of the databank of the National Library of Medicine of the American National Institute of Health (site: <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>) using the lexical couples (elderly OR aging AND spirituality OR religion” gives, in fact 27,327 bibliographical references containing at least two of the four factors (the research included publications relative to the period between January 1966 and January 2005). Adding to the key-words mentioned also the couple “ethic OR bioethics” (but in a period between 1970 – the year in which the term “bioethics” was coined – and 2005), the result is still 16, 225.

<sup>152</sup> There is not much research on the condition of old age involving these aspects. In particular, in Italy are available two investigations carried out on a sample (about three thousand elderly persons each), both carried out by the Università Cattolica del Sacro Cuore (UCSC). The first (UCSC Molise), in the Molise region, at the end of the 1980s, within the “Subproject B” (Investigation of the ethical, religious and psycho-geriatrics problems of the elderly population of the Molise region with the scientific guidance of the UCSC’s Centre of Bioethics) of the “Active Aging Research Project and the results of which are published in E. Sgreccia, S. Burgalassi, G. Fasanella (eds.), *Anzianità e valori*, Milan, Vita e Pensiero, 1991; L. Antico, R. Bernabei, F. Caretta., M. Petrini, A. Sgadari, *Anziano Salute Società*, Vita e Pensiero, Milan 1991; L. Antico, E. Sgreccia (eds.), *Anzianità creativa*, Vita e Pensiero, Milan 1989. The second (UCSC Calabria), still under the scientific guidance of the UCSC’s Centre of Bioethics, carried out at the end of the 1990s in the Calabria region for the “Facite” Foundation in Catanzaro, the data of which are reported in C. De Rose, D. Sacchini (eds.), *L’età in gioco. Anziani in Calabria tra vecchie e nuove identità*, Soveria Mannelli, Rubbettino 2002.

<sup>153</sup> There is a vast literature on the importance of spirituality and religion in order to improve the quality of life of the elderly. Amongst others, cf. Petrini M., *La spiritualità della persona anziana*, in E. Sgreccia (ed.), *Persona e terza età: assistenza, inserimento, partecipazione*, Edizioni Teotókos, Siracusa 1994, pp.187-206, p. 191; L. Sandrin, F. Caretta, M. Petrini, *Anziani oggi. Una sfida per la medicina, la società e la Chiesa*, Torino, Edizioni Camilliane, 1995; M. Petrini, *La spiritualità della persona anziana*, in Sgreccia, (ed.), *Persona e terza età*, pp. 187-206; M. Petrini, F. Caretta, L. Antico, R. Bernabei, *L’assistenza alla persona anziana. Aspetti teologici, etici, clinici, assistenziali, pastorali*, 3 volumes, CEPISAG, Rome 1994; R. Bleistein, *Il tempo libero e la terza età. Riflessioni per una pastorale degli anziani*, La Civiltà Cattolica 1998, III, pp.239-253; J. S. Levin, R.J Taylor., *Age differences in patterns and correlates of the frequency of prayer*, *Gerontologist*, 1997, 37, pp.75-88; S. Acquaviva, E. Pace, *Sociologia delle religioni. Problemi e Prospettive*, Carocci, Roma 1998, p.102; A Donghi., *La liturgia e la preghiera degli anziani*, *Anime e Corpi*, 1999, 204-205, p.429; V. Cesareo, R. Cipriani, F. Garelli, C.Lanzetti, G. Rovati, *La religiosità in Italia*, Arnoldo Mondadori Editore, Milan 1995; S. Burgalassi, C. Prandi, S. Martelli (eds.), *Immagini della religiosità in Italia*, Franco Angeli, Milan, 1993; S. Burgalassi, *La condizione anziana. Un approccio globale a livello antropologico e sociologico*, *Medicina e Morale* 1977, 3, pp.259-284 and, finally, a part of the research carried out by the Eurispes, The Third Report on the Condition of the Elderly in Italy, 1992 (<http://www.mix.it/eurispes/EURISPES/168/default.htm> and <http://www.mix.it/eurispes/EURISPES/137/8a.htm#1>).

it opens a view on a world that is mostly existential linked to many other factors (being satisfied with life, quality of life, perception of time, etc.).

In addition, we must consider that the spiritual component becomes more evident in old age that, often, is the time in which the desire to be reassured about a future life is stronger. From the studies available, it clearly emerges that religion greatly influences the quality of life of the elderly, whether they are self-sufficient or disabled. This is confirmed in a personalistic idea of the quality of life, according to which the person's well-being must be assessed globally, including also needs and desires, which are aimed at values that, alone, realise the plenitude of the person<sup>154</sup>.

It has been stated that old age is the time of changes (socially, physically-biologically and with regards to values): these changes can be traumatising and destabilising for the elderly, because they lack those points of reference characterising their whole life journey. With regards to this, the "ad hoc" investigations show that, for many, religion is one of those cornerstones that with age do not falter, they actually get stronger or, if they were not very solid in youth, they can have, in old age, more weight and space. Religiosity gives the elderly stability and a good dose of certainties that help them face possible problems related to age. The ethico-religious values given in the first instance by the family of origin and accepted, almost automatically, during youth, become in old age something integral to personal life.

The general process of secularisation in today's society has affected the elderly less, both for generational and existential reasons, as old age represents a life cycle "that inevitably leads to questioning the meaning of life and the destiny of man after death, namely, to develop or recuperate a sensibility for the central themes of each experience or religious message"<sup>155</sup>.

In fact the elderly sees a series of traumatising changes that tend to overturn all their certainties, making them feel completely (or partially) inadequate to the new reality that is happening. The elderly realise that between their world and that of the new generations there is often no continuity (in this sense religiosity is a very indicative example), there is no real transferral of values.

Today's society has modified the values felt as important by the elderly. Personal dignity is substituted by criteria of pure efficiency, functionality and usefulness: "the other is appreciated not for what he/she is but for what he/she has, does, gives"<sup>156</sup>. It is evident that today's society is permeated by a strong pragmatic empiricism that leads man to value most of all, if not only, factuality rather than ideality. It is the homo oeconomicus o homo technicus (therefore of "doing") taking over the homo humanus (or of "being") that, alone, can guarantee to man the recuperation of his lost integrity<sup>157</sup>. All the currents of thought, religion and culture, which play their anthropological game on the value-person and, amongst those also the Christian vision, can work together to regain a sense of being.

---

<sup>154</sup> E. Sgreccia, *Bioetica, società, sanità e qualità di vita*, in ID., *Manuale di bioetica. II. Aspetti medico-sociali, Vita e Pensiero*, Milan 2002, p.16.

<sup>155</sup> M.C. Romano, G.B. Sgritta, *Uguale ma diversi, diversi ma uguali*, in *Anziani '98. Tra uguaglianza e diversità* (Second Report on the condition of the elderly, by the Federazione Nazionale Pensionati CISL), Roma, Edizioni Lavoro, 1999, p. 93.

<sup>156</sup> Giovanni Paolo II, Lettera enciclica "*Evangelium vitae*", 25.3.1995, n. 23.

<sup>157</sup> Cfr. K. Wojtyła, *La visione antropologica della "Humanae vitae"*, Lateranum 1978, p.129.

Religion can represent, therefore, a valid instrument to regain a world of values that the industrialisation and modernisation process has progressively weakened. It is also for this reason that time for the elderly gradually loses the shape of real and tangible time and becomes transcendental and spiritual time, which focuses particularly on the eschatological world. The elderly are in this way put in the condition of giving meaning again to their lives, so strongly connoted by changes<sup>158</sup>.

The logic that permeates contemporary reality has profoundly and radically changed the expectations and meanings to give to life. In this sense, the objective of the elderly becomes, more or less consciously, regaining the spiritual, interior and human world.

The re-emergence of the religious dimension represents – in many of the cases studied – a link with their past youth often connoted by a strong sense of religion. The continuity happens more easily in the spiritual dimension than in the physical-corporeal one where the elderly feels fragile and vulnerable, as well as contingent. Through the spiritual world we can regain the “civility of being”, which reveals itself “at the contemplative moment, in the search for the sign and it can be found within the meaning”<sup>159</sup>. After all, wisdom and maturity that characterise old age, confer to this particular phase of human life a different meaning and purpose, as we should be aiming at realising a more profound interiority and searching for values that transcend material reality.

### 3.2.1. The universe of values in the life of the elderly

The moral dimension – both with regards to choices of personal values and ethical issues with mostly a social relevance – is a particularly interesting field of investigation. Not only, however, as such, but also in relation to other aspects: the education received within the family and in the classical educational “institutions”: school, church, work. This gains more relevance not so much and not only for the elderly of today, but also for those of tomorrow. More recently, bioethics has also looked in depth into ethical issues arising during old age<sup>160</sup>.

---

<sup>158</sup> It must also be noted that both the tout court meaning of religion and accepting a certain church is more often found in women than men and among those of a mature age or old age than younger people (cf. Cesareo, Cipriani, Garelli, Lanzetti, Rovati, *La religiosità in Italia*, Burgalassi, Prandi, *Immagini della religiosità in Italia*, Martelli (eds.).

<sup>159</sup> E. Sgreccia, *Bioetica e tecnologia*, in ID., *Manuale di bioetica. I. Fondamenti ed etica biomedica*, Vita e Pensiero, Milan 1999, p. 779.

<sup>160</sup> This can also be found in encyclopaedic texts of reference like, for example, the contributions in Post S.G. (ed.), *Encyclopedia of Bioethics*, vol. 1, New York, MacMillan Reference USA – Thomson Gale, 2004, Jecker N.S.: *Societal Aging*, pp. 101-104; Cole T.R., Holstein M., *Old Age*, pp. 109-112 and *Anti-Aging interventions: ethical and social issues*, pp. 112-116. Cf. also: E. Sgreccia, *Bioetica, anzianità e invecchiamento delle popolazioni*, in ID., *Manuale di Bioetica. II. Aspetti medico-sociali*, Vita e Pensiero, Milan 2002, pp. 497-557; Soldini M., U. Accettella, S. Burgalassi (ed.), *La bioetica e l'anziano*, Edizioni ISB, Acireale 1999; G. Acocella, *Questioni di bioetica e terza età*, in Federazione Nazionale Pensionati CISL (ed.), *Anziani 2000. Third Report on the condition of the elderly*, Edizioni Lavoro, Rome 2000, pp.137-151; R. Cipriani, *La religione dei valori*, Salvatore Sciascia Editore, Caltanissetta-Roma 1992. For an investigation of the ethical problems arising in geriatrics, read also, M. Petrini, F. Caretta, L. Antico, R. Bernabei, *Etica e Geriatria*, CEPSAG, Rome 1993. Finally, interesting is also the study carried out on a sample of 250 women over seventy-five from the Marche, in which the theme of spirituality/religion was tackled, and found in the volume by A.M. Vissani, E. Salvi, *La donna marchigiana. Una femminilità vissuta in pienezza*, CEPSAG-UCSC, Rome 1998.

Overall, the available literature indicates some general tendencies. The values of today's elderly, at least in the European western latitudes, shows two main elements: 1. A dishomogeneity in comparison to their awareness of the relationship anthropology/value; 2. With regards to values, it would seem that there is a widespread homogeneity regarding the received ethical "models", with a significant prevalence of work on other aspects that could have previous bioethical relevance<sup>161</sup>.

From what we have said so far, however, comes a question about why literature refers to a certain "isolation" from the decisional and educational processes of the original family, of a subtle "silencing" of the elderly's voice of experience. Maybe the solution could be found in regaining and promoting the culture of being, starting with focusing on the person in the environment where all the phases of his/her existence in the world happen: the family. And culture of being means presuming that at its basis there is a plenary culture of life that necessarily leads then – not before – to its quality, which has sense and meaning only if related to life: in fact "quality is an attribute, a disposition that gains sense if referred to the substance"<sup>162</sup> and looks first of all at the plenitude of the person, the values that fund it.

From recuperating the being and existence of man in all his phases derives then the focus on the exquisitely human possibility of choice and, therefore, on the ethical dimension without which the values are seen only in their eudemonistic, economic quality, satisfied by needs. We must instead go further and recognise in the spiritual infrahuman values, in the moral value (and in the religious one as the last awaited passage) the objectives to reach as a mature expression of humanity, in youth and in old age. Therefore we must look for a "high" quantity of values, according to the precise scale of priorities just mentioned, otherwise we will breathlessly search to satisfy false, needless needs and never be fulfilled, following only the philosophy of Having that leads us inevitably to being a "one dimensional" man<sup>163</sup>, a man who has lost the best part of himself. On the other hand, in a similar "logic" the elderly plays a game that is lost from the beginning, because of the characteristics of the existential and biological condition he lives. To confirm this, it is indicative that also relatively to suffering, from the studies emerges a very significant warning for all ages: being must be able to prevail on the culture of doing and producing to allow the human soul to go through all the steps of his/her evolution. It is only in this dimension, in fact, that "the elderly don't only go towards the darkness, but towards the full being of the person: the truth is at the end of the journey, truth and joy are found in the realised completeness"<sup>164</sup>.

---

<sup>161</sup> This can be seen in, D. Sacchini, S.Giardina, E. Sgreccia, *Orientamento ai valori, etica sociale e qualità della vita*, in De Rose, Sacchini (ed.), *L'età in gioco...*, pp. 109-152.

<sup>162</sup> *Ibidem.*, *Bioetica e terza età: qualità della vita, valori, creatività e problematiche etiche*, in ID. (ed.), *Persona e terza età...*, pp. 227-253.

<sup>163</sup> H. Marcuse, *L'uomo a una dimensione* (1964), Torino, Einaudi, 1991.

<sup>164</sup> E. Sgreccia, *Anzianità: valori, creatività...* in Antico, Sgreccia (ed.), *Anzianità creativa...*, p. 106.

## PART TWO: THE NON-SELF-SUFFICIENT ELDERLY AND THE ETHICS OF CARE

The varied and difficult world of the elderly seems the object of rhetorical and repetitive propositions, which are never actually realised.

The ONU initiatives, which in the last few years studied the extraordinary worldwide extent of ageing, are well known, with the elaboration of “Plans of action” and “Principles” founded on independence, participation, care, self-fulfilment and dignity, and in 2002 it called together the World Assembly on Ageing in Madrid. Since then, no concrete programme for the involvement of the elderly in the social, productive, economic and cultural life has been carried out (only fragmentary initiatives and reflections within other programmes like the fight against exclusion or discrimination, and healthcare resolutions like Alzheimer).

The hoped for “Society for all ages” does not happen if not in the propositions of a certain cultural elite, despite the fact that the suffering of the elderly grows, especially in developing Countries, where there’s war, where revolutions and terrorism cause every day tens of victims: the required dignity, participations and independence, apart from praise-worthy considerations that should take into account the longitudinal evolution of life rather than standardised transversal situations, are still an option that benefits few fortunate people in the developed countries. It also does not seem widespread the value of an authentic solidarity, which every man – regardless of the society in which he lives and his beliefs – can and must show solidarity towards every other man, of which the elderly are objects of attention but also, and maybe mostly, active subjects, capable of offering whatever unique

### 4. Ageing

Ageing causes the progressive loss of the organism’s ability to adapt to the environment, because of the depletion of functional reserves. In order to understand the complex mechanisms that cause it, various theories have been formulated, amongst the most accredited that of the “free radicals and crosslinking”, of the “altered protein synthesis” and of the molecular clock or “Hayflick phenomenon”<sup>165</sup>, which responds better to the demands of science.

The ageing process does not appear as a uniform and homogeneous phenomenon, especially from a psychological point of view. The factors affecting it are several: the genetic make-up, illnesses and traumas, education, experiences lived, losses suffered, the semantics of loved ones, the opportunities and difficulties encountered, the characteristics of the family and social environment and most of all the desire to “be and live”. There is a life and an ageing for every person, each individual is unconsciously responsible for his/her own growth, also by facing the environment and the events that characterise it. In this phase of

---

<sup>165</sup> The studies carried out on cultures of fibroblasts extracted from the lung of a foetus, lead to a rapid initial multiplication of these cells, followed by a slower growth (senescent phase), until they reach the end of the cellular divisions. Hayflick deduced that, as the fibroblasts cannot multiply beyond a certain number, there had to be a “molecular clock” able to regulate their reproduction. The only cells capable of going beyond this anticipated limit of multiplication are the neoplastic ones.

life, the family, social and care environment, love and motivational components gain relevant importance. The life lived and the life we are living can affect further capabilities of growth without limitations until the last instant, as demonstrated by art history, literature, science, but also the individual's daily life, as he/she can find in him/herself, in the last part of life, the strength for "the last brush-stroke... the one that gives more light and maybe gives the final meaning to the painting"<sup>166</sup>.

If certain biological determinants cannot be corrected, other factors are susceptible to change, for example the physical decay that follows inactivity and can cause that serious functional degradation called "hypokinetic syndrome", responsible or co-responsible for a great number of hospital admissions of elderly patients in rehabilitation centres. Physical activity is able to prolong survival by increasing aerobic capabilities, mobility and the stability of the spine and the muscular strength, of significantly attenuating the reduction of the hematic fluid in the brain and the inadequacy of cognitive performances that happen with retirement, of carrying out a protective action towards the susceptibility to coronary diseases and mortality, a significant role in the primary and secondary prevention of strokes, hypertension, peripheral arteriopathy and diabetic nephropathy, cancer of the colon, breast and female genitalia. It can cause an increase in the ability to communicate in patients affected by Alzheimer. The most important neuroscientific discoveries of the last years contributed to overcome the ancient assumption that saw the brain as an organ destined exclusively to involution and the loss of cells. If it is true that getting old there is a reduction in neurons, it is also true that the nervous cells are able to reconstruct and compensate for the missing parts and reactivate the acquiescent neuronal stations. In this sense, an appropriate environmental stimulation is very important for the recuperation of psychological competences, relational and social.

With regards to the different functions, it is sometimes possible to have a reduction in the psycho-motor skills, especially in relation to the time necessary to make decisions. Awareness does not seem to decrease in normal conditions, but there can be, more frequently than in youth, episodes of mental confusion that are not necessarily attributable to pathological states. Self-awareness, namely, the awareness of the Individual that intertwines and links with the so-called "feelings of the Individual", is generally influenced by serious psychological suffering. In the elderly, it can be connected to memory disorders, in particular with regards to iconic memory (sensory or very short term) and short-term memory, which is less active with a decrease in the ability to remember more recent facts, whilst the ability to remember past events remains particularly lively. In conditions of psycho-physical well-being, the elderly are able to learn<sup>167</sup> and know as well as the young and the adults, although they might need longer times to assimilate it. The motivations, in any case, are essential, as – on the contrary – not enough active participation considerably reduces memory and highlights learning difficulties. We can also observe a certain reduction in the attention span. The weakening of eyesight and hearing can lessen perceptive capabilities. Cultural isolation, a low economic and social level, emphasise psy-

---

<sup>166</sup> Holmes Wendel, in R. Levi Montalcini, *L'asso nella manica a brandelli*. Baldini & Castoldi, Milan 1998. The whole quotation is as follows: "life is not like drawing conclusions, but life is like painting a picture, and therefore the last brush-stroke can be the one that gives more light and maybe gives the final meaning to the painting".

<sup>167</sup> Old age begins when the ability to learn stops. A. Morandotti, *Le minime di Morandotti Scheuwiller*, Milan 1980.

chological decline. On the contrary, social integration and higher cultural levels are the premises for a better old age and longevity. Especially as the elderly are often able to supplement any deficiencies with other qualities like continuity, prudence, experience, motivation, the ability to control emotions, to reflect and synthesize, being more precise as well as preserving important functions, like language, thought, perception, attention and recognition<sup>168</sup>.

Despite a general and progressive decline of sexual activity linked to age, sex and sexuality represent for the elderly an integral part of the experience of living, which does not mean only with a physical relationship, but it is associated to a psychological and emotional point of view with the creation of a profound intimacy between partners<sup>169</sup>. The reduction in potency decreases slowly during the 7th decade and it becomes more marked in the 8th and can be of a certain relevance only after 75 years of age. The reduction is due not only to physiopathological and socio-environmental factors, but also by the rise or increase in pathologies able to interfere with sexual activity, which can stop due to different causes in the two sexes. In women it is generally linked to the husband's presence and capability, whilst for men it is almost always due to their incapability.

It is in any case important to overturn the prejudices regarding the sex life of the elderly as something non-existent, inconvenient, inappropriate and dangerous for their health and its cessation as an unstoppable event linked to the passing of time. In Italy relationships between elderly people are on the increase and start more frequently when work, children and family life are a part of the past<sup>170</sup>. According to sociologists, soon elderly couples who love each other and decide to start their last journey together (which in their enthusiasm is never the last) will no longer be a rarity or a novelty. However, cultural stereotypes mean that these relationships are often hidden, derided, or opposed, especially if the elderly involved are widowed and alone.

In synthesis, in old age, especially psychologically, nothing must be considered with approximation and relegated to the commonplace of the known, the diagnosis and the symptom<sup>171</sup>. Following the direction of the so-called ageism, namely, the stereotype according to which reaching a certain age is the same as being old, with all the burden of pathologies that can create functional dependence, is certainly out of place, because the third age is heterogeneous with regards to self-sufficiency, physical and mental health, quality of life: age cannot represent a criterion to identify a care and/or therapeutic choice and to exclude anybody from therapies aimed at recovery or prolonging life. The period of active old age, which precedes regression by quite a while, requires an approach aimed at active ageing, namely, a creative ageing in good health.

---

<sup>168</sup> R. Levi Montalcini, *L'asso nella manica a brandelli*, Baldini & Castoldi, Milano 1998.

<sup>169</sup> Contrary to common belief, from an investigation conducted by "Ageing Society" (2002), emerges that the elderly maintain, despite their age, an interest for sex. If 65.1% admits they do it very rarely, not for a lack of desire but because they find it difficult to find an available partner, 34.7% state that they maintain an intense sexual activity and 20% confesses they have had a "crush" after 60.

<sup>170</sup> F. Di Iusto, et. al., *La sessualità nella donna anziana*, *Giornale di gerontologia*, 51, 504, n. 6, 2003. Aioli V., *Fuori tempo*. Rizzoli, Milan 2004. L. Sotis, *Le nuove coppie dell'amore a settant'anni*, *Corriere della Sera*, 5/2/2004. P. Ravizza, *Gli affetti non finiscono mai*, *Percorsi*, n. 39, 2003. F.R. De Chateaubriand, *Amore e vecchiaia*, Robin Edizioni, Rome 2002. Ruggeri Fedele (ed.), *Anziani e affettività*. Le dimensioni della problematica in una ricerca proposta dal Sindacato pensionati Italiani CGIL. Franco Angeli, 2000.

<sup>171</sup> A. Tammaro, G. Casale, A. Fristaglia, *Manuale di Geriatria e Gerontologia*, McGraw-Hill, Milan 2000.

For the so-called social ageing, there are no fixed rules by law, unlike for minors (who are such from the moment of birth to their 18th year of age). The law for pensioners regards the elderly, but not even in this case there are precise indications defining the elderly if not through mere taxation practices which can sometimes be interpreted in a variety of ways, a function of professional categories and very often particular situations: just think about baby pensions, forced early retirement or retirement plans agreed with the companies, to the conditions of the magistrates and university professors. If retirement can lead to an early and significant loss of value of the person through the “devaluation of the function of experience”<sup>172</sup>, in the last twenty years the traditional models have progressively lost meaning as both knowledge and experience decrease with old age in relation to the changing of customs and the tumultuous progress of technology that the elderly are often unable to follow.

Generally, the ageing of the population is accompanied by a certain deterioration in professionalism, so that companies often consider elderly employees a burden, because they don't have the necessary professional up-to-date training and tend for this reason to remove them from work or isolate them from the decisional processes of the company through a progressive removal from tasks that can degenerate in the “mobbing” phenomenon. With regards to this, it seems necessary – as suggested by the OCSE reports since the 1990s – to invest more in permanent professional training, which would keep the elderly in touch with innovation and anticipate a flexible retirement, also in the perspective of the most recent policies, which tend to support the recuperation of the elderly in the workplace, especially as the statement according to which “work it is not only a need to earn, but a condition to live”<sup>173</sup> is also true in the third age.

In these conditions the elderly, although with their limitations, will have to be, according to today's trends, more and more a human, professional and cultural resource and for this reason the “threshold of social old age” will increasingly represent a value in itself for each individual, to be considered realistically on the basis of their desire and the ability to do, whilst age, in future years, will be an increasingly less significant indicator of the real conditions and the true needs of the individual. Much more realistically – also from this point of view – the absence of pathologies, self-sufficiency, the ability to be and no longer age, will be what makes a difference.

## 5. The self-sufficient elderly free from serious Pathologies

The elderly who are self-sufficient and free from serious pathologies do not present particular problems. Their condition of well-being depends especially on the possibility of preserving interests regarding and not regarding work, of maintaining contacts with the young, of talking with their mind aimed at the future of the family and society, outside of the usual negative models of old age, without necessarily arising that “respect” that could be the beginning of embarrassment and tolerance, but also without opening the door to attitudes of mere forbearance or compassion.

---

<sup>172</sup> F. Carrieri, R. Catanesi, Il suicidio dell'anziano, *Rass. It. Criminol.*, 1, 51, 1992.

<sup>173</sup> G. Berlinguer, *Salute e disuguaglianza*, The Practitioner, ed.it. November 1989.

Elderly women usually live within the family with the grandchildren who grow, and they are often the guide of the house also financially. With the husbands progressively self-insufficient, they are often able to take on the function of care-giver. The elements that can mark the life of women are the loneliness that follows widowhood, the scantier financial resources, a longer period of disability in relation to the longer life expectancy, the low level of education that can still be found in the older generation but which is progressively improving and will change again in the following decades, depression<sup>174</sup>. The statistics show that women have generally a more unfavourable situation, especially from seventy years of age and beyond, in relation to a worsening of chronic pathologies that are very individual and long-term. Women have a fewer “choices” during their lives compared to men (who more frequently suffer from more lethal and less lasting illnesses like tumours, brain and cardiovascular incidents) and this phenomenon would explain the higher level of suffering of women in old age.

This, even if there’s no lack of examples, and in fact they are increasingly frequent, of middle-aged women different from the traditional ones, where women start their third life radically changing their interests, and are able to tackle new situations with original and constructive initiatives especially doing socio-cultural voluntary work, and they live in parallel – and not always in reduced dimensions – the life of younger women, free from any type of restrictions.

The feeling of detachment from the bodies in which women, but also men, do not recognise themselves anymore and feel as foreign, might have nothing to do with a nostalgia for beauty and youth and often it’s not the little pathologies that limit their freedom! Much more often it’s about – as already mentioned in the “First part” of this Document – of a crisis of identification, which puts self-image into question. When the illusion of eternal youth dissipates, a narcissistic trauma happens, which causes a depressive psychosis. Men and women, in the illusory attempt to find themselves again, to recuperate body and psyche, or at least find a new balance, to alleviate regret and depression, but also face the needs of social life and work, often go through the solutions offered by plastic surgery. The statistic data for plastic surgery and beauty treatments is increasingly significant, even though they mostly refer to ages below 65 years<sup>175</sup>. The consequence is the fact that there is a third age, an unofficial age ignored by gerontology, the “timeless”, those who trust surgery to erase the signs of time, and who achieve inexpressive faces that do not show a person’s life<sup>176</sup>, a sort of aesthetic homologation. Ugo Ojetti’s suggestion, “being able to grow old means being able to find an acceptable compromise between your face, which is that of an old person, and your heart and brain, which are those of a young person”<sup>177</sup>, is still valid and it can represent the turning point that is able to give women a new “untouched” beauty, really lived for the years that will come. Whilst the image of the elderly woman victim of physical decay and serious intellectual problems, which comes from a literature that is now anachronistic or studies centred on hospital or hospice patients, must be considered mostly out of date at least for those below eighty years of age.

---

<sup>174</sup> Depression, “Un male tutto femminile”. Eurispes Survey 28th April 2003. La cura e il ricorso ai servizi sanitari. ISTAT: Indagine Multiscopo sulle famiglie (years 1999-2000), 2003.

<sup>175</sup> American Society for Aesthetic Plastic Surgery, 2002. Only about 5% of the surgery involves women over 65 years of age. Congress of the European Academy of Dermatology and Venereology, Florence November 2004.

<sup>176</sup> M. Venturi, *Segni particolari: ritoccati*, Esperienza 54, 9, 2004.

<sup>177</sup> U. Ojetti, *Sessanta*. 1937.

Sometimes healthy elderly live in public or private institutions. The psychological-social problem of the institutionalised elderly is often seen, and wrongly, as a contrast between family and institution, so that the institution represents an unwanted solution imposed by circumstances or by a family that, for legitimate reasons too, cannot meet the needs of the elderly relative. But we must not overlook the fact that today (and not only from today) the Retirement Home can represent a conscious choice by quite a few self-sufficient elderly, even financially, widowed or not, who want to guarantee themselves an independent life also from a social and emotional point of view. Where, however, they are forced into it, the elderly could have to tackle situations of profound discomfort also in relation to the will to live, socio-cultural training, etc. The impact can be pitiful for a series of problems<sup>178</sup>: living with strangers in relation to the ability to socialise, the risk of withdrawing into themselves and having aggressive crisis towards other residents, the lack of affection, the obligation to follow rules and at times orders, can give the elderly a sense of impotence and “objectuality”; the psycho-physical dependence can lead them to passively abandon themselves to care because of uneasiness, need of affection or company. Obviously such an unfortunate impact can start involutive process through a vicious circle that highlights the feeling of lack of self-esteem and dependence from others.

For the self-sufficient elderly, an emerging problem is finally represented by the fact that grandparents are often penalised by their children’s separation or divorce with regards to an eventual forced interruption of the relationship with the grandchildren. Likewise, the children can suffer another trauma for the loss of the grandparents as historic and emotive memory, which allowed them to perceive the sense of their roots and the continuity of life. Jurisprudence has often confirmed the “grandparents’ right to visit”<sup>179</sup> and stressed the importance of an adequate protection of the bond between grandparents and grandchildren, which is rooted in the family tradition recognised in Art. 29 of the Constitution.

## 6. The fragile elderly

The biggest problems, also from a bioethical point of view, regard the elderly at the limits of self-sufficiency or non-self-sufficient, the so-called fragile elderly, especially where they don’t have their family’s support and have precarious financial conditions. In our country the equation that the elderly can be seen as a patient or an invalid according to the classic aphorism “senectus ispa morbus”, in fact does not seem fully out-dated, at least from a strictly psychological point of view. It is in fact still dominant the attitude of those who feel that the elderly’s illnesses are the consequence of ageing and often destined to evolve fatally. Carelessness and ignorance lead to confuse the onset of old age with pathologies that can still be treated which, if not diagnosed and cured, can be responsible for the loss of self-sufficiency and very high social and human costs. Avoiding this dramatic evolution is the proper duty of geriatrics, which distinguishes it from other medical specialisations.

---

<sup>178</sup> S. Spiridighiozzi, P. Antonelli, A. Bossi, P. Abetti, *L’anziano istituzionalizzato, problematiche e possibili soluzioni*, Difesa Soc, 77,175, 1998.

<sup>179</sup> Civil Cassation, Section I, 26th September 2003, n. 14345, Civil Cassation 25.6.1998 n.9606, Court of Appeal in Lecce section I, 3rd May 2002, n.10, and others.

It must also be considered that geriatrics trials regard essentially cognitive pathologies prevalent in the third age, for which the effort is highest and the results promising, whilst the specific study on the effects of drugs for common pathologies beyond what is known to internal medicine is overlooked, where however the trial subjects rarely are over fifty. The elderly are therefore deprived of the results of adequate studies on drugs and treatments and often treated on the basis of inadequate therapeutic and care treatments, furthermore, with considerable and unjustified financial issues. Regardless of this, the elderly are particular patients, different from adults, a patient often affected by polypathologies the evolution of which can lead to disability. The administration of drugs should therefore be carried out carefully and linked to the specificity of the subject and the particular framework of the disease, with great attention to the collateral effects, and it should not simply follow generic recommendations and precautions. The limited pharmacological trials on the elderly should be considered a discrimination, as if care in old age is not worthy of specific funding, rather than being thought of as the consequence of a prudential attitude in relation to the age of the trials' subjects. Experience instead shows that in old age is still possible to intervene and cure successfully, also surgically, some pathologies (like cardiac ones), with the result of offering to the elderly patient further years of life in good health conditions. Amongst the examples recurring in practice, we mention the lack of geriatrics or psychogeriatrics support in the surgical treatment of serious degenerative or traumatic pathologies of the hip. In these cases, even if the prosthesis is perfectly successful, the development of a latent psychopathology is possible, and it could be avoided with an adequate and preventive support<sup>180</sup>.

Financial incongruences also emerge in the number of hospital admissions of elderly people that are not in line with the ELA ("Essential Levels of Assistance")<sup>181</sup>: according to the AS (Ageing Society) the elderly "parked" in hospital, the lack of provisions on the national territory, the perception of being treated only if they are in hospital, "cost" Italy, every year, 18 million days of unnecessary hospital stays, which could be avoided with a saving of 5.7 billion euros, the amount that, according to the organisation invigilating the State budget, would be necessary to re-address the deficit in this sector. For example: the treatment at home of the over eighties affected by stroke has been found as efficient as that in hospital, with the essential difference of guaranteeing a better quality of life and a certainly lower number of depressive reactions or negative developments of latent psychopathologies.

Of considerable bioethical interest, as well as financial, is the fact that elderly patients are responsible for over half of the pharmaceutical expense of the NHS (51.9%) and of prescriptions by GPs (53.2%), even though they make-up only 21.5% of the patients<sup>182</sup>. These data could be less worrying if the "Report on the State of healthcare in the Country 2001-2002" did not highlight that the treatments are "inappropriate in 25% of cases and cause the waste of 8 billion euros a year". The Italian Society of Geriatrics and Gerontology emphasized how there are 150,000 hospital admissions a year due to the secondary effects

---

<sup>180</sup> L.M. Pernigotti, M. Simoncini, I costi della vecchiaia: dove nascono nuovi obiettivi di ricerca in Geriatria. *G. Gerontol.* 53, 6, 2005.

<sup>181</sup> From the report on the "Stato di salute e prestazioni sanitarie nella popolazione anziana", Direzione Generale della Programmazione Sanitaria del Ministero della Salute, April 2003.

<sup>182</sup> 2001 Report by the Arno Project (Cineca, Consorzio Mario Negri Sud), *24 Ore Sanita'*, 27.5.2003.

of medicines, wrong or inappropriate mixing, taking the wrong medicines<sup>183</sup>. It is an alarming sign of the situation of fragility and insufficient care in which a lot of the elderly live. Often they are risks associated to the impossibility of going out of the house to go to the doctor or to the need to sort things out by themselves in some way. To this data, we must add that of the mistakes in hospital prescriptions, which are almost all avoidable: they are 15 out of 100 prescriptions (preliminary communication by the ISHM, in the absence of official national statistics<sup>184</sup>).

The integrated home care (IHC) could guarantee in Italy as well, as happens in other countries, a more accurate socio-welfare-healthcare support, even though it is not easy to access reliable data for a comparison with other European countries, because the generic term “home care” includes a broad and diversified range of services, often with different objectives and methods, given by a variety of institutions, public and/or private, within each country. The largest use of this type of care can be found in Denmark (24.6%), the average in northern countries is in any case over 10%, and it is much lower in the South (only 3% of the elderly). According to the 2004 Censis report, less than a third of the Italian population over sixty is aware of the existence of the “integrated home care” (IHC) service. To complicate the situation, there is the fact that a large part of the South of Italy (about a quarter<sup>185</sup>) does not have it. In addition, if the service can be activated quickly in the North East (within 48 hours, or at the latest within a week) following a request to the appropriate local health authority and after an assessment by the Geriatrics Assessment Unit integrated by specialist assistance, in the South the time is certainly longer (even over a month).

Nevertheless, the IHC is preferred by all European governments to fight the risk of institutionalisation, to guarantee the elderly a better quality of life and still allow, wherever possible, a certain social involvement. The care is better from a point of view of services and costs and it is largely preferred by the patients, who can stay in their environment, surrounded by the people and things they love, with the memories of happy moments, and recurring to hospitalisation, even if only in the daytime, in case of a worsening of the pathology or the need for tests. It is evident that home care cannot be imposed to the patients and their families. The generosity and love of the family – although essential to keep within a human dimension the condition of isolation that often the patient and the elderly have to bear – are not always sufficient to tackle complex problems which, even when not emergencies, can require particularly challenging provisions. For example, the influence of architectural barriers can be a serious obstacle for the needs of disabled elderly people and for the rehabilitation treatment carried out with the IHC. The centre of all action and decisions, natural link between the healthcare institution and the patients, is the GP, who suggests and supports specialist interventions, in agreement with the patient as long as he/she is able to understand and express a valid consent. It is evident that basic medicine sometimes is unable to tackle the problems of the elderly, in fact in our universities there is no teaching towards the appropriate instruments to assess the psychophysical and social capabilities of the elderly, the multidisciplinary approach in the study of the elderly patient, the

---

<sup>183</sup> Studio Sofia, National Congress of the Italian Society of Geriatrics and Gerontology, Florence 3.11.2004.

<sup>184</sup> Italian Society of Hospital Medicine (ISHM), XXV national Congress, Rome, March 2005.

<sup>185</sup> Italian Caritas and Zancan Foundation, 2004 Report on “Esclusione sociale e cittadinanza incompiuta”, Feltrinelli, 2004.

use of simple diagnostic means in the surgery or at the patient's home, the communication with the elderly patient that has its peculiarities, the identification of behavioural changes and the possibility of a fast and appropriate treatment. The geriatrics doctor should then be the main figure of reference in the treatment of the elderly patient<sup>186</sup>, but often he/she isn't, as geriatrics is assimilated to any other medical field. And internal medicine cannot assume this role, as it is directed essentially to the study of acute pathologies, devoid of specific references to the polypathology of the elderly, to geriatrics rehabilitation, to the peculiarities of nutrition for the elderly, etc.

With regards to residential institutions (Residenze Assistenziali [RA], e Residenze Sanitarie Assistenziali [RSA], according to the Italian terminology) the comparison with other countries is complex because of the dishomogeneity of a variety of organisational and economic characteristics, and because of the functions they absolve. A good example however is Denmark, which – like other North European countries – trialled interesting initiatives: since 1988, after a twenty year experience, took hold the political choice of building more RSA and protected houses and change the existing ones into housing for the elderly with flexible services in line with their needs. The experience of these countries is such that their structural standards relative to comfort were ahead of the Italian ones already in 1967<sup>187</sup>. It is more than evident that the difference must be resolved as soon as possible in order to improve availability, accessibility, organisation, standard of living, quality of care in those fundamental institutions that are the RAs and RSAs, taking into account that northern countries in the last ten years are increasingly focusing their attention on improving the quality of the environment and services, eliminating, where possible, the most unpleasant aspects of shared accommodation and favouring intimate spaces, personalised care, respect for the normal rhythm of daily life, to overcome the concept of residential structure with the offer of “protected accommodation”. These often come from transforming the traditional shared residences adapted to the needs of those who lose their autonomy and can carry on living independently with the help of home care and the guarantee of more safety also for the spreading of information technology or telematics applied to the accommodations and automated instruments to help carry out daily activities. The flexibility and personalisation of the services with regards to social and healthcare integrated services is guaranteed by personalised care, according to the policies regarding keeping the elderly in their homes.

In South European countries however, the interest for traditional residential structures is continuing to grow very slowly at least in Italy, which is late in the care strategies for the elderly and not yet able to concretely pursue choices of significant bioethical interest with the dual aim of reducing the costs of care and guaranteeing a better quality of life at the elderly's home. The National Healthcare Service in any case, despite the well-known daily difficulties, remains one of the few in the world that guarantees to the citizens, free of charge, integrative healthcare assistance.

A further aspect to take into account is the fact that the nursing staff, and especially social-healthcare staff, is unfortunately often low in numbers. The problem regards all the

---

<sup>186</sup> G. Salvioli, *Gli anziani oggi*, G. Gerontol., 52, 162, 2004.

<sup>187</sup> 98.5% of the rooms were single rooms (in Italy they house up to four beds), 75% of the rooms was at least 15 square meters (in Italy they are generally 12 square meters), 75% of the rooms had an en-suite bathroom (in Italy there is a bathroom every two rooms), 80% of the rooms was accessible, without help, to the elderly in wheelchairs.

European countries where in the last decade the number of unqualified employees in residential and home services has increased six times. There can be a variety of problems linked to staff, frequent, in particular, the so-called burn out<sup>188</sup>, which can lead to serious crisis of depression and especially when in contact with terminally ill patients affected by neoplasia and dementia, and that represents the major cause of defections. The characteristics of the mentally ill patient (aggression and violent behaviours) can cause considerable stress to the staff, which can lead to a climate of mutual violence.

Voluntary work is obligatory, also to compensate for the deficiencies, and, with an increase of about 120% in the last years, so much so that it provides care for eight million elderly and patients<sup>189</sup>, often beyond the simple “healthcare action”. For the further developments of care, we can only wait for the concrete provisions of the European Parliament in reference to the proposals put forward and the most recent resolutions<sup>190</sup>.

Of particular importance are the psychiatric pathologies that affect the elderly. According to the OMS, depression represents the main cause of invalidity (12% of cases), partly also because of the low cultural level, the precarious financial situation and the pathologies that affect the elderly. Dementia affects a little less than a million Italians, but the number is destined to double by 2050 for the combined effect of the longer life expectancy and the better state of health of the general population. The 60-70% of cases of serious cognitive deterioration that can be observed in old age are of the Alzheimer’s type (AD), the incidence of which increases exponentially with age. The direct and indirect costs are up to 35-50 thousand euros a year per patient<sup>191</sup>. They can often feel persecuted or jealous, which can lead to dramatic gestures seen as unavoidable. The changes that involve the physical and especially psychological personality of the elderly can unleash antisocial behaviours mostly if isolation is compounded by unfavourable environmental circumstances and alcohol abuse<sup>192</sup>. The criminal activities of the elderly generally involve GBH against partner and family, up to murdering their wife<sup>193</sup>, paedophilia and sexual crimes<sup>194</sup>. In some cases they are the expression of behavioural problems, depression or paranoia.

---

<sup>188</sup> C. Maslach, A. Pines, *The burn out syndrome in the day care setting*, Child Care Quarterly, 6, 100, 1977. M. Piccione, *L’etica nella pratica psichiatrica*, Masson, Milan 1999.

<sup>189</sup> Plesis, with the contribution of Farmindustria, “Primo rapporto sull’esperienza sociale del volontariato sanitaria e assistenziale”. *Il Sole 24 Ore sanità*, 2-8 December 2003. The Istat carried out the fourth survey on voluntary organisations registered in the different regions and autonomous provinces on the 31<sup>st</sup> of December 2001.

<sup>190</sup> The second European Conference of the Regional Healthcare and Social Affairs Ministers (our regional councillors), Milan 2002, *Sole 24 Ore Sanità*, 19<sup>th</sup> of November 2002, suggested the institution of a new professional figure of “elderly assistant”, something between a minder and a specialist nurse, provided with a specific diploma. In May 2004, the EU Commission adopted the report on the healthcare for the elderly. The common objectives are the following: 1) guarantee the access to treatments based on the principles of equality and solidarity, 2) promote a high level healthcare for a better quality of life, suggest treatments of verified scientific validity, checks and tests of verification, 3) ensure that the healthcare system is financially sustainable.

<sup>191</sup> Italian Caritas and Zancan Foundation, Feltrinelli, 2004.

<sup>192</sup> F. Carrieri, O. Greco, R. Catanesi, *La vecchiaia. Aspetti criminologici e psichiatrico forensi*. Giuffrè, Milano, 1992.

<sup>193</sup> N. Maurri, L. Malavolti, G. Tartaro, *Uxoricide nel settore medico legale fiorentino*, *Rass. Criminol.*, 18, 621, 1987.

<sup>194</sup> G.B. Traverso, F. Carter. *Considerazioni criminologiche sul reato di violenza carnale in Italia*, *Riv.It.Med.Leg.* 1,486,1979. V. Oddone, *Delinquenza con i capelli bianchi*, *Minerva medicoleg.* 34, 159, 1984.

Sometimes retirement itself – in predisposed subjects – can cause considerable depressive reactions for the feeling of belonging to an age group that is socially marginalised, which often means loss of affection and finances, especially when it coincides with structural changes in the family (grown up and independent children who don't look up to the father as their point of reference anymore). The serious sense of uneasiness that sometimes affects the elderly can be favoured and worsened by a series of other phenomena like technological progress, changing cultural models, institutional crisis, progressive loss of certain and shared ideals able to alter the intellectual reality of the elderly and cause a further distancing. This complex situation can create and support a worrying state of tension with a loss of aims and trust, fear, dejection, inefficiency, states of anxiety and considerable levels of depression that can be the beginning – in predisposed subjects – of violent behaviours that the elderly can carry out especially against themselves. Usually men are affected, but women can also be affected when family involvement does not remain alive and prevalent, as work represents more and more frequently not just a way to financially support the family, but an internal need, a need to confront ourselves and show our qualities also outside of the family.

The problems stopping the weaker age groups from fully accessing the services are the difficulty of access or the lack of integration between the primary care given by family doctors and other territorial services for psychiatric care, especially in the southern regions, where the consequences of the lack of collaboration (in over half the cases) between family doctors and Mental Hygiene services are worrying. A very serious consequence is taking away from these particularly fragile people an indispensable therapeutic continuity.

Faced with the deficiencies of state care, families turn to the international work market that gives opportunities at accessible prices. Private initiative takes the place of state care through the so-called helpers<sup>195</sup>, to whose instinct we entrust the precious thing that is our loved ones. These cohabitations are born out of need, sometimes they go against what the elderly want but often reach an acceptable balance, creating connections of affections and solidarity.

We cannot overlook, also from a bioethical point of view, the problems the elderly face in prison, even though they can seem of secondary importance due to the small percentage of over-sixty detainees, whilst the law guarantees a quality and continuity of care equivalent to that offered to the rest of the population. Bureaucracy is however slow and clunky: often the clinical record is not filled in properly in the biggest prisons also for a lack of continuity of care from doctors and specialists; the delay in carrying out the check-ups can be considerable, especially if they require transferring the detainee in a state hospital, which happens with difficulty and at times fatally late from the time of request. The advice of the legal doctor and other specialists nominated by the judicial authority, but also in this case the investigation can be long for the need of related assessments that, often, even if simple, require excessive waiting, which can only be explained by an inefficient bureaucracy. Sometimes there are a variety of consultancies, including those requested by the detainee, and the more serious the crime and the detention regime, the more months they take. Their

---

<sup>195</sup> We must strongly stress how the term “helper” is offensive for the elderly: it implies the idea of a personal inferiority and a paternalistic and authoritarian view, only falsely “caring”. The NBC believes that the term must be substituted, not only in acts and documents, but also, hopefully, in common talk. A possible alternative is “care assistant”.

condition can worsen, the admission into a centre that is fully equipped for the pathology can be late and death can paradoxically “eliminate” any problems with regards to providing care. Overcrowding, promiscuity, infective diseases, violence between inmates, lack of privacy in shared cells and the humiliating living conditions of the detainees, especially elderly, definitely affect negatively the chance of a true social rehabilitation, so that the stay in prison becomes increasingly a journey towards marginalisation. Even though we don’t have specific statistics for the third age, the incidence of psychiatric disorders like depression and the growth in deaths due to suicides are relatively frequent.

Finally, we must mention the problem of frauds that in the last years afflict an increasing number of elderly people (a 471% increase from 2001 and 2003<sup>196</sup>). The moral and psychological damage is great, both because of depression due to the feeling of uselessness, and for the loss of objects of high personal significance even though at times of little value. The scope of the phenomenon is such that it requires specific interventions, but the little inclination to report frauds, considerably worsens the risk of meeting unscrupulous people.

### ***6.1. Operators, services, people: resources for the elderly***

Following the considerations on the peculiarities of old age, it is important to consider who the operators caring for the elderly are today. A better understanding of their peculiarities can allow an evaluation of the professional resources available today to the elderly, as well as, naturally, the GP or family doctor or the geriatrics doctor.

The nurse responsible for the general nursing care, previously called “professional nurse”, is the professional responsible for the care, both nursing and basic care. To achieve this, he/she uses care projects for the individual or group or community, based on nursing diagnosis<sup>197</sup>. These projects start from identifying the needs of the individual, to assess his/her need or not or care; then, following this assessment, the nurse can identify the specific problems for which the person needs nursing care and/or basic care, planning to resolve this with appropriate interventions. This planning therefore will include interventions that will have to be carried out directly by the nurse and those that will be entrusted to the SHO: these will vary according to the context, the conditions of the person in care, the presence or not of other people as resources.

Together with the district nurse, many Italian cities are developing pilot trials suggested by the National Federation of the *Ipasvi* Colleges, which aim at actualising taking charge of the elderly. In line with already consolidated European experiences, in nursing care there are suggestions for the family nurse, that is, a professional who, together with the GP, takes charge and follows in time the evolution of the person’s state of health, offering continuity of care and also personalised care, to exceed the standardised offer of services, therefore rigid in a certain way and focused on the provisions to offer instead than on the person to assist. The family nurse follows a certain number of individuals, verifying in time the evolution of their situation, activating and/or highlighting to the doctor the need to have human (professional and ad hoc operators) and material (e.g. integrated care) resources for each single case.

---

<sup>196</sup> Agenzia d’informazione Auser vol.8, 13, 2005.

<sup>197</sup> Cf. J. Juall Carpenito, *Diagnosi Infermieristiche*, Sorbona, Milano 2001.

The socio-healthcare operator (Sho) is a figure supporting care, who acts in collaboration with the nurse and social security, directly looking after basic care, namely, the care once given by the patriarchal family, but today disappeared for the evolution towards mono-nuclear families. Without a doubt, the appearance on the socio-healthcare scene of personnel to support care, has meant a step forward in taking charge and managing the needs of the elderly population, too often afflicted by chronic-degenerative pathologies in addition to the effects of old age. So it happens that the person lives in conditions of mortification and decline of their dignity of person: for example for the impossibility of washing regularly because of lowering in strength and functional competence, or feeding themselves regularly because of the lack of self-sufficiency in doing the shopping and cooking the meals.

The welfare assistant is the professional who operates in prevention, patient's support and recovery, for groups or communities who find themselves in situations of need and social difficulty. Through aimed projects and a network approach, it deals with creating opportunities of recovery for disadvantaged individuals, also in relation to problems of the specific community he/she has been entrusted with: in fact he/she acts on a national basis or within structures of reference. Within the Healthcare Residences, the welfare assistant is often present as the Manager, taking care of daily issues and the more general choices of people sometimes alone and/or far from their loved ones despite their wishes.

Relatively to the services for the elderly, we distinguish:

The socio-healthcare district, in its more precise meaning of group of people, geographic area and network of services, it is the place where there's a tendency to maintain the well-being of the citizens by offering information, advice, services for the population. It is therefore not a building that houses operators and services, which are offered following a request by an interested individual, but the houses, schools, factories, offices where people pass their daily life, using the help of operators (GPs, nurses, welfare assistants, Sho, psychologists, etc.). The activities of prevention, care and rehabilitation are in this way taken directly to the individual's home (healthcare and social home care), or in the study and work environment (educational interventions in schools, checks, health and safety in the workplace, etc.) or finally centralised in purpose built structures, namely, socio-healthcare centres. The services that can be given at home include, integrated, medical care, specialist doctors, nursing, functional rehabilitation and/or recovery, as well as those of a social nature. Some regions consider complementary services those regarding meals, clothes washing, ironing, organised by the district. The access to the service can be requested by the interested individuals, by the GP, the hospital the individual is staying at, directing the assisted towards a return home, according to the different cases, day hospital or Assisted Healthcare Residence. The visits are spread throughout the week, with variable frequency according to the cases, including also festive shifts.

Assisted Healthcare Residence (Rsa) is a place that offers nursing and basic care, as well as protection and housing rehabilitation and care to individuals with incurable pathologies, at home. Within the Rsa the guests must be able to find a situation as much as possible similar to the one at home; internal and external communal spaces, but also areas more appropriate to a minimum of privacy, are essential requisites of these structures. They are part of the network of national services that depend on the district's socio-healthcare activities; their organisational and housing organisation is given to a manager who is not a doctor. With regards to personnel, it will include nurses, health support personnel, therapists, educators. The personnel for specialist activities however is not full time.

The Residence for the Elderly (Ra) is instead generally used to house elderly people, who are still self-sufficient; in these cases it is especially the social issue that is at the basis of the need to access it. Consequently, the internal organisation will provide housing comforts and recreational activities that are generally intense. A particular experience with regards to this is that of the Social centre or the Residential centre for the Elderly, which has been realised (and at times called) differently in the various regions.

To substitute the all-encompassing rest-homes, typical of a few years ago, some places have developed Centres for the Elderly, which join the function of housing and day centre. In this way, more needs are looked after without however arriving at the structure for the non-self-sufficient: it is for totally or partially self-sufficient elderly who mostly have housing issues (e.g. notice to leave their home, architectural barriers, no lift, forced cohabitations), or loneliness, or problems of psychological safety. The residents, who live in small accommodations, are offered essential services like a canteen, bar, environmental cleaning. Whenever possible, the elderly remain the owners of their home, caring personally for their daily needs. In this type of climate, in addition, cooperation between the elderly is facilitated, and this positively affects maintaining the levels of autonomy also for individuals who are very old. There is care, but it certainly does not assume the rhythms and ways of care that are typical of other structures, so that it does not repress individual freedom. This type of structure is inspired to Anglo-Saxon and Scandinavian models, with the building of Centres for the Elderly in cities, so that they include individuals who are otherwise marginalised in still lively social situations, avoiding eradicating the elderly from their previous housing context.

The day centres welcome people who need forms of assistance, care, integration (elderly, disabled, drug-addicts, psychiatric patients) for a period of time limited to a day. Their purpose is to favour socialisation and recovery with simple crafts and manual work (ceramics, drawing on fabric, woodwork, other) using also the support of specific operators (event organisers, educators, occupational therapists). The Centre must be given spaces for recreational activities and a canteen. The permanence in the Centre for some hours in the day alleviates and supports, at the same time, also the user's family; those who take responsibility for these individuals undergo considerable stress, therefore their quality of life must also be protected, as much as possible, as well as the patient's.

The Family Homes are structures of limited dimensions, destined to welcome people of various ages, so that they recreate a climate of cohabitation typical of the family. The organisation of the internal spaces and the life that goes on in it is very similar to a domestic context.

The Day Hospital is the structure that welcomes users who need complex therapeutic or diagnostic treatments, for a limited amount of time. Normally, it is annexed to the hospital, and it uses its general services. Its opening times to the public last between seven and twelve hours. The personnel that works in it (doctors, nurses, other professionals according to the type of intervention: rehabilitation therapists, podologists, dieticians) is permanently assigned to this service and in any case to the hospital OU of reference. The day hospital is born to answer treatment needs and it requires an extended stay in the premises, but not a full time stay; users can in this way have their needs satisfied without undergoing a protracted stay. Examples of this are the day surgery, which today is increasingly substituting hospital stays for general surgery: they are units dedicated to surgery of limited extent, which can be carried out in a day and therefore it avoids the client a stay in hospi-

tal. From this, derives that the organisation of this facility must be able to use the hospital's general services (laundry, kitchen, other), but to conclude in any case the day's activities. This means savings with regards to resources, personnel, buildings, as well as advantages easily gained by the users (staying in their homes, less discomfort for the family, real times answers to care needs).

The hospital today is destined to review its aims, to focus particularly on individuals in acute and post-acute phases, with professional human resources and instruments of advanced level. These are medium sized hospitals, which generally include the basic sectors of Medicine and Surgery, as well as other operative units of variable dimensions and quantity. In comparison to the importance it has always had in our NHS, today its position is decidedly less important. The current state of health of the population, the development of alternative services allowed by medicine to reduce the acute phases, make it today a place reserved to a few limited cases, which however need advanced resources and care methods. Therefore hospitals are getting ready to be increasingly less usual places of care, to become services destined to high intensity treatment needs. From a structural point of view, the hospital building is slowly evolving towards more flexible units, with different levels of care: an intensive one, or high care, and one for convalescence or monitored stabilisation, or low care. The accredited structures operate in close synergy with public structures, and equally called to respond to the same standards expected by public structures.

## 7. Marginalised elderly

Loneliness can come from widowhood, the loss of children and family, poverty; it's especially the complex heterogeneous dynamics of the big metropolitan cities that favour phenomena of marginalisation or self-marginalisation especially for elderly people who can live vegetating, get ill, commit suicide, die in the street or in conditions of material and moral degradation<sup>198</sup>. Not unusually the elderly are forgotten in institutions or communities, in imaginary hospices, even in their homes and within the family they are deprived of affection, sometimes forced to give proxies and donations, or blackmailed to give a house, sometimes victim of the family's neurosis, blamed for their inabilities and needs, mistreated, scorned, malnourished, mocked and even pushed to commit suicide. Dying alone is frequent, especially during the summer and the body can be found by the family members after many days, when they come back from their holidays or by firemen called by a neighbour. But we have not found that in case of death, even when due to the family's abandonment, this has been reported to the police.

We must not forget, in the more general problem of the state of abandonment and marginalisation, the accidents at home. Less numerous than suicides, they are often the symptom of the state of need and vulnerability that is dramatically expressed with an accident, mostly avoidable and containable in its gravity, if the elderly were helped quickly. Often abandonment continues in the morgue, as it happened in France in August 2003 and sadly shown in the news. The fact that the families forget their parents or grandparents, denying

---

<sup>198</sup> According to ISTAT data (2001) the elderly represent 56.1% of the people who live alone (31% are male, 69% female).

them also the funeral and not only for financial reasons, is unfortunately frequent also in our country, so much so that forced interment often happens without the family's involvement, paid for by the Council and with a magistrate's order, at times after months or years, for the need to free the cells.

And if society is indifferent towards the socially useless elderly, governments, the parliament, the regions often issue plans that mostly are not applied or cannot be applied even though they represent the marginalised elderly – away from culture, productivity and increasingly from the social context -, a reality in any case numerically important.

### 8. Mistreatment of the elderly

The mistreatment of the elderly is contemplated in the law as crimes of domestic violence (Art. 610 penal code) and personal injury accidents (articles 582 and 583 penal code). Many dramatic events remain “buried” within the family or institution, especially if the crime is carried out by the family and the victim does not report it because affected by cognitive problems or afraid of further violence. Legally relevant is the abandonment of an incapable person (Art. 591), an eventuality that can regard also the elderly. As it is a crime that can be prosecuted *ex officio* in these cases a report detailing a complaint is compulsory.

Not reporting the phenomenon of the mistreatment of an elderly is due, at times, to the understandable reservation of the victim, to his/her hope that the aggressor will have a different attitude, to shame, to the not infrequent complicity of third parties within the family.

The forensic doctor who operates in public structures could be very useful to colleagues and in particular to the GP to diagnose and assess cases of violence that are difficult to interpret also in order to decide to send the report to the legal authorities. But this possibility is not taken into consideration by the Local Health Authorities, despite it has been hoped for at times.

Relevant is the mistreatment in Institutions to which we have to add the carelessness and superficiality of the doctors, the inattention of the educators, and sometimes the lack of training of the police. The phenomenon, although widely known, has been so far underestimated both from a quantitative point of view and with regards to gravity. In the USA, according to the National Elder Abuse Incidence Study<sup>199</sup>, at least one and a half millions elderly people every year are abused even though, probably, the phenomenon is much bigger. Psychological violence escapes any control, especially as in many cases it happens within the family or in an isolated victim-aggressor relationship of subjugation. Carelessness is a very frequent form of mistreatment that involves personal needs, clothes, food, lack of care, lack of cleanliness, drug poisoning or overdoses due to distraction, inadequate health-care assistance. Very frequent the use of physical restraint, verbal and emotional abuse, foul language, the theft of personal belongings, blackmail, manipulation, etc. Significant also the incidence of “institutional” causes indirectly responsible for the discomfort of the elderly residents, linked to the lack of funds destined to care, a run-down environment, the lack of training of the care personnel. Often - as already stated – those responsible can be

---

<sup>199</sup> The National Elder Abuse Incidence Study. Final Report, September 1998.

the care operators and the orderlies<sup>200</sup>, generally badly paid, in insufficient numbers in comparison to the resources, often subjected to the burn-out phenomenon, with a progressive lack of interest for work, victims of a condition of psychological strain (and often also physical), of the progressive loss of ideals, a feeling of impotence and failure for the overwhelming imbalance between needs and resources, between ideal and reality, between what the assisted ask for and the possibilities of answering even elementary needs<sup>201</sup>.

It's sufficient to check the media to have an idea of the conditions of the elderly in some public and private institutions, whether paid for as part of the National Health Service or not, and of the serious physical harm to the guests that ends in death. Repeated inspections by the NAS in the last few years have highlighted dramatic deficiencies. According to the Ministry of Health in the summer of 2003 on 685 institutions undergoing an inspection, 281 were not in line with the law.

The conditions of mistreatment are evidently different, peculiar and more serious in developing countries<sup>202</sup>, in particular African countries where elderly people (especially women) are often subjected to physical violence as they are accused of bringing bad luck to the community and being the cause of floods, droughts, diseases and death. For these reasons they can be ostracised, tortured and mutilated, and sometimes they are murdered if they refuse to leave the village.

Elderly people can also be directly involved in the consequences of wars, revolutions and ideological intolerance when they are painfully forced to escape; but they can also suffer indirectly when they are not taken into consideration and they are overlooked by the plans of humanitarian assistance. In refugee camps the elderly come off worse and suffer discriminations when forced to compete for the distribution of food and healthcare. Violence linked to HIV/AIDS is frequent in those countries that have been more strongly affected by it: elderly women are those who carry most of the burden of assisting relatives who are dying and orphaned children and can be forced into isolation as family members of the diseased, by whom they are often infected for having looked after them.

Suicide is a phenomenon of considerable importance and, without a doubt, linked to situations of personal discomfort but also to an objective condition of maladjustment and social and family marginalisation which the elderly can find themselves in. If the suicide of a young person causes great emotion, the elderly or aged who commits suicide is often overlooked not only by public opinion, but even by the institutions<sup>203</sup>. Suicide is sometimes seen as a rational choice that implies a sort of evaluation of our existence, of the suffering due to debilitating chronic illnesses, even psychiatric, prevention remaining in any case insufficient. The rate of suicides increases vertiginously with age, as demonstrated by the statistics of the different medico-legal schools in our country. Old age, loneliness, relationship problems, chronic illnesses, are the most important factors that lead to suicide, worsened

---

<sup>200</sup> K. Pillemer, D.W. Moore, *Abuse of patients in nursing Homes. Findings from a survey of staff*, *Gerontologist* 29, 314, 1989; D.M. Goodridge, P. Johnston, M. Thomson, *Conflict and aggression as stressors in the work environment of nursing assistants*, *J. Elder Abuse* 8, 49, 1996.

<sup>201</sup> L. Sandrin, "Aiutare senza bruciarsi. Come superare il burn-out nelle professioni di aiuto", Edizioni Paoline, Milan 2004.

<sup>202</sup> Second World Assembly on Ageing. Madrid, Spain, 8-12 April 2002.

<sup>203</sup> D. De Leo, A. Caneva, M. Predieri, M. Cadamuro, I. Pavan, WHO European Multicentric Study on Parasuicide. Rilevamenti dell'unità operativa di Padova nel primo anno di sorveglianza epidemiologica. In De Leo D., *Aspetti clinici del comportamento suicidiario*, Liviana, Padova 1990.

by mistreatment and marginalisation. Taking into account the data on the population, the percentage of suicides committed by unemployed people is shocking compared to that of working people<sup>204</sup>.

## 9. The elderly from a legal point of view

If the law defines the minor, it rightly does not deal with the elderly, whose state can be clarified by medicine, psychology, sociology, but certainly not by codes that include generic regulations referring also to the incapacities of the elderly, but not specifically to them (like lack of civil rights, incapacitation, ability to write their testament, natural incapability). The Cassation Court clarified that “old age” as such is not a physical or mental illness<sup>205</sup>. In effect, identifying the elderly and differentiating them from other adult citizens could have been a form of discrimination: the elderly who is able and active is therefore, and rightly, an individual like any other from a legal point of view, maintaining the full entitlement to his/her rights as citizen. Even though, not uncommonly, in daily life, there is a subtle line of marginalisation from a psychological point of view. Only the needy elderly, ill and invalid, are taken into account in the law, but only because they become part of certain categories at risk (the poor, the chronically ill, those who are not self-sufficient, the unable, etc.), maintaining certain protective measures “also in order to prevent and remove the conditions that can contribute to their marginalisation”<sup>206</sup>.

Law number 6 in 2006, which has a very relevant ethical and practical meaning, has instituted the role of the support administrator who proposes to support and limit the ability to act of those who find it “impossible, even partially or temporarily, to look after their own interests” like the elderly, the terminally ill, the blind, alcoholics, drug addicts, those in prison, without recurring to interdiction or incapacitation.

Amongst the legal issues that can arise in old age because of common pathological conditions, of particular importance is the eventual inability to give a valid consent to medical-surgical intervention<sup>207</sup>, also considered that wife and children don’t have any rights with regards to this. As with any adult individual who is not interdicted, only the doctor can assess if in his/her particular case the patient is in a condition of “natural incapacity” and eventually request the intervention of the judge supervising a guardianship. Keeping in mind that in urgent cases the doctor must in any case intervene within the limits of the treatments that cannot be procrastinated and are indispensable to get over an emergency.

Another aspect that deserves to be taken in consideration from a bioethical point of view is that of compensation due to liability that, in the case of the elderly, can have per-

---

<sup>204</sup> Abroad the phenomenon can be considerable, especially in France, where the rate of mortality for the over-seventy-fives is 150 on 100000. In our country, with regards to the socio-working conditions, the number of suicides amongst “retirees” is high, in 2000, according to the Istat, 1156 cases, in comparison to 997 suicides amongst the “workers”, even though they are much more.

<sup>205</sup> G. Iadecola, *La tutela dell'uomo, del paziente, della famiglia*, G. Gerontol., 51, 425, 2003.

<sup>206</sup> Law No. 833 of the 23.12.1978, which instituted the National Healthcare Service, Art. 2, Art. 14.

<sup>207</sup> Also see the NBC document “Information and consent to the medical intervention” of the 20<sup>th</sup> of June 1992.

spectives that are strongly penalising. As well known, a biological damage<sup>208</sup> causes the loss of the right to health that is constitutionally guaranteed as an inviolable human right (Art. 2), specifically protected (Art. 32) in a dynamic and functional sense (Art. 3). The forensic doctor, as well as indicating the days of the illness and the percentage of invalidity in reference to the so-called “static” biological damage that is compensated according to charts determined by law (57/2001, 273/2002) that fix an amount that increases in relation to the percentage of invalidity and decreases in relation to age, it must describe all the negative consequences of the “way of being” of the damaged, like the limitations of dynamic relational possibilities, the things he/she must give up, the effect on the quality of life, the chances of survival, etc. These injuries, which could be compensated by the judge without limitations (law 57/2001), have been strongly devalued by the 273/2002 in the sense that the amount given as compensation cannot be over a fifth of that given for a static biological damage. Having said that, there are two significant problems in compensating harm to the elderly: 1. The progressive reduction of the compensation for the “static biological damage” with the increase in age on the basis that the person has fewer years to live (but the law does not take into account the mechanisms of adaptation and compensation that in the young can considerably reduce the effective injury, whilst the entity of the damage tends to be greater for the elderly); 2. The fact that in the elderly the consequences of what is a small lesion for a young person (for example the fracture of a metatarsus) can considerably alter the quality of life for the elderly and make it impossible to have the pleasure of a short walk and give them in any case daily life problems that can be compensated only partially by the judge. Not to mention the unfair devaluation of the aesthetic damage to the elderly (sometimes responsible for relevant psychological effects) who, like everyone else, have the right to look after their appearance. Also an eventual damage to the sexual capacity risks of being essentially overlooked, especially for women, even though sex and sexuality are an integral part of the experience of living for the elderly too.

## Conclusions

The NBC felt the need to draw attention once again – within the limits of our task – to the “moral” condition of the elderly, the full understanding of which is the premise for an effective emphasis on friendship and support for the people who, in ever increasing numbers, live to old age.

We cannot in fact reason merely in demographic and economic terms about the ageing population and the relative consequences for public and private budgets, without consider-

---

<sup>208</sup> F. D. Busnelli, *Natura del danno biologico: profili giuridici. Atti del Convegno nazionale “Il danno alla persona: tutela civilistica e previdenziale a confronto”*, Florence, pp.17-19, October 1996. M., Bargagna F.D. Busnelli (eds.), *Rapporto sullo stato della giurisprudenza in tema di danno alla salute*, CEDAM, Padova 1996. Fiori A., *La stima personalizzata del danno alla salute: a chi compete e con quale metodo*, Dir. Econ. Ass., 343, 1998. F.D. Busnelli, *Il punto di vista del giurista*, *Danno e Resp.* 728, 1999. G. Umani Ronchi, N.M. Di Luca, G. Bolino, *Alcune puntualizzazioni circa la valutazione medico legale del danno biologico e del danno biologico da morte*, *Jura Med.* 12,167, 1999. M.Bargagna, M. Canale, F. Consigliere, L. Palmieri, Umani Ronchi G., *Guida orientativa per la valutazione del danno biologico permanente*, III ed. Giuffrè, Milan 2001. G.B. Petti, *Il risarcimento dei danni, biologico, genetico, esistenziale*, Utet, Turin 2002.

ing – also – the “equal dignity” of the citizens, regardless of age, health conditions and the contribution they can make with their “presence” to the global well-being of society.

This equal dignity also includes a series of “rights”, which must be intended as requisites to the support that is right for the community – on the basis of the “social citizenship pact” – to ensure with the widest redistributive range possible also to those who have contributed to the collective well-being in the past and continues, in some form, to produce in the present. A community that has amongst its duties that of looking at the elderly with a mind empty of false as well as dangerous commonplaces and stereotypes.

As in the past the minor’s “right to rights” was identified, it is fair today to talk about the elderly’s “right to rights”, interpreting the intentions of Art. 25 of the Charter of Fundamental Rights of the European Union in which “the Union recognises and respects the rights of the elderly to lead a life of dignity and independence” in which for the first time the right of the elderly as individual is recognised, a legitimised individual. This right derives from old age because it is thought that the person is in a phase of biological life in which he/she can be in conditions of diminished capacity of self-support and is exposed to more risks. For this reason his/her rights must be protected, recognised and satisfied.

In this framework, the NBC hopes for the institution of an Observatory on the condition of the elderly to verify the adoption of national and international regulations regarding them.

1. The following propositions summarise the context of these rights:

- The elderly are people and as such they must be respected;
- The elderly have the right and duty to promote their human and especially spiritual resources;
- Society has the ethical duty to facilitate the promotion of a dignified life for the elderly;
- The elderly have the right to be treated according to principles of fairness and justice, regardless of their level of self-sufficiency and health.

2. From the point of view of healthcare and medical training, it must be said that not always degree courses teach geriatrics well. Often they are instead lacking in the multidisciplinary approach necessary to manage elderly patients, inadequate in the practical use of simple diagnostic means, insufficient in the culture and ethics of communication with the patient that is often overlooked, as the doctor limits him/herself to contact in the surgery with the family. It is necessary to re-train the teaching of geriatrics and geriatric sciences also for the purposes of a rehabilitation of the elderly, the prevention of latent psychopathologies and disability. It is important to develop and broaden specialist schools, considering the fact that geriatric doctors should be the point of reference for integrated home-care. It is also appropriate to reinforce experimentation, also outside of anti-dementia drugs, in order to avoid depriving the elderly of the results of appropriate studies rather than entrust themselves to generic therapeutic and care protocols, inadequate and expensive. With regards to the role of the doctor in the tragic problem of mistreatment, the NBC hopes that the forensic doctor, involved in public healthcare assistance, will bring his/her experience to the study of this phenomenon in institutions and within the family, not only as an expert who is eventually legally entrusted with the task, but mostly as a specialist who, fully respecting privacy, is available to doctors and GPs to assess cases that are difficult to

interpret. The forensic doctor is able to advise the GP, taking into account that mistreatments are often hidden and in general kept quiet by the patient, who fears worse problems and, despite everything, being removed from the family.

3. It seems clear that experience, at least in our Country, the (psychological, social, economic) well-being of the elderly is strongly linked to the family context in which they generally live, where intra-family relationships can have for the elderly a particular relevance after retirement. It seems increasingly evident that the “crisis” of the intra-family relationship has an apparent effect on the “fragility” of the condition of old age. The percentage of the elderly who live alone is increasing.

The recent institution of the support administrator is certainly proof that society is sensitive also to needs that – especially for the elderly who live alone, without a family – are present in daily life when self-sufficiency is at least partially lost.

We also want to stress that family’s affection and care, first of all, are still today the “natural” elements that reassure and support the elderly. But it seems increasingly evident that also the sensitivity, altruism, enthusiasm of those who operate public and private healthcare and social services, can help the elderly to fight isolation, demoralisation for the loss of self-sufficiency and reinforce the conviction of being of value and still having “value” for others.

4. For operational purposes, the distinction between self-sufficient elderly and non-self-sufficient (dependant) elderly has valid justification, although there are middle ways between these extreme states.

For the self-sufficient elderly, wanting to remain active and continue to produce an income for their family, we should provide the chance of work, proportionate to the abilities and physical and mental resources available. The NBC is aware of the difficulties inherent to the practical realisation of this objective, which however must be supported (also due to the positive result offered for example by groups of active voluntary work and social cooperatives formed by the elderly, fully involved in productive activities, etc.) also for the message of “intergenerational solidarity” that it can give.

5. The NBC is fully aware that the condition of the non-self-sufficient elderly is particularly delicate – from a bioethical as well as organisational and political point of view. The NBC concludes this reflection stopping on the brink of terminal illness, palliative care, death, because these topics are – if anything – the object of other, more specific reflections (on some of which, in addition, the NBC has already produced previous documents: see for example Definition and Detection of Human Death (15th of February 1991); Opinion on the Resolution Proposal Concerning Assistance to Terminally Ill Patients (6th of September 1991); End-of-Life Issues in Bioethics (14th July 1995); Pain Therapy: Bioethical Guidelines (30th of March 2001); NBC Opinion on Advanced Treatment Statements (18th of December 2003); Nourishment and Hydration of Patients in Persistent Vegetative State (30th of September 2005).

The NBC in any case stresses the fragile condition of the elderly, which worsens – in the natural development of life – sliding in time, almost without fail, into dependence, a phenomenon of personal and social bioethical interest, more relevant as life expectancy increases.

The NBC stresses however, that in any age and in any circumstance, the non-sufficient elderly preserve their inalienable characteristics of human being and citizen, a dual “value” that protects their dignity, rights and interests.

6. The NBC notes that the evolution of the international debate on the “rights of the elderly” has produced documents of considerable interest, but their application remains always the choice of individual countries, as much as it is allowed by their legislations and finances. For our country, what has been elaborated and established in the “Objective project for the elderly” remains an unavoidable point of reference.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**DIFFERENTIATED DIET AND INTERCULTURALITY.  
BIOETHICAL GUIDELINES**

17<sup>th</sup> of March 2006



## PRESENTATION

It is well-known how the issues of intercultural bioethics are complex and thorny and how, at the same time, they elicit not only doctrinal reflections and pragmatic stances, but also (and especially for some) curiosity and emotions, the kind of emotions we feel whenever we are confronted with rigorous intellectual honesty by the “other” and with the universe of practices and values ??that, if he/she is a member of a different culture, he/she inevitably carries. In several occasions, the National Bioethics Committee has come into contact, albeit indirectly, with significant intercultural issues: I like to remember, in particular, the 1998 reflection on *Circumcision*, when the NBC took an unequivocal position against femal genital mutilation. More subtle, although less pressing issues, still related to multicultural bioethics, were tackled by the Committee in its opinion entitled *Ritual Slaughter and Animal Suffering*, approved on the 19<sup>th</sup> of September 2003. The Opinion presented here comes from the reflection of a Working Group activated on the 19<sup>th</sup> of November 2004 and entrusted to the care of Prof. Sergio Belardinelli and Silvio Ferrari. Participating colleagues were Salvatore Amato, Luisa Battaglia, Maria Luisa di Pietro, Laura Palazzani, Giancarlo Umani Ronchi. The Group also benefited from the active contribution of Patrizia Rosicarelli, from the Rome Town Council and Aldo Morrone, from the San Gallicano Hospital in Rome, whose competent availability has been fruitfully used by the Committee and we therefore thank them for their generous cooperation.

The document prepared by the Working Group was submitted to the Committee, gathered in the plenary meeting of the 17<sup>th</sup> of March 2006 and was approved with a vote in favour by all of those present (there was one abstention, that of Prof. Mauro Barni). Approving this document, the Committee hopes that the issue of diet within institutions such as schools, hospitals, prisons, is duly taken seriously by the competent authorities; even if it does not belong to the category of the most divisive bioethical issues, such as the “big issues” pertaining to the life and death, which are obviously the ones that raise the interest of public opinion as a whole the most, it activates significant dilemmas of ethics and conscience, which would be simplistic and even naive to underestimate. The level of bioethical consciousness of a country and a society should be perceived starting from the sympathy we are able to raise also on matters that are only seemingly of a marginal nature, like the one presented in this text.

*The President of the National Bioethics Committee*  
*Prof. Francesco D'Agostino*

## INTRODUCTION

In a society where people of different faiths, ethnic origins and philosophical convictions coexist, the issue of diet takes on a certain relevance for cultural, religious and social reasons. Although the issue of diet choices involves a variety of spheres of human life, in the current historical moment it seems appropriate to focus on the food policies adopted by public institutions in our country, characterized by the growing presence of individuals who have eating habits that are different from the majority of the population. The choices made in this respect in schools, hospitals, prisons and army barracks constitute an important element in the process of fostering a harmonious coexistence devoid of tensions between people belonging to different ethnic, religious and cultural communities. It therefore does not surprise us that periodically controversies and disagreements arise with regards to the appropriateness of anticipating differentiated contents and times to supply food to students, prisoners, hospital patients, soldiers, because of their principles or religious beliefs: underlying these controversies are in fact different projects of integration.

In this context, it happens that the diet issue is used instrumentally, sacrificing people's concrete interests in order to give priority to one or other governmental strategy about immigrant communities in our country. To prevent this incorrect approach to alter the terms in which the issue of differentiated diet must be considered, it is appropriate to identify some general principles to serve as guide.

The first question is whether and why diet differences due to ethnic diversity and religious or philosophical beliefs deserve respect. The answer is tied to the link between food and culture: these differences express the identity of a person or a group of people, namely, the core principles and values from which you must move to integrate the differences between cultures, avoiding assimilation or separation, which can lead to uniform non-differentiation and discriminating marginalization. Respecting diet diversity usually does not come into conflict with the values and inalienable rights that must be respected by all members of a social community and therefore it is possible to move from a sympathetic approach to these diversities to assess how they can become a factor for mutual enrichment.

Which different diets deserve respect is the second question to ask. It is evident that an unmotivated aversion to a particular food is not a sufficient reason to request a differentiated "menu" in the canteen of a public institution; a better foundation would have a claim based on a traditional diet due to ethnic or geographic origin, which is potentially an element of wealth for the whole community and yet the case of dietary prescriptions based on religious or philosophical ideas is more meaningful in illustrating the personal and profound commitment to a certain vision of life and the world. Each of these hypotheses requires consideration and differentiated treatment.

With regards to this, the respect for the freedom of conscience and religion directly or indirectly guaranteed by our legal system provides a first indication in negative, because it forbids forcing someone directly or indirectly to swallow foods against their will. This means that, in public institutions, a person should never be put in front of a choice between eating or violating their religious or philosophical beliefs. But the guarantee of this minimal level is only the first step: in a truly intercultural bioethical perspective, it is in fact possible, remaining within affordable costs, to find paths that allow not only claiming the right to maintain our food traditions, but also presenting them as an enriching element for the entire community.

## Nutrition at school

The characteristic feature of school is to be, together with the family, the main place where a person's educational process takes place.

The issue of a differentiated diet at school must therefore be placed in the context of nutritional education, which is not limited to teaching how to eat properly and in a way that is suited to the individual growth, but also includes the learning of the cultural meaning of food and nutrition, in which is implicit a way of relating to our history, the environment in which we live, the relationship with other members of the community we grew up in, the way in which we see our relationship with other living beings.

In a society characterized by the coexistence of multiple cultural identities, nutritional education also means educating about the diversity of traditions and food choices that, through the students and their families, are present in the school. In this perspective nutritional education means teaching and enriching our "food culture" by trying and appreciating foods and a diet that are typical of other ethnic, cultural and religious traditions or "styles" of eating dependent on choices that involve a person's entire life.

In particular, this approach to food diversity can tackle with more balance the issue of religious dietary laws, releasing it from all claims that it is simply about identity, which may exacerbate the differences preventing the mutual contact between different cultures. When there are no significant drawbacks, these provisions should be respected and, where possible, emphasised. Also to protect the freedom of religion, it seems appropriate that the availability of other foods (e.g. eggs or beans) is always guaranteed to students, who for religious reasons do not eat certain foods (e.g. pork); and when possible and appropriate (and here comes into play the type of dietary requirement, the number of applicants, etc.) students must have the chance to consume food prepared according to the prescriptions of their religion, by setting up differentiated menus in school or at least allowing these foods to be brought in by an outside caterer (at the expense of the student).

## Nutrition in hospital

If the school's identifying feature is education, for hospital's is health: the purpose for which hospitals exist is to recover or, where this is not possible, be assisted in the state of illness.

The issue of nutrition must be examined in light of those objectives: but, within health facilities, it takes a broader focus that extends to taking medicines. In fact, the prescription of a particular food or medicine can be of great importance for the care of a patient: but it is possible that, for cultural or religious reasons, he/she refuses (more or less openly) to take the food or the medicine, thereby undermining the effectiveness of therapy; or it is possible that, while observing the doctor's prescription, the patient perceives it as an imposition inconsistent with his/her deepest convictions and lives in a state of tension that does not contribute to the success of the therapy. Patient's care requires in these cases the exploration of all the alternatives in an attempt to identify therapeutic strategies that have, in that situation, the highest possibility of success.

To this end, it is first of all necessary to ensure that doctors and nurses have the training essential to correctly read the food requests - often manifested in implied or indirect

form - of patients who come from very different religious or cultural contexts and are poorly understood by medical staff. Beyond the problems of communication and interpretation (in the broadest sense of the word) of the needs expressed by the patient, it is then about providing the training required to develop, for example, diets that take into account the religious or cultural requirements, to formulate therapies that concentrate the intake of medicines and food at certain times (e.g. the obligation of fasting during the day for Muslims during Ramadan) or are able to achieve their goals without consuming certain substances. In this perspective it is also appropriate to spread the knowledge of religious precepts that allow to shorten or stop fasting and eat foods normally forbidden: all religions, in fact, anticipate exemptions from complying with diet precepts in the case of illness, but not always these exceptions are known to patient. In this area, as in the communication with the patient, the work of cultural mediators and religious authorities belonging to the patient's community may be valuable.

A degree of organization of hospital services does not seem to be particularly complicated or expensive to extend the possibility of a differentiated diet, already anticipated for therapeutic reasons, to patients who have special dietary needs for religious or cultural reasons.

### Nutrition in prison

A test of particular importance to recognize, with regards to respecting the dignity of every human being, the meaning of diet choices of a cultural and most of all religious character is made up of the rules relating to food for detainees.

The consideration of dietary needs arising from the traditions of a country or religious beliefs is, in fact, an element of focus on very personal aspects of our life: it constitutes, therefore, a model of interpersonal relationships marked by acceptance and mutual recognition, helping to strengthen, in all those involved, the authority of the fundamental rights in our legislation.

Allowing those affected by restrictions on personal freedom to be able - still - to eat following their conscience and without diminishing his/her culture, should not however be a pure formality, but be framed within a commitment designed to ensure that the individual concerned will examine consciously (also in relation to protection of his/her health) certain rules or traditions, capturing their authentic meaning and making them clear to others: without excluding, therefore, as long as there are no problems of conscience, an openness to know and share eating habits different from those familiar to him/her.

Therefore, it is about taking steps to ensure that respect for the abovementioned needs does not become a factor of exclusion or division, but of integration.

In this context, the reference expressed in Art. 11, paragraph 4, of the Italian Penitentiary Law (DPR No. 230/2002) to the duty to take into account the requirements of the different religious faiths in creating the menus, but only 'when possible' appears - in its generality - an understatement. This is also in light of the importance attached to *religion* amongst the condemned or the prisoner's "treatment aspects" in art. 15, first paragraph, of the penitentiary law (Law No. 354/1975); also in light of the fact that prison has been for some time now, statistically, the most multi-ethnic place in our society. Therefore, certain details seem important, such as those in a Circular by the Department of Penitentiary

Administration in November 2001, about the specific contents of menus that are respectful of religious needs and about the time to supply food with regards to complying with the requirements of the Islamic Ramadan: which is an unrenounceable link to the respect to be given, generally, to religious requirements about food.

With regards to the peculiar reality represented by the execution phase of a criminal penalty, the prescriptions under examination should therefore be considered as a factor relevant to the consolidation, by the prisoner, of all the necessary conditions to express his/her identity and for a mature management of him/herself and of his/her conduct, as well as for the purpose of being open to a type of respect and concern for the needs inherent to the dignity of any individual.

#### **Nutrition in army barracks**

Also in army barracks, as in prison, law and order issues prevent the individual from fulfilling his/her own food needs. As conscription is no longer mandatory, those same guarantees of protection expected in any other work relationship should apply. Again, however, the delicate function of social integration that the military service can have, forces us to guarantee respect for the individual's fundamental values and therefore of his/her most intimate religious and cultural beliefs.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**BIOETHICS AND REHABILITATION**

17<sup>th</sup> of March 2006



## PRESENTATION

Prompted by a request from the *'Our Family Association'*, whose main centre is in Ponte Lambro (Como), which conducts meritorious research, treatment and rehabilitation of persons with disabilities, the *Italian National Bioethics Committee*, in the plenary session on November 19<sup>th</sup> 2004, unanimously decided to enable a working group on *Bioethics and Rehabilitation*. The group was composed of the following members of the NBC, Professors Battaglia, Binetti, Bompiani, Borgia, Flamigni, Palazzani, Umani Ronchi; the appointed group coordinators were Professors Michele Schiavone and Maria Luisa Di Pietro. We are especially grateful to Professor Di Pietro, because she took on the burden to materially produce, after numerous group sessions, the final draft of the document, which was presented to the Committee in the plenary session on February 17<sup>th</sup> 2006, and then definitively and unanimously approved on March 17<sup>th</sup>.

Few will miss the importance of this text, which expands the traditional view of clinical bioethics, activating psychological, social and anthropological considerations of extreme importance. Attentive readers will notice how in these pages we do indeed emphasize the indisputable merits of "scientific" medicine, but we also and above all firmly maintain the immense importance of a commitment that is interdisciplinary, integrated and *humane* to the problem of disability with regard to its optimal treatment. Despite the lucid, coherent, and even sophisticated *doctrinal* dimensions of 'medical ethics and bioethics, the fact remains that no practicing of *care* may ultimately be true to itself if it is thought that it can only be rooted in the power of thought: it is the *encounter* with those who ask to be treated that is ultimately decisive: general good will and, even worse, warm, generous, but often ineffectual, emotionality, is of course not enough for the seriousness of this *encounter*. This NBC document wishes to call all those who operate in this sector and all those who have public health and welfare responsibilities to their cultural, social and even *epistemological* responsibilities. But, in addition, and this needs to be strongly emphasized, it also intends to call to mind that the authenticity of bioethics is expressed the moment it proves to be powerful enough to extend relational practice, able to sublimate the mere *being-with-the other* into the more difficult, but far more existentially authentic *being-for-the-other*.

*President of the Italian National Bioethics Committee*  
*Prof. Francesco D'Agostino*

## 1. Premise

The issue of rehabilitation has been subjected to bioethical reflection only recently: for a number of reasons, including the late integration of this medical branch in the programmatic scheme of the International Health System and the complexity of the issue faced with different forms of disability and rehabilitation commitment. Moreover, the debate - specifically bioethical - the exercise of patient autonomy, quality of life, justice and allocation of resources, as well as the dramatic increase in the number of people with disabilities (as a result of road and work accidents and the rising average age of the population), have encouraged a systematic treatment of the subject only from the late 70's. There are, as a result, the first publications on the subject and the first declarations made by international bodies<sup>209</sup>.

Among the obtained results there has been a gradual but irreversible disruption of the taboos associated with disability and rehabilitation, and a different approach - even linguistically - to the person with disabilities. In fact, no longer referred to as "invalid", "handicapped", "disabled" but rather "person with disability" in order to focus on the value of every human person regardless of his condition, and that the disability is not to be considered objectively negative but rather in relation to a physical, cultural and societal environment which is unable to exploit the possessed potential<sup>210</sup> (hence the term "differently able person" or "diversely able person"). The particle "with" also limits the connotation attached to the person stressing the fact that it is an achieved rather than a subjective attribute.

The different linguistic approach, in turn, has brought additional elements of justification to rehabilitative intervention, in particular, and the taking care of people with disabilities in general. Furthermore, "pre-occupation" for others has, in fact, always been conditioned by the recognition of their value and that of their being taken care of, even before being a question of *decisions*, it is, a matter of *vision*, i.e. the ability to see ' the other in his concrete needs as a human being.

## 2. The reason of rehabilitation

Even the concept of "rehabilitation" has undergone a transformation, over the last few years: developing from a medical-curative centered concept on functional deficiencies to an

---

<sup>209</sup> See, for example, the articles and items published in *Archives of physical medicine and rehabilitation* (1980), *Hastings Center Report* (1987) and the *Encyclopedia of Bioethics* (1978, 1995). Among the first international action, we recall the *Declaration on the Rights of Persons with Disabilities* United Nations (1975) and *Resolution AP (84) 3* of the Council of Europe - Committee of Ministers (1984), which summarizes the principles of social and cultural inclusion of the person with disability.

<sup>210</sup> As is known, the international classification of impairments, disabilities and handicaps (*International Classification of Impairments, Disabilities and Special Needs*, "ICIDH") proposed by the World Health Organization (WHO) in 1980, was the first attempt to overcome the traditional model that identified illness through a simple nosological classification and excluded any other element with the function to determine well-being. The ICIDH is based on three parameters that are closely related: 1. the functional damage (*Impairment*: impairment or organic lesion), 2. the loss of personal skills (*Disability*: partial or total reduction of ability to perform an activity), 3. the consequent existential disadvantages (*Handicap*: reduction of the holding of a role as a consequence of the *impairment* and/or *disability*). It is therefore evident that the person is not judged according to his ability to work alone but also to his potential resources that enable active social and relational participation. A reflection - as we shall see below - is developed parallel to the evolution of the concept of health.

approach that looks at the person being rehabilitated in a comprehensive way in order to achieve an improvement in their quality of life.

In general, the term “rehabilitation” all therapeutic interventions (*treatments*) and welfare (*care*) that have as their purpose the (partial or total) recovery of impaired abilities (at different levels: mild, medium, severe) due to congenital or acquired pathologies (neurological, cognitive, psychic) and the valorization of existing potential (sensory, motor or psychic) to enable and achieve the best insertion and integration within the family and social context.

Rehabilitation deals with various types of people with disabilities: those with temporary impairments or those who are able to recuperate the state of bodily function prior to the trauma or disease or the onset of the severe and irreversible impairments.

Rehabilitation - we read in the Guidelines for rehabilitation activities approved in 1998 by the Standing State-Region Conference - is “a process of problem solving and education during which a person moves to reach the best level possible of physical, functional, social and emotional life, with the least possible restriction of operational decisions [...] about the rehabilitation process, concerns, in addition to strictly clinical aspects, also psychological and social aspects. To reach a good level of effectiveness of any proposed rehabilitation, for any individual, it must therefore be focused on multiple targets, planned in an orderly manner, so that the autonomy reached in different areas can result in the autonomy of the person as a whole and, in any case, a better quality of the person’s life”<sup>211</sup>.

Rehabilitation may involve motor function, language, acquisition strategies, etc., and the choice of interventions –not always easy and immediate solutions - is performed according to the type of disability or disabilities that is prevalent, balancing both the strengths and needs of the person with disability. In fact, if you do not take into account the needs of the person with disabilities, you run the risk of achieving only a reduction of the disability to the extent that there is the extreme possibility of inducing others.

The term “rehabilitative medicine”, instead, indicates - on the one hand - all the operators of instruments and techniques dedicated to medical rehabilitation, and - on the other - a discipline with its theoretical basis and practical applications.

Therefore, next to medical rehabilitation (defined as prevention, containment or removal of disability), it is possible, then, to identify - even if the distinction is not always clear cut - social rehabilitation which has as its purpose the prevention and demolishing

---

<sup>211</sup> And also in the same document we read: “Rehabilitation is also a process, describable as a set of actions aimed at countering the findings of deficits, to support achievement of maximum levels of physical, mental and social autonomy and to promote psychic well-being and the widest expression of affective and relational life. In such a global vision rehabilitation thus becomes a process that articulates skills, networking services and integration between health and social rehabilitation and as such is a right that must be enjoyed throughout the national territory and therefore any shortcomings must be punished but systems should also be activated to incentivize and reward. It should be stressed that proper implementation of rehabilitation strategies produces substantial savings in follow-up actions and the resources required should also come from a rationalization of interventions based on surveys of local needs and availability, the rigor of the methodologies and data in scientific research. Each intervention of rehabilitation before being generalized must pass the test of scientific validation: people or families can not be deceived, nor asked to pay for services whose effectiveness has not been proven. Health and social funds can not be directed to interventions of unproven efficacy, while interventions of proven efficiency remain without funding. Rehabilitation is therefore a global process so that integration between health and social services becomes essential” (Standing Conference Measure for representatives of the State, Regions and Autonomous Provinces of Trento and Bolzano, May 7th 1998 in the Official Gazette of May 30th 1998, n. 124).

of barriers. In fact, rehabilitative intervention, while having an immediate horizon located in the injured and dysfunctional body, also has a wider horizon and this is the whole personality considered by itself and as regards family, social and occupational inclusion<sup>212</sup>.

We could therefore, think of rehabilitative medicine as four concentric circles - proceeding from the inside out - namely: 1. the injured organ and its dysfunction (primary damage); 2. prevention of secondary damage (e.g. developmental delays in children and adult functional imbalances) and tertiary (e.g. position defects, deformities, painful and dystrophic syndromes resulting from inactivity); 3. the totality of the person in all his physical, mental, moral and spiritual components; 4. Society is called on to prevent, provide resources, personnel and facilities and to elicit a clear desire for solidarity<sup>213</sup>.

Rehabilitative intervention has found, therefore justification in the evolution of the concept of health, which - as is known - has received different interpretations over time which has influenced the aims and methods of health intervention. Given that outlining the concept of health - as indeed the specular concept of the disease - is somewhat complex and not unique<sup>214</sup>, it is possible to schematically identify at least three paradigms:

a. HEALTH AS AN "ABSENCE OF DISEASE." According to this paradigm, health is equivalent solely to the condition of physical efficiency or absence of disease, and the request - implicit or explicit - of the patient to return to the pre-existing condition prior to the onset of the morbid condition. In this perspective, the only purpose of health intervention is the diagnosis and treatment of the disease in order to eliminate the physical symptoms. This is an organismic vision that not only does not affect the other dimensions of the person (mental, spiritual, social) but which also reduces the disease to an incidental event in the life of the subject.

b. HEALTH AS A "STATE OF COMPLETE WELL-BEING." The World Health Organization - in 1946 - defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"<sup>215</sup> - This definition looks at the person in a global sense (physical, psychological and social) and exceeds the organismic view of health, it must be thought out and promoted through projects that embrace physical, psychic and social well-being. The same medicine, which once occupied almost exclusively the cure of disease, is expanding the possibilities of intervention: from diagnostic-therapeutic medicine to also rehabilitative medicine. On closer inspection, however, the

---

<sup>212</sup> The above is justified even in art. 3 of the Constitution, which - after repeating the equal dignity of all citizens - states: "[...] and 'It is the task of the Republic to remove those obstacles of an economic or social nature which constrain the freedom and equality among citizens, prevent the full development of the human person and the effective participation of all workers in the political, economic and social development of the country'".

<sup>213</sup> E. Sgreccia, *Bioetica, handicap e riabilitazione*. In *Manuale di Bioetica. Aspetti medico-sociali*, vol. II, Vita e Pensiero, Milan 2002, p. 459.

<sup>214</sup> C. Boorse, *Health as theoretical concept*, *Philosophy of Science* 1997, 44, pp. 542-573; D. Engelhardt, *Health and disease. History of a concept*. In Reich W. (ed.), *Encyclopedia of Bioethics*, Mac Millan, New York 1995, vol. II, pp. 1085-1092.

<sup>215</sup> Subsequently, the World Health Organization has included the concept of reproductive health: "Reproductive health is a state of complete physical, mental and social well-being not just the absence of disease or infirmity, in all areas related to reproductive system and its functions and processes". To this central issue even in the discussion on disability, the National Bioethics Committee reserves the right to dedicate a subsequent document.

WHO definition, while having the advantage of presenting a proposal with a multidimensional and holistic vision of health, can promote a reading of health as efficiency contributing also to create unrealistic expectations about the possibilities of the same medicine. Health as a state of complete physical, psychological and social well-being may in fact never be realized or realized rarely with the risk - not just theoretical - of overly extending the boundaries and to be confronted with demands that have nothing to do with the pathology itself.

c. HEALTH AS “BALANCE”. If one looks globally at man, health and illness do not seem extrinsic factors to everyday experience but rather subjective experiences. Health thus becomes a kind of *balance* in the flow of everyday experience: a quiet *balance*, a *balance* that is not static but dynamic an intrasomatic equilibrium, intra- and inter-personal. The alteration of this balance can cause illness, illness which no longer takes on the characteristics of a simple incident, but it becomes an opportunity to seek a new balance through a process of growth, awareness and responsibility. The person becomes healthy to the extent that he is capable of living in a conscious and free manner, exploiting all the energy in his possession. The person is, by contrast, ill or incapable, or not sufficiently able to manage his life in a conscious and free manner, and exploit his skills and energies. This being understood, health is not a fact: it is an achievement; it is not acquired once and for all, but should be continuously sought; it is a task, a lifestyle, which is enhanced by the ethical dimension that encompasses the other (organic, mental, and environmental) dimensions. It is in this sense that health is also defined in relation to non-medical factors (nutrition, working conditions, housing, etc.) which may be affected by individual and collective choices. It is in the light of this interpretation of the concept of health that, in addition to diagnosis, treatment and rehabilitation, prevention also has its part, and is aimed at encouraging behaviour that can prevent the onset of diseases and/or break down of psycho-physical balance. The promotion and protection of health becomes – not just a right – but first and foremost, a real duty, which is made real through prevention or cure to recuperate health, as far as possible, when disease has already compromised it. The paradigm of “health as a balance” does not intend to deny or question that advances in Medicine are due almost exclusively to so-called Scientific Medicine, that is, the set of doctrines and remedies based on scientific assumptions of the proposed treatments and rigorous testing regarding both successes, and failures even in rehabilitation<sup>216</sup>. There is, however, the will to highlight how the same Scientific Medicine is the appropriate response to the health needs of man, but that it should be accompanied by a “global” system that permits even other dimensions of the “good” of the person to emerge.

Even the inclusion of non-medical factors in the concept of health has made it possible also to develop an important distinction between disability and illness, the WHO, discharging the Classification of Functioning, Disability and Health (*ICF* as abbreviated in English) as a model of cultural approach to disability, has emphasized that disability is a characteristic that belongs to all mankind. It is in a bio-psycho-social perspective that therapeutic and curative intervention is reformulated, rather than concentrating only on medical factors, highlighting the impact of a hostile environment and a non-inclusive society. The approach

---

<sup>216</sup> Cf. Italian National Bioethics Committee, *Aims, Risks, and limitations of Medicine*, Rome 14<sup>th</sup> of December 2001.

to achieve the condition of equilibrium or health becomes so personalized, and is related to the life<sup>217</sup> and relational environment.

This document does not examine individual clinical situations (Table 1) or the variety of rehabilitative interventions available today, but will present only elements of reflection on rehabilitation in general and on bioethical issues related to it. Neither does it enter into the delicate and complex area of psychiatric rehabilitation, to which the Italian National Bioethics Committee will devote a subsequent document to follow on from the previous one on “Psychiatry and Mental Health: bioethical guidelines”, published in 2000.

### 3. Rehabilitation as a bioethical problem,

At the moment of planning one or more rehabilitative interventions on a person, there are some obvious common elements that can be summarized as follows<sup>218</sup>:

- **historicity:** intervention must be closely linked to the diagnosis and take account of any rehabilitation, educational or therapeutic rehabilitation that has already been carried out;
- **globality:** to take charge of the care of the person always involves both the emotional and cognitive side;
- **personal involvement:** the success or failure of rehabilitation interventions is directly proportional to the active participation of the person concerned and / or his family to the project, the degree of commitment and depth of motivation;
- **pursued objective:** that is the improvement of the quality of life in a perspective that regards the whole span of life, which requires not only a prior evaluation of disability and existing potential but also the needs of the person and available resources. It is a question of human resources (the person with disabilities, the family, friends and health professionals, teachers, etc.) and material resources (tools, space, organization of time);

---

<sup>217</sup> Interesting is the definition of the assumption of responsibility “care for people with disabilities” first developed by the National Conference on Handicap, Rome, 2000, the “care for people with disabilities” expressed as “the *continuous and integrated process* by which there must be assured the *governing of all the coordinated interventions on the conditions which hinder their inclusion in society, education and work*, and is aimed at encouraging the most complete unfolding of the personality of individuals. In a framework based on the new WHO classification ICIDH-2, the taking of responsibility should be defined as *the strategy of attention of care services, evenly distributed on the territory, to the disadvantaged condition of persons with disabilities*. This strategy of attention must be carefully manifest through the provision of public or private services, in coordinated interventions, and with the necessary continuity, having the purpose of *enhancing the skills and abilities of people with disabilities* and to work with the appropriate resources and skills for the achievement of equality of conditions among citizens by limiting or eliminating social and cultural discrimination. The taking of responsibility is one of the key moments for the establishing and maintaining of the relationship regarding person/family/service system/and social context. It is therefore a process that, respectful of individual choices of people with disabilities and their families, is influenced by the extent and quality of existing resources, the levels of integration between services and institutions as well as their ability to ensure continuity with the consistent evolution of life’s course. It is then a process that requires careful attention to the intervention of broad interinstitutional expression and in the stages of evolutionary transition of particular significance, such as childhood/adolescence, or adolescence/adulthood”.

<sup>218</sup> M. Zanobini, M.C. Usai, *Psicologia dell’handicap e della riabilitazione*, Franco Angeli, Milan 1997.

- *timely planning*: a rehabilitative intervention should be based on a theoretical scientific model according to which realistically achievable goals are set in the short and long term, appropriate methodologies and work tools and methods of verification of achieved results. A lax approach could, in fact, lead not only to little or no effective intervention, but also the belief that nothing can be done, and reduce the strength of that key factor which is motivated commitment.

Tabella 1. Classification of impairments and disabilities (Capodaglio, 1995).

<p><u>Categories of Impairments</u></p>	<ul style="list-style-type: none"> <li>- <i>Intellectual disabilities</i>: these include intelligence, memory and thought;</li> <li>- <i>Other psychological impairments</i>: include impairments that interfere with basic functions of the constituents of mental life (consciousness, perception and attention, emotional functions, patterns of behaviour);</li> <li>- <i>Language impairments</i>: refer to the understanding and use of language and its associated functions, including learning;</li> <li>- <i>Hearing impairment</i>: not only refer to the ear, but also to the structures and associated functions. The most important subclass consists of impairments that relate to the hearing function;</li> <li>- <i>Eye impairments</i>: do not refer only to the eye, but also to the structures and associated functions, including the eyelids. The most important subclass consists of the visual function;</li> <li>- <i>Visceral impairments</i>: include impairments to the internal organs and other special functions;</li> <li>- <i>Skeletal impairments</i>: include mechanical and motor disorders of the face, head, neck, trunk and limbs. Excluding more obviously disfiguring impairments;</li> <li>- <i>Disfiguring impairments</i>: include those impairments with the potential to interfere with or disrupt social relations. Conditions that may not be the result of specific diseases affecting the control of bodily functions are included;</li> <li>- <i>Generalized impairments, sensory or other</i>: include multiple impairments, serious impairment of continence, metabolic impairments, and sensory impairments of various body areas.</li> </ul>
<p><u>Categories of Disability</u></p>	<ul style="list-style-type: none"> <li>- <i>Behaviour disability</i>: refers to an individual's awareness and ability to behave, both in daily activities and in relations with others, and include the ability to learn;</li> <li>- <i>Communication disabilities</i>: refers to an individual's ability to generate and send messages and receive messages and understand;</li> <li>- <i>Personal Care disability</i>: refers to an individual's ability to fend for themselves with regard to basic physiological activities, such as the evacuation-urination, nurturing, self-care, hygiene and dressing;</li> <li>- <i>Locomotor disability</i>: refers to the disability of the individual to perform tasks associated with movement, both of oneself and that of objects from one place to another. General mobility and consideration of the degree to which it can be recovered with aids are excluded;</li> <li>- <i>Disabilities in the use of the body</i>: refer to an individual's ability to perform typical activities associated with the use of body parts and derivative activities as the execution of tasks associated with the residence of the individual;</li> </ul>

- *Dexterity disability*: refers to the dexterity and skill of body movements, including manipulative skills and the ability to adjust control mechanisms: The ability to write or use signs is precluded;

- *Situational disability*: these have been included for practical reasons, particularly with regard to reciprocal specification of the environment;

- *Special skills disability*: include individual skills and talents required by professional relocation, such as behavioral skills (intelligence, motivation, perception, learning ability, memory, etc), ability to perform tasks (programming tasks, solve problems, etc.);

- *Other limitations of the activity*: include unmet needs in other parts of the classification.

It follows that the issue of rehabilitation - although all the criteria of legitimacy that apply to any diagnostic and therapeutic choice remain valid – submits itself to bioethical reflection with some distinctive characteristics that differentiate it from other areas of medicine:

- the necessary and constant reference to a global vision of the person with disability perceived not only in the totality of his being but also as someone inserted in a particular socio-environmental situation, from which it is impossible to parcel out the person and/or his disability or give a “reading” outside the context of life and relationships;
- the dilation of time as rehabilitative interventions may be prolonged over a period (months, years), making the priority the re-reading of methods of communication and the obtainment of consent and continued involvement - even in terms of motivation – of the person with disability: it is a progressive process with constantly updated achievement of results;
- the multiplication of those involved even as a result of the involvement also of the family of the person with disability. And, especially in the case of a child, the family itself becomes a participating collaborator in the rehabilitation process;
- the unpredictability of the results due to the dynamism of rehabilitative interventions and the difficulty of quantifying existing and hidden potential in the person with disabilities which - often - exceed expectations. It is for this reason that all persons with disabilities should be considered in their uniqueness and excluding the limitation in order to apprehend what can they can give.

Bioethical reflection is, then, called into question at different levels: anthropologically (in determining the meaning of the body, and therefore impairment of the body), on an ethical level (in identifying reference criteria for those involved in rehabilitation, directly involved in determining and implementing the rehabilitation program, and for the person with disability, whose autonomy may however be limited or conditioned), at the judicial level (in identifying the person with disability as a subject with rights) and on a political and social level (in planning and allocating resources to invest in rehabilitation and the planning of intervention directed at the inclusion of the person in the community).

#### 4. The human corporality and experience of limit

The *ethos* of the experience of disability is, the body, perceived not as an “object” in its raw facticity but rather as a body that is “lived”, and “personal”, that body in which and

through which we exist, in actual fact the body that we are. It is worth recalling here Husserl's famous distinction between *Körper* and *Leib*, where *Körper* indicates the body as a simple object and *Leib* indicates the lived body or the awareness of one's own body, and Scheler between *Geist* (the spiritual world), *Ich* (the psychic world), *Körper* (the physical world) and *Leib* (the unitary form of all organic sensations).

The "lived body", could also be defined as "corporality", precisely to show the whole of human subjectivity under the aspect of its bodily condition as constitutive of its personal identity. It is specifically this lived body that becomes the crossroads of the encounter and interchange of the multiple dimensions of the person: through the body the person can express himself, it is through the body that every interpersonal relationship is possible, through the body one finds a place in the world, and is added to the flow of human time.

Man – as Hengstenberg wrote – "is not just an animal organism with the addition of consciousness which elevates it. Man is 'the only being who has a body, while in the animal we can only talk about organism[...] The addressing of objectivity (or the sense of objectivity) has cooperated in the morphology of the limbs and human organs, and the same applies for the body'"<sup>219</sup>.

As an experience of a personal body, disability is not just about physicality or just the psyche. Any impairment of somatic integrity or functionality has, more or less serious repercussions on the psyche, influencing the definition of body image, the structuring of personal identity, personal way of relating to others; but in the same way any impairment or alteration of the psychic sphere involves different reflections on the perception of one's corporality and physical integrity, to our being in the world and entering into relations with others and, therefore, on the construction of the self and the definition of one's identity. The "I" that lives, feels, understands, suffers, hopes is spiritual and corporeal combined together.

On the other hand, the experience of the limitation that disability inevitably implies is not an experience extraneous to human existence, indeed the opposite could be said, that is, that the limitation is an essential dimension of human experience. As Nussbaum correctly writes, "we must not think about the needs of adults and children with disabilities as something that refers to a very particular condition of life, easily distinguishable from the cases that "are classed as standard" It is, instead, a situation full of implications also because of the way we think about our parents when they grow old, and the needs that we ourselves will probably have if we live long enough. As life expectancy grows, the relative independence enjoyed by many of us ends up appearing as a condition that is only temporary, as a stage in life which we gradually enter, but that we all are going to leave all too quickly. Even during the prime of life many of people come to experience long or short periods in which they are forced to live in a state of extreme dependence on others – such as after surgery or after a serious injury, or during a period of depression or severe stress"<sup>220</sup>.

Not expressible in terms of acceptance or rejection, the experience of limit is clear and constitutive of human nature itself: "That man has an "I" that can not leave the course of dramatic action into which it was born, and he can not leave to consider what to play. He is now in the game, without his ever being asked if he wanted to play"<sup>221</sup>.

<sup>219</sup> H.E. Hengstenberg, *Philosophische Antropologie*, Pustet, Munchen- Salzburg 1984, pp. 81-82.

<sup>220</sup> M. Nussbaum, *Giustizia sociale e dignità umana*, trad. it., Il Mulino, Bologna 2002, pp. 30-31.

<sup>221</sup> H.U. Von Balthasar, *Teodrammatica. II. Le persone del dramma: l'uomo in Dio*, Jaca Book, Milan 1992, p. 323.

The limit is, therefore, part of its objective dimension of human experience, but as it is a completed life experience it involves an alteration of life and subjectively also forces to rethink one's potential. In this sense, the experience of limit is not an experience of what is absent but rather of what is possessed and the limit of disability should not be read as a listing of what is "missing" but enhancement of what is possessed.

If these conclusions are accepted to be shared, it follows that the existential value to be pursued in rehabilitation is that of enhancement of the person. In fact, in disability difference can be concrete related to the ability to do or not do something, to perform or not perform a certain task, but it does not exist as regards a person's value, the right to be human, or in the dignity of being called by one's name. And it is precisely from these considerations that there has been - as mentioned in the premise - an evolution of the concept of handicap, not only a semantic evolution but an evolution in both content and anthropological foundations.

See in this regard, the aforementioned features of the International Classification of Functioning, Disability and Health approved by WHO in 2001, where disabilities are described in a different way, in reference to the environment in which a person lives with their own abilities, large or small as they may be, and - as already mentioned - the terms "handicap" and "handicapped" disappear, and are replaced with the term "disability", "activity", "social participation" and "person with disability" or "differently able person". Terms, which have always had a negative connotation, consequently acquire a positive valence and interactions between the various factors that constitute health or disability have become more complex, making it possible to understand particular situations and also give due regard to the context, both personal and environmental. The assessment of health status can not then be made ignoring the complex relationships between mind, body, environment, contexts and culture.

Among the positive consequences of this approach, there is no doubt the belief that if a person can not - for example - move, is actually the world around him not able to accept him. We are no longer then, faced with a "motor disabled person" but rather a "person who can not climb if the house does not have a ramp" it is not the limitations of the body that should concern us but rather the reasons why it is not possible to participate in social life. This change requires the removal of the sense of being a "bearer of disadvantage" to people with different abilities, but rather to evaluate them according to abilities and *performance*<sup>222</sup>. We must, therefore, work by providing everything that can lead to full participation in the social and relational life of each person and at the same time, try to break down every barrier that prevents the full exploitation of the different realities in the social fabric. This objective that goes beyond the concept of "integration" is expressed in terms of "inclusion".

---

<sup>222</sup> The first signs of this approach are already evident in the document *Rules for equalizing the opportunities of persons with disabilities* (1993) of the United Nations, consisting of 22 rules that "apply to support the process by which the various systems of society, the material picture, services and activities and the information is made accessible to all, especially to people with disabilities." It appears clear, therefore, how the idea of "social disadvantage" of people with disabilities is increasingly outlined, and that it should be tackled with the same intensity with which physical rehabilitation is provided for. These principles have been stated more clearly in 2002, within the document *Examination and evaluation of the world programme of action concerning disabled persons* which - on presentation to the General Assembly - has formed the basis for the *Resolution A/RES/56/163 and the subsequent approval of the International Convention on the Protection and Promotion of the Rights and Dignity of Persons with Disabilities* ([www.un.org/esa/socdev/enable](http://www.un.org/esa/socdev/enable)).

Indeed, “social inclusion” is very different from “integration”: while “integration” means the inclusion of people in an established context of rules and principles and the person with disability has to adapt to what has already been decided by the community that integrates him, inclusion, however, is based on the participation of the individual in the decision-making and planning of the whole community that takes into account cultural, religious and psycho-physical diversity of the person entering the community. The role of the person with disability is thus equal to that of other individuals who are already included. This approach rejects any form of institutionalization as a discriminatory approach that has produced the social and individual depletion of persons. In fact, the separate paths of rehabilitation - in special and segregated places- inevitably reduce the relationship with society, and imposes perception models of inadequacy and inability and exclude people with disabilities from having the possibility of equal exchange of experiences and skills.

Another new element, present within the international documents of European and international agencies, is the approach to people with disabilities based on respect for human rights<sup>223</sup>. People with disabilities, particularly serious ones, having become invisible citizens due to segregating treatments and social exclusion, are often discriminated against and are without equal opportunities compared to other citizens, in addition to which there is a continued violation of actual human rights<sup>224</sup>.

---

<sup>223</sup>In the field of human rights, see: the *Declaration of the Rights of Persons with Disabilities* (1975) of the United Nations (Articles 3. And 10 states that the “handicapped person” is entitled to respect for his dignity and must enjoy the same fundamental rights of citizens of the same age), the *Convention for the Protection of Human Rights and Fundamental Freedoms* (1950) of the Council of Europe (art. 14 settled the condemnation of all forms of discrimination, which leads to include - though not explicitly - the discrimination of the person with disabilities), the *European Social Charter* (1996) the Council of Europe, - developing the principles of the Convention of 1950 from an economic and social aspect - states the rights of persons with disabilities to be integrated into general education, teaching and training by limiting the use of specialized facilities to cases of necessity, to be assured access to the labor market in a fair manner and be guaranteed that States will implement all necessary measures to overcome obstacles to integration and social participation, and the *Recommendation R (92) 6 for the construction of a coherent policy for people with disabilities and the Resolution AP (95) 3 on the professional assessment of the handicapped* Council of Europe, inspired by the examination of “capacity” rather than “disability” (incapability); *Resolution of 17<sup>th</sup> June 1999* of the Council of the European Union, which calls on States to strengthen their national policies in this regard, and in relation to persons with disabilities, and the *Charter of Fundamental Rights of the European Union* (2000), which in articles 21 and 26 reinforce the principles of interdiction of any discrimination and calls for respect for the rights of persons with disabilities to participate in community life. It appears, therefore, clear that internationally there has been constant attention to ethical and legal issues, particularly – in the first phase – to the affirmation of rights without any distinction between types of causal onset but rather to the capacity of recovery, and - in a second phase – to implementation of full participation in social life including work [see, also documents the International Labour Organization - ILO Convention-including *Convention n. 159-1983* and the Document *Collection of practical guidelines for the management of disability in the workplace* (2001)], as a right belonging to every person even those with disabilities work is a condition included in the defining of the concept of human dignity).

<sup>224</sup> As regards the Italian situation, this reaffirmation of rights is already listed in the Constitution, where it is claimed - among other things - the principles of removing barriers that limit the full development of human personality. The course of implementation of rights in terms of legislation has not always been easy, but it is a fact that it has reflected the evolution of conceptual and cultural models of disability over the years. An important step - among many - was, however, the approval of Law No. 104/1992 (*Framework Law for the assistance, social integration and rights of disabled people*) in the Ordinary Supplement to Official Gazette of February 17, 1992, No 39). As regards - in particular – rehabilitative intervention, article 5 paragraph c, reads: “The removal of the invalidating causes, promotion of autonomy and the achievement of social integration are objectives pursued through the following [...] to guarantee the timely intervention of therapeutic and rehabilitative services, to ensure the recovery consented by scientific knowledge and techniques currently available, the maintenance of the handicapped person in the family and society, his integration and participation in social life.

## 5. Ethical interpretations of rehabilitation

In the context of bioethical reflection on rehabilitation, it is possible to identify the best method of approach, which moving from specific readings of the meaning of the body and the person, subsequently, go on to propose different solutions on the ethical, legal, political and social level.

➤ Functionalist approach. Rehabilitation is seen as a health practice that has as its goal the identification of technical tools and procedures necessary to enable a person to recover only in terms of physical efficiency and autonomy, neglecting the other personal dimensions (psychological, emotional, relational, etc.) and not taking into account the social and relational environment. It is an approach that mostly considers the human body as a material entity separate from the personal dimension and evaluates the person with disability only on the basis of his functional capabilities. The ethical, legal and socio-political consequences of this approach may concern, above all, those who are in situations of extreme physical frailty. Since the feasibility and the establishment of a rehabilitation program (and the related allocation of resources, economic and human resources for this purpose) would depend on the valuation of real or foreseeable possibility of recovery in terms of efficiency and autonomy, those who seem - for clinical conditions - unable to do so may not be appropriately considered and therefore, would be left out of social policy. This shortage would be then be filled by spontaneous and, therefore, occasional, charity and solidarity inspired by feelings of sympathy or social opportunity.

➤ Contractarian approach. The contractarian approach moves from respecting autonomy (in the sense of full capacity of self-awareness, self-determination, rationality of the individual able to stipulate contracts and exchanges with other individuals, in conditions of symmetry and reciprocity) and attaches to rehabilitation a predominantly autonomous and individualistic value. Consequently, the planning of rehabilitation (in inter-individual and social terms), on the one hand, depends on the autonomous choice of the person with disabilities – a choice in itself that is not always possible – and on the other hand, closely related to the expectation of recovery of full capacity for autonomy in the sense of self-sufficiency, self-awareness and self-determination of the individual. To the extent that this objective is not considered accessible, because there are no conditions to achieve it, to do so, the cost of rehabilitation would not be considered justifiable.

Both the functionalist approach and the contractual approach can produce - absurdly - two completely opposite outcomes: the “abandonment” of rehabilitation’ and “aggressive” rehabilitation. Indeed, insofar as it is believed that the person should be rehabilitated only in anticipation of the total recovery of efficiency and autonomy, it can result in a defeatist attitude (the decision not to activate a rehabilitation program in the case of the desired objective not being reached and the benefit obtained does not justify the cost and human commitment) or - by contrast - an overly interventionist attitude (choosing to activate all possible and available resources to achieve the objective at any cost, even if there are no objective conditions of total recovery, in a race for efficiency, productivity and autonomy at any cost).

➤ Human rights-based approach. Since people with disabilities often live in conditions of discrimination, the aim of rehabilitative intervention and “enabling” intervention is to restore the condition of parity, in terms of opportunities, that are the right of the human person regardless of his condition. The “enabling” attribute indicates that there is no need to restore the impaired function of the body, but rather, to acquire the ability to perform the activities associated with it even if in different ways. For example, in the case of the inability to walk, rather than insist on achieving a standing position – if, at all achievable – rehabilitating the person to achieve this standard of mobility, one can intervene to make the person acquire a new skill linked to the use of a wheelchair: and this choice does not change, of course, his dignity as a human being. This new cultural approach focuses on *empowerment* of the person with disabilities<sup>225</sup>, which starting from the person’s functional limitations, develops paths of growth, awareness and the acquisition of skills and abilities that enhance their independence and the ability of self-determination, promoting their social inclusion. In addition, new forms of support are also developing, not least the *peer counsellor*, the availability of personal assistants, and the use of ever new technologies<sup>226</sup>. This approach, which moves from the recognition of the value of the person regardless of his condition and that, in the case of a person with disability, aims to increase the chances of self-determination, autonomy, independence and inter-independence, is extremely appreciated. At the same time, however, it puts forward some questions on bioethics: to what extent and by what methods should one intervene in the course of rehabilitation? In order to obtain informed consent is it necessary to provide a person with information even on possible alternatives to the traditional rehabilitation model (for example, using a wheelchair instead of rehabilitation – possibly – to walking)? How should the rights of persons with disabilities be respected when they can not represent themselves? When and under what conditions is there a non-proportionality of rehabilitative interventions to the extent of producing talk of “aggressive rehabilitation”<sup>227</sup>?

---

<sup>225</sup> The essential tools of *empowerment* are education and information, the enhancement of skills and abilities, the change of perspective and perception of one’s condition, produce stimuli and motivation to change life. The *empowerment* for disabled people covers several aspects: emotional (reformulation of emotions to build and transform rather than to limit and destroy), perceptual (re-definition of life experiences on the basis of the social model), intellectual (understanding of the cultural tools to be acquired and the learning of their language), behavioral (transformation of human and social relations on the basis of the new awareness), enabling (learning to do things in a different way), rehabilitative (changing the way we do things by introducing new approaches). The main instruments of action are the personalized projects of life, drawn through the active participation of the persons concerned.

<sup>226</sup> See - for Italy - Law 328/2000 (*Framework law for the implementation of the integrated system of interventions and social services*), as art. 14 reads: “To achieve the full integration of disabled people in art. 3 of Law 5 February 1992 n. 104, in the context of family and social life, as well as courses in education or vocational education and work, the municipalities in consultation with the local health units, shall provide, on request, an individual project, as established by paragraph 2. 2. Within available resources according to plans laid down in Articles 18 and 19, the individual project includes, in addition to evaluating diagnostic and functional performance of treatment and rehabilitation paid by the NHS, the services of the person provided by the council in a direct and accredited form, with particular reference to recovery and social integration as well as the economic measures necessary to overcome poverty, marginalization and social exclusion. In the individual project the potential and any potential support of the family are defined [...]” (in the Ordinary Supplement to Official Gazette of November 13, 2000, No. 265). Again: Law n. 4/2004 *Provisions to support the access to information technologies for the disabled* in the Official Gazette of January 17, 2004, No 13).

<sup>227</sup> See: Disabled Peoples’ International - Europe, *Dichiarazione di orientamento sulla nuova genetica e le persone con disabilità*, 2000.

➤ Integral approach. The integral approach regards rehabilitation as a set of interventions (not only medical) that move from the taking charge of the whole of the person with disabilities, considered in the totality of components, and not only in its mere physical dimension. Indeed, ability itself is not simplistically identified as “normal” functionality. On the anthropological level the corporality is perceived in the meta-biological dimension, irreducible in its parts since the same human organism is more than the sum or juxtaposition of parts, and the person is to be recognized in his dimension of being, irreducible to exterior expression and serial functions or capabilities that do not exhaust “the” subject but they are “of the” subject.

According to this view, the subject pre-exists those same functions, it is the indispensable substrate for their manifestation, the function is actualized as a consequence, moreover, partial and incidental, which presupposes the existence of a human person as a whole (abstract qualities do not exist; there are only the concrete determinations of a specific existing embodied entity).

The integral approach to the person with disability, in this way, moves the barycentre from appearing to being and recognizes the immeasurable value of man regardless of the functions he is able to carry out: the absence of certain functions (transient or permanent) does not, therefore, negate, personal existence that remains such by nature of the fact that it pre-exists qualities. It is the body of the person with disability in “residuality” conditions (no longer being) or in a condition of “deprivation” (never being) – that is to say, of non-implementation, temporary or permanent of certain functions (due to the presence of external or internal factors that prevent its manifestation) – that does not negate the nature of being. It follows that the subject with disability, is always and nevertheless a person, because even though he is in existential conditions which prevent the manifestation of certain properties or behaviour, the lack of functions does not modify nature. There is the primacy of being a person over that of becoming a body.

The integral approach finds, on an ethical level, the duty to respect those who do not fully exercise their skills and abilities: the bioethical question arises because there are existential conditions of fragility and weakness in which one can not live without the help of others. In these cases health care and biomedical practices have to deal with those who are not able to live the fullness of the potential inscribed in human nature.

The being a person imposes itself even for those who can not decide, think, feel, understand, and therefore, also for the person whose abilities have been diminished or reduced: in this sense it captures the scope of the doctrine of human rights, which are intrinsic to the person and not a mere consequence of their recognition.

If it is true that every man is a subject of rights, it is starting from his corporality, whether ill, deformed, inert or unconscious, that he deserves protection. The law is then called upon to defend the equality of men: in this sense the body, every human body is bearer of an objective right, it is a “strong” legal otherness that asks to be recognized and to which every man has a debt (even apart from the recognition of one’s entitlements).

Even the person who is no longer able to claim their rights, who is in an existential condition of impairment, who needs the help of others to exist and to improve his condition, “calls for” the protection of the law.

## 6. Integral approach and rehabilitation

In the light of an integral approach rehabilitation is not only planning of therapeutic and care interventions for the recovery of (sensory, motor, cognitive) functions, but it is a global project for the person with disability that involves several levels: physical, psychological, ethical and spiritual. Rehabilitation thus becomes a dynamic project, an ongoing process, which should always be able to readjust to the objective situation: diagnosis allows definition (sometimes not so accurately) of the initial condition (through the identification of the pathological cause and consequences that it has produced on the individual, distinguishing primary, secondary and tertiary damage), but it is not always possible to establish a precise prognosis (either in terms of time, or in terms of future results). Rehabilitation is an often long and arduous journey on a winding road or uphill, where often the ultimate goal can not be seen. This is a course of action that presupposes relationality (in terms of collaboration, trust, solidarity and support) those starting out on their journey include: the person with disability, the doctor, rehabilitation therapists, and family.

Moving, therefore, from the assumption that a person - even in conditions of residual life (i.e. of not full manifestation of ability, now or expected in the future) - is a fully-fledged person, endowed with dignity in the strong sense and rights in the same way as any other man, and that dependency is a constitutive dimension of the human being (we always depend on others, to varying degrees in our lifetime), rehabilitation is to be considered much more than merely a biomedical practice: to “rehabilitate” means to activate a series of therapeutic interventions but also and above all human, on the individual body. It is for this reason that one should always take into consideration the overall good of the person with disabilities, in the recomposing of his structural balance. Based on the empirical evaluation of what is predictably recoverable regarding the objective disability, it is essential that the activation of the recovery strategy arises from the sharing of the project, from a “rehabilitative” alliance stimulated by continuous dialogue and mutual cooperation of all the parties involved.

It is essential that the physician, with appropriate gradualness, tells the person with disability, and – where possible, subject to his consent - the members of his family about the objective conditions of the impairment and the predictable possibilities of recovery: it is then up to the physician and rehabilitation therapist (as well as the family members) to help the person with disability to accept their condition, to understand that health is not full physical, psychological, and social well-being, but - as already stated - a dynamic equilibrium able to adapt to different situations, to accept limitations and reorganize daily life and relationality with others precisely on the basis of conscious awareness (which is neither unconscious removal nor resigned acceptance) of the limitations. The person with disability should also be helped to accept the eventual impossibility of recovering the original state of full functionality, by motivating him to undertake rehabilitation and by avoiding on the one hand, the giving of hasty guarantees of assured success, and, on the other hand, the suppression of hopes for improvement where these objective conditions may exist.

In this context, the role - in particular – of the rehabilitation therapist is not only technical: it is not just to restore the use of a function of a limb, organ or capability, but also to establish a continuous human relationship with the person with disability in a condition of vulnerability and fragility. Rehabilitation is not an action that the person undergoes passively (e.g. surgery), but rather it requires active interaction of both parties: the rehabilita-

tion therapist who work and the person with disability who actively participates. In this sense, the inner motivation and personal commitment to recovery are an essential and crucial element for a good result, to the extent that, not only can the use of affected functions be recovered, but also in order to evoke residual potential and mobilize inner compensatory energies.

Psychological and human support, as well as functional intervention, becomes essential to avoid the sense of despair and failure that can lead to regression and prevent rehabilitative progress: the objective must be to channel energies for one's recovery and enhancement - a task that often the person with disability does not feel prepared for - avoiding excess paternalism or emotional involvement that create victimhood. In this sense, adequate training of rehabilitation therapists to bioethical values should be promoted: In addition to professional competence and continuous scientific updating in collaboration with other health professionals involved to prepare the therapeutic-rehabilitative treatment program of the person with disability, the rehabilitation therapist must be educated to devotion to the other, to the capability of self-sacrifice and solidarity in the conviction of the value of the donation of time and energy even if the results may be uncertain or limited.

The realization, then, of these objectives means to provide - especially in public facilities - appropriate organization of work: the issue of bioethics concerns, then, not only the health personnel but also the institutions in which they work. Indeed, one could argue that the institutions they work for are - somehow - a kind of moral agent that provides the service. This interpretation of the organization as a moral agent moves from the fact that whoever is providing the service can not be seen in an impersonal way: an organization is always the result of the relationship between people who are in it and, therefore, the organization uses these people to accomplish a service.

On the issue of training health care professionals, the National Bioethics Committee has already intervened in 1991 with the document, "Bioethics and education in the health care system", to which we refer for analysis of the theoretical and applicative basis of the dynamics of trainer / formation.

Some professional and human qualities become - in particular - essential to a good relationship between the rehabilitation therapist and the person with disabilities: the ability to comprehend needs, empathic listening that avoids the risks of attachment and the consequent inability to make decisions, the availability to dialogue, recognition of achieved results and the stimulation of therapeutic collaboration; professional autonomy, the ability to work as a team; the intellectual honesty in admitting one's limitations, professional secrecy and respect for privacy, availability of the involvement of family members. It is, therefore, necessary to enhance the capabilities of the person with disabilities and change the perspective of his life: an important example of this approach is the interventions linked to the treatment of paraplegics and tetraplegics in the unipolar spinal unit.

The role of the family of the person with disability is therefore, essential; they can integrate - with the affective and emotional component - the rehabilitation project: the person must feel that others are able to accept him also with disabilities. The not full capacity of extrinsic manifestation of efficiency and autonomy should not compromise in human terms, interpersonal relations; the family remains the main place where the person with disability can mature this awareness, inwardly and gradually. In this sense even the family must not be left alone in this difficult task to which it is often not prepared: the doctor and rehabilitation therapist must constantly communicate with the family, to provide - subject to con-

sent, where possible - the person with disability with information to provide support, in the awareness of the delicacy and preciousness of the contribution in a perspective of co-responsibility. We must focus on the role of the family, in particular, when we consider the minor with disabilities.

Lastly, the role of society is important. The rehabilitation project is completed with the inclusion of the individual in society: it is essential to promote a social culture that knows how to favourably accept and rethink the value of man beyond psycho-physical incidentals. Inclusion and integration is to be understood at two levels: at the empirical level (by breaking down the architectural barriers, thinking ethically justified any expenditure that knows how to give hope to sufferers) and the human level (by breaking down the barriers and prejudices of the mind). Bureaucratic state intervention is not, therefore sufficient (providing opportunities for care or assistance), but it is absolutely essential to provide a human investment, and a community commitment, so as to avoid forms of loneliness and marginalization, and to look upon the capabilities of each person as richness, preciousness, a human "capital". Even if rehabilitation has costs and does not always pay off (in terms of achieved objectives), even faced with the rehabilitation of severe and unrecoverable disability, proportional intervention, capable of enhancing as far as possible and restoring meaning and hope to a difficult life, always finds justification.

The ethical commitment in the rehabilitation process is divided, therefore, in different levels:

- the person with disability, whose efforts should be supported - if possible - by a desire for the realization of values such as confidence in the future, the ability to make sense of existing capabilities and their lives;
- the doctor and the rehabilitation therapist, who should be able to create a climate of collaboration and trust, which has a decisive role on the rehabilitation process;
- the family, which should be the first social structure involved in the course of action of rehabilitation;
- voluntary work and network of friends, which should give constant support to the family in order to facilitate the increase of the capacity of the person with disability to undertake / resume interpersonal relationships, thus avoiding attitudes of passivity and regression that could be developed by living exclusively in the family environment;
- political institutions, should be aware that proper planning in the allocation of resources can not be separated from assistance to people with disabilities and rehabilitation, even if this requires prolonged intervention with not always positive results, they can not ignore the other problems connected to disability, such as school/education and employment/professional insertion. The ethical commitment of those taking the public decisions, should therefore be, to undertake a social health program aimed at the achievement of "global rehabilitation" which translates into non-discriminatory access to health care, equal opportunities for a person with disability and a person without disability, the proper application of the principle of justice as a response to the needs of the person, the real inclusion in family, social, political, economic and religious life, the promotion of scientific research in rehabilitation, in the accessibility to prosthetic aids.

## 7. Models of relationship

Rehabilitative medicine includes a variety of a medical, psychological and psychosocial interventions because it is offered to people who may have a wide variety of disabilities with varying degrees of impairment of their autonomy. This variety of external situations is also reflected in a wide variety of internal situations: from the experience of pain to striving to hope, anger, the desire to get involved, from awareness of unconscious acceptance as in the case of severe mental illness. Also the situations of support may be quite different: from assistance at home to admittance to hospitals or specialized clinics for rehabilitation.

From a bioethical point of view of rehabilitation what emerges - as already stated - is that it must be appropriate and effective for the condition of the person with disability and that it should be implemented in a timely and continuative manner as required. The timeliness of the intervention requires on the one hand, early diagnosis and, on the other, the availability of people, vehicles and facilities, calling into question issues related to the organization of the health system and the availability of financial resources which will be discussed in a later paragraph. However, equally important is scientific expertise and the human “qualities” of doctors and rehabilitation therapists, as well as the collaboration between the doctors and rehabilitation therapists around the person with disability in the conduction of the rehabilitation project: a system of cooperation that must be based on the real-sharing not only of the scientific and ethical aspects, of ethical guidelines and cultural language, but also of the methods and procedures related to evaluation and intervention, and the parameters to test achieved results. The goal is the recovery of the person as a whole, of his autonomy and quality of life: therefore, any “conflict” between rehabilitative methodologies is counterproductive. The choice should be dictated solely by the good of the person with disabilities, the complexity of the situation, and from the peculiarity of the circumstances.

It is also true that, unlike most of the medical or surgical interventions, there is great difficulty in the field of rehabilitation to make a prognosis that has a margin of certainty: it is, in fact, difficult to predict “if” and “to what extent” the person will be able to recover damaged functions and which “collateral cycles” he will be able to activate to compensate for the loss of some abilities. It is for this reason that it is very difficult to determine in advance whether or not it is proportionate to the person with disability to continue a rehabilitation program, if the lack of efficacy is linked to low motivation/participation or, objectively, if there is no possibility of recovery. There may be situations in which it is believed that the time to suspend the rehabilitative intervention: but even when the rehabilitation of an organ or function is not possible, one should never stop “rehabilitating” the person, in order to balance their disability with the acquisition and consolidation of other faculties, keeping him active and creative making the most of his mental, spiritual and moral capabilities. One must always remain open to hope even in the face of limitation, and before rehabilitation idealized as omnipotent, but failed in its overall intent.

To promote the continuity of interventions, taking charge of the whole person, providing hope: in other words, taking “care”, becoming a “travelling companion” of the person with disability and - if necessary - of his family.

It is for these reasons that among the possible relationship models, particularly as regards rehabilitation therapist and person with disability, the educational model - which

will be discussed later - appears to be the most appropriate. Before analyzing the individual models, we want to clarify that the continuous reference to the rehabilitation therapist is not an attempt to overshadow the figure of the doctor or doctors who are involved in the rehabilitative process, but rather to highlight that due to the specific roles and continuity in time, it is precisely the rehabilitation therapist that is mostly involved.

There have been identified some models of relationships between rehabilitation therapist and person with disabilities<sup>228</sup>, among which, the following seem important:

- the paternalistic model, which focuses - as is known - on the principle of beneficence and justifies the rehabilitative intervention even in the absence of information and consent of the person with disability. Although appropriate and fully justified in situations where the person with disability is not aware of his state, the paternalistic model loses, however, view of the main purpose of rehabilitation, that is, to restore - if possible - autonomy to the person with disability, whose freedom of choice is constrained by the decision of the rehabilitation therapist and any possible refusal to continue treatment is experienced by the latter as a form of opposition and not as a symptom of a deep discomfort;
- the agreement model, which provides for the planning of interventions by the rehabilitation therapist and the person with disabilities with the relative consent of the latter, after the assessment of the risks and benefits. Notwithstanding the absolute centrality of informed consent<sup>229</sup>, it should be noted that the detection of consent may be particularly sensitive and complex in the presence of a mental disability or psychological reactions (fear, anxiety, depression, regression, etc..) when faced with a situation of motor or sensory disability;
- the “educational model”, looks not only at the technical intervention but to the whole person to help him become aware of his actions and responsibilities, providing adequate and commensurate information and the criteria for evaluation and arousing motivation in the commitment to the rehabilitation process.

According to this interpretation, which seems the most appropriate in a context of rehabilitation, the rehabilitation therapist is not only a technician but also an “educator” in the sense that he must be able to involve the person with disability, providing confidence and serenity. A relationship which - as it is interpersonal - involves the necessity of the ethical dimension, if only for the continuous endeavour of the person with disability and rehabilitation therapist to overcome psychological barriers and personal beliefs, and to compensate for any possible and insurmountable limits, to develop new potentialities of the integral personality.

The individuality of the person with disability has been reaffirmed in the interaction with the rehabilitation therapist, whose significant objective must be to understand and not to direct: each definition of ability should be based on the perception that the person with disability has of himself as - again as far as possible – he is the subject of the choices. A part-

---

<sup>228</sup> Cf. also: W. Reich (ed.), *Encyclopedia of Bioethics*, Mac Millan, New York 1995, vol. II (*Rehabilitation Medicine*, pp. 2255-2260).

<sup>229</sup> Not forgetting the huge amount of literature, the multiple interventions national and international interventions and the documents of the National Bioethics Committee on informed consent, we want to mention here – because it is last in chronological order - the Universal Declaration on Bioethics and Human Rights of UNESCO.

nership, therefore, between the rehabilitation therapist and the person with disability that must be equal and based on doing “together” in a process of mutual enrichment and not on doing “for” someone or “to” someone. A partnership in which, at some point, the rehabilitation therapist should merely have the role of a “travel companion”. A collaboration that has as its objective to help the person with disabilities to participate in an authentic way in the outside world and to build a life that is his personal life, open to the future just like that of every other human being.

### **8. Information and consent to the rehabilitation process**

In the educational model “information” is a central element. As concerns the topic of information, the National Bioethics Committee has already intervened - in 1992 - with a document entitled “Information and consent to medical act”, in which there are given detailed and clear indications given that may be useful for reflection. It is recommended, in fact, that in case of major diseases and prolonged diagnostic procedures and therapeutic procedures the physician-patient relationship can not be limited to a single, fleeting encounter; the curer must have sufficient skills in psychology to enable the understanding of the personality the patient and his environmental conditions, on the basis of which to adjust his behavior in supplying the information; if the nature of that information can be the cause of particular concerns and suffering to the patient, it must be given with caution, using non-traumatic terminology and always providing evidence to give the hope of one, albeit difficult, chance of success; information about the diagnostic and therapeutic program must be truthful and complete, but limited to those items that the culture and psychological condition of the patient are able to understand and accept, without exasperated details of data (the exact percentages - moreover difficult to define - of complications, mortality, functional failures) that involve the scientific aspects of the treatment. In any case, the patient should be placed in a position to exercise his rights properly, and therefore form a specific will, as regards the advancements and alternatives that are proposed to him; the responsibility to inform the patient lies with the director, in the public health facility, and in any case on whoever has the duty to perform or coordinate.”

The first thing to consider is, therefore, information on the damage, on the possibilities of recovery, possible irreversibility: a duty to inform which, in the case of rehabilitation, involves not only the doctor but also the rehabilitation therapist with whom the person with disability and perhaps his family have more direct contact.

Informing means telling the truth about the conditions of the disabled person, on the possibilities of recovery: it is a truth that has specific peculiarities as in all medical practice. In fact, in human relations there can be identified - based on the quality - four types of truth: direct truth as a response to a usually simple question; factual true that refers to an objective reality; personal truth which imparts a more intimate reality (feelings, emotions); interpretative or hermeneutic truth, which is the most complex because the communicator must try to understand the possible reactions of those listening. The truth to tell the person with disabilities and his family is certainly an interpretative or hermeneutic truth.

It is for this reason that it should be offered only after preparing others to receive it: a truth to be placed within an existential truth, which always knows how to give value to life and also its harsh events, a truth, which must always be open to hope, because not only is

it greater than any possible disability but it is also greater than a single person's life; a truth that health professionals are not always able to communicate, unable - often - to help the person with disabilities and his family to withstand the impact of news with a traumatic content; a truth that must be provided gradually, because, especially in the case of the child, no family - no matter how well-functioning - can at the same time deal with news of the disability itself, knowledge of the details related to the specific condition of his family member and the details regarding possible intervention; a truth, that to be communicated requires several interviews in order to understand the specific needs of each person and on this basis to calibrate the possible range of supports and services, a truth that no one ultimately possesses, given the unpredictability of the future and capability of the individual to develop the abilities present.

Information is followed by the obtaining of consent in relation to the capability of the person with disability to take an independent decision; and even when the capacity to make a choice is reduced, assent must - where possible - always be sought. On the other hand, the patient's consent and cooperation are the decisive element of the successful of the rehabilitative intervention, and moreover, the great relevance of motivation means that collaboration is always sought and not only in the presence of dangerous and invasive intervention.

In other words, in the rehabilitative process, consent is not an "event" but a "process" in a continuous search for communication and collaboration not only between the person with disabilities and rehabilitation therapist, but also between the various rehabilitation therapists of different expertise should they be present.

The construction of consent is not only a technical and legal moment, but it is morally relevant: it is not enough that the rehabilitation therapist can identify the objective possibility of recovery, functionality and autonomy based on scientifically recognized parameters, but it is necessary that the objectives of the rehabilitation therapist should also be the same as those of the person with disabilities and, if necessary, of the family.

It can, however, happen that there may be no consistency between the objectives of the rehabilitation therapist and the person with disability: there are those who, in the event of this, suggest acceptance of the choice of the person with disability, since - if he is not cooperative - will try to hinder in all ways the rehabilitation process. But perhaps more than passively accepting a partial objective even if shared, the rehabilitation therapist should ask himself why this situation has arisen, and attempt to remove any possible obstacles.

If these objectives are not shared this may also ensue among the rehabilitation therapists who have taken charge of the same person with disabilities: the lack of unity of the team can, without a doubt, affect the success of therapeutic interventions and the serenity of the person with disability, therefore it is fitting to reconstruct a unity of methods, intent and languages in order to have appropriate cooperation for the good of the person taken charge of.

As already said, if in the case of a decision to discontinue rehabilitation interventions one must never renounce "rehabilitation" of the person: often, however, the main problem is not the choice made by the persons involved (rehabilitation therapist or person with disabilities) but rather a shortage of public health resources and the inability of many to make use of private health care. The concept of justice and solidarity, referred to in paragraph 6 of this document must be called into question here.

## 9. The case of a minor

The birth of a child with disability or the discovery after birth that the child has disabilities “is an event that causes strong maladjustment in every family”<sup>230</sup>. Each component can react to the situation in different ways over time also in relation to family dynamics and mutual adjustments. In this reflection we focus in particular on the reaction of parents, but we must not neglect the experiences of the brothers of a child with disability<sup>231</sup>.

For parents it is often the sudden and painful “awakening” from a dream: the “dreamed” child, the child imagined, that is no longer there; there is the real child with its problems. Parents need to abandon the dream and face the reality; they must fall in love with a child which with its disability, seems to have “disappointed” their plans and desires. The path of acceptance is not easy: it lasts - at times - a lifetime; it is marked by the same emotions that come into play in mourning for a real death; a grief that becomes chronic in the constant comparison with other children, the “mirror” image that reminds of the dream and emphasizes its distance from reality.

How should the news of their child’s disability be given to parents? This is the first moment - for the doctor and rehabilitation therapists - when this ethical question is strongly raised. It is the beginning of the story, of the journey: which truth should be told to parents?

Referring to the preceding paragraph in which this aspect has already been analyzed, we want to emphasize that communication of the truth can also affect the second moment of strong emphasis on ethic, that is, the choice of the rehabilitation process. In fact, if there is a delay in making and communicating a diagnosis and in indicating / providing the appropriate supports and services, this may cause serious problems in the subsequent process of rehabilitation of the child. Many parents were disoriented when faced with a discovery that not only created in them so many interrogatives about the future of the child, but also put them in a position of not knowing what to do for it. Consequently, the attention that first focused on the child is moved and focused on its “problem”: the child itself became a “problem” in the parents’ existence. Each human individual is, however, valued for what he is and not for what he can do and the awareness of being faced, first and foremost, a child, a person, not just a problem, must be a support to the commitment to “restore to the parents their child as a child and not only as a “problem,” the “dreamed” child, even if it has some limitations and to live the recovery processes trusting in hope”<sup>232</sup>.

A hope that can become real when the parents realize that their child - albeit slowly - begins to respond and that these responses may also depend on the actions of the parents themselves who find how to be useful again to their child. A child must be considered in its totality and in its uniqueness. Globality: because - as said - the recovery goes beyond the physical or psychic disabilities of the child, involving the whole personality; uniqueness: because the hidden potential of the child with disability often exceed expectations.

---

<sup>230</sup> M.M. Pierro, *Presentazione*, in *Handicap e collasso familiare*, Quaderni di psicoterapia infantile 1994, 29, p. 19.

<sup>231</sup> E. Dall’Aglia, *Handicap e famiglia*. In *Handicap e collasso familiare*, Quaderni di Psicoterapie infantile, 29, Borla, Milan 1994.

<sup>232</sup> M.L. Di Pietro, L. Di Pietro, “*Accompagnare*” *il bambino con disabilità e i suoi genitori: problematiche bioetiche*, Ospedale Pediatrico Bambino Gesù - Formazione continua in Pediatria, Il Pensiero Scientifico Editore, 2006 (1), pp. 9-12.

Hope, however, should be nourished and sustained: this is what is asked by those parents who, day after day, struggle with difficulties, prejudices, and indifference. It is the indifference of others and the consequent sense of loneliness, lack of listening, the modesty of doubt and despair, the having to live every conquest in front of strangers, the fight to assert one's rights, which discourage most parents of children with disability. Promoting the acquaintance of other families with the same experiences or who have already been down the same path is always a great help for those confronted for the first time with a new situation; to prepare the rehabilitation therapists to help parents, aware that there are times when one must stand back and allow the emotional experience of the child and his parents to find its place; to make it clear to teachers that it is important not only to be there but also to be able to maintain a relationship with the child with disabilities in an active and discreet manner. In the name of subsidiarity the good of each person must be sought and supported where it is most needed.

During accompaniment, inevitably, the strain of this journey is experienced: new needs arise, new relationships with the realities that the child faces, time after time. One experiences disappointment when the outside world does not accept the child in its uniqueness and beauty, emphasizing only its limitations. In a society geared to efficiency and success, many parents consider the scholastic performance<sup>233</sup> of their child of fundamental importance and to be able to demonstrate that your child has abilities. For the parents of a child with disability, it is a painful situation to go through: they can not enter the "race of pride" with other parents; they are worried that their child growing up can be excluded by peers, and suffer loneliness, not being understood, accepted and loved.

The child must, however, be recognized with its potential and it is always important to keep this in mind so that the perception of limitations does not prevail over the perception of what the child can give. To grow up the child needs to be loved for what he is and not what he should be. Normality for the child is what he feels to be; he builds a sense of self based on the image which, in particular, the eyes and expression of the mother's face send back to him.

It is a case, then, of believing in the child, in his strength and his beauty, overcoming two prejudices that prevent a complete vision of reality: that people who can not perform certain activities are inferior to others and that, they are however, not sound of mind. On the other hand, even the way of classifying disability, the listing what is absent, has always been a sign of this prejudice: impairment is expressed as a percentage an indication of the closeness to "normality". To exploit potential means that in order to make the most of what the child with disability has, the enhancing of potential means to give space and provide the tools in order that children with disabilities can express themselves. And, in a society in which the common good is expressed through everyone's good, it is not diversity in the body that should be a cause of concern but - as already mentioned- the reasons why participation in social life is not possible.

It is the responsibility of whoever has taken charge of the child with disability to

---

<sup>233</sup> Without going into the subject of the scholastic integration of persons with disabilities, we will just recall some normative references, including the aforementioned Law No. 104/1992 and Law No. 53/2003 on *the Government Delegation for the definition of the general rules on education and essential levels of performance in education and training* (in the Gazzetta Ufficiale of April 2nd 2003, n. 77).

encourage, develop and to use their potential and to accept the disability. Particular care is needed in childhood and adolescence, when the person with disability begins to be aware of their condition and wonders “why am I not healthy?” No one can give an answer to this question but it is, of course, an invitation to relate to the pain that is manifested, to respect that person, who carries a burden: a burden that can not be eliminated but can be relieved. It is a person who has potential and unexpected qualities, not least a great attention to the things around him and a profound sensitivity: to highlight potential and qualities could be a way of helping them to live with more serenity personal limitations.

In addition to those who accept their own limitations, and collaborate in the rehabilitation process, there may be, however, those who have an oppositional approach: what should be done? Could insisting in the rehabilitative process constitute a sort of “persistent” rehabilitation that does not respect the person? This is a situation which - as previously stated - puts forward a number of ethical questions for which it is hard to find an answer: we should aim towards finding a balance to be created - each time - in respect of the child’s personality. This balance may also help to avoid falling into the temptation to “persistently” continue intervention on the child.

The child has potential, but also limitations, neither the one nor the other must prevail. It is important not to give up when faced with limitation but it is also important not to persist against it: this obstinate persistence arises from the non-acceptance of limit, with the risk that the child is once again thought of as a “problem” and not as a person. We must allow ourselves to be questioned by the limit and try to accept it as an opportunity to look at life differently, in the awareness that the limit has always a greater richness to reveal.

## 10. Society and the choice of rehabilitation

The ethics of rehabilitation should be placed, then, onto a higher and more general level: that of social and health choices. The majority of the more recent reflections recognize that modern society must assume its responsibilities towards people with disabilities: in fact, the person with disability has particular “needs” to reach a satisfactory standard of the “quality of life” that respects and no longer denies his dignity as a man.

However, still today, there are those who refuse the application of the concept of justice - socially and necessarily - to meet the needs of people with disabilities, as justice is paid by giving to the other of what is his, even if liberality with regard to persons with disabilities is not denied. The negation of the concept of justice is opposed by Nussbaum, who raises three problems - in his view - consequence of the failing to take account of the specific determination of human dignity: the first two concern “the fair treatment of a person with mental or physical disabilities that needs a high amount of care throughout the course of his life”<sup>234</sup> and also the support and care towards those “who are independent in certain periods of life and conversely live in a state of deep dependence”<sup>235</sup>. The third, however, concerns the problem of providing proper consideration of the persons involved in the care practices. Nussbaum claims that we should take account of the “burden on the people who

---

<sup>234</sup> Nussbaum, *Giustizia sociale e dignità umana*, p. 32.

<sup>235</sup> *Ibidem*.

care for those who live in a state of dependency. These people need many things: the recognition that their activity is a form of employment, both human and financial support; the possibility of a profitable and rewarding career and of participating in social and political life.”<sup>236</sup>

Contrary positions or positions otherwise reserved against the principle of justice are not of course satisfactory for the people with disabilities, who consider it a social duty that there should be real and equal “solidarity” to them.

Apart from any possible extreme positions, it must, however, be recognized that in contemporary society a more widespread “sensitivity” to people with disabilities has been gained. It should, first of all, be cited that the full recognition of their “citizenship” with the affirmation of the equality of fundamental rights of the differently able person as for any other citizen and the faculty or legal right to exercise all rights (with their respective duties) that he is able to exercise. In Italy, the aforementioned Law n.104/1992 is a testimony of the journey undertaken and the achieved legal recognition of full citizenship.

The person with disability has, no doubt, special needs, which an organized society must bear due to the same principle of sociability and reciprocity that should characterize human relationships. Hence the support and assistance (of various kinds from material and psychological to spiritual) that the community can and must make available, to the extent of available resources: for education, training, health and social care and so on, as modulated in the variety of life situations. The same family environment, which can not and neither must be replaced in this primary care, may have its limits (human, technical and economic limits) and must be helped in its tasks with a number of measures. In this sense, the State must intervene with its care facilities or by private initiative or voluntary work, in order to enable a person with disabilities to use all their existing capabilities and collaborate, as possible, to the common interest. Hence, the right to socialization, education and employment, these are also proportional of course to life-situations.

These principles – be they different in form from State to State - are clarified, or however, derive from constitutional rulings and the same international community espouses them now with documents of a high moral profile and programs focused on practical implementation.

The need to deal with limited economic resources still poses some problems from an organizational point of view, not least the definition of eligibility criteria for rehabilitation in public facilities especially when the demand exceeds the availability in terms of personnel, space and means. We can recall here, by analogy, the *triage* criteria to be met - as is known - the principle of equality and equal dignity, in this case, people with disabilities since everyone has the same personal value and should not be discriminated against.

Referring to the National Bioethics Committee document “Bioethical guidelines for equal access to healthcare” of 2001, it should be noted - here - that no health system can be considered fair if it were to limit itself to making rehabilitation available only to those who are financially solvent.

As concerns the possible criteria for selection they can be summarized as follows in order of importance: 1. need for rehabilitation; 2. urgency as the need to act quickly could affect the outcome of the intervention itself, 3. list, or order of booking. On the other hand,

---

<sup>236</sup> *Ibi.*, p. 33.

to be rejected as discriminatory, are criteria based on age, geographic area of origin, balance only based on cost / benefit, the most useful in social and employment terms as regards the person with disabilities to be rehabilitated.

In conclusion it must be reiterated, however, that intervention on a social level should always be strongly supported by a culture of favourable acceptance, so it is clear that there are not only changes to the terminology with which to define the condition of disability but that the same terms are given - and not only in terms of positive law - a real content. The words may be, of course, cause and “symptom” of a cultural revolution, but these must be followed by facts: a “signal” that highlights the difficulty of the person with disability, the fear of being abandoned, the anguish of those parents who are confronted with the painful thought of “what will happen when we aren’t alive” must truly become everyone’s problem along with the complete willingness to assume this responsibility.

### Summary and recommendations

Since the late ’70s, the issue of rehabilitation of persons with disabilities has been the subject of careful consideration at both national and international level, with a growing interest also in bioethics. In Italy, Law 833/1978 art. 1 introduces - among the key objectives of the NHS - the issue of rehabilitation. It therefore has been possible to highlight not only the medical aspects of rehabilitation, but also the social aspects, with their reference horizon in the person considered in all his globality and in relation to his living and relational environment. “Foundation” of this approach is a dynamic conception of health: a condition and a lifestyle that must constantly be sought and that also embraces the ethical dimensions, behavior and life choices. The promotion and protection of health becomes a duty of the individual and society and finds accomplishment in prevention or cure and that can make rehabilitation a technical and cultural tool.

Starting from these considerations and prompted to address the issues of rehabilitation, the NBC has prepared the following document with the intention to present elements of reflection on rehabilitation in general and on the bioethical issues related to it, leaving out - as this is beyond its duties - an analysis of individual clinical situations as well as the description of the multiplicity of rehabilitative interventions available today. The document does not address the complex issue of psychiatric rehabilitation, which the NBC sets aside for possible more specific reflection.

“Rehabilitation” is defined as the set of therapeutic interventions (treatment) and welfare (care) that have as their purpose the recovery (partial or total) of impaired abilities due to congenital or acquired pathologies and the enhancing of existing potential (sensory, motor, psychic) to enable and achieve greater inclusion of the person with disabilities within family and social life. The rehabilitation process is concerned, therefore, in addition to strictly clinical aspects, also with psychological and social aspects. To reach a good level of effectiveness, any rehabilitation project must, therefore, be focused on multiple targets, able to take into account the needs of the person, so that the autonomy that can be reached in different areas may result in the autonomy of the person as a whole and however, in an improvement of the quality of life.

Accordingly, the issue of rehabilitation is presented for bioethical reflection with some unique characteristics that differentiate it from other areas of medicine:

- the necessary and constant reference to a global vision of the person with disabilities, understood in the totality of his being and as such included in a particular social and environmental situation;
- the dilation of time since rehabilitative interventions may last for months or years, thus making the priority a re-reading of the methods of communication and the obtaining of consent and continued involvement - even motivational involvement – of the person with disabilities;
- the multiplication of those involved also including the family of the person with disabilities. And, especially in the case of the child, the family itself becomes a participating collaborator in the rehabilitation process;
- the unpredictability of the results due to the dynamism of rehabilitative interventions and the difficulty of quantifying - in the person with disabilities - existing and hidden potential which can exceed expectations. This requires, among other things, that the proposal of a rehabilitative process moves from a science-based theoretical model by which to establish realistically achievable objectives in the short and long term, appropriate methodologies and tools and methods to verify achieved results. A lax approach could, in fact, lead not only to little or no effective intervention, but also generate the belief that nothing can be done, and reduce the strength of that key factor which is motivated commitment.

Bioethical reflection is, then, called into question at different levels: anthropological level (in determining the meaning of corporality and person); on an ethical level (in identifying reference criteria for rehabilitation professionals directly involved in the determining and implementation of the rehabilitation program, and for the person with disabilities, whose autonomy may however be limited or conditioned), at the legal level (in identifying the person with disabilities as a subject with rights) at the social-political level (in planning and allocating resources to invest in rehabilitation and the planning of intervention directed at the inclusion of the person in the community).

Starting from the analysis completed at these levels, the NBC has made the following observations and recommendations.

1. The *ethos* of the experience of disability is the body, not as an “object” perceived in its mere physicality, but rather as a corporality that is “lived” as “body”, an expression of human subjectivity of the bodily dimension as constitutive to the identity of the person. As the experience of a personal body, disability does not only concern physicality or only the psyche, but both of these dimensions. Disability becomes experience and perspective of limitation in the knowledge that it is a constitutive and objective part of human life: in this sense, the limitation may be the opportunity to rethink one’s potential and the disability should be seen not as an expression of what is absent but as a means to enhance what is possessed. It is precisely starting from these considerations that we have witnessed an evolution in the concept of “handicap”, not only a semantic evolution but an evolution in both content and anthropological foundations, also evident in the documents approved by the World Health Organization and United Nations. These changes have brought about, firstly, the bringing of attention to the different abilities rather than disabilities, assessing them – therefore – as capabilities and *performance*. The aim of rehabilitation should therefore be to

ensure the full participation of every person in social and relational life, trying to break down every barrier that prevents full enhancement and social inclusion, i.e. participation in decision making and programmers of the entire community.

2. As a response to the “needs” of the disabled person, an “integral” ethical approach is deemed the most appropriate, which takes into account the totality of the subject to be rehabilitated, and - shifting the barycentre of the reflection from appearing to being - recognizes man’s value regardless of the functions that he is able to carry out. In light of the integral approach, rehabilitation involves different levels (physical, psychological, ethical and spiritual) and presents itself as a dynamic project, always able to adjust to the objective situation and that to be accomplished must move from its being shared by all the subjects involved in a sort of enlarged “rehabilitative” alliance grounded in constant dialogue and mutual cooperation. On the other hand, rehabilitation, is not undergone passively, but rather to carried out as active interaction, giving rise to inner motivation and personal commitment to recovery, evoking all existing potential and mobilizing inner energies and for the full development of the self. To this end, the NBC considers it essential to operate in two directions: to promote appropriate training of health personnel - and, in particular, rehabilitation therapists - to bioethical values, and firstly, to the dedication to the other, the ability of solidarity, empathy, in fostering the development of a social culture centered on favourable acceptance and inclusion and who knows how to rethink the value of man beyond that of psycho-physical incidentals. At the empirical level, it involves the removal of architectural barriers and ethically justifies every expense, able to give back hope to those suffering; on the human level it is necessary to break down the barriers of the mind and common prejudices.

3. The rehabilitation process, as described, may be carried out within a relational model of an “educational” type, which looks not only at technical intervention but to the whole person to help him acquire - as far as possible - an awareness of his actions and his own responsibility, by providing appropriate and proportionate information, evaluation criteria and arousing motivation as regards commitment. In the context of this report, the aim of those engaged in rehabilitation must be to understand and not to direct, in order to build collaboration focused on “working together”. For this reason, a special role is played by the phase of information and detection of consent to the rehabilitative process. By reference to the Document “Information and consent to medical treatment” (1992), the NBC reiterates the essential and required elements of informed consent in the context of rehabilitation as a form of safeguard of the ethical dimension of the relationship. In particular, it is recommended that special attention should be given to the content of the information (to damage, the likelihood of recovery, possible irreversibility) the recipients of the information (person with disability and family), taking care - to communicate a truth that is in its same nature interpretative or hermeneutic - to predict and understand the possible reactions of those listening. A truth that must be global, open to hope, and gradual, and which is to be communicated within a “process” of accompaniment in which there is the ongoing search for consensus in terms of mutual cooperation, and first and foremost, the identification of common objectives.

4. Strong support should be given to the families that have a person with severe disabilities and, in particular, a child with disabilities. In this case, it should be noted how the news of their child’s disability may require an additional emotional input from parents and the son in them feelings of anxiety and distress “from abandonment” on the part of society.

Alongside the need to ensure each family only a short time for diagnosis and the start of rehabilitation intervention, it should be stressed how fundamental it is to secure the active participation of the family in the rehabilitation process, in order to find further help to elaborate the loss of the “dreamed” child and to feel useful for the “real” child. The realization of this project has to start from looking at the globality and uniqueness of the child: globality, because the recovery goes beyond the physical or psychic situation of the child with disability, and involves the whole personality; uniqueness, because the hidden potential of children with disabilities greatly exceeds expectations. From this perspective, it is essential that those engaged in the rehabilitation take an ethical stance inclined to: supporting and encouraging the parents’ hope; capable of listening; fostering solidarity among families who live through the same experience or who have undertaken the same journey; forming oneself on the ethical and humane level to know how to establish a genuine relationship of assistance to families; including through promoting subsidiarity even through public support measures. The objective to be reached must be the enhancement of the potential that the child with disabilities has, giving space and offering the tools for its expression. Therefore, it is the task of whoever accompanies children with disabilities to encourage them to develop and use their potential and accept their disability, helping them to live serenely with their limitation.

5. The acceptance of limitation is a bioethical problem which concerns not only the child with disability but also the adult with disability, as well as those involved in rehabilitation. Particularly delicate is the situation where the person with disability develops oppositional dynamics and refuses to cooperate in the rehabilitative process. In this case, there might be the doubt that the insistence on rehabilitation could constitute a sort of aggressive “rehabilitation”, for this assessment the criterion of proportionality is not enough if it is not included in the search for equilibrium to be created each time in accordance with the personality of the person with disability. The search for balance, consequently leads to being confronted with existing potential but also with the limit: and if one should not give up when faced with limit, neither must one relentlessly persist against it. Aggressive “rehabilitation” arises exactly from non-acceptance of limits and carries with it the risk of starting to think again of the person with disability not as a person but as a “problem”.

6. The ethics of rehabilitation should be placed, then, on a more general level: that of political and health choices. This area of reflection must move from awareness of the special needs of persons with disabilities, to which modern society has to undertake very specific duties. In particular, the principles and objectives that should guide policy and health choices must be: the principle of sociability and reciprocity in human relationships, support and assistance that the community should make accessible in proportion to available resources, the intervention of the State with its care facilities; the principle of subsidiarity, with the promotion of private initiatives and voluntary work; the protection of the right to socialization, schooling and employment; the principle of equality, of equal dignity and equal access to rehabilitation of persons with disabilities in public and private facilities. In particular, the criteria for selecting patients for access to rehabilitation, in the presence of demand exceeding supply of services, can be schematized according to a hierarchical order: the need for rehabilitation, urgency, since not intervening in a timely manner could jeopardize the outcome of the intervention; the list, or order of booking.

Based on these premises, the NBC puts forward some indications of bioethical commitment:

- the right to rehabilitation of the person with disability should always be recognized and strongly supported as part of the essential respect for the equal dignity of all human beings;
- society should undertake, both culturally and economically, to provide assistance to persons with disabilities and those who are not self-sufficient even if the rehabilitation should require lengthy intervention and give not always positive results, and it should not ignore the other problems related to disability, such as inclusion in school / education and employment / professions;
- there should be adequate attention - within university courses - to the comprehensive formation of health workers involved in rehabilitation, so as to offer them not only technical and scientific skills but also sensitivity to the human problems of the person suffering and the ability to understand the ethical and social responsibilities involved in the action of curing;
- there should be - especially in public facilities - a proper organization of work, because the bioethical issue involves not only the health personnel but also the institutions in which they work;
- there should be strong support given to associations and voluntary work involved in the care of persons with disabilities and assistance to families.
- the development of a culture of rehabilitation should be encouraged, so that it becomes clear that the difficulty of the person with disability, the fear of being abandoned, the anguish of those parents who are confronted with the painful thought of “what will happen when we aren’t alive”, must truly become everyone’s problem along with the complete willingness to assume this responsibility.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**FROM PHARMACOGENETICS TO  
PHARMACOGENOMICS**

21<sup>st</sup> of April 2006



## PRESENTATION

In the National Bioethics Committee plenary meeting of the 25<sup>th</sup> of October 2002, Prof. Luigi De Carli proposed the creation of a working group to update one of the most important Documents published by the NBC in the first years of its activity and precisely in 1994: the Document dedicated to the *Human Genome Project*. According to De Carli it was by now necessary to examine the problems of the so-called postgenomic era, and to shift attention from the study of the genome to that of the proteome. The Committee, unanimously, approved this proposal and asked Prof. De Carli to assume leadership of the working group, which was called *From Genomic to Proteomic*. The group convened for the first time on the 22<sup>nd</sup> of November 2002 and consisted of Prof. Amato, Prof. Bompiani, Prof. Caporale, Prof. Coghi, Prof. Dallapiccola, Prof. Di Pietro, Prof. Eusebi, Prof. Flamigni, Prof. Gaddini, Prof. Marini, Prof. Neri, Prof. Piazza and Prof. Silvestrini. By the second meeting on the 27<sup>th</sup> of February 2003, it was decided that Prof. Bruno Silvestrini should co-lead the group. The following experts, “external” to the Committee, immediately gave their generous availability to collaborate with the NBC: Prof. Rosalia Azzaro, Prof. Mario del Tacca, Prof. Antonio Leone, Prof. Luca Pani. Two hearings were made during the group’s work, one with Prof. Andrea Mattevi on proteomic, on the 19<sup>th</sup> of June 2003, and one with Prof. Gerolamo Lanfranchi on bioinformatics on the 18<sup>th</sup> of November 2004. To all these colleagues go the Committee’s most sincere thanks.

During the group’s work, the two coordinators initially suggested the elaboration of two different documents: one on pharmacogenetics, a theme on which we have a considerable amount of already elaborated and fairly consolidated information, and another one on proteomic, a theme which instead has still uncertain boundaries and needs a more extensive study of different aspects regarding in particular bioinformatics and structural biology. However, in the following work it was decided to concentrate all energies on drawing up one single document, capable of including both of those aspects and which, starting with pharmacogenetics, would trace its evolution towards pharmacogenomics.

The document has therefore assumed the final title of *From Pharmacogenetics to Pharmacogenomics*. Having been presented to the Committee during the plenary meeting of the 21<sup>st</sup> of April 2006, it was unanimously approved. The reader will easily see how it starts with the new direction of genetic analysis, based on a thorough investigation of the genome, and integrated with the study of the interactions between genes and between genes and proteins, and how it highlights the new bioethical problems coming from the personalisation of care imposed by these new horizons of knowledge. We are, with the themes discussed in this document, facing new epistemological horizons, which cannot be reduced to slogans, however effective, like the well known *the right drug to the right patient in the right dosage*: what’s at stake not only mostly escapes public opinion’s understanding, but is generally ignored or not fully known by bioethicists themselves. Nevertheless these are problems that invest not only pharmacological research, but also and above all clinical

practice and that, for this reason, require precise and objective ethical positions. In this document the NBC opens the way to this new thematic horizon, aware of having accomplished, once again, a well thought through pioneering work. The careful reader will notice, in addition, how the document discusses the movement between two different ideas, of relevant interest not only from a medical point of view but also from a bioethical and philosophical point of view in general. The first has been identified by the tendency to see the gene as an autonomous functional entity, able to predetermine, as well as to allow us to predict, the characteristics and behaviours which are the expression of it, whilst the second leads us to consider it as part of a complex, dynamic and highly variable system, subjected to the influence of the genome in its entirety, and of the environment. Against this background, again emerges the problem of the boundary between those events that man is a victim of and those that he is able to influence, becoming their maker and therefore being morally responsible for them.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## SYNTHESIS AND RECOMMENDATIONS

Pharmacogenetics and pharmacogenomics have opened, studying from different and complementary points of view the genetic basis of the response to drugs, new perspectives on the personalisation of care, on the creation of drugs focused on a precise genetic target and on the production of some drugs using not only the traditional chemical synthesis, but also cells, tissues and transgenic animals. Although the response to drugs is influenced by many other factors as well, like the environment, diet, age, lifestyle, state of health or illness, there is still no doubt that the knowledge of the individual genetic characteristics can contribute to the creation of increasingly safer and more effective therapies.

From this, follow a variety of bioethical problems, which include the possible conflict between individual and collective needs and rights, the right distribution of the relative duties and benefits, the unknown outcomes and the risks of interventions which affect, in the wider sense, the course of life itself. The National Bioethics Committee has discussed this on various occasions, both in general and in particular terms, but feels the need to discuss them again in more depth in relation to pharmacological therapy.

For this reason a working group has been created, composed by internal members who are supported by external members, who, in the respect of the institutional tasks of this committee, proposes on the one hand to give a summative view of the topic so that it can be understood also by those who are not in the know, and on the other hand to give some direction for the purpose of the eventual predisposition of legislative acts too.

The first chapter aims to place pharmacogenetics and pharmacogenomics within the process that has transformed genetic in one of the great protagonists of the scientific and technological progress. With the theory of the evolution of the species, it has first outlined the existence of an overall project of life, to which man participates next to all the other living beings, and then with molecular biology has deciphered it, arriving in the end, with biotechnologies, at manipulating it and affecting its course. The relationship of man with nature, intended as a complete living system, has come up again in new terms, giving rise to a series of philosophical and religious, as well as practical, questions. In particular, the problem of the distinction between what is genetically predetermined and what takes form during the course of a life, due to the effect of the environment and of actions that, within the limit in which they are free, require a moral responsibility.

The second chapter is dedicated to the drug. With this term we intend an active ingredient, made up of substances usually able to have a variety of effects and uses dependant, as well as by their intrinsic properties, by the dosage, by the method of administration, by the circumstances and by the individual sensitivity, which is linked both to genetic constitution and to the other factors mentioned above. The term “medicinal” is instead linked to a specific therapeutic application of the drug, which can be of a preventive or a curative type. The marketing of the drug requires a registration with the health authorities and it is often connected with the acquisition of a patent, which ensures its monopoly for a certain amount of time.

Drugs act in two different but interconnected ways: either they act on the organ-

ism, giving it what's necessary and enhancing its internal resources, or they substitute it, acting in its place. The first is typically the case for vitamins and vaccines, the second of antibiotics, of antipsychotics, of antihypertensive and, in the more general sense, of symptomatic agents. The genetic constitution has a critical role in both these types of intervention, but in different forms.

An additional distinction must be highlighted between drugs made of substances of natural origin and those made of artificial ones, synthesised for the first time by man. The first ones are not intrinsically safer than the others, but have a history that involves a wealth of knowledge and experience capable of guiding their use. The second ones have a higher degree of uncertainty and potential dangers. Before being used they require, therefore, a rigorous and thorough trial.

An important aspect of the response to drugs is represented by the processes of pharmacokinetics and metabolism, terms which describe the absorption, the distribution in the tissues, the transformation in active or inactive metabolites and, finally, their excretion through urine, faeces, lungs, skin and other excretory organs. These processes have a genetic basis, but are also subjected to environmental factors, in particular with regards to dietary habits.

There are illnesses in which the genetic or, on the contrary, the environmental element prevails: for example, some genetic anomalies always translate in the same pathology, independently from external factors, as it happens, leaving aside the genetic constitution, in the case of vitamin deficiency and of the exposition to particularly virulent infective agents. In the majority of cases, however, genetic and environmental factors are strongly linked and they mutually affect each other. It follows that the same genetic characteristic can have, according to the environmental conditions, different implications, even opposite ones.

The chapter dedicated to the drug concludes with a mention of the pharmaceutical patent, which tends to enhance the value of the chemical innovation rather than of the therapeutic one. This problem, which, after having distorted research and the development of traditional drugs, risks to have a negative influence on biotechnological products as well, must be looked at in more depth and tackled on a legislative level.

The third chapter focuses on the genetic control of the response to drugs. After some clarifications about the meaning and the use of the terms pharmacogenetics and pharmacogenomics and some historical details, pharmacogenetics' methods of analysis are outlined in their evolution towards genomic and proteomic.

In their widest meaning, pharmacogenetics can be defined as a discipline which studies the genetic basis of the individual differences found in the response to drugs. Pharmacogenomics must not be seen as a simple updating of pharmacogenetics in relation to recent developments in the research on the human genome, but as a new approach, based on the analysis of the genetic variation extended to the whole genome in a dynamic system formed by a net of interactions between genes and proteins.

The research in genetics applied to pharmacology started at the beginning of the 1950s by Arno Motulsky and the term pharmacogenetics was introduced by Vogel in 1959. The conceptual premises, however, had already been advanced by Garrod at the beginning of the 1900s, with the studies on metabolic congenital errors and on the analysis of this illness' segregation within a family.

For pharmacological purposes, the most important stages of the following developments in biochemical and molecular genetics regard the control of the genes' activity, the introduction of DNA recombining techniques, the sequencing of genomes and the structural analysis of proteins, which marks the movement from genomic to proteomic. Between the most recent technical innovations, we mention the "microarray" of DNA and proteins, which allows the simultaneous, structural and functional analysis of a multiplicity of genes and genic products.

The genetic control of the response to drugs can be exercised at different levels: a) the drug's absorption; b) metabolism, transport and elimination; c) target's characteristics; d) adverse reactions. The genetic systems on which this control is based can have different levels of complexity, which go from the simple occurrence of the monogenic inheritance, often described as a simple Mendelian, to those made up of a variety of components that characterise the polygenic and multifactorial inheritance.

In the monogenic inheritance, genetic polymorphisms are of particular relevance, and they are represented by common mutations that can be found in at least one person in a 100, which shape differences in the genetic constitution of an individual or of a population. The minimal variation to generate a polymorphism is the change of a DNA base, which can have an effect on the function of a gene involved in the pathogenetic process or in the response to the pharmacological treatment.

The final effect on the phenotype of the genes controlling the characteristics associated to the pathology cured by a specific drug, or to the drug's metabolism, is a quantitative and qualitative variation, also in the pathological sense, of the response to the drug. The consequences can involve both the therapeutic action, as well as the negative effects, like secondary toxic reactions, intolerance and hypersensitivity.

In defining the genetic basis of the response to drugs is necessary to take into account the margins of uncertainty due to a variety of conditions that can affect the validity of the genetic data. Some of the conditions to be considered are the variations of expressiveness and penetration of the genes responsible and the interactions with other genes.

An important component of the variability in the response to a drug is the environment. The environment can influence the expression of a genetic character the more strongly, the higher is the number of the genes involved. It can be presumed that, with the progress of knowledge, the genome's analysis, until now mostly focused on monogenic systems, could be extended to polygenic systems, which, although more strongly affected by the environmental component, ensure a better adaptation of the pharmacological therapy.

The first phase of the pharmacogenetics analysis consists of identifying and mapping the gene or genes which codify for the potential targets of the drug or those that are in some way involved in its activity. In the following phase we proceed to the isolation and cloning of the gene and, finally, to the DNA sequencing.

The study of the association between the variation of the genes and of the DNA and the response to drugs is made by using appropriate genetic analysis on a sample of subjects treated with the drug, who are compared to a control group (NBC, 1999).

The pharmacogenetics approach offers the double advantage of improving the treatment's efficacy with the choice of the most appropriate drug and of increasing its safety, avoiding the risk of adverse reactions.

The Human Genome Project identified new families of genes, which will be able to function as markers for the diagnosis of an increasing number of hereditary and acquired pathologies and, through their products, they will make available more targets for more and more selective drugs. The accumulation of the necessary information to define the genetic profiles needs the elaboration of data storing and management systems. This need is answered by bioinformatics, which is an area in rapid expansion and a precious work instrument.

Finally, we mention the logical development of pharmacogenetics and pharmacogenomics: genic therapy, the target of which is the gene that directs or regulates the synthesis of the proteic product.

This overall view shows the relevance and at the same time the enormous complexity of this topic. What emerges is a precise indication, in line with what previously discussed: to guarantee to pharmacogenetics and pharmacogenomics the necessary resources at every level, from basic research to practical applications, but without distracting attention from other opportunities which, if pursued in the appropriate manner, can give us more extensive and immediate benefits.

The chapter concludes with some examples which tend to further highlight the complexity of the topic. In particular, we must stress the importance of the psychological aspects, which substantially affect the outcomes of medical care.

The fourth chapter suggests a strictly bioethical reflection. We stress both the link between pharmacogenetics and pharmacogenomics, as well as the boost given to these two disciplines by the mapping and the sequencing of the human genome, remembering that the NBC has previously expressed a positive judgement on these developments, obviously for as much as they contribute to the welfare and health of man.

Although pharmacogenetics and pharmacogenomics studies have not yet led to extensive practical applications, the efforts to link the results of the pharmacological action to a person's genetic structure seems to deserve support also in relation to the unavoidable genetic singularity of each person. The judgement appears positive if we obtain – from this link – more therapeutic benefits and a reduction of the risk of adverse reactions, according to the principle of “beneficiality” and “non-harmfulness”. This direction of research, however, must not lead to an exasperation of the “genetic reductionism”, both as a line of thought, as well as a will to overcome the interrelations that human organisms – also in their physicality – develop with the environment.

We must identify those human illnesses which will be the primary object of research as well as scientific and economic effort. It would not be ethically right to turn our attention to pathologies for which effective and safe drugs are already available, for exclusively commercial reasons, overlooking those which have a limited epidemiological incidence, but stand out because of the high variability and uncertainty of therapeutic responses or by a high frequency of adverse reactions. The development of this branch of research can contribute, due to the characteristic of basing itself on the evaluation of very analytical parameters of living structures, to the knowledge and the correction of some imbalances, innate or acquired, existing

between men with regards to their health. This development, if aimed at those who have most need of it, is inspired by principles of justice, with particular attention to the right to health care, which is one of medicine's fundamental principles.

With regards to the investigation on man, we refer to national and international criteria referring on one hand to the trial of drugs and, on the other hand, to genetic investigations, having as objective the care of both the ill patient and the healthy subject. In these conclusions, we don't deem necessary to further dwell on these criteria, either than for stressing that they concern the solidity of the scientific premises of each investigation, the evaluation of the relationship risk/benefit, free and informed consent; the care of privacy, the accurate preservation of samples and documentation, the obligation of sharing the outcomes.

From this, emerge some suggestions, which can be summarised as follows:

1. In a general sense, we stress the value of scientific and technological research as an instrument of progress and the moral obligation of ensuring adequate support for it, also in the law, in terms of human and economic resources;
2. Support of cutting-edge research must not compromise, however, the enhancement of already acquired scientific knowledge, which is simply waiting to be translated into practical applications;
3. With regards to pharmacogenetics and pharmacogenomics, genetic analysis should be considered, for those cases in which the link between genetic constitution and response to drug is certain, as one of the fundamental criteria of therapeutic choice;
4. We recommend that genetic analysis is kept in higher consideration also in drugs trials, as well as in medical and epidemiological research in general, in order to consolidate and extend knowledge in this sector;
5. We draw attention on a crucial, but little known, aspect of the patent: the excessive weight which it attributes to the chemical novelty, even to the detriment of the therapeutic benefit. This anomaly must be investigated and, eventually, corrected in the law;
6. Finally, we highlight that pharmacogenetics and pharmacogenomics are at a critical turning point in scientific and technological progress, which for the first time offers man the opportunity to directly intervene on the project of life. Consequently, it is of fundamental importance for the scientific community to promote information to the public that is not only correct, but also clear and accessible to all. Only in this way it will be possible to spread a climate of trusting and mutual collaboration, indispensable to achieve the hypothesised benefits from this important chapter of development of knowledge.

## 1. Preliminary considerations

After physics, genetics has asserted itself as one of the main protagonists of scientific, cognitive in general and technological progress. It has given strength to the idea that life is sustained by a unitary project in which all living beings participate, even if some have only reached the first pages, whilst man has arrived, in terms of

individual and social organisation and complexity, further. It has clarified the molecular basis of this project and has allowed us to intervene in it not only indirectly, as it used to happen before, but with direct interventions, which allow us to take it apart, rebuild it, eliminate some traits and introduce others. Many foods are already produced today with GMO, which are genetically modified organisms, whilst cloning allows us to obtain genetically identical copies of living beings, even in species that put aside asexual reproduction millions of years ago, opting for sexual reproduction.

The benefits that medicine can achieve from this are evident. Genetic anomalies involved in hereditary diseases can be identified with increasing accuracy. In the case of somatic cells, they are already, in some cases, susceptible of correction. With regards to the genetic therapy of the germinal line, which would reverberate on the descendants, the National Bioethics Committee has in the past expressed the opinion that it could not be “suggested and accepted in the case of man for a variety of technical, scientific, social and, therefore, also legal and ethical reasons”; it did not exclude, in addition, that “the acquisition of new knowledge and the development of genetic engineering techniques could make it more targeted and safer” (NBC, 1991). The social, legal and ethical perplexities remain, but in the meantime the scientific and technical progress has been so fast, that it could soon be possible. In a more general sense, diagnosis and therapy, including pharmacological therapy, of all illnesses will improve.

The possible dangers are just as evident as the benefits. First of all we risk, in the enthusiasm given by the successes of research on the genome, to underestimate the pathologies linked to environmental factors and to not allow sufficient resources for the further study and control of them. We can distinguish two large classes, respectively originating from deficiency and from aggression. As these terms indicate, the first is linked to the lack of elements indispensable for the functioning of the organism: not only food, water, salt, air and sunlight, whose importance is known since ancient times, but also vitamins and other substances necessary for good health, some of which we have just begun to know the existence of. The second class depends instead on harmful agents: it includes not only infections, but also different types of tumours and acute and chronic poisoning. Often responsible for this are biological, chemical and physical agents, which, in different doses and circumstances, do not have a harmful, but a protective effect. For example, an excess of food, lipophile vitamins and the exposition to sunlight produce damages as serious as those caused by their absence. To the previously known agents, new ones have been added, like prions and asbestos, but it is reasonable to believe that there are others, which have still not been thoroughly studied.

These pathologies are also partially affected by individual genetic constitution, but an investigation on their environmental causes would have, already in itself, a decisive influence on the population’s state of health. For example, a document by the World Health Organisation states that a reduction in dietary excesses, together with the consumption of fruit and fish in substitution of animal fats, with an increase in physical exercise and the abolition of smoking could reduce cardiocirculatory illnesses by 75%, which in developed countries are the main cause of death and disability (WHO, 2002).

Unlike pathologies of environmental origin, hereditary pathologies are connected to genetic anomalies inherent to the organism from the moment of conception.

Up until now the problem has been tackled by trying to limit its spreading with genetic consultancy and prenatal diagnosis.

The developments on genetic research have opened the way to the correction of these anomalies in somatic cells and, in perspective, also germinal cells. Genetic constitution, however, often gives only one potentiality, which during a person's existence can develop into different psychophysical characteristics, at times even opposite. For example, at the basis of some mental illnesses are genetic traits apparently involved also in artistic, scientific and philosophical creativity (Jamison, 2002; Bogousslavsky and Boller, 2005). It follows that some genetic traits have positive or negative characteristics not per se, but in relation to the environment and the circumstances. Before correcting them or erasing them forever we must study their significance in more depth and, when possible, enhance their positive aspects.

The problem of the multifactorial response to drugs is particularly evident with psychic processes, which often affect not only the illnesses' individual perception, but also its course.

There's nothing less fertile, in science, of the absolute certainties some believe to possess. If, in light of these considerations, we look at what's happened, in our century, in medicine, what we now know that we don't know can really help to understand the meaning of what we know today. In synthesis, we believe we can say that recognising the illnesses' etiological factors has become increasingly harder, the more the discovery of the recognisable ones reduced the field of the not-known. On the contrary, the knowledge of the pathogenic mechanisms, particularly those of illnesses of unknown etiology, have increased, feeding in many the hope of getting, through them, to the discovery of etiological factors. This progressive gap between the known and the unknown, regards the body's illnesses: what resists our ability to know refers essentially to etiological factors. This is a problem linked, in reality, to our ability to know, in other words, our techniques, the methods we use, and the meaning we give to the term "scientific". It is all this that we find, when we approach what we don't know, and it makes us stay in this situation.

The same complexity encountered in the use of the drug can also be found when we try to understand what this means for the patient, the doctor and the drug itself and we try to bring together all eventual acquisitions in this field, in the treatment.

In the last 20-30 years it has been highlighted, in particular in the USA, in England and also in other countries, that the importance given to "scientific" medicine, different from the non-scientific one because it is "evidence based", unlike the other one, is progressively growing. This fact currently influences the choice of treatment and it could also influence the direction of scientific research in the future.

The invitation to caution emerges also from the increasing awareness that the expression of individual genetic traits depends on the complex and variable interactions linking them to the genome's remaining part.

These considerations once again raise the problem of the relationship with the so-called "natural order of things", intended as a whole living system, to which man is subject, as well as protagonist: subject, because he is overcome and dominated by it, protagonist because he also protects the project of life and contributes, both indi-

vidually and through scientific and technological progress, to its development. In contrast to the other living beings with which he shares his part in the whole living system, man has the ability to study it, to find its fundamental laws and to extract from it the instructions and means necessary to satisfy his needs, having as guide not only instinct but reason as well.

The NBC has given its opinion, in various circumstances, on the developments and application of genetics and biotechnologies. It has done this both in a general way and with reference to specific problems, as for example genetic therapy, resources allocation, free and informed consent, trials on humans and animals, the privacy of personal data and the use of transgenic animals (NBC, 1991 a, b; 1992 a, b, c; 1993; 1994 a, b; 1995 a, b; 1997 a, b, c; 1998; 1999; 2000; 2001; 2005). However, it had not, so far, studied in sufficient depth the implications of those developments on pharmacotherapy, which, for good and bad, is one of the most important sectors of medicine.

The working group entrusted with the task of filling this gap feels the need, as a premise to ethical reflection, of illustrating the basic scientific facts: it has been proposed, in particular, on one hand to avoid unrealistic or excessive expectations, on the other hand to identify and clarify the possible applicative implications. The working group has felt the need, in context, to call attention to the big basic choices, faced by medicine, between care and prevention and, in particular, between medical interventions which mobilize and enhance the organism's resources and those that support them externally, acting in its place.

The topic is complex, but we have tried to explain it in terms that are as much as possible accurate, but also understandable by all, including those who are not knowledgeable in this field, respecting the bioethical principle that "the obligation to share, with the authorities and the public, the correct use of resources and research outcomes has become mutual not only between science and politics, but also with regards to civil society" (Azzaro Pulvirenti, 2003).

## 2. The drug

Pharmacology is a discipline in rapid evolution, so it's being articulated in increasingly specialised branches, but it is still founded on some simple notions which cannot be ignored, from whatever perspective and point of view we look at it.

### 2.1. Definition and generalities

This is the first point we need to look at. The World Health Organisation proposes, in one of its documents (WHO, 1973), the following definition: "Any preparation able, when introduced in a living organism, to modify one or more functions". It is a clear definition and it comes from an authoritative source, but it is so synthetic that it requires a detailed commentary, word by word.

"Preparation" can be used to describe an enormous range of substances, on their own or combined in a variety of ways, of molecular dimensions which can vary between few and thousands of units, organic or inorganic, natural or artificial.

Their effects can be chemical, chemical and physical or merely physical, as in the case of some diuretics which boost, through a purely osmotic mechanism, the passing of liquids from one to another compartment of the organism.

The phrase “introduced in a living organism” presents the concept of the intrusion into the organism, which is crucial because the active ingredients of many drugs are substances ordinarily present in the organism, which regulates their concentration and their activity within fixed limits. The external introduction escapes this control, allowing us to get other effects, often drastically different from a quantitative, as well as qualitative, point of view. For example, hexogen adrenalin not only regulates heartbeat and other physiological functions, as it usually does, but it can resolve a heart attack or an anaphylactic shock, which are potentially lethal. In the same way, cortisone can have different effects from those of its endogen correspondent. Insulin, which normally regulates sugar levels, can induce a convulsive state similar to electroshock. With vitamins, the boundary between physiological and pharmacological effects is more uncertain. Generally, we consider as physiological effects those linked to their ingestion through food, and pharmacological effects those caused by a pharmaceutical preparation.

“To modify one or more functions” expresses the fundamental property of drugs, which translates in a wide variety of possible effects, due not only to their intrinsic characteristics of each drug, but also by the dosage, by way it is administered and, in a more general sense, by the methods and circumstances of use. The botulinic toxin, a poison capable of killing thousands of people in minimal quantities, is successfully used against the blepharospasm and other pathologies, as well as in cosmetics to clear facial wrinkles. 100 mg of acetylsalicylic acid, the active ingredient of the common aspirin, inhibits the aggregation of platelets and prevents thrombosis; 300-500 mg of it reduces the production of the chemical mediators of infection and alleviates headaches and other common aches (but can also erode the mucous membranes that cover the gastro-intestinal tract and other areas of the body, causing dangerous haemorrhages); 5000-8000 mg of it shows yet other effects, which allow its use in self-immunitary pathologies, like rheumatoid arthritis. Each of these effects, desired and undesired, can involve a different biological substratum.

In conclusion, all the preparations that have the general characteristics above-mentioned, can be called drugs, but assume one or more specific connotations according to how, on whom and where they are used. In particular, they become drugs when they are used “to prevent or treat human or animal diseases” (Council Directives, 1965).

## *2.2. Two classes of drugs*

Drugs usually connect to receptors located on the surface of or inside the cells, which are the link for or the site of its effects, but other and equally important processes exist. One is represented by the systems of specialised transportation, which let the drug overcome the biological barriers even when its chemical and physical characteristics would not allow it. In addition, there are effects which do not require the receptors’ intervention or specific processes. It is the case, already mentioned, of the movement of liquids due to an osmotic action.

Generally, only the drugs' main properties are studied and exploited, although there are usually more than one. In addition, each of them causes a variety of effects, desired and undesired, which further complicate matters. We must also take into account the environmental effects on the organism, which in time can change the response to the drug. To the so-called "genetic certificate", which suggests the prescription of drugs on the basis of individual characteristics, should therefore be added an "environmental certificate", which is much more difficult to draw up because it is in constant, incessant evolution.

Drugs can be grouped into two fundamental classes, according to whether they support the organism externally, acting in its place, or whether they give it what it needs to function correctly and enhance its dormant properties. In the absence of a generally accepted term, temporarily, those of the first type have been provisionally called "non-physiological" and the others are called "physiological" (Silvestrini, 1987). Non-physiological drugs are typically represented by antibiotics, analgesics and drugs used in the treatment of mental conditions and hypertension. Physiological ones are represented by vitamins and vaccines.

Physiological drugs do not require particular checks before being used because they have a correspondent in the organism's composition and organisation. However, there are circumstances of use in which they cease to be so. This is, for instance, the case of hormones: they are physiological when they are used to cure illnesses caused by a deficiency; they aren't, when they are used otherwise. In the second case, they require the same rigorous tests of non-physiological drugs.

A further distinction must be made between "natural" drugs, made up by substances present in the animal, vegetable and mineral world, and "unnatural" ones, also called "artificial", which are substances synthesised for the first time by man. Chemical synthesis is not, from this point of view, relevant, because the same substance can be extracted by a natural or synthesised source, without this affecting its properties in any way. Natural drugs are not intrinsically safer than the unnatural ones. However, they have an advantage in their history which, if read carefully, gives us precious information on their therapeutic and toxic properties. If they are part of our dietary habits, the comparison between the health conditions of populations who consume them and those who don't, gives us an indication of their effects. In this way it has been possible to identify illnesses linked to either a deficiency in particular substances, like vitamins, or to an excess of other substances, like lead and vitamins themselves.

Unnatural drugs are a recent invention. They are the fruit of human intelligence, but they are often created in laboratories that are far removed from the real conditions of medicine and life in general. Although the trials to which they are subjected before being used are severe, they always present a certain risk. Therefore, between the non-physiological drugs it would be wise to give precedence to the natural ones: unfortunately this simple rule is often not followed, also for patent reasons which will be discussed in point 5.

The drug is a material entity, with physical and chemical properties that explain its effects and allow its qualitative and quantitative determination. The functions of the organism are, however, influenced also by factors that available knowledge and technology let use measure only indirectly, through their effects. This is the case in

psychotherapy and with regards to psychological factors in general, which can affect the course of the illness as much as and at times more than drugs. For example, rigorous clinical studies, carried out in “double blindness” conditions, show that not even the strongest antidepressant is effective for more than 6 patients out of 10, against a response to a placebo which rarely goes below the threshold of 3 patients out of 10. It can be inferred that, on the basis of a simple mathematical calculation, a pharmacological therapy carried out indiscriminately on all those suffering from depression would be useless, as well as potentially harmful, in 7 patients out of 10: in 4 because they do not gain any benefit from it and in 3 because a little psychological help would suffice, like the patient’s participation in a clinical trial, to allow him/her to overcome the morbid episode. Depression affects the mind, but these considerations also apply to physical illnesses. A personalised medical assistance would be preferable to a simply pharmacological one, but it is difficult and not all doctors are able to carry it out. Any reasoning about pharmacogenetics and pharmacogenomics that did not take into account these psychological implications would be incomplete.

### *2.3. Two classes of illnesses*

In the preliminary considerations we have mentioned the existence of two big classes of illnesses: mostly environmental, which are due to external causes, and mostly hereditary, which are inherent to the organism from the moment of conception. The first is subdivided in deficient and aggressive. The topic deserves to be revisited, referring it more explicitly to the opportunities intrinsic to the recent developments in genetics.

Environmental illnesses of the deficiency type are caused by the lack of substances indispensable for the functioning of the body: not only food, water, salt, air and sunlight, the importance of which has been known since ancient times, but also vitamins and other essential substances. We are just beginning to glimpse the importance of some of them. For example, recent epidemiological investigations suggest the protective role of some polyunsaturated acids found in food, called Omega-3, not only in some cardiocirculatory pathologies, but also in auto-degenerative and self-immunitary ones, (Barberger-Gateau et al., 2002). Environmental illnesses of the aggressive type include infections, even prionic ones, as well as some forms of tumours and a variety of degenerative pathologies. The substances that support them are often the same ones that, in different quantities and circumstances, have a protective effect: this is the case of food, kitchen salt, vitamins A and D and the exposition to sunlight, as an excess of those is as fatal as their absence.

Medicine successfully fights against environmental illnesses since ancient times, when their causes were still unknown. It has succeeded in this task especially by protecting man by dangers taking hygienic and sanitary measures. A clear example of this can be found in the ruins of the biggest civilizations that have followed each other on the face of the Earth: sewage systems, aqueducts, canals for the flow of stagnant water, baths, rules for a healthy living. We must think, for example, about the Cloaca Massima in ancient Rome and about its aqueducts, the ruins of which still dominate many landscapes. In addition, we must reflect on the prohibition, recurrent in many cultures, of eating pork and molluscs, which can transmit dangerous

diseases like cysticercoids, typhus and cholera. A similar measure is the boiling of coffee and tea, which is a simple and effective way of sterilising drinks, at the same time improving their taste. The same can be said about daily ablutions, imposed by some religions and carried out even in the desert, where water is precious. Even the religious norm of periodical fasting probably has a therapeutic value, which deserves a more in depth study.

As well as with hygienic and sanitary measures, environmental diseases have been fought using three categories of remedies, which act directly on the organism. The first includes invasive and non-invasive manual interventions, like surgery, medication of injuries, immobilisation of bone fractures, assistance during birth. A great amount of evidence of this can be found both in mummy skeletons and in written texts, like the Hippocratic Oath, which mentions the removal of stones. The second category involves psychological assistance to patients, which implies not only a relief of the symptoms, but also a stirring of dormant internal resources, capable of preventing illnesses or, if they manifest themselves, to concretely affect their course. The third category, which we will look at, includes drugs intended in the general meaning of this term, but used as medicines.

Their first traces go back to prehistoric settlements, where medicinal plants were stored in special areas, separate from the spaces destined to food. With few exceptions, like raw liver used by Hippocrates to cure exophthalmia and rickets, their effects remained of a symptomatic type until relatively recent times. The change happened with the first great, modern physiological remedies, represented respectively by vitamins and vaccines, which act strengthening the organism and mobilising its dormant defences.

The biggest amount of the modern therapeutic arsenal, however, is made up of non-physiological drugs, represented in part by active ingredients extracted from traditional remedies, in part by artificial molecules, that is, recently synthesised molecules. Some have merely symptomatic effects, like morphine, or at least effects limited to the manifestation of the illness, like hypertensive drugs and drugs used to cure mental illnesses, other intervene on the causes of illnesses, like anti-infective chemotherapy and antibiotics. Their common characteristic, the one that sets them apart from physiological drugs, is the newness of their composition and, in large part, of the functioning on the organism. As a consequence, they are distinguished by uncertainties and evident dangers, especially in the case of drugs that lack a natural history, from which to take information about their desired and undesired properties. After the thalidomide tragedy those drugs undergo preventive, severe trials, which however never fully guarantee their safety.

The knowledge of individual genetic characteristics will allow the improvement of both the efficacy and the safety of the entire arsenal available for the fight against environmental illnesses. Drugs will be personalised, adapting the dosage to the needs and to the response of each of us. It will also improve safety, because it will be possible to assess the risk of the undesired effects which have a genetic basis. New perspectives are opening also in drug research, particularly with regards to those drugs that can be used against infections and with regards to the two sides of their intervention: on the one hand against viruses, bacteria and protozoan, on the other hand in favour of the organism defensive mechanisms.

It would be a serious error to proceed without a strategy which takes into account the complexity of the problem, with particular regard to the difference between hygienic-sanitary measures and interventions on the organism, between care and prevention, between physiological and non-physiological, natural and artificial drugs. Without this strategy we risk not only wasting precious resources, but also to feed disillusion and scepticism, which would prevent us getting the benefits inherent to genetics and to its contemporary developments.

These considerations are applicable also to the treatment of the symptoms and, in a more general sense, of the manifestations of hereditary diseases, present in the organism from the moment of conception. Their eradication does not require pharmacological measures, which must be pursued with the caution dictated by an awareness of their biological significance. In fact, even those illnesses which cause disabilities capable of jeopardizing the quality and the duration of life, have merits that have remained in the course of natural selection because, in particular environmental circumstances or conditions, are useful for survival.

Caution is even more important in the case of hereditary diseases linked to genetic abnormalities that can have, according to environmental circumstances or conditions, favourable or unfavourable expressions. A case that illustrates this, but we could mention many others, is the one of the Pima Indians, from Arizona. For thousands of years they have lived as nomads, feeding on fruit, acorns and seeds, the availability of which is subject to strong variations from season to season, as well as from place to place. Therefore, those individuals having a particular gene, called "economiser", have been naturally selected, as it allows the most efficient use of food and the storage, in the form of adipose deposits, of the excess energy. This ability has enabled the survival of the Pima's ancestors, but it has become counterproductive with the overabundance of food. The same population, which in the past was in great physical form, today is exposed to obesity and to the diseases that it brings, starting with diabetes. The knowledge of these types of genetic characteristics is of the utmost importance in establishing the necessary amount of food and other essential elements on the basis of individual needs. Pharmacological problems are therefore connected to dietary ones.

In synthesis, we can state that, whilst some genetic traits have an undisputed pathological connotation, others have positive and negative implications which must be carefully evaluated. This notion too, belongs to the wealth of fundamental knowledge which not only pharmacological research, but also genetic research, cannot leave out of consideration, whatever is the theoretical or applicative, ethical or merely technical perspective from which we look at it.

#### ***2.4. Pharmacokinetics and metabolism***

To achieve the desired effect, a drug must be present in its place of action in the appropriate concentration which, if the dosage and the method of administration are the same, depends on the quantity and the speed of absorption, on the tissue distribution, on the relationship between the free quota and the one linked to the proteins in the blood, on the transformation in active or inactive metabolites, on the excretion through urine, faeces, lungs or skin. All these processes have a genetic

basis, which determines their quality and quantity. For example, some people transform certain drugs in inactive metabolites, others do not have this ability: consequently, a dosage that is therapeutic for the first ones can be toxic for the second ones. However, the response to a drug also depends on environmental factors, which can modify it substantially through the course of its existence.

To understand the importance of this last phenomenon we must go back to the abovementioned notion according to which the drug always represents, even if it is made up of physiological active ingredients, a true “intrusion”, to which the organism reacts with a biochemical and functional counter-adaptation. The first finds its most common expression in the “enzymatic induction”, which consists of an overproduction of the enzymes responsible for the drug’s metabolic transformation. If this transformation translates into an appearance of inactive metabolites, the drug progressively loses its efficacy. In the case of poisons this phenomenon is called mithridatism, from the name of an ancient king who, although he did not have any scientific knowledge, he used science to protect himself from enemies. On the contrary, if the abovementioned transformation translates into the appearance of active metabolites, the drug becomes progressively more active, until it reaches toxic levels. These same processes, respectively of metabolic activation or inactivation, happen also with food, some of which activates the same enzymatic systems as drugs. Therefore, regardless of the genetic basis, the response to drugs can change with time not only as an effect of their previous administration, but also according to dietary habits.

The functional counter-adaptation is instead linked to the activation of systems which have physiological effects opposite to those of the drug: for example, excitement versus sedation, hyperalgesia versus analgesia, bradycardia versus tachycardia, etc. This phenomenon happens with many drugs, but in this way they progressively lose their efficacy, although this is particularly evident with drugs used in the treatment of mental conditions, the effects of which have a mental aspect, allowing their conscious recognition. Therefore, this is typical of the so-called illegal drugs, or abused substances, and it explains addiction, dependence and, when suspended, abstinence (Silvestrini, 2001).

Consequently, more than the response to the drug, what are genetically predetermined are the processes that sustain it, but in the form of a potentiality that can express itself in a variety of ways during our lifetime, even ways that are opposite compared to the initial ones, as an effect of both preexistent pharmacological therapies and diet, as well as other environmental factors.

## **2.5. The patent**

The patent is the administrative certificate of the paternity of an invention and the right to benefit from it, in the respect of the rules of civil cohabitation. Its ethical relevance is mostly linked to the influence it has on the choices of scientific research.

The patent protects a concrete good, which is such because it satisfies a just as concrete need. Its object combines two elements which interlink and support each other: the abstract idea that is its basis and the material instrument that translates

it into practice. The invention can reside in one or the other, but it has a patentable value in the second.

The pharmaceutical patent must be put in this frame, introducing to it a visible anomaly. The problem started in the 1800s, when scientists, who before simply extracted drugs from natural sources or reproduced them maintaining their original characteristics unchanged, began to create them *ex novo*. Following this, artificial molecules have multiplied and they have become part of the composition of the majority of objects of daily use, but at the beginning they were seen as an extraordinary enterprise, linked to creative abilities previously considered to be a divine prerogative. They have therefore given fame and prestige to those who created them and have been thought deserving of a special patent, called “of product”, which highlights the artificial molecule, independently from its practical value. There are also other pharmaceutical patents, like those “of use and procedure”, but they are weaker than the one of product and can be easily overcome.

The abovementioned anomaly means that the chemical novelty has become the main objective of pharmaceutical research, even disregarding the patient’s needs. The proliferation of the so-called “me-too”, repetitive drugs that have taken away a great amount of human and economic resources to other uses potentially more valuable, has its origin largely in this patenting anomaly. In addition artificial molecules are full of unknowns and dangers because, unlike the natural ones, do not have a history able, if carefully read, to guide their uses. As we have previously said, the thalidomide tragedy has pushed health authorities to impose toxicological texts increasingly more severe, which have slowed down the flux of artificial molecules re-evaluating, at the same time, the knowledge and the practical opportunities offered by nature.

The teachings we gain from this can be applied to any type of patent, including the biotechnological patent, as well as to scientific research in general: the value of human invention resides first of all in the benefits that can be achieved. The hope is that this lesson comes from reason, without waiting for it to be imposed by the brutal force of events, and that it translates in legal measures that change the current patenting system.

The extension to the biotechnology sector of the patenting monopoly, conceived and tested in accordance to the traditional industrial field, raises delicate legal problems. On this point, it has great importance to establish if biotechnological patents should be authorised following the classical model of the patenting discipline, according to which the inventor can claim the exclusive right to exploit all the possible future uses of the patented invention, or if the scope of the patent should be limited so that only the use declared in the patent can be claimed (“protection based on purpose”).

The need to adapt the invention patent’s traditional scheme to the specificities of biotechnological invention, in line with the objective of recognising to the patent’s owner a monopoly that does not exceed the real contribution of knowledge he/she has given to society, which would go beyond the function of the patenting institution, is felt especially with reference to: a) the intrinsic characteristics of the patentable matter, which is the biological element, living and self-replicating; b) the effect of blocking research, which would come from the possibility of stating, in the patent’s

request, the characteristics of the biotechnological invention (for example, the physical, chemical or biological properties of a new microorganism) through a general formula, capable of understanding the multiplicity of applicative variations still unknown to the inventor him/herself and therefore susceptible of hindering future research and experimentation.

European law has accepted, with the directive of the European Parliament and of the Council n. 98/44 on the legal protection of the biotechnological invention, a solution of compromise, which, as such, seems at times to be contradictory and appears, in any case, perfectible, to both the supporters and the detractors of the biotechnological patent<sup>237</sup>. In fact, reading it for the first time, the object of the European monopoly on biotechnical invention seems to include only the procedures or products concretely developed by the depository of the patent's request, whilst future experimentation and, with it, the possibility of obtaining other patents of invention, should still be free and licit. In other words, the European directive seems to aim, first of all, to sanctioning exclusively the unauthorised marketing of the procedure or the product containing the patented biological element and not also the research of new uses of already known biological elements. This is the perspective of art. 8 of the directive, which however extends the protection given to the inventor through the patenting monopoly "to all the biological materials deriving from the patented one and having the same properties." Similarly, with regards to the invention's description, art. 13 disciplines in detail the request procedures for a patent and for accessing deposited material, simply establishing, however, that the industrial application for which the patent is requested must be concretely illustrated in the request.

Despite the caution of the European legislator, according to an approach that we could today call "bio-politically correct", numerous doubts about the real scope of directive n. 98/44 have been put forward in the past, especially with regards to the application of biotechnologies on man. We must remember, in fact, that art. 5 of the European directive establishes the absolute prohibition of patenting the human body in the various stages of its constitution and development, and of the mere discovery of its elements, including the partial sequence of a gene. However, this prohibition must be interpreted together with par. 2 of the same directive, in which is stated that an "isolated element of the human body", or otherwise produced through a technical procedure, including the partial sequence of a gene, can be a patentable invention even if the structure of such element is identical to that of a natural element. This specific, problematic aspect, has been recently revisited by the European Parliament, in their decision concerning patents of biological inventions, adopted on the 25th of October 2005, and it stated that "the directive allows the patenting of the human DNA only in relation to one function, but... it is not clear whether the field of the patent's application is limited to the aforementioned function or whether it can

---

<sup>237</sup> In Guce n. L213 of the 30th of July 1998, p. 13. The Directive was implemented in Italy after a significant delay, which earned our country also an infringement procedure of the Community's obligations before the Court of Justice: see the D.L. January 10th, 2006, n. 3, Official Gazette no. 8 of the 11th of January 2006.

extend to other functions”. Recalling in particular the patent given by the European Patenting Office with regards to the selection methods for human germinal cells<sup>238</sup>, the Parliament invited this Office to “give patents on human DNA only in the presence of a concrete application and to limit the patent of invention to such application, so that other users can use and patent the same DNA sequence for other applications (protection based on purpose)”. Finally the Parliament, after stressing that “no consideration regarding research can be more important than that of human dignity”, invited the Commission to study if the interpretation of the directive founded on the so-called protection of purpose could be pursued through a recommendation to the member States or if it is necessary to amend art. 5 of the directive<sup>239</sup>.

### 3. Genetics and drugs

#### 3.1. Definition and historical background

A variety of definitions of “pharmacogenetics” and “pharmacogenomics” can be found in literature. On the first there seems to be widespread consensus: “pharmacogenetics is the study of the effects of the genetic variations in the individual response to drugs, including safety, efficacy and interactions between drugs”. As such, pharmacogenetics is aimed at developing personalised therapies.

However, there is no agreement on the definition of “pharmacogenomics”. Some interpret it simply as an operative evolution of pharmacogenetics because of the developments due especially to DNA sequencing, and therefore they define it as “the study of the genome and of its products (including the RNA and proteins) because such study is connected to the discovery and development of new drugs” (Pharmacogenetics Working Group). Others instead, identify a conceptual difference in comparison to pharmacogenetics: the source of the variations due to the response to drugs studied by pharmacogenetics is of a “structural” type and therefore it is an individual’s static and global characteristic, whilst pharmacogenomics studies a second source of variation which is “functional”, that is, linked to the expression of the genes in the cells and tissues. Whilst the first source is not specific to tissue, the second source is specific to tissue and therefore it is a dynamic and changeable variability factor, in response to endogen and hexogen stimuli (Consortium on Pharmacogenetics).

More in general, pharmacogenetics can be defined as a discipline “looking at the genetic basis of individual differences in the response to drugs”, whilst it is pharmacogenomics that has the task of transferring the new knowledge on the human genome to research, both in order to discover and develop new drugs and

---

<sup>238</sup> See, in particular, the patent n. EP 1257168 of February 2nd, 2005, appealed according to the Convention of Monaco. The recourse is not concluded yet at the time in which one writes. Controversial is the the granting of patents nos. EP1121015, EP1196153 (relating to human germ cells) and EP1121015 (relating to frozen human embryos).

<sup>239</sup> The resolution, not yet published in *Guce*, was approved by a large majority, with 338 votes in favor, 272 against and 35 abstentions.

to identify new therapies. However, even in recent studies, pharmacogenetics is interpreted in both ways. The two terms in reality are not interchangeable, because pharmacogenomics is not only an updating of pharmacogenetics to the most recent advancements in the knowledge and analysis techniques of the structure and organisation of the human genome, but represents also a new approach to the study of genetic variations associated to the response to drugs. The analysis is extended to the whole genome and is carried out in a dynamic system formed by a net of interactions of genes and proteins functions. In this way, it is possible to obtain a better resolution of the targets and to further personalise treatments, adapting them to individual genetic characteristics. In addition, pharmacogenomics allows us to create drugs and treatments that are entirely new, starting with genic “constructions” of human origin, produced with genetic engineering techniques and inserted in guest cells of microorganisms or animals in an *in vitro* culture for the synthesis of proteins with pharmacological activity. This way, a new generation of re-combined drugs is born. In addition, chemical synthesis will be increasingly substituted by biological synthesis.

Pharmacogenetics is a sector of research since the 1950s with Arno Motulsky, who identified in genetic variations the origin of the individual differences in the response to pharmacological treatment. The term was introduced in medicine by F. Vogel in 1959, as a science that looks into the genetic basis of the variability in the response to drugs. However, the conceptual premises were expressed by Garrod who, at the beginning of the 1890s, with his essay on congenital metabolic errors and on the analysis of the segregation of such defects in certain families, founded human genetics.

Garrod guessed the existence of chains of biochemical reactions in the biotransformation of precursors and intermediates of the final products of metabolism and hinted that the different responses to medicinal substances and to infective agents could be linked to individual specificities in these processes. These studies of a mostly speculative character, inspired to the criteria of classic genetic analysis, opened the way to more experimental disciplines like biological chemistry, molecular biology and pharmacology. Important stages in the further developments of molecular genetics with regards to pharmacology has been the research on the genetic control of biosynthesis, which took us to the formulation of the hypothesis “a gene – an enzyme”, at the beginning of the 1940s; the definition of the DNA structure, the deciphering of the genetic code and the elaboration of the models of the genes’ regulating activity in the 50s and 60s; the introduction of the re-combined DNA techniques, thanks to the discovery of restriction enzymes and the finalisation of the techniques of DNA sequencing, in the 70s; the production of re-combined drugs in bacteria and the operative project for the determination of the sequence of the entire human genome, in the 80s. One of the most recent technical innovations is the DNA microarray, which allows the simultaneous analysis of increasingly extensive series of genes in order to identify their mutations and to characterise their expression within different tissues, in normal and pathological conditions. From the analysis of genes and their interactions to that of proteins: the so-called “post-genomic” era, which will concentrate on proteomic, has started.

### 3.2. Genetic control of the response to drugs

Individual differences in the response to drugs are commonly found in therapeutic practice and they can be attributed to a variety of factors, which are for the most part uncontrollable. The rapid progresses in molecular genetic analysis, cytological and formal, have allowed us to greatly reduce this margin of imponderability, leading to the identification of the components that are qualitatively and quantitatively definable. The genetic control of the response to drugs can be exercised at different levels: a) drug absorption, b) metabolism, transport and elimination, c) target characteristics, d) adverse reactions. The target definition is an essential phase in the creation of therapeutic instruments that are increasingly focused and effective. Genetic systems on which this control is carried out can have various degrees of complexity, which go from the simplest situation of the monogenetic inheritance, often defined as simple Mendelian, to systems made up of a variety of components, which characterises polygenetic inheritance. In the monogenetic or oligogenic inheritance, of particular relevance are the genetic polymorphisms, which shape situations of diversity in the genetic constitution of individuals or populations that can be characterised also as ethnical groups. What we define as polymorphic is a character and the gene that determines it, when that same gene presents itself in different variants with a frequency that significantly exceeds that of the rate of spontaneous mutation. For many genes this frequency is arbitrarily fixed to 1%. In a wider sense, the term polymorphism is applied to any variant DNA sequence.

We can estimate the possible differences in the DNA sequence of two individuals chosen randomly in the population, to 2-3 millions. The minimal variation that can generate a polymorphism is the change in a DNA base. Single nucleotides polymorphisms, the so-called SNP, are a systematic find extended to the whole genome, with the accumulation of sequencing data. The majority of SNP is devoid of genetic effect. The substitution of a single nucleotide can happen inside a gene of a codifying or non-codifying region, it is a regulating sequence near or far from the gene or outside the gene, in a non-codifying region. It must be remembered that more than 80% of the genome is made up by this last type of sequences formed by low or high repetition elements, assembled in arrangements of various dimensions. When the change happens in a sequence inside the codifying region of the gene, it can lead to the synthesis of abnormal proteins, whilst when it happens in a regulating sequence we have a variation in the quantity of proteins produced, with consequent imbalances in the function, very often defective. In this way, alterations in the DNA sequence can cause the loss or the change of the normal activity of a gene that manages the synthesis of a protein, directly or indirectly involved in the pathological process sensitive to the drug, in the mechanism of action, in the metabolism or in the transportation of the drug.

Polymorphisms for single nucleotides, when they manifest an effect, are often associated to an alteration in the activity of a protein. More extensive and complex forms of genetic variation that create polymorphisms are the deletions, that is, the removal of one or few nucleotides in the DNA sequence, duplications, that is, the addition of one or more supernumerary copies of a DNA segment, the repetition of short sequences of DNA in tandem in a variable number (VNTR), chromosomal

micro-rearrangements. More extensive chromosomal rearrangements and variations in the number of chromosomes generally are part of the chromosomal pathology.

A sequence variation that has no effect on the structure and function of a gene or of a regulating element involved in the response to a drug or in the genesis of an illness sensitive to a drug, can be equally instrumental in pharmacogenetics analysis as it can be used as marker. Its physical association with the genic variant, in fact, allows us to locate it and to study its hereditary transmission.

The final effect on the phenotype of genes that control characteristics associated to the pathology cured by a specific drug or characteristics linked to the metabolism of the drug, will be a reduction to a different level, until the complete absence of the response or an altered response. The manifestation regards both therapeutic effect, and adverse effects, like secondary toxic reactions, intolerance and hypersensitivity.

As typical examples of genetic polymorphisms influencing the drug's action, the ones regarding anti-cancer drugs must be mentioned. It has been proven that the genetic constitution of both the tumour and the patient, can influence the outcome of a pharmacological treatment. Therefore the maximum efficacy of an anti-cancer drug requires that it is made to fit not only the particular tumour and the phase of its development but also the individual genotype. The activity of enzymes degrading antitumour compounds like 6-mercaptopurine, 6-thioguanine and 5-fluorouracil is extremely variable because of a variety of genic mutations; the consequent enzymatic deficit can determine serious systematic toxicities. This explains the close associations between genotypic variants for the drugs' metabolism and adverse reactions. A further element of complexity is given by the interaction between genes regulating the progression of the neoplastic disease and genes that modulate the effect of the anti-cancer drug.

In defining the genetic basis of the diversity in the response to a drug treatment, it is necessary to take into account the boundaries of uncertainty due to a series of conditions that can affect the validity of the genetic data. We must first of all consider that the correspondence genotype-phenotype is not a constant relationship: the lack of correlation can be due to variations in the expression and penetration of the genes that control functions inherent to the illness, the drug's operating mechanism or its metabolism. The expression measures the intensity of the character under analysis, whilst the penetration indicates the frequency with which the genic variant present in the individual manifests itself. Variables to be considered are the operating methods and times of the genes involved. We know genes variants which increase the probability of the onset of an illness or the sensitivity to pathogen agents; an important source of variation can be the beginning of the illness, which can be early or late. Another element of interference is the interaction of the genes identified as responsible for the pharmacological response with other genes, the allelic forms of which can vary from individual to individual. These interferences strongly limit the classic pharmacogenetic analysis confined to one or few genes directly involved in the response to drugs. In pharmacogenomics this limitation is considerably reduced, as the analysis can be carried out on an extensive amount of genes at the same time, since it studies their expression.

An important component of the variability in the response to drugs, is the environment.

The correlation genotype-phenotype and the dynamics of populations of characters with regard to their sensitivity to the drug's therapeutic and toxic effects, must be considered from a flexible, Darwinian point of view. This must take into account some effects that in the conventional evolutionist models have been often neglected. One of the most important ones is the so-called "niche construction", according to which living organisms, and the human species is no exception, not only can adapt to different environments, mostly through mutation and selection, but in part they also contribute to their creation. Darwin himself realised that organisms can change the environment in a way that can affect their evolution, creating new selective pressures. In this perspective the link between organisms and environment is a two way relationship. The notion that the genes' action is outside the organism's confines, has been referred to using the term "extended phenotype". This concept is supported by that of "phenotypic plasticity". There are many examples of niche constructions in animal species and especially in man. Culture must be considered as a niche that man constantly changes, whilst at the same time enduring its effects. Diet and the use of drugs are subjected to these feedback mechanisms (retroaction). A typical case is that of the tolerance to lactose in the adult, developed in European populations in the course of a few thousand years, which has followed from the "cultural" practice of consuming cow milk. These considerations highlight the difficulties in the use of genotypic data in the choices linked to pharmacological therapies.

Easily identifiable environmental factors are the interactions with other drugs, health conditions and the patient's lifestyle. The higher is the multiplicity of genes involved, the more the environment can affect the manifestation of a genetic character. A typical polygenic arrangement is formed by a higher number of genes of the same type with additive action or of a different type, all concurring in determining the character; the inheritance of quantitative type causes a constant variation. The analysis of polygenic analysis is complex and genotypisation is problematic, as it cannot be done directly from known data, but through elaborate statistical methods. In the studies on the genetic determinism of the response to drugs, until now attention has been focused on monogenic and oligogenic systems. But it can be presumed that with the development of knowledge on the genome, analysis can be extended also to polygenic systems, with the consequent increase of selected classes of patients that can be subjected to the treatment and a better adjustment to pharmacological therapy.

### *3.3. Methods of genetic analysis*

The first phase of pharmacogenetic analysis consists in identifying and mapping the gene or the genes that are the potential targets of the drug or are in some way involved in controlling their activity. The conventional method identifies the phenotypic variation and from this goes back to the genic product and to the gene responsible. This is then located on the chromosomes through cytogenetic analysis techniques, formal genetic analysis, familiar studies and molecular analysis. With the same techniques, mutants characterisation can be carried out. In a following phase

we proceed to the gene's isolation and cloning and finally to DNA sequencing. Data and materials extracted from these analyses are essential to the execution of pharmacological tests.

Genetic variations that can be inherited certainly have a determining role in human pathology. Family history is one of the most important risk factors for most illnesses, from cardiovascular ones, to cancer, to obesity, to autoimmune forms, to psychiatric disorders and to diabetes, just to mention the ones with the highest socio-sanitary effect. The identification of the "illness" genes and of their variants is an essential phase in the creation of preventive, diagnostic and therapeutic measures.

Until now, we have identified more than a thousand genes responsible for simple Mendelian hereditary illnesses, which are relatively rare, in which the genetic component is prevalent: In these cases the variation of a single gene is necessary and sufficient cause for the pathology's development. But the majority of common illnesses are due to the combined effect of a number of variations of the DNA sequence, to which must be added the interaction with environmental factors. Genetic studies on this type of illnesses are based on the investigation of families and populations. These methods' limitations depend essentially on the reduced analysis capabilities, when the genetic component has a low incidence, and from the restrictions of the DNA regions that can be explored for the sequence variations. A complete analysis of an illness genetic determinism would involve the examination of all the genetic differences of a large sample of affected individuals and of control. This can be achieved only with the sequencing of the entire genome of each individual. An approximation to this theoretic objective can be a systematic analysis of all the known genetic variables extended to the whole genome, in different populations, to establish their role in the onset of illnesses. These studies are based on the connection between DNA's polymorphic variants, for single nucleotides (SNP) with specific alleles (alternative forms of specific genes). A particular combination of alleles along the chromosomes is called haplotype.

An international project finalised to the constitution of a data bank on the sequence variations generally found in the human genome, was undertaken in 2002 by a Consortium called HapMap (Haplotype Map). The aim was to give information that could guide the study of the genetic basis of illness. Recent is the publication, by this Consortium, of the data relative to a million polymorphic variants for single nucleotides, on a sample of 269 individuals belonging to four populations. As well as representing an inestimable resource for medical genetic and for the study of the structure, the function and the evolution of the human genome, with particular attention to recombining processes, the map of human haplotypes can be an extremely useful instrument for pharmacogenomics, as it can accelerate the development of the knowledge of those genome variations that determine the differences in the response to drugs.

The gene's identification and localisation in its variant forms can be achieved even without knowing the protein and the physiological mechanism involved, using the method called of inverse genetics, which "infers" the protein of the DNA sequence, once it has been located on the chromosome. The study of the association between genes variations and DNA and differences in the response to drugs, is done using appropriate genetic tests on sections of individuals treated with drugs, com-

pared with control samples. This allows us to assign to a certain genetic constitution, within defined confidence boundaries, the type of response expected in therapeutic treatment. For a complete description of these tests' typology, of the conditions and the application criteria and of the related bioethical problems, we refer you to the NBC's document "Bioethical Trends in Genetic Tests" (NBC, 1999).

Pharmacogenetics' final objective is the use of knowledge, of methodologies and of genetic data to improve drugs' safety and efficacy. With regards to safety, the pharmacogenetics approach offers the advantage of avoiding inappropriate therapeutic treatments that can present risks for the patient due mainly to adverse reactions. Efficacy can be improved in two ways: a) with the choice of the most appropriate drug in use and with the planning of new drugs, operating on the basis of the data on the patient's genetic characteristics and on the illness's genetic variants; b) with the drug's prescription and dosage adjusted to the different metabolic capabilities linked to the patient's genetic constitution.

Genomics has added a new dimension to pharmacogenetic research. The genome project has allowed us to identify a great number of new genes, of which however we still don't know the function. Particular interest is therefore directed to functional genomic and especially to the techniques of genic expression profiles, through DNA microarray and proteic pattern analysis. The study of transcription profiles can be done through different types of comparisons: affected cells and normal cells, cells treated with drugs and non-treated cells, cells that respond to therapy and resistant cells. Experimentation can be conducted both *in vitro*, on cellular cultures, and *in vitro* in the patient's clinical trials. The transcriptoma's analysis with microarray allows us to classify genes in distinct groups that contain already known genes and new genes. Very often the genes in these groups, co-regulated, share a specific biological function essential in the operating mechanism or in the transformation of a drug. Only the genome's systematic analysis can allow this type of studies, which are precluded or at least limited by classic pharmacogenetics. Protein analysis can use proteic microarray, mass spectrometry, nuclear magnetic resonance and, for structural studies, methods of X rays refraction. The definition of the exact three-dimensional configuration of a protein allows us to find the point in which the action of a drug could activate or deactivate the function.

Complementary technologies, which are part of functional genomic and proteomic, allow the simultaneous study of thousands of genes and proteins and the resolution of their structure with the possibility of recognizing markers for the diagnosis of an growing number of hereditary and acquired pathologies and of identifying new targets for treatment that includes increasingly selective drugs.

A recent estimate based on the complete sequencing of the human genome fixes to about 32,000 the number of human genes, a bit more that twice the amount of genes of the *Drosophila melanogaster* midge. Extrapolating data recently obtained in mice, this number could shrink further to 20,000, whilst it would be about 10 times higher than the number of a RNA transcript.

It is evident that the functional evolution of proteins in superior eukaryotes is more the result of a combinatory diversification of regulation nets than of a proportional increase in the number of genes. Understanding the connections between proteins and between genes within the net of cellular signals is a necessary premise for

the selection of drugs' targets and this is the principle challenge awaiting pharmacogenomics.

The completion of the human genome sequence has created the conditions for the development of highly specific drugs, adapted to each patient's genetically determined individual characteristics.

Structural biology is one of the vanguard disciplines in the sector of molecular biology. In particular, bio-crystallography is, par excellence, experimental methodology that allows us to discover the disposition in space (in other words, the structure) of atoms constituting biological macromolecules, whether they are proteins, DNA, sugars or even an entire virus. Crystallographic analysis through X ray diffraction can be compared to a special form of microscopy. In the case of the most familiar optical microscopy, the sample (for example a cell) is illuminated with electromagnetic radiation, in the band of the visible, to wavelengths (350-800 nm) appropriate to resolving its fine particulars at the microscopic levels (the nucleus of a cell has typical dimension of about 500 nm). In the same way X rays, belonging to the electromagnetic spectrum with wavelengths near 0,1 nm, allow us to separately observe (resolve) the single atoms of a macromolecule, identifying their position with a precision of 0,01 nm in the context of the three-dimensional structure, for example of an enzyme. The potentiality of these methods within biological research, to study the structure and functionality of proteins, has been known since the 1930s. However, the lack of appropriate experimental support has limited its effective development until the beginning of the 1980s, when progress in biochemical and biomolecular methodologies have provided analysable samples in significant quantities (tens of hundreds of mg) and to a high level of purity. In fact, these are essential conditions for the growth of proteic crystals (or nucleic acid) of dimensions and quality appropriate to bio-crystallographic investigations.

The attraction of bio-crystallography consists in its ability to reveal the extraordinary complexity of biological macromolecules. They are involved in all chemical reactions within living organisms. These reactions span from metabolism linked to energy production, to reactions causing the development of muscular force; from giving the ability of vision, to the mechanisms of immunitary defence; from the reproductive processes, to processes connected to cerebral and nervous activity. Bio-crystallographic study of biological macromolecules, and of proteins in particular, has revealed the extreme complexity of these molecules, which have a multiplicity of functions associated with a strong structural variability. The knowledge of the functioning structure and mechanism of biological macromolecules does not have only a value in itself, as scientific knowledge. In fact, because of the central role of the molecules that are the object of bio-crystallographic study, this knowledge has an enormous applicative potential. It is not by chance that the "colossuses" of the chemical and pharmaceutical industry finance research groups in the bio-crystallographic field. The study of the structure of biological macromolecules can allow the development of compounds that change these molecules' functionality. These compounds can be used as drugs. The famous "cocktail" of drugs currently used in the cure of AIDS was born, in part at least, by the bio-crystallographic study of the proteins produced by the virus. In addition, knowledge of the structure can allow the use of proteins useful to chemical synthesis and to the production of substances that

are of interest to industry. In the same way, currently in the developmental phase are technologies that allow the removal from the environment of noxious chemical compounds through the use of enzymatic proteins, capable of making such compound innocuous (the so-called "bioremediation").

In this context, structural genomics constitutes a new area of research within structural biology. It has the objective of studying the structure of biological macromolecules, proteins in particular, with semi-automated methods. In other words, to classic genomics, which led to the reading of the whole DNA of various living organisms (including man, the so-called "Genome Program"), is now added the possibility of deciphering the three-dimensional atomic structure of proteins codified from genes, the sequence of which has been obtained by genomic studies. Structural genomics is a worldwide initiative that however sees Japan and United States at the cutting-edge. Last year, the "National Institute of General Medical Sciences" (NIGMS) financed 7 pilot centres, the activity of which will extend for ten years. In the first five years, their aim is to define the technologies for the automation of crystallographic methodologies. In the second five years, it is foreseen that the use of the developed technologies will allow the determination of the three-dimensional atomic structure of literally thousands of human proteins and of other organisms, some of which are pathogens (for example the *Mycobacterium tuberculosis*, the etiological agent of TBC).

The pharmacogenomics approach does not only consent the personalisation of therapy but allows us to choose the best possible target for each patient. An approach to the research of new targets of therapy and to the development of new drugs, is that of chemical genomics, which integrates combining chemistry with the technique of transcriptional profiles, with proteomic, with informatics and with miniaturisation technologies. With this method the biological effect desired in a model system is researched through the screening of extensive collections of different compounds. A sign of activity is the starting point for the development of a new drug but also for the study of molecular mechanisms involved in the function under examination. In a way, the paradigm of genomic chemistry is a return to the empirical research of substances with pharmacological activity. Of growing importance in the rational development of drugs, are the methods of computerised stimulation and of analysis of the three-dimensional structure of the drug-receptor complex, through X rays diffraction. Crystallographic analysis furnishes a unique and irreplaceable approach for the construction and assembly of proteic molecules with enzymatic activity of interest to industry and pharmacology.

The accumulation of the necessary information for the definition of genetic profiles, for the application of appropriate algorithms and for their elaborations, makes it necessary to develop increasingly sophisticated systems for data depositing and management. For this, bioinformatics represents an area in rapid expansion and an instrument of work necessary to pharmacogenomics.

From the last decade of last century, a new era in genetic studies has opened. In fact until then, it was in the tradition and in the possibilities of genetic research to tackle the study and the function of single genes. Thanks to the enormous technological progress of that time, new disciplines have been born, which allow us to tackle, decipher and analyse the global genetic information present in and expressed by

groups of cells, tissues, and even an entire organism. Genomics aims at analysing the sequence and function of an organism's entire DNA; Transcriptomics studies the fraction of the genome that is transcribed in RNA and determines the expression level of all transcribed genes. In the same way, Proteomics tends to identify and quantify all proteins, including also the different post-translation modifications they can undergo. Finally, Metabolomics tries to link all the information obtained with the abovementioned approaches, coordinating genes, transcripts and proteins in integrated functional nets. These experimental approaches are applied to single cells, to tissues, organs or entire organisms in the most diverse physiological or pathological conditions of embryonic development or differentiation.

At the same time and as support to these new disciplines, a new branch of informatics has developed, Bio-informatics, which applies programming and computer calculus to the management and interpretation of genomic data. For example, new languages, called BioLims, have been developed and applied to the management of genome sequencing projects: in fact, through these instruments, all the complex experimental passages necessary to deciphering a genome can be coordinated and controlled. BioLims can coordinate the work of the robotic instruments used to treat thousands of samples together with manual work or the experimenters' analysis, controlling the flux of information in experimental passages and recording the "history" of every sample. As the deciphering of a genome can be defined as the ordered reconstruction of a puzzle often made up of millions of pieces, we can easily imagine the essential advantages these informatics approaches have brought to genomics. Bio-informatics has in addition developed numerous instruments that allow us to predict, from the knowledge of the simple DNA sequence, the gene's function and regulation, the function and structure of the protein eventually codified, up to the presence of genes and proteins with similar functions in other species ("Gnomon" project). Informatics algorithms with which we can study the function of a DNA sequence completely *in silico* are evolving very rapidly and are often now a premise to finding experimental hypothesis of study on genic functionality. Other algorithms have turned out to be essential for the assembly of complete sequences of very big genomes, as for example BLAT, which allows the multiple aligning of strings of very long sequences.

The results of very numerous projects currently being carried out throughout the world in the field of genomic disciplines, in the great majority of cases, are put into public access databanks (GeneBank, EBI, GEO, SwissProt, etc.). These databases contain not only the information of gene and genome sequences obtained so far, but also information of functional genomics, like those extracted from the analysis of transcriptomes and proteomes. This information is constantly integrated thanks to instruments of informatics analysis that have led to the construction of genomic-functional databanks in which, from a single information (the sequence of a transcript or the structure of a proteic pattern), we can easily go back to all the connected information in a process of data mining that is increasingly facilitated. A significant result of these new generations of databanks is that, for example, of the integration of data of global genic expression with those of proteomics, which will allow an increasingly complete view of molecular bases of cellular metabolism.

Even the functional analysis of genes has had a remarkable development in scale and technologies until recently used to study single genes, are now applied to hundreds of genes at the same time. We only need to think about the silencing, destruction or genic super-expression projects on a large scale already carried out on model organisms (yeast, the *Caenorhabditis elegans* nematode, *Drosophila melanogaster* and the mouse) and the projects of systematic analysis of proteic interactions in vitro and in vivo carried out in yeast and in the cells of mammals. These projects are collecting a vast amount of functional data that must be interconnected, with specific bio-informatics instruments, to those already present in genomic databanks.

The exponential growth of the data produced by genomic disciplines allows us to imagine the increasingly important role of bio-informatics instruments. The number of genomes that are deciphered is in constant increase, due on the one hand to the use of the centres of genomic sequencing and on the other hand to technological advancements: recently, it has been introduced on the market an automatic sequencer able to complete the sequence of a bacteria genome of medium dimensions (4 megabases) in only 5 hours. In addition, it is thinkable that we can begin to tackle the complete sequencing of genomes of different individuals of the same species (personalised genomics). For example, a recent project by the National Cancer Institute USA, predicts the complete sequencing of the cellular genome of human tumours of different neoplastic evolution, to map, once and for all, all the variations, at the DNA level, that accompany the process of evolution of neoplastic cells. New and more advanced algorithms are therefore necessary to manage the quantity of genomic data that will accumulate. In order to effectively tackle specific research topics, it is increasingly necessary to start from the accumulated genomic data and the researcher cannot, seen their growing complexity, manage them manually, instead he/she will have to use specific bio-informatics tools, capable of organising this information in an integrated and finite manner. Only this way we will be able to tackle complex problems like the evolution of chromosomes and genomes in the scale of evolution, the relationship between the global genic expression in determinate pathologies and the profiles of genomic variations (SNP), as well as the prediction of molecular mechanisms involved in the regulation of complex cellular functions.

Because therapy's ultimate target can be considered the gene that directs or regulates the synthesis of the protein, gene therapy is the logical development of pharmacogenomics. The concept of therapeutic gene, which is now used in place of the restrictive concept of therapy of the gene, has widened the application field of gene therapy, which interests now a growing variety of pathologies, from hereditary ones to acquired ones, from monofactorial ones to multifactorial ones.

The impact of genomic on pharmacology is not limited to the innovation and development of drugs production, with predictions that are not easy with regards to its width and the times of realisation, but it certainly interests basic research in the current time. In fact, the discovery of new markers for the diagnosis and of new therapeutic targets for the treatment of hereditary and acquired diseases, in general contributes to increasing our knowledge of biological processes mechanisms that are at the basis of physiology and pathology.

### *3.4. Personalisation of care*

The systematic analysis of the genome has facilitated, also thanks to the discovery of single nucleotide polymorphisms (SNP) and to the development of the techniques for their identification, the research of genetic determinants involved in the susceptibility to illnesses. The investigations, until now mostly directed to the most common pathologies and to those with the strongest socio-sanitary impact, are carried out with a variety of approaches: studies of association on a large scale, like those regarding polymorphisms linked to general morbidity; research focused on genetic factors involved in specific pathologies, like Parkinson disease; polymorphic mutations and variants of already known genes, like those linked to cerebral ischemia, to psoriasis, and to rheumatoid arthritis. Focus of the study are also the SNP haplotypes, typical of the genes for which we have proved or guessed an association with a particular illness, like Hirschsprung, Alzheimer and Parkinson, or with a syndrome, like the obsessive-compulsive one.

The study of the genes involved in the genesis and development of the pathological process offers the opportunity of both improving existing pharmacological therapy, and giving it new targets. According to a recent investigation, more than 500 products of known human genes have been identified as target for the drugs currently in use and it is predicted that such number can be increased, including also genes and genic products capable of functioning like therapeutic effectors, to 5,000-10,000. In fact, genes and proteins, as well as interacting with drugs, can also have a direct therapeutic function.

However, as observed in previous chapters, it must be stressed that individual differences in the response to drugs can depend on genes involved in the drugs' metabolism and transportation, as well as on their direct effects. In these circumstances, environmental factors can have a prevalent role. A typical case is the one of bio-transforming enzymes in the liver, belonging to the family cytochrome P450, the first of which was mapped in 1987: being equal the genetic determinants, a drug can be active or inactive in line with functional level of these processes, which depend on previous expositions not only to the drug in consideration, but also to structurally similar substances contained in food.

Despite the complexity of the problem, there is no doubt that genetics can give a precious contribution to pharmacological therapy, improving both its safety and its efficacy. This is demonstrated by the two examples listed below, the first regarding some drugs used in psychiatry, the second regarding the inhibitors of growth factors in oncology.

An example of the possible contribution of pharmacogenetics and pharmacogenomics to the personalisation of care is given by the so-called Malignant Neuroleptic Syndrome, potentially fatal, identified by the following clinical manifestations: hyperpiesia, muscular rigidity, akinesia, vegetative problems (irregularity of the heartbeat and of arterial pressure, sweating, tachycardia, arrhythmia) and alterations of the conscious state, up to shock and coma. The treatment of this syndrome consists of immediately suspending the administration of antipsychotic drugs and instituting an intensive symptomatic therapy aimed, in particular, to reducing hyperthermia and correcting dehydration. As well as the antipsy-

chotics haloperidol, clozapina, olanzapine, quetiapina, risperidone and ropinirole, have also been involved in this syndrome antidepressant drugs belonging to the tricyclic class.

The Malignant Neuroleptic Syndrome tends to manifest itself with higher frequency and gravity in patients who are carriers of a genetic anomaly caused by the dopamine receptor D2, which reduces the affinity for the ligand dopamine and it is responsible for a hypo-dopaminergic state that is gravely emphasised by anti-dopaminergic drugs, like antipsychotics. The genotype of the patients affected by this syndrome is characterised by the polymorphism of the gene that codifies for the dopamine receptor (DRD) and for the restriction enzyme TaqI A. This polymorphism translates in a reduction of the relative density and receptorial function. The frequency of the genotype A1 is much higher in patients affected by the abovementioned Neuroleptic Syndrome (93.3%) than in others (57.2%) (Suzuki et al., 2001).

This knowledge offers the opportunity not to eliminate, but to reduce the risk of a dangerous collateral effect of some drugs of psychiatric use, carefully evaluating the patient's genotype before starting the therapy.

Another example of the possible contribution to pharmacogenetics and pharmacogenomics to the personalisation of care, is given by the studies on the inhibitors of growth factors, the receptors of which are frequently amplified by the tumoral pathology, so that it confers to it a more aggressive clinical outcome. The pharmacological targets more studied in solid tumors are erbB1 (EGFR or HER1) and erbB2 (HER2/neu), two proteins that belong to the erbB family. ErbB1 is a transmembrane glycoprotein of 170 kD, that forms homo- (erbB1/erbB1) or hetero-dimers (erbB1/erbB2, erbB1/erbB3) with other members of the family following the link with EGF or other ligands. These include the transforming growth factor  $\cdot$  (TGF- $\cdot$ ). ErbB2, a tyrosine-kinase of 185 kd anchored to the cellular membrane. Although its ligand has not yet been identified, it is known that this protein is the preferential partner of heterodimerizations within this family. Cases of genic amplifications, mutations and over-expression of erbB members have been reported in numerous neoplasms, including glyco-blastomas, mammary, pulmonary, colonic, bladder and head-neck tumors. The inhibitors of the receptor tyrosine-kinase (RTK) gefitinib and erlotinib block the activation of the transduction system of the signal triggered by the erbB1's RTK, whilst cetuximab and trastuzumab monoclonal antibodies act respectively on erbB1 and erbB2. The treatment with these drugs has led to significant clinical responses in patients affected by pulmonary tumour "not in small cells" (gefitinib, erlotinib), cancer of the colon-rectum (cetuximab) and mammary neoplasia (trastuzumab). Resistance phenomena to EGF-RTK inhibitors and to monoclonal antibodies anti-erbB1 can happen in tumours that present the most frequent mutation of EGFR, that is, EGFRvIII ( $\epsilon$ EGFR or del2-7EGFR). This mutation is characterised by the deletion of the exons 2-7 in the mRNA of EGFR and codifies for an extra-cellular domain of bond for EGF truncated, with a constitutive activity, independent from the interaction with the ligand. Recent studies have demonstrated the existence of specific somatic mutations, regarding the genic portion that codifies for the domain tyrosine-kinase of the receptor EGFR.

The gefitinib, the trastuzumab and other growth factors inhibitors are indicat-

ed in around 10% of patients affected by pulmonary tumour “not in small cells”, correspondent to those in which we can find the abovementioned mutations (Bussolati et al., 2005; Kobayashi et al., 2005).

This exposition has been purposefully filled with technical details in order to show the topic’s complexity and the high specialisation of the researchers involved. In addition, we must take into account that the optimization of the anti-tumoral therapy that can be achieved with growth inhibitors translates not in a recovery, but in an increase in survival so far documented in a relatively modest percentage of patients with precise characteristics, which constitute a very small amount of the tumoral pathology.

The abovementioned examples give rise to some reflections of basic importance. On the one hand there’s no doubt that genetic research opens a series of concrete perspectives to medicine, in particular with regards to the personalisation of care. On the other hand it absorbs an enormous amount of human and economic resources: we must avoid the risk that this might be to the detriment of other opportunities, which could give us quicker and more extensive healthcare benefits. We must think, as an example, to the campaigns against smoking, which largely manifests its carcinogen action independently from genetic individual characteristics; or, with regards to psychiatric pathology, to the shortages that exist in the support of mental patients.

#### 4. Bioethical aspects

##### 4.1. General considerations

1. Pharmacogenetic and pharmacogenomic research constitutes a concrete expression of the very strong impulse given to the whole field of genetic research since the mapping and sequencing of the human genome, announced on the 12th of February 2001.

First of all, we must stress the significance and cultural value, as well as the scientific value, of the new trend, defined in terms of functional and proteomic genomics.

The knowledge on the functioning of the genes that can derive from it, is in itself a source of progress that must be judged as ethically positive if it contributes to the human good. Many of those who commented on the achievement of the awaited goal of the publication of 90% of the human genome (I.M.G.S.C.; Nature, 2001; Venier J. et al., 2001)<sup>240</sup> agreed in stating that, in itself, the knowledge of the genic sequence does not offer new perspectives in the interpretation of the functioning of the gene, both as single entity and as unity of genes, if we don’t also know the products of already formed genes.

Having already began to research, for the past few decades and especially in the last few years, the nature, structure and special configuration of particular proteins

---

<sup>240</sup> I.M.G.S.C., Nature, 2001, 409; pp. 860-921; Venier J. et al., Science, 2001, 291, pp. 1304-51.

in relation to the presence and activity of certain genes, single or associated, and of their mutations, we have started this new stage in the exploration of nature.

The rapid progress of analysis techniques with a high level of automatization and of bioinformatics, as research that until a few years ago required a very long time, today can be carried out in a short time, has focused public attention on this field of research, boosting the investigation of ethical and regulating problems raised by research, both in its possible applications in clinical practice and in the supply of healthcare. This field of research is still in its infancy and therefore it is not possible to entirely predict its potential and its development: for this reason, however, it offers the rare opportunity of exploring in their entirety their ethical, social, legal and economic problems whilst the field is still at its developing stage and can be shaped early.

2. We must immediately observe that this specific sector of genetic research does not present aspects involving the appeal to “ultimate ethical principles” and therefore, presumably, it is not susceptible of generating conflicting principles. Both the aim of the research (improving human beings’ health and reducing costs, both in terms of pain as well as economically) and the methods used to pursue them, seem devoid of irreducible moral controversies and, in effect, there doesn’t seem to be any position contrary to pharmacological and pharmacogenomic research in principle (if not those, thankfully in a minority, inspired by a pre-conditioned refusal of scientific innovation). We can raise a general question on global justice and it regards the morality of allocating considerable resources to a type of research the benefits of which will undoubtedly fall (and at least for a long period of time) only on patients who possess higher financial means, with the risk, therefore, of worsening the already existing inequalities in the access to medical care. Although interesting, and even crucial for a global cultural assessment of the most advanced trends of biomedical research, the topic goes beyond this document’s limits. Finally, we must also observe that bioethical problems raised by this specific field of research are not qualitative different from those regarding the entire field of advanced biomedical research and therefore can be tackled with the application, and the eventual adaptation in the specific case, of well tried general principles and normative instruments expressed in numerous national and international documents.

3. With regards to an ethical judgement on experimentation in pharmacogenomics, we maintain the general ethical considerations already codified by bioethical reflection on biomedical research and held as rules within national, international and European law.

With this premise, it seems possible to state:

a) With regards to the “specific” pharmacogenomic and proteomic research we can also refer to the rules on the research on the human genome, inspired to protection principles elaborated from the late 1940s until today – and by now presiding every investigation of the human being.

General and founding principles are enunciated in solemn documents, like for example the Convention on Human Rights and Biomedicine (1997) Oviedo and the

relative “Research Additional Protocol”, and in addition in the “UNESCO’s Universal Declaration on the Human Genome and Human Rights” (1996)<sup>241</sup>.

b) As well as these general and founding principles, there are a variety of derivations, expressed in documents (national or international, with a different legal authority) regarding also practical aspects of conducting research of a genetic character, which would apply also to extensions of research in the proteomic field.

4. Because of what stated above, bioethical problems posed by pharmacogenetics in its development toward pharmacogenomics, regard the evaluation and assessment (both at the level of research and of applicative pitfalls) of the benefits and the costs/risks, aiming at identifying the most appropriate rules to maximise the first and minimise the second. From the analysis of relevant literature, benefits and risks can be so summarised:

a) Benefits

- understanding of the genetic bases of the mechanism of response to drugs;
- development of new, more effective and safe drugs, and in a quicker and less costly manner, thanks to clinical studies of new conception;
- a safer (in relation to adverse events) and more effective (with the possibility of distinguishing the non-responsive or slow and the quick responsive) use of drugs, with consequent savings in costs for the SSN
- Improvement in the post-market pharmacovigilance of drugs, which can also allow the protection of benefiting drugs that in some genotypes can have adverse effects (and that today are withdrawn from the market).

---

<sup>241</sup> We recall the following fundamental principles with the original wording:Text of the Oviedo Convention:

“Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine”(Art.1).

“The interests and welfare of the human being shall prevail over the sole interest of society or science”(Art.2).

Text of the Additional Protocol:

“Parties to this Protocol shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to any research involving interventions on human beings in the field of biomedicine”.

Universal Declaration on the Human Genome of the UNESCO:

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

In addition to these general principles , there are several derived principles, expressed in documents (national or international of different legal force) regarding practical aspects of conducting genetic research, which would also apply to extensions of the same in the field of proteomics.

#### b) Risks

- connected to finding, using and preserving biological finds necessary to research;
- connected to the use of obtained information, to avoid discriminate uses;
- connected to the inclusion and exclusion of clinical studies;
- connected to the eventual worsening of the phenomenon of orphan illnesses;
- connected to the introduction of pharmacogenetics tests insufficiently validated.

5. Before moving on to a more specific analysis, it is necessary to put forward a general, although synthetic, reflection about the conceptual frame within which the assessment of the benefits-costs/risks must take form, in order to be accurate, balanced and therefore productive. However, such a reflection does not specifically regard the pharmacogenetic sector, but the entire field of genetic research, it is here aimed at highlighting some aspects, surfaced in the course of the debate, from the various interweaving of which could derive, at the same time, an exaggerated over-estimation of the benefits: in both cases the conditions for an accurate assessment (and, therefore, for the elaboration of efficient public policies) are lacking and instead the wrong perception of what is at play in genetic research, of what we can realistically expect and of what we must carefully avoid, is fuelled and confirmed, also by the public.

From the point of view of distorted perceptions, we could expect a further push towards the so-called “radical genetic reductionism”, or “genetic determinism”, already widespread today in many environments, with the statement that each manifestation of the phenotype, and even in human behaviour, is linked to (and determined by) a particular genetic asset: in this case, in the reductionistic equation, in proteomics research only that particular protein should be substituted to the gene and the result would not change.

R. Lewontine, S. Rose and J. Kamin (1984) proposed a reflection on the negative consequences of a reductionistic formulation, which they identify at the scientific level in the wrong conception of biological processes, complex by nature; at the ethical-social level in fatalism, in de-responsabilisation and, at the level of research policies, in the pursuing of the wrong objectives in the allocation of resources. The same author concludes that new knowledge derived from the study of the human genome, used in a correct and appropriate manner, offers the possibility of improving the quality of life in our society, but they must be taken away from the reductionist matrix and inserted in an integrated vision of human biology, in its individual and social dimension.

Although this is, in reality, a general theme that involves the entire field of genetic research, a mention of it, especially for certain cultural and public policies effects, can be useful also in our context, particularly because genetic reductionism, beyond its most general cultural aspects, could lead, in our specific field, to “miracle” and therefore unrealistic expectations with regards to the predicting power of pharmacogenetics tests: instead of seeing, more realistically, pharmacogenetic information as having probabilistic nature (from this specific problems, which we will see later, are generated) and of balancing it with other factors that influence the individual

response to drugs, a reductionistic mentality could see this information as final and omni-comprehensive. The slogan that summarises pharmacogenetics' ideal objective ("the right drug to the right patient in the right dosage") is only a slogan, although captivating.

6. It is important first of all to distinguish between genetic reductionism as research methodology and genetic reductionism as ideology. The first is simply the fundamental nucleus of the complex's comprehension program, starting with the simplest, which is at the basis of molecular biology and would implicate the idea that living creatures' essential properties could be interpreted by looking at the structure and functions of their macromolecules, capable of transmitting, replicating and reading genetic information, that is the radical innovation of molecular biology. Applied to the field under consideration, this idea implies that any phenotypic trait, both normal and pathological, can be brought back, completely or partially, to events connected to the structure and functioning of genes.

Naturally, it is still under discussion to what point it is possible to push the explanation model described above and in what measure (and when) biomedical research that adopts this model (including pharmacogenetic research) will be able to give rise to therapeutic options capable of affecting, in a statistically significant way, people's health. There are a variety of different points of view regarding this. The most widespread opinion is that the impact in clinical studies of what is happening in the most advanced genetic research will be of such magnitude that it will bring a real revolution in the way we practice medicine. But more cautious scholars bring attention to how the results transferred to clinical practice, at least at the therapeutic level, are up to now more promised than realised and that, in any case, the entity of this revolution must not be emphasised because, for example, its impact on the way in which the most common multifactorial illnesses are diagnosed and cured will not be relevant, because the correlation between genotype and phenotype is in this case very weak and there's no benefit in massively turning to genetics (Holtzman and Marteau, 2000).

It will only be the further development of research on the genome (which, as we will see, is affected by numerous scientific and social factors) to decide who is right. What we need to stress is that genetic reductionism as methodology must not be confused with genetic reductionism as ideology, which is a more complex cultural phenomenon and only partially linked, maybe even a bit paradoxically, to the success achieved through the analytical and reductionist model in the program of research pursued by molecular biology (S. Sarkar, 1998)<sup>242</sup>. The basic idea is that genes will have such an important part in our life that they will cause a cultural and spiritual impoverishment which, in the old question of the relationship between nature and culture, would bring back the dominance of nature, obviously with all the consequences this would cause – even, for example, in terms of the education or racist policies that could follow. The debate provoked by Wilson's thesis, for example, is well known, as is the new polemics on the old question of the genetic root of intelli-

---

<sup>242</sup> See S. Sarkar, *Genetics and Reductionism*, Cambridge Mass., Cambridge University Press.

gence aroused by the publication of a book by Herrnstein and Murray (R.J. Herrnstein, C. Murray, 1994)<sup>243</sup>. The old genetic determinism could be resurrected, that is, the 1920s 1930s trend to favour the genetic explanation not only for illnesses and the response to drugs, but for any type of “deviation” from social norm. Of course we all know that the development of molecular biology has defeated this old determinism: no serious scientist today would support the thesis “a gene, a trait” in a deterministic manner and without distinguishing, for example, between monogenic traits, multifactorial traits, etc. And however today – because of the success of molecular genetics and of its promises amplified by mass media always looking for a scoop (like: intelligence gene discovered) – we are looking at a kind of return to this determinism which, in popular culture, seems to have become a true mystique of the gene (D. Nelkin, S. Lindee, 2006)<sup>244</sup>, with its liturgy and even its own relics, where genes seems to have the same importance of the soul in religion. With regards to this, we talk of a kind of “genetic essentialism”.

It is however clear that genetic determinism and reductionism, just as the eventual clinical reductionism – which is only a bad way to practice any medicine, not only genetic medicine – are not the necessary and inevitable result of a molecular genetic research and therefore they should not be listed as some of the “risks” of such research. They are a problem with regards to how society perceives and receives the advancements of science and, therefore, a problem of cultural politics, of great importance especially in a country like ours, in which the process of circulation of scientific knowledge is slow. If this is true, the criticism of genetic reductionism as ideology implies the cultural commitment of preparing society to welcome and to be able to evaluate, in their right dimension, the results of genetic research, which does not need to be exalted in order to produce its positive effects. This is without a doubt a crucial duty, which public authority must undertake: otherwise we risk having instruments of great efficacy without however being adequately prepared to use them to our patients’ benefit.

The intervention that can be hypothesised in order to reduce the distorted interpretations present in public opinion, seem therefore linked to the general increase of the knowledge about the functioning of both genes and the proteins regulated by them.

Much could be derived by the action of cultural organisations (public and/or private) aimed at facilitating the correct interpretation of messages; from technically exact information, sober and devoid of emphasis in indicating future possibilities, by both journalists and doctors.

A great responsibility must be attributed also to the researchers’ professional transparency and propriety.

The UNESCO’s “Universal Declaration on the Human Genome and Human Rights” (1996) in art. 13 states in the following terms what is must be done in the matter (responsibility ethics):

---

<sup>243</sup> R.J. Herrnstein, C. Murray, *The Bell Curve: Intelligence and Class Structure in American Life*, New York, Free Press, 1994.

<sup>244</sup> See D. Nelkin, S. Lindee, *The DNA Mystique. The Gene as a Cultural Icon*, New York, Freeman & Comp., 1995. The measures envisaged to reduce misinterpretations amongst public opinion seem to relate to the increased general knowledge of how both genes and proteins regulated by them work.

“The responsibilities inherent in the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of its ethical and social implications”.

This does not mean disregarding the freedom of research and of the communication of ideas.

The focus on the ethics of research can have the function of a stimulus rather than an obstacle to scientific progress and its productivity pitfalls, as well as spreading in public opinion the positive image of a responsible science.

From this point of view, it was recently launched the Commission’s Recommendation of March 2005, regarding the researchers’ European charter and a code of conduct for the employment of researchers<sup>245</sup>. This, although it recognises that its “final political objective is to contribute to the development of a European market of attractive, open and sustainable work for the researchers” (considering 8), it however recommends: “3. Member states, in elaborating and adopting their strategies... adequately take into account and inspire themselves to general principles and Charter regulations...”.

It’s important to stress that in this Charter, between “General principles and requirements applied to researchers” are expressly mentioned: “freedom of research<sup>246</sup>, ethical principles<sup>247</sup>, professional responsibility<sup>248</sup>, spreading and enhancement of the results”<sup>249</sup>.

To elevate the level of knowledge and awareness, both of the researchers and of the public, of the problems involved, is not an easy task to perform, but it is now unavoidable, as it is well illustrated in the action plan in “Science and Society” launched by the European Commission and by the European Parliament in the VI Frame Program (2002-2006)<sup>250</sup> and also present in the VII FP (2007-2013).

We must add that some governments has already taken this task very seriously: for example, in the recent white Book by the English government, dedicated to the programmatic lines for concretising the potentiality of genetic research in the distribution of healthcare, chapters 4 and 6 are dedicated to illustrating the measures (and the relative investments) in the field of medical education and workers’ train-

---

<sup>245</sup> Official Journal of the European Union , 22.3.2005, L 75/67-77.

<sup>246</sup> Researchers should focus their research for the good of mankind and for expanding the frontiers of scientific knowledge, while enjoying the freedom of thought and expression, and freedom to identify methods to solve problems, according to ethical principles and practices recognized.

<sup>247</sup> *Ivi*.

<sup>248</sup> “ Researchers should make every effort to ensure that their values are useful to society and not duplicate research previously carried out elsewhere ...” *ibidem*.

<sup>249</sup> All researchers should ensure, in accordance with contractual requirements, that the results of their research are diffused and valorized, e.g. communicated, transferred into other research contexts or, if appropriate, commercialized. The researchers, in particular, are expected to ensure that research is fruitful and that results are either valorized or made accessible to the public (or both) wherever possible...” *ibidem*.

<sup>250</sup> Official Journal of the European Communities c. 315, 17th of December 2002.

ing and in the field of the promotion of public awareness and trust<sup>251</sup>. It is important to highlight that this white book is maybe, at least in Europe, the first document of a governing authority that, in the context of a clear awareness of the profound changes that genetics will produce in the medium term in the delivery of basic health-care, dedicates considerable attention to pharmacogenetics: and not only at the informative level, but also allocating investments aimed at a specific field, that of pharmacogenetics for drugs already in use in the therapy of common illnesses, a sector that does not seem attractive for investments by private companies, but that is of great interest for people's health and can produce, already in the short term, considerable savings in pharmaceutical expense.

7. As we said, ethical questions posed by pharmacogenetics are not qualitatively different from those posed by genetic research in general and therefore we can assume that the conceptual and normative instruments already elaborated for the last one, are applicable also to the first, naturally with the adaptations that might be necessary to better grasp this field's specificity. According to a trend by now widespread in literature, we can identify the ethical problems arising from pharmacogenetics<sup>252</sup> with reference to three levels: a) basic research; b) applicative research (especially pharmacological); c) application in clinical practice. In all three levels – and, obviously, with a different importance in each on them – bioethical problems involve essentially the following points:

- a. the correct management of acquired information;
- b. problems relative to the informed consent, to privacy and to confidentiality;
- c. ethical and social implications of stratification;
- d. implications with regards to equality in the access to medical care.

#### *4.2. Basic research: ethical judgement on current knowledge*

1. At the general level of pharmacological research, the fundamental problem regards the control of the flux of information. Pharmacogenetic research aims at establishing the influence of the genotypic variability in the response to drugs, influence that – as mentioned above – is one of the factors (and certainly not the only one) determining individual response. To identify this specific factor, research needs to collect, preserve and analyse DNA samples. This need is common to the entire field of genetic research and poses the same problems that are at the centre of the debate on Biobanks (a European picture of the debate on national legislations can be seen in Survey on Opinions from National Ethics Committee of Similar bodies, public debate and national legislation in relation to human biobanks, Brussels, 2002; cf. also Data storage and DNA Banking, Report of the European Society of Human

---

<sup>251</sup> Department of Health, *Our Inheritance, our Future. Realising the potential of genetics in the NHS*, London, 2003.

<sup>252</sup> Once again we remind that in this document the terms pharmacogenetics and pharmacogenomics are related to the study of the genetic basis of individual response to drugs by taking into account respectively, the individual genetic traits or the genome as a whole.

Genetics, of June 2000, to be updated). Three regulating principles have arisen: obtaining the informed consent, protecting privacy and guaranteeing confidentiality. These are by now largely consolidated principles in the general sector of biomedical research and in the more specific one of genetic research, of which therefore we need to explain the meaning and the applicative modalities in relation to the specific field of pharmacogenetics, because of the specific characteristics of this research and, especially, because of the potentially enormous quantity of information that the research can collect and preserve.

2. The topic of the informed consent must be analysed under three main aspects: i) its extension; ii) its content; iii) its new modalities. Taking for granted, obviously, the general principle that the obtaining of consent must be preceded by correct, ample and comprehensible information (particularly difficult task for a geneticist), even from the point of view of terminology, the first problem (the extension of consent) regards the times, uses and people authorised access. We can, for exposition reasons, identify two extreme hypotheses, in between which there are a variety of other hypothesis. The first (ample consent) is that in which the consent is equal to a sort of blank cheque that the subject gives to the researcher both in relation to the time limitations in the use of the samples, in relation to their use in other research connected or following the first one, and finally in relation to other potential sample users. Although advantageous for the aims of the research, this hypothesis is considered lacking from an ethical point of view because it contradicts the main objective of the informed consent, that is, to put the subject in the condition of evaluating the costs and the benefits of his/her participation to the research: no evaluation is obviously possible when it is not clear what research will be carried out, with what aims and by whom. We still need to discuss whether, as long as clearly illustrated, this hypothesis remains available to the subject, as it can be founded on the conscious desire to offer a contribution to the progress of biomedical research. However, even in this case – and in relation to the possible risks (see later) – it should be accompanied, because of its range, by a very high level of protection of confidentiality.

The other extreme is the hypothesis of a consent “restricted” to the use of the DNA sample for a limited time, for a clearly limited research and only for the researcher that requests it. This is, essentially, the model that has prevailed in the first attempts at adding a pharmacogenetic sub-protocol to the normal protocols of pharmacological experimentation. Its excessively restricted character is however negatively judged, especially because it would imply – should the development of research require an extension – a new procedure to obtain consent, with the relative costs. It is in any case possible, in between these two extremes, to hypothesise models capable of conciliating, at the maximum degree possible, the needs of the research and of guaranteeing the respect of an individual’s dignity and of the subject’s rights. Although in a field in such rapid evolution it is not possible to dictate rigid and uniform rules, it can be stressed the general principle that anything we ask the subject to consent to, must be explained in detail, with rigorous and understandable language in the consent form and it must be made the object of clear communication, open to any requests of clarification.

3. Going on to the second aspect (the contents), literature stresses in particular the following points. First of all, an accurate and impartial illustration of the benefits (if there are any) and of the risks of the participation to research. With risks, obviously we don't mean those linked to sample collection methodologies (really minimal), but those psycho-social following from the improper or unauthorised use of information. For this reason – secondly – the specific illustration of the procedures needed is necessary in order to safeguard privacy and confidentiality: not, therefore, only the simple reference to the regulations already existing with regards to this, but the explicit indication of the techniques used to preserve the biological sample and the information, the people that have access to it and for what aims, the person responsible for the entire procedure, etc. Thirdly, the research sponsor and the possibility that it will generate marketable results will have to be indicated. Finally, the consent must include the mention of the possibility that in the course of research information might be discovered, secondary to the aim of the research and potentially beneficial (but also involving psycho-social risks) for the subject: in this case, it will have to be clearly detailed what happens to this information, who assesses its credibility, who has the task of informing the subject and, obviously, if the subject needs to be informed or not.

4. The topic of “secondary information” is often recalled in the debate as a potential risk of pharmacological research, but according to some it is overestimated: the possibility that a pharmacogenetic research might also discover information that can be linked to genetic illnesses or to the predisposition to genetic illnesses, is very low and it is a function of the technology that is employed. The trend is going towards using very selective and targeted genetic markers, which are not able to identify predispositions to illnesses or other secondary information. If this is true – the object of contention is this – then it would be improper to apply, to pharmacogenetic tests, the regulating instruments, more stringent and rigorous with regards to the guarantees for patients, created for the tests to diagnose genetic illnesses (or the predisposition to illnesses). Although it can be hoped that no improper burdens are imposed on a sector of research on the basis of the simple fact that it belongs to a “sensitive” field like genetic research, it is certain that the loosening of the limitations must be compatible with the guarantee and the protection of privacy and confidentiality. We can in fact hypothesise that, even in the most favourable research circumstances, pharmacogenetics' data can generate secondary information to which others could be interested in and have access to. These are some of those circumstances mentioned in literature: a) the genotype that influences the response to drugs plays a role in the predisposition and/or the evolution of a certain illness, or in the sensitivity in the dependency from drugs or other substances; b) a pharmacogenetic test can even bring information with regards to the non-paternity (a “slow acetylated” child cannot be the son/daughter of a father who does not even have one of the alleles responsible for this recessive trait); c) the mere fact of being declared non-responder to a certain drug or to a class of drugs can have consequences, when, for example, that drug is the only one effective against a certain illness: virtually, the subject is declared incurable.

5. The third aspect (the new modalities) regards the topic of the “group consent”, a topic that is increasingly under scrutiny in the investigations on ethical issues of genetic research in general (especially of the populationistic type). The main idea comes from the preoccupation that a certain individual, even if he/she has not actively participated (or has refused to do so) to research, could still receive from it a psycho-social damage (in the form of a stigmatisation or discrimination) consequent to being perceived as a member of the social group, easily identifiable, on which the research is conducted. We can hypothesise, for example, that pharmacogenetic research can find out if a social group identifiable on ethnic or racial bases (terms still used in common language) is non-responder to a certain drug: in determinate conditions, this could translate in discriminations in the access to treatments, which, in the specific case, could be connected to prejudice towards an ethnical background and would involve all the individuals belonging to a group, even those who did not directly participate to the research. Obviously, it is well known that genetic variability within a group can be even higher to that existing between groups and therefore the problem is not scientific as much as of public perception and recalls, once again, the need for a profound work of education and information, which we have mentioned before. With regards to the point under examination, we cannot hypothesise that the very speculative expectation of an indirect damage consequent to research the subject has not consented to, can present a sort of veto from all those belonging to the group, that research should be conducted only on consenting individuals. We can hope – in special cases and when research regards groups that can be considered vulnerable – that obtaining an individual’s informed consent must be preceded and accompanied by a correct sensibilisation and consultation campaign. Good examples are not lacking in connected sectors (for example, the screening campaign for the Tay-Sachs disease in Hebrews of Askenazi origin or that for thalassemia in Cyprus); and in any case it is a topic we must take into account, also in relation to the topic of the “shared” character of genetic information: everything that is discovered on an individual’s genetic make-up gives information not only on that individual, but also on his/her relatives. The topic is not specific of pharmacology, but poses also in this sector a problem of management of information that gives rise to the need to develop genetic counselling.

#### *4.3. Protection of privacy*

1. There are already numerous regulations aimed at protecting individuals from the damages resulting from the improper or unauthorised use of genetic information (prohibition of discriminating on a genetic basis, also in the field of work and insurance: etc. quote). The procedures of protection and guarantee must be already carried out during the research and – as we said – they must be accurately described in the informed consent form. Even if we still don’t have a complete uniformity in the terminology, generally we distinguish between three different procedures applicable to biological samples for the control of the flux of information: identifiability, codification (simple or double), anonymisation.

2. With the first system the identity of the research subject remains identifiable

throughout the course of the research. From the researcher's point of view, the advantage of the identifiability is that it allows the integration of genetic information with other medical information recorded or obtainable from the subject and this increases the data's reliability, as well as the possibility of using new data that had not been contemplated as important at the beginning of the study. From the subject's point of view, the advantage is that eventual interesting information with regards to the subject's care, can be communicated to him/her, in the abovementioned ways. This system's disadvantages derive from the low protection levels ensured: the eventual secondary information derived from research can be linked to the subject and this represents a source of not always easily controllable risk.

3. The second system ensures a higher level of protection and has two variants. In the single code system an identification number links the sample to the subject. The code is only known to the researcher and can be used to identify the subject within the limitations and the cases mentioned in the informed consent form, where even other people that, in certain circumstances, can have access to the code, can be listed. Even higher is the level of protection ensured by the double code system, where the sample's identification number and the subject's identification number are linked to a code known only to the researcher. This system is considered more appropriate to reconcile the needs of the research and the protection of the subjects' interests. It leaves the possibility of accessing other medical data, eventually necessary for the research, open and more controllable, without the researcher being able to go back to the subject's personal identity. However it has considerably higher costs in comparison to the other systems and poses the problem (crucial for the procedure's conformity to standards) of the identification of the organism qualified to hold the connecting code. With regards to this, in literature there is talk of the creation of "intermediary fiduciary organisms" on which to entrust the management of this task: but the issue could be more general and involve the entire system of collection, preservation and treatment of biological samples (the problem of biobanks). An additional and important problem is the fact that there are, already in existence, in public and private institutions, banks of biological material and information, the collection of which has been carried out using very different modalities.

4. The third system involves the complete anonymisation of the sample and this naturally eliminates any possible risk linked to the malfunctioning of the previous systems, offering the subject the highest guarantees with regards to the eventual damages resulting from his/her participation to the research. Anonymous or subsequently anonymised samples are preserved in already existing biobanks and it is common practice to allow new research to be carried out on them, as long as they are approved by the Ethical Committee. This system presents some disadvantages. First of all, the impossibility of accessing other medical information about the subject reduces the value of the acquired pharmacogenetic data, which – as abovementioned – depends also on the comparison with other factors that determine the response to drugs. Secondly, it becomes impossible to communicate to the subject any eventual secondary information that could be useful for his/her health and/or care.

#### *4.4. From the planning to the development of new drugs*

1. One of the sectors in which research in pharmacogenetics could produce good results in a reasonably short time, is that of the research and experimentation of new drugs. The scientific aspects connected to this issue have already been examined, as also the ethical aspects linked to the collection, preservation and treatment of biological samples necessary to create a consistent database of genotype-phenotype correlations. To complete the picture, and in order to highlight other aspects that need clarification, we examine in synthesis the main implications of pharmacogenetics on the way in which base research and clinical studies are currently designed and managed.

A better understanding, from a genetic point of view, of the biological mechanisms that contribute to the pathogenesis of an illness can lead, on the one hand, to more efficient and safe treatments with already existing drugs and, on the other hand, to identifying new targets for new drugs.

With regards to the first aspect, there is already considerable evidence of the benefits that the knowledge of the pharmacogenetic profile can have in the personalisation of therapy with existing drugs. We must not however make the mistake of overestimating the impact of pharmacogenetics in this field. In many cases, the concretisation of such an impact would be extremely expensive and the benefits, from the patient's point of view, very limited, especially when adverse reactions are light or moderate and the illness can be treated with other drugs. In other cases, however, using pharmacogenetics can have undoubted benefits, capable of adequately making up for the higher costs. This is the case with regards to seriously disabling illnesses (like schizophrenia) or life-threatening ones (like tumors), against which we have efficient drugs that however work only in a limited percentage of patients and/or have very serious side effects. However, the pursuing of these undoubted benefits could be hindered by the problem of the costs of the research for the elaboration of validating tests, especially with regards to drugs that are not covered by a patent anymore. According to some, the public authority should intervene in this sector, both indirectly (through the creation of incentives of various nature, like what is happening in the case of the so-called orphan illnesses), and directly, supporting research in public structures with finalised projects.

2. Moving now on to the second aspect, pharmacogenomics will allow us to considerably increase the number of biological targets for the drugs (as already stated in the NBC document on Ethical Committees in 1999). These drugs will then have to undergo clinical experimentation and one of the issues under discussion is whether – and eventually which - changes in the current regulations should be introduced in order to respond to the needs of pharmacogenetics.

Many authors, for example, agree in believing that the application of pharmacogenetics to the clinical development of drugs will require substantial changes in the design of the studies (for instance, with a greater focus on phase II base studies in comparison to the current one and a considerable decrease in the number of samples in phase III studies) and therefore a re-examination of the ethical principles on which human trials are based.

It will be in fact possible to enlist in clinical trials only responsive subjects, excluding the unresponsive ones. The ethical basis for such an exclusion is in the regulations that currently control the carrying out of clinical trials: not to expose the subjects enlisted in the trial to unnecessary or excessive risks and in any case risks that are not compensated by any benefits: if we don't know that a certain individual does not respond to a certain drug, enlisting him/her means exposing him/her to an unnecessary risk, without any compensating benefits for him or the research.

We must however be careful that the exclusion is based on individual genetic information and not – for reasons of convenience – on the mere fact that the individual belongs to a group in which we know there's no response to a drug: as we stated with regards to the “group consent”, such an exclusion could be perceived as discrimination and would not have a scientific basis.

**3.** The nature and the scope of the needed changes in regulations also depend on new perspectives and the speed of their concretisation, linked to the influence of a variety of factors, not excluding financial ones. Currently, regulatory authorities (FDA and EMEA, for example) do not require the incorporation of pharmacogenetics in drug experimentation protocols in order to obtain the authorisation to market. It must however be highlighted that in November 2003 FDA issued the first Draft Guidance (updated in 2005) for researchers who intend to communicate pharmacological data obtained in the course of clinical experimentations. This voluntary regime could quickly change, as research continues. According to a recent inquest, within 5 years 50% of clinical studies will involve getting the participants' genetic data and, according to some authors, by 2014 all new drugs will have been obtained through procedures that will use pharmacogenetic analysis. These estimates are based on the speed of innovation in this field, thanks to bioinformatics, and to the relatively increasingly lower cost of pharmacogenetics tests, and they also take into account that, as a growing mass of information becomes available and is attainable, other factors could push in this direction. A first factor, for example, is connected to the fact – abovementioned – that pharmacogenetics, as well as improving the therapeutic efficacy of drugs, promises also to improve safety, reducing or avoiding adverse reactions. As soon as the available data will allow us to make reliable correlations, both on the already existing drugs and the new ones, the pharmaceutical industry will be increasingly pushed – also in order to avoid being taken to court for negligence – to incorporate pharmacogenetics in the design of clinical studies and, consequently, in the instructions for the administration of the drugs produced. There is a lot of discussion about the reliability of these predictions: but in reality, what is under discussion is the speed of evolution, not its direction.

**4.** A second factor is linked to costs. Also with regards to this, the assessments are quite variable and in any case speculative. The most widespread opinion is that, in the short and medium term, we must not expect a decrease of the costs in drugs' development and experimentation, especially – as we were saying – because phase II will require a definite increase in the amount of patients in order to ensure the possibility of identifying a relevant number of variables, whilst the decrease of the number of samples for phase III is still controversial. It is difficult to say whether in the

long term there will be a change of direction, but it is plausible to think that, in any case, the application of pharmacogenetics will improve the quality and efficacy of the drugs development process. Today the development of a drug requires about 10-15 years and the percentage of molecules which are of potential therapeutic interest to reach the market is below 0.1%. Excluding other factors (including the convenience of the pharmaceutical industry), pharmacogenetics could increase these percentages and contribute in reducing the number of drugs that are then recalled from the market because of adverse reactions. Finally, in the current state of affairs, it is very difficult to hypothesise whether pharmacogenetics will translate in a lowering of the cost of drugs, even if undoubtedly, thanks to the better efficacy and safety promised by the “personalisation of therapy”, it will have a positive impact on people’s health and on the overall costs incurred by the health authorities. These results, however, will raise some problems with regards to guaranteeing equality in the access to medical care.

#### *4.5. The stratification problem: illnesses and orphan genotypes*

1. The slogan “the right drug to the right patient in the right dosage” is often recalled in this debate, as the ultimate objective of pharmacogenetics. Naturally, this is an idealistic objective, because it would mean the total stratification of the patients in subgroups, each of which could even contain a single individual. However, leaving this futuristic possibility to one side, there is no doubt that pharmacogenetic research is destined to stratify (some prefer to say: differentiate) in subgroups both the patients (on the basis of their profiles of response to drugs), and the illnesses, giving rise to a new “molecular taxonomy of illnesses”, that is, the idea that certain illnesses, up until now considered a single condition, present in reality, from a genetic point of view, a more heterogeneous picture and therefore require differentiated treatments, or “made to measure” treatments for that single patient and with minimal side effects.

Essentially, today it becomes possible to give scientific basis to phenomena already known since before the development of pharmacogenetics: for example, the phenomenon of drugs that do not go beyond phase II because they do not demonstrate sufficient efficacy and/or safety to justify the passage to phase III and therefore they are abandoned; or the calculations of costs-benefits which influence (or determine) the inclusion or exclusion of a drug from the list of those offered by the health authorities; or even the phenomenon of drugs that are recalled from the market for the high number of adverse reactions registered (and of which, thanks to pharmacogenetics, we could suggest the recovery). The only difference is that before the advent of pharmacogenetics the incidence of these phenomena and the relative evaluations, also in terms of public policies, could be ascertained only on a statistical basis and after the event, with the relative costs, especially with regards to pain, that this involves. Pharmacogenetics could allow us to prevent the occurrence of these phenomena and this undoubtedly represents a benefit: the real problem is creating the right conditions to pursue this benefit, avoiding adverse reactions in terms of justice and equality in the access to medical care, or even in terms of denying access to those genotypes who, we have ascertained, cannot metabolise a certain

drug. This phenomenon could become more pronounced in the future for reasons connected to investment policies in pharmacological research by the pharmaceutical industry.

2. Stratification in fact seems to be a relevant factor for the development of new drugs aimed at specific genetic traits in serious illnesses (like tumors) and potentially, as tests become less costly and more reliable in predicting the drugs' efficacy and safety, for the entire field of pharmacological research. This trend is in itself undoubtedly beneficial, but pursuing it could be hindered by socio-economical factors and could in any case lead to unique consequences. Although this is not the place to look at this issue in more depth, it is known that in the last few years, also because of the economic scale that can be obtained, there is a concentration process in the pharmaceutical sector and in biomedical research in general, which has led to the creation of multinational colossuses with investment policies that are oriented (we say this without any negative undertones) to profit. Data shows that the profit of many companies (which also covers the costs of any research that did not have positive outcomes) derive from a relatively small number of "blockbuster" drugs, that is, drugs capable of reaching a vast population of patients. An excessive fragmentation of the market could go against the interest of pharmaceutical industry which, in order to reach the same quantity of patients, would have to develop different versions of the same drug or different drugs, with the consequent increase in costs. Even if, in literature, it is also suggested the possibility that small companies could find it convenient to concentrate on a niche in the market and that, in addition, patients could be induced to willingly pay more for a drug that is certainly efficient (other conditions being equal) and safer, costs would be prohibitive in any case and health authorities would be subjected to hardly bearable economic pressures. These are, obviously, possibilities that can currently only be hypothesised, but that should not be undervalued in order to already identify possible corrections. In the debate, two possible avenues are indicated.

3. The first is that of a larger direct involvement of the public sector in financing research, particularly with regards to fields of great interest to people's health (and potentially susceptible of lowering the costs incurred by health authorities), but not attractive to private companies. Currently the percentage of public investments in the pharmaceutical sector is around 10% of the total and it is not realistic (although desirable) to expect that this percentage will increase considerably in a reasonable amount of time. However, it can be a good base for experimenting new forms of collaboration between public and private, which in pharmacogenetics has already produced a few interesting experiences (cf. *Nature Medicine's* editorial of May 2000 titled *The need for private-public partnership*). These experiences – which involve overcoming a mutual mistrust between public and private, and entail new forms of synergy and interexchange between academic research and private research – can be developed usefully and in this direction – with regards to biotechnologies in general – is also moving the European Commission with the document *Life Sciences and Biotechnologies: A Strategy for Europe*, Brussels, 2002.

The second avenue (not alternative, but complementary to the first) consists in creating conditions in which private companies find it convenient to invest and to continue to invest in pharmacogenetics. The model is the one used to tackle the phenomenon of orphan illnesses. In the USA already exists, since 1983, the Orphan drugs Act (revised in 1994) and, in Europe, in 2000, the European Regulation on Orphan medicinal products was issued, which establishes the conditions (only partially super-imposable) in which an illness can be declared orphan and the relative drug chosen to enjoy its benefits (fiscal and of other nature: for example, the extension of the patent's validity). It is difficult to predict what changes (especially in terms of numbers) will be necessary to make to this model in order to apply it to pharmacogenetics. The model has been designed to tackle the exceptions to the current standard of research and development of drugs; if the exception, as a consequence of extensive stratification, becomes the rule, the whole system will have to be redesigned and nobody is able to predict its scope and costs.

#### *4.6. Pharmacogenetics and clinical practice*

1. Even if the situation described above is certainly not foreseeable in the near future, there is no doubt that pharmacogenetics is destined to have an increasing impact in clinical practice and in the issuing of healthcare, especially pharmacological care, where the personalisation of therapy could involve, in some cases, certain savings, not only economical but mainly of pain, in the short term as well. Certainly this impact will be realised in a very gradual manner, but it is already possible to foresee the problems it will create and therefore to study the best measures to tackle them. If we avoid the temptations of genetic determinism, such problems can be brought back to well tried principles and regulations, which only need to be perfected in order to allow a correct and fair management of these new potentialities. The most adequate starting point to identify these problems, is to understand what implications pharmacogenetics could have for doctors, patients and other potentially interested subjects.

2. The first point to stress, is that the transferral of pharmacogenetic knowledge about the single patient to an improvement of therapeutic efficacy and drug safety, presumes the availability and administration of reliable and validated tests and therefore it involves the same problems of information and consent already tackled in the general case of diagnostic tests and in particular genetic tests. As abovementioned, some scholars have highlighted that pharmacogenetic tests produce data with an information content different from that of tests for the diagnosis of genetic illnesses (also in relation to the possible psychological and social pitfalls) and therefore they could require less stringent safeguard procedures. We can also see that there are distinctions to be made with regards to the tests' targets: one thing are tests conducted on mutated DNA in tumoral tissues (as in the case of administering Herceptin, which is expressly indicated only for tumors that present a specific somatic mutation); a different thing is the analysis of the patient's genotype, even for just pharmacogenetic aims. Apart from the already mentioned fact that such tests can directly or indirectly lead to "secondary information", it should be maintained

that – also because of the sensitive character of genetic information and of the current common perception of hereditary phenomena – caution suggests to maintain, for pharmacogenetic tests on patients, the same standards currently applied to other genetic tests, especially in relation to the quality of information to be given. In any case, the speed and extension with which pharmacogenetics will be integrated in clinical practice depends on many factors, partially economic (we will discuss it later), partially educative and cultural. Many investigations highlight, for example, the gaps in medical training with regards to the entire genetic field and it is therefore clear that the topic, abovementioned, of the promotion of training and information will be crucial to turning these new instruments into clinical practice. However, as it is unrealistic to think that every doctor will become an expert in the administration and interpretation of pharmacogenetic tests, it will be important to think about territorial structures as points of reference: and anyway the integration of pharmacogenetics in routine clinical practice will require the availability of “user-friendly” technologies, easily carried out, therefore creating the problem (discussed later) of the direct access to the consumer, without the mediation of a health professional.

Even hypothesising the rosiest outcome, the substantial help that pharmacogenetics will be able to give doctors and patients involves problems that must be reflected upon.

3. As we have recalled, currently – and apart from special cases like Herceptin and a few other drugs recently produced – regulating authorities do not require, if not on a voluntary basis, pharmacogenetic information as part of the documentation to obtain the authorisation to market a drug and, therefore, the genetic profile is not part of the treatment instructions. It is plausible to think that this situation will change quite quickly, even if gradually, and this poses questions that are the object of debate. Professional ethics forces doctors to give patients the best treatment available for their illness and without a doubt pharmacogenetics is destined to change something in the standard procedure through which choices have been made up until now. Will the doctor be able to prescribe a drug specifically targeted at a certain genotype, if the patient refuses to undergo the test? And how can we evaluate the case in which the test result only allows a probabilistic interpretation with regards to the efficacy and/or safety? What can be considered an acceptable risk boundary, also in consideration of the fact that the drug could be the only available one for that illness? In literature the answers to these and other questions are very variable, but there is agreement in believing that these are not new questions and that, therefore, the answers can be found through a patient analysis of each single situation in the light of existing principles and regulations.

4. We must also consider the fact that, as has already happened for many diagnostic tests and as it is also happening for genetic tests, the availability of “user-friendly” pharmacogenetic tests could increment the direct marketing of the tests to the consumer (and internet sites already exist). There is a general tendency to discourage the self-administration of genetic tests, but is it not at all clear what control instruments could be set up to manage this phenomenon, also because it is not sure that, at least in certain situation, a patient who demands direct access, that is, with-

out the doctor's mediation, to tests could not also advance some argument in support of his/her demand. For example, in a care system based on private insurance, the mere fact of undergoing a pharmacogenetic test could attract the insurance company's attention on the individual. To avoid losing the advantages of better drug efficacy and safety, an individual could therefore use pharmacogenetic tests directly. Always with regards to direct marketing, we must also remember that, potentially, pharmacogenetic tests can expand beyond the medical field. We can hypothesise, for example, that they can be useful in setting up a dietary regime, or a regime of nutritional supplements etc.: all of this would without a doubt create a push for the market, which someone could exploit.

5. Leaving behind all these possible situations and focusing on the medical field, we can conclude that, all considered, pharmacogenetics represents a positive prospect for the doctor and the patient. We can also add that it represents an interesting prospect also for society as a whole and for health authorities, because – after the initial phase in which considerable investment is required – a more efficient and safe administration of drugs can lead to substantial savings. The cost of “wasted” drugs and the cost of treating adverse reactions to drugs are quite high (DATI) and the hope is that pharmacogenetics will have an effect on them. At this level, however – and always in the hypothesis of a widespread integration of pharmacogenetics in clinical practice – there could be problems (also not new) with the rationality of the allocation of scarce, or in any case limited, resources destined to healthcare: these are problems that have different scopes according to whether we are considering public, private or mixed health systems. If – as we hypothesise – future generations of drugs will have a pharmacogenetic basis and, therefore, the instructions for administration will require a test to identify the patients they can be administered to, health authorities could elaborate regulations that, having to answer to the overall logic of health economy, could be in conflict with the individual's interests. For example, a health authority could decide to allocate a very expensive drug only to patients qualified as “fully responsive” and to deny it to “little responsive” patients: the decision could be easily founded on common pharmaco-economic principles which, although trying – and this is the shared hope – to integrate equity considerations in the access to medical care, is strongly limited by aggregative macro-economic approaches, which are not sensitive to the individual distribution of benefits. But – as we were saying – this is not a topic specific of pharmacogenetic, even if it could be exacerbated as a consequence of a heavy integration of pharmacogenetics in healthcare.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**ETHICS, HEALTH AND NEW INFORMATION TECHNOLOGIES**

21<sup>st</sup> of April 2006



## PRESENTATION

The new information technologies constitute and metaphorically make up a territory that by now seems, *wrongly*, familiar, whilst it is still not only largely unexplored, but mostly undefined in its real boundaries. If it is true that communication represents the horizon of experience that more than any other marks post-modernity and if it is true that the *network* today is the essential core of global communication, it is also true that the potential of this method of communication still seems (aside from all the technical and operative implications) epistemologically ambiguous. The network, in fact, does not only multiply, almost indefinitely, the possibility of communication, but it alters its *quality* and probably its identity. And therefore, consequently, we start to perceive how human identity itself is altered, according to dynamics that only few are, today, able to foresee, but that already reveal themselves to be highly incisive. From this point of view, it is easy to understand how even medicine is challenged by the new information technologies and how it inevitably suffers, because of them, *pressure* capable of changing its essence. It is enough to justify the bioethical interest on the issue that is the object of reflection by the *National Bioethics Committee* and that already gives substance to the document presented here.

It is thanks to Prof. Adriano Bompiani that, during the plenary meeting of the 23<sup>rd</sup> of April 2004, agreements were collected to start a Working Group aimed at elaborating a document to study in more depth the bioethical aspects of the use of the internet in the medical-healthcare sector. When creating the Working Group, the Committee unanimously asked Prof. Bompiani to become its moderator.

The relevance of this topic explains the significant number of Committee members who decided to take part in the Group's work: Prof. Amato, Prof. Battaglia, Prof. Binetti, Prof. Borgia, Prof. Caporale, Prof. Coghi, Prof. Marini, Prof. Neri and Prof. Umani Ronchi. Prof. Eusebi also actively intervened in later meetings. The Group, which met altogether eight times, worked from the 17<sup>th</sup> of June 2004 to the 16<sup>th</sup> of March 2006, using also the contribution of "experts", who generously answered our invitation to collaborate positively. They are: Dr. Giovanni Buttarelli, General Secretary of the Privacy Guarantor Authority, Prof. Angelo Serio, professor of statistics and healthcare information technology at "La Sapienza" University of Rome; Dr. Eugenio Santorio, Responsible for the Laboratory of Healthcare Information technology at the Institute for Pharmacological Research "Mario Negri" in Milan; Dr. Paola Mosconi, Responsible for the Research Laboratory on Citizens' Involvement in Healthcare at the "Mario Negri" Institute; Dr. Giovanni Alopone, Responsible for the Oncology Transactional and Outcome Research Laboratory, at the same Institute; Dr. Maurizio Bonati, Responsible for the Laboratory for Maternal and Infant Health, also at the "Mario Negri" Institute in Milan and finally Col. Umberto Rapetto, Commander of the *Nucleo speciale frodi telematiche* part of the Guardia di Finanza. The draft of the document, written by Prof. Bompiani, Prof. Amato and in particular Prof. Marini, was then presented to the attention of the Committee gathered in plenary meeting, which, after in depth discussion, approved it unanimously in the Plenary meeting of the 21<sup>st</sup> of April 2006.

As highlighted in the same document, the NBC text follows the initiatives of other supranational bodies that elaborated similar documents on this issue, which have been the object of careful evaluation by the Committee. Here we must recall in particular:

*The European Group on ethics in sciences and new technologies* operating as part of

the European Commission (EGE), which, on the 30<sup>th</sup> of July 1999 issued an *Avis* titled *Ethical Issues of the Use of Personal Health Data in the Information Society*;

The Council of Europe (C.E.) that, after promoting the *Convention on Information and Legal Cooperation concerning the "Information Society Services"*, produced further materials, amongst which we must mention those destined more specifically to the healthcare sector and in particular the two *Recommendations* of the Committee of Ministers to Member States, the R(97)5 relative to the protection of medical data and the R(99)5, on the protection of privacy when using the Internet;

The Recommendation Project by the CDSP, European Health Committee which should – if approved by the Committee of Ministers – regulate the impact of informatics in the healthcare sector, with particular attention to the use of the Internet (SP-IMP/TECH).

Although we don't presume to have carried out this task without oversights, but being aware of its quality, the *National Bioethics Committee* recommends reading this document to the public, not only bioethicists, and more in general to all those who are interested in the newer and more urgent healthcare issues, but also to those who know well how urgent it is by now to seriously question ourselves about the boundaries of the *post-human*.

*President of the National Bioethics Committee*  
*Prof. Francesco D'Agostino*

## CHAPTER I: GENERAL OUTLINES OF MEDICAL INFORMATICS

### 1. Premise

The concepts of information and communication have general anthropological characteristics in each human activity, and particular characteristics in each activity considered. Information and communication today enjoy instruments that have multiplied a great deal the possibilities of increasing, storing, analysing, disseminating, etc. the information available, therefore multiplying the ability to communicate. So, information technology is born, which is a specialised human activity that elaborates models, creates systems and finally operates with appropriate tools in the information sector.

In this document we will examine some aspects of the application of informatics to medicine.

Governments and healthcare organisations believe that the spreading of information technology can improve patients' safety, guide clinical choices and eliminate at least some of the imbalances existing in the distribution and fruition of healthcare services. These are "positive", bioethically relevant objectives; however internet communication (which today is the most common method – but not the only one – of informatics communication) in pursuing these objectives can be the source of danger/harm for the user, like any other system of information can be, after all, when used inappropriately.

From this dual point of view, the issue also interested the NBC, which believed it was appropriate to examine the various aspects of the dissemination of informatics communication in today's society, in view of the right to the protection of health, seen – as known – as a human right.

This analysis will tackle, after having looked briefly at "medical informatics", especially "internet communication", which has a particular role in the use of informatics also in the healthcare sector and for health protection, in the widest sense of the term.

Coherently with the aims and the style adopted in previous NBC documents, this work also wants to present public opinion a series of information and reflections on the use of this widespread means of communication in the healthcare sector, in a clear and informative way.

In particular, we will focus on the ethico-legal aspects of the correct use of the internet, highlighting not only the positive features, but also the risks of an irresponsible use.

#### 1.1 *Some definitions*

Not focusing, at the moment, on broader reflections regarding the stated autonomy of medical informatics as a discipline, it seems appropriate to recall – however – the definition of medical informatics that does not seem – reductively – to refer to the mere (instrumental) use of calculators in medicine.

##### Definitions

This cultural and operative area, according to the World Health Organisation, must in fact be intended as all the applications of the appropriate methods and techniques to the sciences of information, computerisation, network organisation and communication with the objective of supporting healthcare and the disciplines concerning it, like medicine, dentistry, nursing sciences, pharmacy, etc. (Power, 1999).

An equivalent, shorter, definition is that of Talmon and Hasman:

Medical informatics can be defined as the discipline concerned with the systematic processing of data, information and knowledge in the cultural field of medicine through appropriate technical means.

Its “domain” extends to the computational and informational aspects of the processes involved in medicine and healthcare.

It has a dual use:

- a) giving solutions to problems connected to data processing, information and knowledge, produced by medical “procedures”;
- b) studying the general principles applied to this processing (Talmon and Hasman, 2002).

According to this perspective, medicine involves activities that can be broken down into their individual processes (biological, communicative, decisional, educational/formative, organisational, computational, etc.) and in each of them informatics can intervene with appropriate models and algorithms.

For the concept of processing, it is better to use the broad definition found in the recent “Personal data protection code” (enabling Act No. 127/2001), which states:

*processing shall mean any operation, or set of operations, carried out with or without the help of electronic or automated means, concerning the collection, recording, organisation, keeping, interrogation, elaboration, modification, selection, retrieval, comparison, utilisation, interconnection, blocking, communication, dissemination, erasure and destruction of data, whether the latter are contained or not in a data bank.*

According to some, the numerous fields of intervention – indicated by the Italian legislation but fully in line with international Regulations – would make medical informatics a transversal “medical” (or at least biomedical-healthcare) discipline, whilst according to others medical informatics remains closer to “engineering”, “ontologically”, than to medical sciences (Shahar, 2002). In any case, it must be considered at least as inter-disciplinary.

According to Schortliffe, 2001, medical informatics as a discipline concerns not only the treatment and use of biomedical information, but also the study of the “nature” of medical information, and this is a task that (at least today) we assign to medical epistemology.

### ***1.3. A general illustration of the current applications of medical-health informatics***

Abandoning, at the moment, this area of reflection, we will now try, in a preliminary and certainly not exhaustive way, to make a list of the currently more widespread applications of medical informatics.

This immediately demands some clarifications:

Medical informatics:

- concerns all citizens, in general, but more directly (according to the programmes activated) healthcare administrators, healthcare personnel at any level, biomedical researchers, teachers and students in training courses, patients, etc.
- its main objectives are the participation to programmes of:
  1. Health protection and treatment of illness
  2. Management of healthcare systems
  3. Facilitation of biomedical research.

This broad presence of informatics in healthcare can be found, necessarily, with those “sensitive data” that, according to their definition are, with regards to medicine, in partic-

ular “personal data able to reveal health and sex life”, but more in general also those classified as sensitive but not medical, which, in the exercise of the profession, can become known to the doctor (e.g. racial and ethnical origin, religious, philosophical, or other kinds of beliefs, etc.).

Finally, we must clarify that medical informatics concerns most of all, but not exclusively, “personal data of the individual”, but can involve also eventually “sensitive” information regarding other forms in which the legal concept of person is expressed. In the already mentioned Code, they are indicated as data regarding “Any information relating to natural or legal persons, bodies or associations that are or can be identified, even indirectly, by reference to any other information, including a personal identification number”.

Concluding this preliminary information, we will say that what characterises this cultural and operative sector, from an ethical point of view, is the ethically correct use of information.

We therefore arrive to that definition of medical informatics that is more restrictive – in a way – but appropriately finalised to this aspect, given by the Manchester University Medical Information Working Group: “*medical informatics involves a responsible use of information in support to healthcare*”.

This is the definition that – beyond the recurrent discussions about the epistemological and disciplinary autonomy of informatics and of medical informatics in particular – interests the doctor as any citizen and any patient, because it highlights a responsible and finalised use of informatics, as a group of methodologies, algorithms and instruments that process data and information in support of those particular models of relations between individuals that are health, illness and the organisation of healthcare.

#### ***1.4. Opportunities and difficulties in the development of health informatics; the arrival of the internet***

An Opinion (surprising, from a certain point of view) has been expressed that the Information and Communication industry in general is sceptic about the profitability of the healthcare market, seen as hospital and basic medicine IT systems do not operate for profit, and doctors tend to use computers – especially personal ones – more for memorising their patients’ personal data than for a necessary and quality support to their daily work through “expert systems”, etc.

On the other hand, what has been stated by Musen (2001) is just as true, namely, that modern software systems have become so complex that they demand personnel, resources and economic support capabilities that only profit-making, large-scale software engineering organisations can guarantee.

It must be recognised that medical informatics is particularly complex, as the analysis of its components, the memorisation and the processing of the elements that constitute it, have a series of highly hierarchical levels, if we want to achieve a high and correct clinical use (BLOIS, 1984), levels that require particularly expert personnel. However, there has been progress since the time Blois expressed these views.

Interesting applications for the integral, multimedia memorisation of the data, have since been acquired as part of the intra-hospital’s management of the patient, so that the possibility of elaborating information on various lines of research becomes increasingly

more concrete and current: e.g. according to nosography (Weed, 1968, 1971); symptomatology (Aranda, 1974); therapeutic choices (e.g. Acheson, 1972; Ferri, 1995, etc.).

The development of these large intra-hospital “archives” will certainly allow positive progress in epidemiological research, but also contribute to the analysis of the efficacy-efficiency of the patient’s treatment (Ferri et al. 1998; Staccini et al. 1999, etc.), an argument that today is at the centre of the debate on the organisation of healthcare.

Currently, the more extensive and detailed support of the user’s requests/needs (doctor and patient) in the context of the policy of health is seen as the most important development opportunity for medical informatics; in addition, we identify outlines of development in the fact that informatics is increasingly integrated with the processes of molecular medicine as they are clarified, becoming not only support systems, but also new fields of research for biologists and clinical doctors (Kulikoski, 2002).

The “tout court” challenge of informatics – as a specific field of research – would be to identify organisational and application principles in support of the different disciplines that intervene in the knowledge of health and of relative promotional behaviours, in order to develop specific systems to follow the various problems at the different levels and help resolve them: consequently we move, for some, from the concept of medical informatics to that of “healthcare informatics”, which would better express this complexity and broadness of applicative horizons.

## CHAPTER II: THE POTENTIAL OF THE INTERNET IN THE HEALTHCARE SECTOR

### 2.1. The specificity of internet communication

We must recognise that the progress of the last few decades in the informatics sector have allowed the manifestation of a growing trend of using electronic technologies in the “exchange” of information between people. The exchange of information regards in practice any sector of associative life and it contributes to the so-called “globalisation process” of society.

An optimistic attitude has appeared towards the tumultuous development of the internet, in the context of which “healthcare information”, exchanged with the public by those responsible for the healthcare system at different levels, also partially happens.

The advent of the Internet, a system based on the interconnection of numerous (and heterogeneous) communication networks, created for military research projects in the 60s and immediately welcomed as an easy means of communication amongst a restricted “network” of university researchers, in a few years has demonstrated such usefulness that it has extended to any sphere of worldwide communication.

According to G. Gottardi (2003) “*From a technical point of view the internet can be defined as all the technologies and solutions that allow the interconnection and exchange of data between computers. Its importance however is in the applications that it is able to hold. (...) The total freedom of access, without ties and technical mediations, at virtually no cost, and the continuous improvement of its performance has led to a growth in the infrastructure and in the number of users to levels unimaginable until a few years ago.*

*Currently, the growth is linked especially to the increase of business applications that the network is able to support”.*

The growing success recorded in the dissemination of the services offered by the internet is in fact due to factors that are quite simple and appreciated by the users: the substantial simplicity of the technology (limited volume of the appliances, limited cost of purchase and use, the possibility of connecting through the usual phone lines or consolidated systems of communication like ADSL, etc.), the possibility of learning to use it with relative ease already as teenagers, the widespread network connection, which opens direct and specific possibilities of dialogue between individuals that were unseen until now; the ease with which, from home and without having to face the convulsive rhythms of the metropolis, we can carry out many operations of daily life, finance and even culture.

The *freedom of expression*, according to some sociologists, is the main success factor of the internet, because it allows the open communication of our ideas and feelings, (anonymously, if we want), directed to “global” interlocutors, even far and unknown, who come into contact with the communicator.

There are some authoritative monographs illustrating these phenomena in detail, but they also offer different opinions in their interpretation. On the one hand the value of the INTERNET as a “cult of the freedom of expression” is highlighted – focusing on the personality of the individual who presents him/herself to an international audience – with a freedom that provoked, in some contexts, also the “maniacal cult” of the INTERNET (on which focused Theodor Roszak, 1986; A. Matterlart, 1999; PH. Breton, 2000; Kimberly Young, 2000, and others), interpreting the Internet almost as a new religion of existence. On

the other hand, are highlighted the risks for the more normal and traditional associative life, based on personal encounters, where, as well as the ideas expressed we value the words, the looks, the movements, etc., all means of communication that – it has been said (PH. Breton, 2000) – are even repugnant to the obsessive “surfer”, sunk in loneliness.

The NBC does not mean, with this document, to focus on these phenomena – which are certainly also deserving of ethical consideration – but it chooses to reflect on a more common use of web communication, namely, a “*useful tool*” to pursue individual interests, and amongst them we must mention “health protection”, which so much occupies and/or preoccupies people, especially in mature societies.

## 2.2. A general look at the dissemination of websites and the reasons for the growing use of the internet in healthcare

The Censis-Forum for biomedical research placed, in 2001, an estimate by JUPITER et al (2000) of the foreseeable number of European “internauts” at around 129 millions in 2002 (equal to 34.3% of the population). The Italian Internet observatory estimated 10 million internauts at the end of 2000 (18% of the population), and the CENSIS-FORUM estimated them at 20 millions in 2005 (equal to 42.7% of the adult population).

In a few years, there has been a considerable increase in the questions regarding health in the information transmitted via the Internet, and in the same way the offer of health services by doctors, healthcare organisations, etc. has increased (Wyatt, 1997; Jadad and Gagliardi, 1989, etc.) especially in countries with a free healthcare market.

It has been estimated that the number of websites that – on the planet – offer healthcare information, already in 1999 was 100,000 (Eysenbach G. and Diepgen data, 1999), number agreed upon by a communication of the European Commission in November 2002.

The HEALTH on the NET FOUNDATION in 2003 estimated that 35% of European users were patients searching for medical-healthcare information, and the CENSIS-FORUM RBM estimated at 4 millions the Italians searching for healthcare information on the web (26% of the total users in 2005).

When it concerns critical pathologies, these numbers are even higher, as shown by a 2003 research estimating that 39% of the cancer patients directly researched information on the Internet, along with another 15%-20% of patients for whom this research was carried out by third parties, generally family or friends (Eysenbach Ca Cancer J Clin, 2003).

Without prejudice for the accuracy and the revision of the numbers, the breadth of the phenomenon allows the creation of the concept of “web as medical-healthcare consultant”.

The reasons of this growing interest can be listed as follows (CENSIS-FORUM, 2001):

*The easy and immediate access* to a practically unlimited source of information;

- *the possibility of comparing different versions and points of view* on the same topic (the growing request for a second opinion);
- *the possibility of surfing through levels of differentiated in depth studies*, according to personal needs;
- *the possibility of reaching niches of the market* which are, for various reasons, difficult to access, in order to know, compare or simply test the market;
- *the possibility of contacting bodies*, associations or people in various ways involved in the topic of interest, able to redirect the user’s choices and opinions.

Sociological investigation allows distinguishing the interest of the consumer from that of the healthcare manager as follows:

From the consumer's point of view:

- the Internet offers, indubitably, many facilitations in accessing medical and healthcare information, and it contributes to “equal opportunities” between citizens and the “ubiquity” of information, which crosses frontiers. It can act, therefore, as an increment to the freedom of choice.

There are, in addition, advantages also from the point of view of the healthcare organisation.

Correlated to precise territorial areas; information via the Internet is useful in finding available services, what is on offer on the market, and – if the descriptions are correct – supplies knowledge of waiting times and booking methods, and anything else that can be useful to the user.

From the point of view of the healthcare administrator:

- In general, healthcare administrators are in favour of the dissemination of health information in particular sectors, because information meets expectations positively and supports the citizens' healthcare education by those responsible for care institutions. In fact, through the Internet we can achieve a capillary dissemination of the notion of healthcare prevention, vaccinations, diagnostic tests, etc., aimed at large and indeterminate strata of the population using the web. Also it supports information on the services offered.

In conclusion, the Internet can contribute to the maintenance and increase of the level of individual health, promoting as much as possible personal autonomy and strengthening the right to health protection.

### 2.3. Assessing the quality of information

There are many websites that are structured in a variety of ways according to the finality pursued also in the health sector.

Naturally, this immediately poses the question of the “quality” of information transmitted through this tool of information/ production/distribution.

As rightly stated by C. Prins and M. Schellekens (2004), looking at the rapid increase in the number of messages (information) and users following the years after the 1999 evaluation, we must harbour the founded doubt of whether the information coming from such an extensive tool is always correct, complete and legitimate.

These Authors highlight the frequent lack of clear details about the source, name, address and credentials of the “provider” supplying the information, and about who compiled it, the date and the constant updating of it, the procedures and criteria adopted to select it.

Studies carried out in various medical sectors, in addition, highlight how scientific information supplied by medical websites is often lacking (Eysenbach et al, 2002), even arriving at suggesting remedies that are not coherent with the main international guidelines in tackling simple situations like managing a child's cough (Pandolfini et al, 2000) and temperature (Impicciatore et al, 1997).

Assessing the “quality” of healthcare information represents the first problem at the centre of most of the NBC's bioethical reflection.

As well as the observations, regarding this, found in literature, documenting its incompleteness in particular cases, a further in depth study can come from investigating the “guidelines” by international organisations, regarding the deontology of those operating through the internet, which all recommend accurate information.

The methods to measure and guarantee the quality of the medical information put on the web, develop following three outlines (E. Santoro of the “Mario Negri” Institute 2001): a) the use of self-regulation codes (or guidelines) by those creating the site, b) the use of control services through reviews/revisions of the sites, c) the adoption of PICS (Platform for Internet Content Selection) to describe the content of the sites.

Self-regulation codes comprise a number of principles that, although they do not evaluate a site, give rules that allow the assessment of its reliability and accuracy.

The first self-regulation code suggested by the scientific community is that developed in 1997 by the main international biomedical journals (International Committee of Medical Journal Editors JAMA, 1997).

This code identifies as reliable those sites that require the following information: the author’s name, his/her credentials and the declaration of eventual conflicts of interest, the organisation he/she belongs to, the editor’s name, the bibliography used, information about the ownership and copyright of the site, date and modification of the document.

The HON code (called HON code and proposed in 1997 by the Health on the Net Foundation) includes many criteria indentified by the International Committee of Medical Journal Editors and it is the system of self-certification (which in the last few years has become a system of certification that the owners of the sites require and that the organisation gives only after verifying that the criteria are followed correctly – verification that is carried out annually) which is most used today (<http://www.hon.ch/HONcode/Conduct.html>). With regards to the previously illustrated code, the HON code also guarantees a verification support of the certification that the user can eventually use.

The principles suggested by these codes can be used also as guidelines by citizens, to assess the reliability and accuracy of a site, even though this does not have any self-certification system. It is on the basis of these considerations, that in recent years the development of useful tools for this purpose has proliferated, increasingly aimed at the consumer/citizen. Amongst the better known ones, it is possible to mention the DISCERN project (<http://www.discern.org.uk>) by the Oxford University and, in Italy, the tool “Misurasiti” in the portal “Partecipasalute”.

There can be two types of services reviewing/revisioning medical sites:

- general services, comprising known research engines like Google, which cover a wide range of topics, with selection and assessment criteria that are in general quite vague.
- specialist services (amongst the Italian examples we can cite the tools developed by the Institute for Pharmacological Research “Mario Negri” called ONCO.CARE – <http://www.omcocre.it> – and CARDIO.CARE – <http://www.cardiocare.it>) which give formal criteria and precise rules in the selection and assessment of the medical resources to bring to the citizens’ attention.

There are also “rating” systems expressing the quality with a number (Star System) between 0 and 5, established by an Editorial Committee on the basis of elements like reliability, completeness of information, use of multimedia, public access typology.

The PICS labels, created at the end of the 1990s to filter information on the network, have then been suggested to select medical resources on the internet. The labels, compiled

according to certain criteria of guarantee, indicate whether and which documents to access. The European Union funded, between 2000 and 2003, research projects on the applicability of these systems to websites containing healthcare information. Amongst the most interesting projects we can mention MedCERTAIN (<http://www.medcertain.org>) and MedCIRCLE (<http://www.medicircle.org>), which studied and implemented a vocabulary called HIDDEL vocabulary (“Health Information Disclosure, Description and Evaluation Language”) based on the MedPICS system (“Medical Platform for Internet Content Selection), an extension of PICS. However, these systems are still in the experimental phase and have never found, even in recent years, a solid application.

Despite these efforts, it seems evident that – currently – many websites do not offer sufficient guarantee of “transparency”, as the adoption of certification criteria is still limited.

Recently, C.PRINS and M. SCHELLENS (2004) wondered what legal aspects are taken into account in the initiatives of full “transparency”: they risk becoming a source of complaint and compensation requests by those who expose themselves on the internet by name, whilst this does not happen to those who maintain their anonymity.

If this interpretation is true, we understand (although it cannot be justified from the point of view of the “consumer”) the lack of support for the “guidelines”.

#### 2.4. Risks of the improper use of the internet in clinical medicine

But, as known, the exercise of clinical medicine itself, aimed at the individual, can be changed by the use of the internet, which allows the patient to consult the doctor “from a distance” and this fact can be the source of advantages (at least in some circumstances) if the individual who is (clinically) well known to the trusted doctor, but it can be the source of serious problems if the individual is unknown, or has symptoms that can be necessarily interpreted only with a clinical examination.

Some investigations tried to identify the reasons for the citizens’ growing interest in healthcare communication via the internet, attributing it to the dissatisfaction they still feel after talking to the doctor “face to face” (Spielberg, 1997/1998), to being less uneasy and more open in the way they express themselves anonymously via the internet due to the nature and the method of posing the questions (Borowitz and Wyatt, 1998); to the desire of having a second opinion (also from unknown doctors) about their ailments (Eysenbach G., Diepgen, 1999), without their GP knowing, etc.

It seems difficult to establish how frequent these “motives” are, but the fact that they have been mentioned invites doctors to take them into account, in order to stimulate a “friendly”, “empathic” and non-paternalistic behaviour towards the patient, in line with the well known and widespread bioethical principle of the correct “therapeutic alliance”.

Concluding these quick observations, it must be highlighted that many authors focused on the opportunities offered by the internet for the protection of health, amongst which we mention M.D.C. Roscam Abbing (2000), C. Prins and M. Schellens (2004) – members of authoritative International Organisations – who however did not hesitate to warn against the problems of its use, which are due, at least in part – to the lack of (or just started) development of the quality criteria for the management of health websites. The field of “marketing”, which appears to become increasingly important (through, for example, the offer of “DIY” tests for the HIV infection (Roscam – Abbing, 2000), but the same problem can be

seen for some genetic tests) cannot fail to raise apprehension, if it's not balanced by a great "transparency" on the origin of the information and the "reliability" on the indications (scientific and/or practical, behavioural etc.) suggested on the internet.

The growing request to receive information via the internet about the illnesses and care strategies contested in many countries, involves the increase of the responses on the net, which must be scientifically accurate and appropriate, to avoid risks of harm or even harm due to inaccurate information. This, which is a general problem of communication, tackled also by civil law both theoretically and practically (see for example Businelli, 1997), has a growing relevance from the point of view of public healthcare. In fact, it has been noted for some time that the number of consumers ("internet surfers") who believe they can find direct answers to their health problems on the internet, without medical help, is rapidly increasing (Ferguson, 1998); therefore, it seems appropriate for the healthcare authority to be vigilant, so that the information given to the patients is adequate and leads to a choice that is not shaped by commercial speculation, which can be harmful to health. But most of all it is considered inappropriate for the profession (and a source of risk both for the patient and for the organised healthcare structure) that some doctors can derive evident financial gain from this kind of communication with patients they do not know directly (see Ferguson, 1998), they have never examined and have contacted outside of the rules codified by their profession.

Scientific societies should also collaborate towards the objective, cited by many, to protect the quality of information and the professional orders by being vigilant of marketing behaviours. However, it is still to be established with which chances of success, in sectors where business competition with regards to offer is very open and anonymity is allowed. In conclusion, we believe that the screening and validation process of medical information (contents, presentation methods and sources) and healthcare marketing still require considerable reflection in its social and technical aspects (Morris et 1997; Brown et al. 2000, etc.), and these points will be discussed more in depth later, in the following part of the text, from a legal point of view.

Finally, it has been mentioned, more than once – in literature – not only the extreme dishomogeneity in the quality of information, but also the uncertainty in the protection of privacy (Jadad, 1998, 1999; Eysenbach and Diepgen, 1998; Silber et al.; Federal Trade Commission, etc.).

We must appreciate the initiative of the American Medical Informatics Association, aimed at developing guidelines for the use of internet information, and the adoption of them by the Association's websites (AMIA), guidelines that are proposed also by other independent "providers" (not linked to the Association: Winker et al., 2000). Also appreciated is the initiative of the same American Medical Informatics Association, which has developed guidelines (immediately adopted by the American Medical Association) regulating the doctor-patient relationship in case electronic mail is used (Kane et al J Am Med Inform Assoc, 1998).

## 2.5. The situation in Italy

Although not many investigations have been carried out so far, the situation in Italy does not seem to be very different from the general situation just illustrated.

A recent CENSIS-FORUM R.B.M. (2005) study classifies as follows a sample of 190 sites on the basis of their founding characteristics and the services on offer:

Institutional sites – created by individuals who work in Italy in the organisation and management of healthcare policies and by bodies representing healthcare institutions (26.30%).

Pharmaceutical industry sites: sites of companies producing and/or marketing medicines in Italy (22.60%).

Patients' Associations sites: they collect the requests/interests of the individuals affected by definite pathologies (26.80%).

Wide-ranging sites: involved, regardless of the nature of the individual, in the dissemination of information in the health sector (24.20%).

The institutional sites in Italy are mostly those managed by organisations like the Istituto Superiore di Sanita', the Ministry of Health, the Italian Medicines Agency, Regional Healthcare Services Agencies, medical-scientific societies and Italian universities.

Amongst international sites, particularly qualified are those of the European Medicines Agency (EMA), which comprises the Council of Europe, the WHO, where we can find information about the cure and prevention of main illnesses, the American National Institutes of Health (NIH), one of the main American medical organisations, the National Library of Medicine (NLM), responsible for the development of databases like Medline and PubMed and systems of healthcare information distribution to the public like MedlinePlus, that of the Food and Drug Administration (FDA), the authority responsible for the registration of drugs in the United States, and that of the Centres for Disease Control and Prevention, the American centre responsible for the prevention and control of illnesses.

Pharmaceutical industry sites generally offer different information for three categories of users (doctors, patients, journalists).

Patients' Associations sites are generally reliable, easy to use and often equipped with tools that allow patients to talk to each other.

Wide-ranging sites, although not active in the healthcare world, give information relative to health. This is a very broad category of sites offering different types of information: "encyclopaedic" (through medical dictionaries and health manuals), scientific by giving appropriate "lists" of data found in medical journals, "legal" offering useful information for legal questions linked to health.

With regards to the direction of the information supplied on medical sites, the Censis-Forum RBM 2005 investigation offers the following outline:

1) Updated information on healthcare issues	76 %
With reference to authoritative sources	72 %
With the chance of further study and support	62%
2) References and codes of conduct for the protection of privacy	19 %
3) Business marketing in the health/healthcare sector	18 %
4) Initiatives of social interest	13 %
5) Explicit references to ethical implications and issues	8 %
6) Offer of on-line psychological advice	5%

With regards to the "consumption" of information, in Italy (Censis-Eurisko 2005 data) 26% of research carried out on the web involves issues linked to health and well-being, and this could suggest a slightly lower percentage than the European trend, estimated at 35% of

users by the Health On The Net Foundation (2003). This last research also highlights that these users search especially for information and more in depth studies on illnesses and, even though they are not doctors, they most frequently use specialist sites (70%).

64% of the content of the information, for what can be derived from Censis data, regards research and Congresses, 43% information on specific pathologies, 42% communications between doctors or patients, 28% pharmacotherapy, 25% prevention.

In Italy, the Institute for Pharmacological Research “Mario Negri”, within the research project “*PartecipaSalute - Costruire un’alleanza strategica tra associazioni di pazienti& cittadini e comunità medico scientifica*” – tackled, on the project’s site (<http://www.partecipasalute.it>), the issue of the quality of the sites dealing with health issues. In particular, on the site, on the basis of some assessment tools already existing in literature, the reader is presented with a self-assessment grid to establish the quality, accuracy and updating of the information on the net (<http://www.partecipasalute.it/informati-bene/misura-siti.php>). The grid is regularly applied to medical and health sites, selected and collected under the heading “Good site of the week”.

The 10 questions on which “Misurasiti” is based are:

1. Are the authors of the content named?
2. Are the sources of the information indicated?
3. Is there a date for the updating of the content?
4. Is it clear who the site “belongs” to?
5. Are eventual sponsors mentioned?
6. How is advertising presented? Is it separated from the rest of the content?
7. Are eventual conflicts of interest declared?
8. Are the site’s objectives clear?
9. Does the site give details on other sources of information?
10. Does the site help the user to make in choices and decisions regarding his/her health?

On the basis of previous experience, within the research project “Internet as a tool of research and information on chronic pain in the cancer patient” there is an adaptation of the methods and tools of “Evidence Based Medicine” to the resources available on the internet on the issue of chronic pain in cancer patients. The project is taking shape through a collection of qualitative-quantitative data to apply to internet resources and to therefore assess the results obtained.

The CENSIS-FORUM R.B.M. (2005) investigation also proposes four parameters that could be used to build an assessment “model” for the quality of the site, with relative overall point index, that is:

- Reliability of information.
- Ease of use (the ease with which the users gain the required information).
- Variety of the content presented on the website.
- Genericity (level of the answers).

In the Italian situation, as examined by this investigation and on the basis of an index from 0 to 20, we would have the following votes:

Site classification	Parameters			
	Reliability	Ease of use	Variety of content	Genericity
Istitutional	11,6	11,4	9,1	5,3
Pharmaceutical industry	10,0	9,6	5,5	5,6
Patient's associations	12,0	9,4	9,8	4,2
Wide-ranging	10,4	9,5	9,0	6,3
Overall average index	11,1	10,0	8,5	5,3

The investigation allowed the verification of: a) a considerable variety of content; b) the good quality, in general, of medical-healthcare information on Italian websites, from the point of view of their reliability, and of the ease of use; c) the reduced variety that can be found on the sites managed by the industry due to the higher specialisation of the content; d) the higher “genericity” of the information given by generalist sites and the lower “genericity” of the information given by patients’ associations (especially for specific pathologies).

Certainly, the values of the genericity index (around 5-6 out of 20) highlight the fact that there still are a certain number of sites that do not give very in depth information, without any reference to authoritative sources, which do not explain their title and aims or guarantee privacy.

The investigation has also verified that the certification given by the Health On The Net Foundation is declared only on 7.4% of the sites in the Countries taken into account, whilst only the 19.5% of them explain their privacy policy to the user and guarantee that the data relative to research or issues explored by the users will not be disseminated (76.8%).

## 2.6 Conclusions

Waiting to develop wider bioethical reflections at the end of this discussion, it seems appropriate to reach a first conclusion: the negative implication of the abovementioned genericity is even worse if it appears on sites that also cover pathology, as the presence of unreliable or not updated information for those users who are not doctors can worsen the user’s emotive state, who does not find what he/she needs in the doctor-patient communication and can turn to wrong or inadequate behaviours.

There are here two points of considerable bioethical relevance: the need to guarantee the quality of information the users can access and the need to train them so that they can recognise the most authoritative sources. This would avoid the risk of the uncontrolled dissemination of vague knowledge confusing (or, worse, harming) the users, especially if they are not doctors. On the portal of the Partecipasalute project (<http://partecipasalute.it>) there are for example links that help surfing, giving, at the same time, useful tools to understand the typology and quality of the sites.

We must not underestimate the risk that overturning, also chronologically, the doctor-patient relationship, exposes those looking for information on their own or a loved one’s state of health, to a serious emotive involvement, both for the difficulty of giving the information its proper importance, as well as for not being able to share – as is the case in a good doctor-patient relationship – his/her anxiety with someone who can keep it in check.

## CHAPTER III: INFORMATION TECHNOLOGY AND INTERNET AS TRAINING TOOLS IN MEDICINE

This commitment of ICT to give information from afar is, maybe, the best known one in the medical sector, but it also is not devoid of problems.

In particular, we will focus on the use of the INTERNET, which represents the way in which a considerable amount of the information used in the programmes of medical training is shared.

Some evaluations can be – briefly – summarised as follows:

### 3.1. Teaching materials

A debate that is increasingly intense, at least in some Countries (e.g. the USA), concerns the costs, the intellectual ownership, the preservation and the long-term validity of the teaching material supplied in informatics (Butler Campbell, 2002; Nazional Acc. Press, 2000; Meroy and Maux, 2002; Lindberg, 2002).

The costs seem constantly growing, and various measures have been taken – by some journals and organisations producing IT materials – to make the various products more accessible to the members of the same organisations (e.g., in the case under examination the IMIA, namely, the International Medical Informatics Association), including amongst the facilitations the purchase of software for doctors and students, the access to “guidelines” for IT research, etc.

With regards to intellectual ownership, generally we think that once the author publishes the work on a scientific journal, even if on-line, and gives up the copyright requested by the editor, the work can be reproduced by third parties on condition that it is not used for profit and commercialisation, citing, in any case, its origin. We will later focus on some legal aspects regarding this issue.

### 3.2. The learning of basic facts

In the learning of basic facts in formative curricula based on the discipline’s system, medical informatics teaching has by now a considerable importance, next to “frontal” or magisterial teaching, in almost all the Faculties and degree/diploma Courses. Appropriately organised (and eventually managed by a “tutor” for the research of the sources) it can broaden the angle of the information and raise more cognitive interest (curiosity) from the pupil, facilitate the guided link between different topics, etc., but a great part of its success depends on the quality of the programmes on offer (Hadad and Gagliardi, 1998; Lindberg and Humphreys B., 1998, etc.). Very useful is the following verification, an interactive discussion, in small groups, with the “tutor”, of the experience had and the knowledge achieved.

In this type of teaching, generally the student – at least if belonging to the most recent generations – uses means (internet, videos, etc) he already knows how to use.

### 3.3. “Problem solving” methods

In learning with the “problem based learning” criterion, based on the identification of all of the cultural, social, professional, technical etc. aspects linked to the solution of specific medical problems usually found in the profession (on issues decided by the teaching staff, but left to the choice of the students to a certain extent), the recourse to information technology seems even more independent and distinctive compared to the traditional method: reading, comprehension, mnemonic learning, etc, whilst the teaching work of support, assessment, criticism etc. appears more intense and structured.

In this type of learning, the use of the means is more elaborate, asking the students to perfect also the use of the method through stimulations, self-assessments, etc. (Hasman and Boshuizen, 2001, etc).

### 3.4. Creating the programmes

All these developments, in any case, whether they have a teaching-learning content or whether they are based on the “problem-based solving” criterion, require a considerable effort in organising and updating the IT programmes available in the teaching centre and the teachers’ and students’ full knowledge of how to use them, which is tested in certain centres (see for example Dorman et al. 2003, Foster and Dorman, 2003, etc.).

Positive experiences in the use of IT in medical education have been highlighted also by Italian schools (De Salvo et al., 1991; Merigliano and Da Lio, 1991; Valdenassi et al., 1991; Molino, 1990; Merigliano, 1987; Albano, 1987; Cartabellotta and Notarbartolo, 1997); and others. The interactive relationship with the student-user, possible with IT methods, facilitates learning, the methodology of clinical reasoning; alternative diagnosis; self-assessment. A. Romanini (1987) stresses, in particular, not only the breadth of the applications, but also the need for the teacher to be prepared to elaborate and manage techniques of information technology in his/her subject.

Marchisio and Curtoni (1999) assess the chances to “train” the students to the appropriate research of information (also for their following permanent learning) offered by the use of the internet. The increasingly widespread dissemination of the tool and the growing network of sites regarding medicine cannot be – in the end – ignored any longer, but the student must learn to find the sources and evaluate their reliability (that is, how serious and scientific they are).

### 3.5 Teachers’ training and behaviour

The development and use of informatics in teaching also create the need to change the training and behaviour of the teacher (see in general P.C. Rivoltella, 2002).

These changes could be identified as follows:

- A re-definition of the role (less hierarchical, less “frontal” and more “lateral” towards the student);
- An increase of the workload (more structured organisation of the work, preparation of on-line material, management of communication tools – mailing, forum, chat);

- The need, in view of the previous point, to build and manage teaching teams with diversified responsibilities (tutoring, problem solving, more in depth study of the subject);
- Moving the core of education from the teaching to the student's learning;
- The progressive increase of a culture of monitoring and assessment as the usual habitus of teaching rather than as an isolated, summarising final moment.

We in any case stress the importance of being competent – as a teacher – in the various actions that identify the teaching process in its various places (classroom, web, video-conference, on-line course, etc.), to better use the teaching potential.

### 3.6 Verification of the literature available in the profession exercised

In some Countries, electronic communication in the profession has had a considerable development, which is based on the immediate verification of the literature available in order to reach the best clinical decision possible in certain circumstances, in the patient's interest. On the other hand, on the internet there are a variety of sources of this kind (often accessible for free) like bibliographic databases (for example Medline - <http://www.pubmed.gov>), registers of clinical trials (for example Clinicaltrials.gov - <http://www.clinicaltrials.gov>), guidelines databases (for example the National Guidelines Programme - <http://www.pnlg.it>), the Cochrane Library (<http://www.thecochranelibrary.com>), and the articles published in international biomedical journals (<http://www.pubmed-central.com>). This could be called an “immediate teaching” tool that the GP can use to bring him/herself up to date, when needed.

The increasingly widespread use of computers also in GP surgeries (for example in the United Kingdom, in 2000, 99% of General Practitioners – GPs – had computers, used by 85% of GPs in prescriptions) makes the use of this criterion possible, which however – in the study by Robinson et al., 2003 – seems still limited, despite the fact that it could be the opportunity for the doctor to learn and improve whilst working. Even though in most of the current clinical activity medical judgement is based on the “memorisation” of that illness and on the “experience” of the observed cases, which lead him/her to “facilitated” diagnostic and therapeutic conclusions, there are circumstances in which the doctor feels the need to compare his/her knowledge with the experience of others and with the wider knowledge of the scientific literature available. For this reason, the quick availability, in the place of work, of this information can have its optimal realisation through informatics.

### 3.7 Training for IT operators in the medical sector

With regards to the creation of specific roles of IT operators in the medical sector, various suggestions have been made in connection with the increasingly specialist development of technologies in particular subject areas (Hoffman and Asch, 2001, Covvey et al., 2001, etc.) or with the needs to use calculators in the IT support to nursing (Staggers et al., 2001) or of programmes for healthcare IT operators at the administrative or executive level, etc.) (Yasnoff et al., 2001).

According to Douglas and Hovenga (2002) there still is no general consensus on the level of competence needed for each of these “roles” in the IT profession in the medical-

healthcare sector, but there is agreement on the usefulness of having operators with this kind of training.

### **3.3 Conclusions: the generalised need for IT training for healthcare personnel**

It seems clear that the issue of training is – today – of major interest. We can share the two main avenues of development stated by Houx (2002):

Training programmes in medical and healthcare informatics for all health operators, seen as users of information technology as part of school teaching programmes. An appropriate “modulation” of the complexity and the objectives seems necessary.

Specialist programmes for specialist IT operators, for a personal professional “career” in Universities, Research institutes, hospitals, industries in this sector, etc., as “producers” of new applications and/or hardware managers.

In conclusion, we have seen the doctors’ growing interest towards the use of the internet both as an instrument of professional training, competitive [for reasons of ease and cost also in comparison to the conventional professional training meetings: Wiecha (2004)], as well as for a generic monitoring of patients’ homecare.

However, this still meets with considerable difficulties regarding its acceptability by patients and technology providers (Atack et al., 2004), but also for the still insufficient medical training in the use of the web as part of the doctor’s university studies (Jones and M. Clarke (2004); Wiecha (2004)). This must be increased not only from the point of view of the dissemination and correct technical use, but also from a deontological perspective of ethical responsibility.

## CHAPTER IV: OUTLINES OF INTERNATIONAL LAWS

### 4.1. Introduction: a general look at the legal problems raised by the dissemination of the internet

The dissemination of the internet has raised a series of legal problems which have caused an in depth and still current debate. Some of these problems, in truth, are not specific to the Internet, even though the dissemination of the “Web of webs” strengthened them and forced the attention of the wider public on them.

This can be said, first of all, of the introduction of IT communication in private and commercial law (particularly with regards to the electronic document and the digital signature) and for the issues relative to the so-called “distance contracts” (perfecting the contract or the consumer’s protection, for example, even though on the Web the strategies of commercial communication can be much more invasive than traditional ones), as they are mostly events that precede the arrival of the internet.

The penal profiles on the internet are similarly devoid of truly new elements, as they are essentially linked to the problem of repressing, using traditional means, behaviours characterised by the extreme difficulty of location. These are behaviours belonging to two large categories, according to whether the IT programme is used to commit common crimes or is, in itself, the object of transgression. A hybrid and very widespread type of transgression is illegal duplication (the so-called software piracy), however, amongst them, more worrying are the behaviours leading to the dissemination on the Web of illicit images, especially regarding child pornography. In this field, as also in the wider context of the protection of privacy for internet users, the need to resolve, at its origin, the conflict between legal rights that are in some ways in contrast, is keenly felt: the protection of the sexual modesty and the freedom of information, in the first case *privacy* and in the second freedom of communication.

With regards to the fields under consideration, therefore, it is possible to state that the conflict between different needs of protection has highlighted the true nature of the internet, that is, a simple but effective sounding board for ideas, principles and solutions found in the real world.

More new elements are offered, instead, by the field of intellectual property, with particular reference to the registration of the so-called domain names and the counterfeit use of the company’s distinctive logo in domain names. This aspect, truly peculiar of the internet, highlights the fundamental problem of creating Web regulations that are in line with its nature of international means of communication, identifying, for this purpose, adequate methods and tools. And this is the field in which the law becomes more uncertain, taking into account the relative unfamiliarity of the internet with some traditional legal principles and rules and, in particular, the aversion shown by the same operators and users towards any form of regulation of Web applications, both internationally and in Italian legislation. This has led to a growing number of technical regulations and elaborate standard programmes in *cyberspace*, accepted and used consensually by internet users, for the main purpose of ensuring the interconnection and universal interoperability of the Web, that is: “*in extreme synthesis – the link between different IT and/or telecommunication systems according to particular technical methodologies, in order to allow the elaboration and transmission of data and information*”.

In this chapter, the NBC intended to inform the reader about the main international and European legal documents, recalling the need for a correct management of the internet/processing of sensitive data/health relationship.

The issue of buying medicines for human consumption through the internet will then be given particular mention, as it highlights some critical aspects that are truly peculiar of the application of the internet to the medical sector.

The development of new technologies and the potential shown by their use in medicine and healthcare, first of all highlighted the need to ensure adequate legal protection to healthcare information, answered by the measures adopted internationally by the World Health Organisation, by the Council of Europe and by the European Community. These are measures that identify some fundamental principles for the collection and processing of personal data, proposing to find the balancing point between contrasting subjective positions, and defining the transformation of the main instrument for the protection of personal information from a generic obligation to abstain from intrusive behaviours in the personal sphere to a much more penetrating power of control on the flow of information that is continually generated. Regarding this, it is important to stress that the need to have more incisive forms of protection is mostly felt with regards to personal information intimately connected with individual, family and inherited biological identity, the handling of which can be particularly harmful to fundamental rights: to the consolidated category of the so-called sensitive data, concerning the state of health, racial or ethnic origin, political opinions, religious beliefs and sexual preferences, we have to add the new category of “extremely sensitive data” which is, in particular, genetic information. However, the same international regulations allow the distinction, with regards to positive discipline, between “generic data” and “medical data”, and it is at the second category of data that the following considerations are aimed.

## 4.2. The protection of medical data with international legal tools

### *Universal International Legislation*

With regards to this, we must highlight, from the point of view of universal international legislation, the “**eHealth**” **Resolution** adopted by the 58<sup>th</sup> World Assembly of the World Health Organisation, on the 16<sup>th</sup>-25<sup>th</sup> of May 2005<sup>253</sup>, in which the WHO asked the member states to create centres of excellence for the development of telemedicine practices, to consider the opportunity to create and develop national electronic systems for public healthcare and to improve, by incrementing the availability of information, the ability to monitor and control pathologies and healthcare emergencies. The principles inspiring this resolution were already the object of the **eHealth Code of Ethics**, approved on the 18<sup>th</sup> of May 2000 by an international association of healthcare operators in telemedicine (Internet Healthcare Coalition) within the eHealth Ethics Initiative, carried out with the support of the World Health Organisation. This document stated that the use of the internet for reasons concerning the state of health should not prejudice the principles safeguarding needs of general interest, like transparency and privacy. From the point of view of the protection of priva-

---

<sup>253</sup> Cf. Resolution WHA58.28.

cy in particular, the document recognised the right of the individual to be adequately informed in order to be able to be in control of the processing of his/her personal information, as well as the possibility to exercise the right to correct, integrate and delete his/her healthcare information. Finally, the document hoped for the encryption of all healthcare data used, as well as the traceability of the use of the same data.

More recently, another body operating internationally, the International Working Group on Data Protection in Telecommunications (IWGDPT)<sup>254</sup>, has created a working document, the **Draft Working Paper on Electronic Health Record**, on the processing of healthcare data by making electronic clinical records available *on-line*<sup>255</sup>. The document presents the first experiences realised in some legislations in order to link, nationally, the individual healthcare structures (public and/or private), also extending the access to healthcare information to all professional operators. However, as well as the advantages of these technological solutions, in particular due to the lower cost of processing healthcare information, the integral accessibility of the data for the patient's advantage, and the overall efficiency of the healthcare system, the document highlights also the risks relative to the use of the internet, especially in the framework of the protection of privacy of the healthcare data processed and professional secrecy. In particular, the document highlights that one of the first limitations to the functioning of *on-line* clinical records, comes from the need to have the consent of the interested party every time an individual different from his/her GP wants to access the patient's healthcare information.

#### *a) European regional law*

As to European regional laws, the **Oviedo Convention** recognises in Art. 10 the individual right to the protection of private life in relation to information about his or her state of health, as well as the right to know or ignore said information<sup>256</sup>. This directive is the synthesis of the activity carried out by the Council of Europe about to the protection of privacy when processing healthcare data, protection that finds its general basis in Art. 8 of the 1950's European Convention for the Protection of Human Rights and Fundamental Freedoms. In this context, we must first of all recall that the Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data, in force since the 1<sup>st</sup> of October 1985<sup>257</sup>, which gives special protection to sensitive data, in consideration of the discriminatory use of them (Art. 6), and authorises the processing of such data only with appropriate safeguards given by domestic regulations<sup>258</sup>. The agreement also sanctions the

---

<sup>254</sup> This organisation, created in 1983 within the International Conference of Data Protection and Privacy Commissioners, groups together the representatives of the national authorities for personal data protection, of the international organisations overseeing the issue of privacy and of the scientists and experts in privacy and telecommunications.

<sup>255</sup> This document was approved during the 33<sup>th</sup> meeting in Berlin on the 6<sup>th</sup>-7<sup>th</sup> September 2005.

<sup>256</sup> The Convention however accepts, exceptionally and in the exclusive interest of the patient, that national legislations can restrict access to the exercise of those rights (Art. 10, paragraph 3).

<sup>257</sup> The convention was adopted by the Committee of Ministers in the Council of Europe on the 17<sup>th</sup> of December 1980 and it was open to the signature of the member states on the 23<sup>th</sup> of January 1981 in Strasburg. Italy ratified the Convention with Law No. 98 of the 21<sup>st</sup> of February 1989 (in *Gazzetta Ufficiale*, Ordinary Supplement, number 66 of the 20<sup>th</sup> of March 1989).

<sup>258</sup> See, for Italy, Legislative Decree number 196 of the 30<sup>th</sup> of June 2003 "Code on the Protection of Personal Data" (in *Gazzetta Ufficiale*, No. 174 of the 29<sup>th</sup> of July 2003, *Ordinary Supplement* number 123), as well as the autho-

right to access personal data, which allows the interested party to check the accuracy, level of update and pertinence of the information collected, in line with the declared purposes (Art. 8).

In this context we must also recall the **Recommendations of the Committee of Ministers of the Council of Europe with regards to the processing of healthcare data**. First of all, we highlight *Recommendation R(97) 5, of the 13<sup>th</sup> of February 1997, relative to the automated processing of healthcare data* (which substituted Recommendation R(81) 1, of the 23<sup>rd</sup> of January 1981)<sup>259</sup>. This Recommendation establishes the rules on the collection and automated processing of all medical data; it determines the principles to safeguard genetic data and it contains definitions allowing the distinction, for the purposes of positive discipline, between medical data and genetic data. In particular, on the basis of the Recommendation, we intend as medical data all personal data regarding the health of the individual, including data with a clear and close link with health, and as genetic data, instead, all data, of any kind, referring to the hereditary characteristics of an individual or regarding the genetic inheritance of a group of individuals<sup>260</sup>.

More recently, *Recommendation R(2004) 17 relative to the impact of information technology on the protection of health – “The patient and the Internet”* was adopted. This Recommendation recognises the citizens’ fundamental right to access information on healthcare issues; asks for the review of policies, laws, and general practice limiting the patient’s access to information disseminated through the internet or other means of communication; asks for the development at the international level of common approaches for the optimal use of the internet by patients and citizens, promoting criteria for the transnational exchange of information between patients and doctors; and it hopes for the resolution of conflicts, real and potential, between the legislation on data protection and the patients’ freedom of access to information beyond national boundaries. With regards to the guidelines attached to the Recommendation, the document by the Council of Europe states the principle according to which confidentiality measures must be introduced to guarantee the patient’s right to self-determination, anticipating that the legal basis for the processing can

---

risations of the Guarantor for the Protection of Personal Data relative to the handling of data revealing the state of health and sex life, adopted since November 1997 (finally, see authorisation number 2/2004 of the 30<sup>th</sup> of June 2004, in *Gazzetta Ufficiale* number 190 of the 14<sup>th</sup> of August 2004). Exceptions to the general tone of the Convention are presented in Art. 9, referring to the necessary measures, in a democratic society, to ensure the prevalence of the relevant public interests, the safeguard of the interested party and the protection of the rights and freedoms of others.

<sup>259</sup> We recollect, with regards to this, that this Recommendation discusses the processing of healthcare data, with particular reference to data found in medical registers, defining “medical data” any data that includes information relative to the psychological and physical health of an individual in the past, present or future.

<sup>260</sup> The cited document can be found in *Textes du Conseil de l’Europe en matière de bioéthique*, Strasbourg, 2005. It is important to remember, in addition, that the activity of the Council of Europe with regards to the protection of privacy in the automated processing of personal data extends, amongst others, to the insurance sector [Recommendation R(2002) 9, on the protection of personal data collected and handled for insurance purposes], the internet [Recommendation R(99) 5 of the 23<sup>rd</sup> of February 1999, including the guidelines for the protection of people with regards to the collection and processing of personal data in information], statistical research [Recommendation R(97) 18, of the 30<sup>th</sup> of September 1997], social security [Recommendation R(86) 1, of the 23<sup>rd</sup> of January 1986], public safety [Recommendation R(87) 15, of the 15<sup>th</sup> of September 1987], work [Recommendation R(89) 2, of the 18<sup>th</sup> of January 1989] and penal justice [Recommendation R(92) 1, of the 10<sup>th</sup> of February 1992].

be found in the consent, the contract or the law; it also recommends that the patient's identification is not required in order to access healthcare information on the internet, unless the individual's identity is not prevented, for example, from accessing a healthcare service, for medical-legal or financial reasons; finally, in order to guarantee the users' confidentiality and safety, it recommends the member states to promote the dissemination of digital signatures and digital identities and it asks for the institution of authorities and committees responsible for the elaboration of specific privacy and safety criteria in member states.

### 4.3. The protection of medical data in European Community laws

The legal protection of information regarding the state of health is ensured, in European Community laws, by the **Directive of the European Parliament and Council number 95/46 of the 24<sup>th</sup> of October 1995, relative to the protection of individuals with regard to the processing of personal data and on the free movement of such data**<sup>261</sup>.

This directive completes and integrates the principles of the Convention of the Council of Europe, recalled above, reinforcing significantly the protection given by the Convention to the interested parties, as well as in a different legislation. In fact, whilst international agreements state the principle of the free movement of personal data and recognise to the individual a simple power of control on the accurate automated processing of these data, legitimate in itself, the directive attributes to the interested parties the right to authorise or not the processing itself (not only when automated), the legitimacy of which is in this way subordinated to the guarantees sanctioned by European Community law<sup>262</sup>.

In this context, the directive establishes the general principle of the unequivocal consent of the data subject to the processing of personal data, intended as manifestation of free, specific and informed will (articles 2 and 7). In particular, for what concerns the processing of the so-called sensitive data (amongst which, as we have said, we can include those relative to the state of health), the directive requires the explicit consent of the data subjects

---

<sup>261</sup> In *Guce* number L281 of the 23<sup>rd</sup> of November 1995, p. 31, integrated by the Commission's decision number 2002/16, of the 27<sup>th</sup> of December 2001, relative to the typical contractual clauses for the transferral of personal data to those responsible for the processing resident in other countries, according to directive 95/46 (in *Guce* number L6 of the 10<sup>th</sup> of January 2002, p. 52). We recall that other acts by the European Community regulate specific aspects of the protection of privacy in relation to the processing of personal data, like regulation number 45/2001 of the 18<sup>th</sup> of December 2000 of the European Parliament and of the Council, on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (in *Guce* number L8 of the 12<sup>th</sup> of January 2001, p.1), which was put into force by Council deliberation number 2000/31, of the 8<sup>th</sup> of June 2000, on certain legal aspects of information society services, in particular electronic commerce, in the internal market: the so-called directive on electronic commerce (in *Guce* number L178 of the 17<sup>th</sup> of July 2000, p. 1), and the directive of the European Parliament and of the Council number 97/66, concerning the processing of personal data and the protection of privacy in the telecommunications sector (in *Guce* number L24 of the 30<sup>th</sup> of January 1998, p. 1), abrogated and substituted by the directive of the European Parliament and of the Council number 2002/58, of the 12<sup>th</sup> of July 2002, concerning the processing of personal data and the protection of privacy in the electronic communications sector (in *Guce* number L201 of the 31<sup>st</sup> of July 2002, p. 1).

<sup>262</sup> Note that the field of material applications for the directive is broader than that of the Convention of the Council of Europe, because the European Community act concerns public and private archives both manual and automated.

(Art. 8). Dispensations to the general legitimate management of the processing of information are anticipated for cases, clearly listed in the directive, in which the interest towards the movement of data is believed to be prevalent (for prevention, medical diagnostic and administration of care), on condition that the processing of data is carried out by a health-care operator sworn to professional secrecy (Art. 8, paragraph 2 and 3)<sup>263</sup>.

In matters of electronic healthcare we also recall, with regards to political trends, the **Ministerial Declaration of the Member States of the European Union, of the Acceding and Associated Countries, adopted in the framework of the e-Health 2003 Conference**. This Declaration, in defining e-Health as the use of modern information and communication technologies to meet the needs of citizens, patients, healthcare professionals and healthcare providers, as well as policy makers, recognises that efficient national planning and evaluation of health policies require speedy, accurate and comprehensive exchange of data between member states with regards to communicating relevant best practices, and recommends that the accessibility to appropriate healthcare information is guaranteed by the use of secure and shared e-Health applications<sup>264</sup>. In this perspective, the project eHealth Impact, funded by the European Commission, developed a large database concerning 100 case studies relative to the application of procedures to supply healthcare services through the use of telematic networks<sup>265</sup>.

In the perspective of the adoption of a specific discipline in the European Community with regards to electronic healthcare, we also find the Communication of the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Regional Committees on **“Electronic Healthcare – making healthcare better for European citizens: an action plan for a European e-Health Area”** [document COM(2004) 356 def.], adopted on the 30<sup>th</sup> of April 2004. The Action plan indicates, amongst the concrete measures for the creation of a “European electronic healthcare area”, the use of information and telematics technologies for prescriptions, medical records, patient identification and health cards, as well as the dissemination of broadband networks destined to manage healthcare systems. The aim is to agree, before the end of 2006, uniform methods among the member states for the identification of patients and to define norms for the interoperability of clinical data and on-line medical records.

We must finally recall the opinion adopted by the European Group on Ethics in Science and New Technologies (EGE), relative to **“Ethical issues of healthcare in the information society”** of the 30<sup>th</sup> of July 1999, which states the principles of the patient’s consent to the collection and processing of medical data, to the confidentiality of healthcare information, even after the death of the data subject, to professional secrecy. The opinion of the EGE also requires the creation of a system of accreditation for those who carry out the process-

---

<sup>263</sup> For a comment on the European Community directive see also L. Boulanger et al., La protection des données à caractère personnel en droit communautaire, in *Journal Trimestrielle de Droit Européen*, 1997, n. 40, p. 121 and following., n. 41, p. 145 and following, n. 42, p. 173 and following, and Y. Callens, The Privacy Directive and the Use of Medical Data for Research Purposes, in *European Journal of Health Law*, 1997, p. 309 and following.

<sup>264</sup> Note that eHealth is part of the objectives of the 2005 eEurope Action Plan, adopted with the Communication of the Commission to the European Council, the European Parliament, the European Economic and Social Committee and the Regional Committees, of the 28<sup>th</sup> of May 2002, “eEurope”.

<sup>265</sup> Cf. site: [www.ehealth-impact.org](http://www.ehealth-impact.org).

ing of medical data in healthcare, due to the sensitivity of these operations and the peculiar responsibilities of the individuals working in the medical-healthcare field, and it excludes direct access by third parties, like employers or insurance companies, to the medical information of the employee or the insured: in this perspective, setting up suitable safety mechanisms, like for example encrypting information, or the adoption of close circuit systems, becomes of significant importance. The document also requires that the information found in electronic healthcare paperwork is only that for which the interested party has given his/her consent and that he/she can restrict access to some of the information contained in it and finally hopes for the adoption of some regulations in the European Community, like a directive on the protection of medical data and a Recommendation including a Charter for the European Patient, introducing a specific discipline with regards to the issues considered<sup>266</sup>.

#### 4.4 Medicines and the Internet

An issue of particular importance is that relative to the purchase of medicines for human consumption on-line, thanks to the electronic network (so called virtual pharmacies).

The main legal problems linked or due to this habit, quickly spreading in the United States of America as well as Europe, can be found first of all in the difficulty for consumers to verify if the medicine purchased on-line has, both in its country of origin (where it was made) and in the country of destination (where the consumer resides), the authorisation for its introduction on the market, which generally is aimed at ensuring the conformity of the medicine to the criteria of quality, safety and efficacy required by law. Specific relevance is given, from the point of view indicated, to the problems relative to the qualification of the products marketed on-line (which in some legislations can be included in the category of medicines for human consumption, whilst others can classify them, for example, “food supplements” or “nutritional products”) and to the violation of eventual, further requirements mentioned in the appropriate regulation, both in the country of origin and in the country of destination (mainly the obligation to have a doctor’s prescription for the delivery of the drugs). The peculiar characteristics of the internet, and in particular the absence of direct contact between the doctor (or the pharmacist) and the patient, can also increase the risk of undesirable or adverse effects deriving from the interaction between medicines, from taking medicines incorrectly or different from those necessary to treat certain pathologies. Finally, particular risks can be posed with regards to the state of preservation of the medicines sold and ordered on-line, as well as the eventual confusion (rectius, counterfeiting) of the medicines on sale, which could contain active ingredients or components different from those required or completely ineffective<sup>267</sup>.

---

<sup>266</sup> Cf. the site: [http://www.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://www.eu.int/comm/european_group_ethics/index_en.htm).

<sup>267</sup> It is enough to access some internet sites to realise the wide range of ways to buy *on-line* offered by virtual “pharmacies”, even for medicines subject to a doctor’s prescription: some sites allow the consumer to “self-prescribe” medicines, “clicking” certain options or filling *on-line* forms, whilst others simply require financial guarantees (like the credit card number) for purchasing any medicine.

The problems described have been tackled in some countries at the national level, both from a legislative and legal perspective, but it is on the results achieved by the regulations of the European Community that we will focus in the following pages, in consideration of the characteristics of the internet and, particularly, of the **transnationality of on-line commercial transactions**. With regards to this, it is appropriate to highlight immediately that, in the legislation under consideration, the evaluation of the problem discussed has been carried out in line with the objective of favouring as much as possible the liberalisation of business exchanges, a fundamental aim of the process of integration in the European Community.

To summarise the regulations of the European Community applicable to the sale, supply and advertising of medicines, we must first of all recall the **Directive of the European Parliament and of the Council number 2001/83 of the 6<sup>th</sup> of November 2001, on the so-called Community Code relating to medicinal products for human use**<sup>268</sup>. This directive, confirming the discipline introduced by the better known Council directive number 65/65 of the 26<sup>th</sup> of January 1965<sup>269</sup>, establishes that no medicine can be put on the market without the “authorisation... by the competent (national) authorities... in accordance with this Directive or... in accordance with Regulation number 2309/93” (cf. Art. 6, number 1)<sup>270</sup>. With regards to the supply of medicines, the discipline in the European Community code, confirming what anticipated by Council Directive number 92/26 of the 31<sup>st</sup> of March 1992<sup>271</sup>, establishes the conditions according to which the medicines authorised to be put on the market are subject to a compulsory doctor’s prescription, like medicines that “are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision” (cf. Art. 71)<sup>272</sup>. With regards, instead, to advertising medicines, the European Community code follows the discipline introduced by Council directive number 92/28, also repealed and substituted by the 2001 act<sup>273</sup>. The current regulation makes it compulsory for member states to prohibit any advertising of medicinal product in respect

---

<sup>268</sup> In *Guce* number L311 of the 28<sup>th</sup> of November 2001, p. 67. The directive has not been adopted in Italy yet.

<sup>269</sup> Directive number 65/65, repealed and substituted by the 2001 code, on the approximation of provisions laid down by law, regulation or administrative action of the member states relating to medicinal products (in *Guce* number L22 of the 9<sup>th</sup> of February 1965, p.369/65).

<sup>270</sup> We recall that the Council regulation number 2309/93 of the 22<sup>nd</sup> of July 1993, relative to European Community procedures for the authorisation and control of medicines (in *Guce* number L214 of the 24<sup>th</sup> of August 1993, p. 1), was modified by the Commission regulation number 649/1998 of the 23<sup>rd</sup> of March 1998 (in *Guce* number L88 of the 24<sup>th</sup> of March 1998, p. 7). It is significant to highlight that the European Community procedure established with regulation number 2309/93 does not prejudice the competences of the member states with regards to fixing the price of medicines, or those relative to the inclusion of medicines in the application field of the national systems of illness insurance on the basis of health, economic and social considerations.

<sup>271</sup> Repealed and substituted by the 2001 code, directive number 92/96 on the classification of the supply of medicines for human use (in *Guce* number L113 of the 30<sup>th</sup> of April 1992, p. 5).

<sup>272</sup> According to the directive mentioned, the compulsory medical prescription extends to medicines often used and, largely, correctly used, if they present a direct or indirect danger to human health, if those medicines contain substances or preparations, the activity and/or adverse reactions of which require further investigation, without exceptions, if those medicines are prescribed by a doctor to be administered parenterally.

<sup>273</sup> In *Guce* number L113, *cit.*, p. 13. Note that directive number 92/28, on the advertising of medicinal products for human use, did not regulate the labelling and the instructions for use of medicines for human consumption: these aspects were the object of the regulation introduced by Council directive number 92/27 (in *Guce* number L113, *cit.*, p. 8), also repealed and substituted by the 2001 European Community code.

of which a marketing authorisation has not been granted (Art. 87); member states shall also prohibit advertising “to the general public” of medicinal products which are available on medical prescription only (Art. 88)<sup>274</sup>.

Other relevant regulations about the on-line sale of medicines are those found in article 14 of the **Directive of the European Parliament and of the Council number 97/7 of the 20<sup>th</sup> of May 1997, on the protection of consumers in respect of distance contracts**<sup>275</sup>, which allows member states to ban “in the general interest, the marketing on its territory of certain goods or services, particularly medicinal products”, and Art. 14 of the directive of the European Parliament and Council number 97/36 of the 30<sup>th</sup> of June 1997 on the so-called teleshopping, which expressly forbids the “telesales of medicines subject to authorisation to be put on the market..., as well as the telesales of medical treatments”<sup>276</sup>.

We must mention the **Directive of the European Parliament and Council number 2000/31 of the 8<sup>th</sup> of June 2000, “on certain legal aspects of information society services, in particular electronic commerce, in the internal market (directive on electronic commerce)”**. This directive is clearly intended to favour the development of electronic commerce, leaving however untouched the level of protection for public healthcare and consumers that is guaranteed by some regulations of European Community law, like those on the advertising of medicines for human use (considering 11)<sup>277</sup>. It is important however to clarify that the field regulated by directive number 2000/31 only includes the requirements for on-line activities (like on-line information, on-line advertising, on-line sales and on-line contracts) and it does not include the legal requirements established by member states with regards to goods (like regulations about security, labelling obligations or regulations concerning product responsibility) or to the delivery and transport of the goods themselves, “including the distribution of medicinal products” (considering 21).

As it is easy to observe, the directive on electronic commerce has a peculiar importance in this matter, even though the predictions found in the preamble to the act do not seem to be in line with the need to ensure, in the European Community, an ordered and safe development of the activity of selling medicines on-line. The European Parliament seems to have realised this, and since 2000 asked the Commission about the risk that the global nature of

---

<sup>274</sup> Part of the prohibition mentioned includes also advertising medicines containing psychotropics or narcotics, as well the mention of the following in the therapeutic instructions: tuberculosis; sexually transmitted diseases; other serious infective illnesses, cancer and other tumors; chronic insomnia; diabetes and other metabolic illnesses (cf. Art. 888, number 2, subsection 2).

<sup>275</sup> In *Guce* number L144 of the 4<sup>th</sup> of June 1997, p. 19. Directive No. 97/7 was amended and integrated a variety of times, lastly with the directive of the European Parliament and of the Council No. 2005/29 of the 11<sup>th</sup> of May 2005 (in *Guce* number L149 of the 11<sup>th</sup> of June 2005, p. 22). The act was adopted in Italy with Legislative Decree number 185 of the 22<sup>nd</sup> of May 1999, published in the *Gazzetta Ufficiale* number 143 of the 21<sup>st</sup> of June 1999.

<sup>276</sup> Directive No. 97/36 is aimed at amending directive No.89/552 of the Council relative to the coordination of certain provisions laid down by law, regulation or and administrative action in member states concerning the pursuit of television broadcasting activities (in *Guce* number L 202 of the 30<sup>th</sup> of July 1997, p. 60). The Act was adopted in Italy with Law No.223 of the 6<sup>th</sup> of August 1990 and with Law No. 122 of the 30<sup>th</sup> of April 1998.

<sup>277</sup> In *Guce* number L.178 of the 17<sup>th</sup> of July 2000, p. 1. The directive was adopted in Italy with Legislative Decree No. 70 of the 9<sup>th</sup> of April 2003, published in the *Gazzetta Ufficiale* No. 87 of the 14<sup>th</sup> of April 2003, Ordinary Supplement number 61. For a comment about European Community regulations applicable to the phenomenon of electronic commerce, see L. Marini, *Electronic Commerce. Aspects of European Community Law*, Padova 2000, in particular p. 131 and following.

the internet allows the advertising and sale of medicines to European consumers by operators working from other countries, in this way, getting around the guaranteed protection of European Community regulations<sup>278</sup>.

The European Community Judiciary Court also passed judgement on this issue, and, with the sentence of the 11<sup>th</sup> of December 2003, in the Case **Deutscher Apothekerverband v. DocMorris NV**, interpreted all the European Community laws applicable to the distance selling of medicines<sup>279</sup>. In effect, the Dutch pharmacy DocMorris, since June 2000, supplied via the internet to German citizens medicines for human use authorised to be put on the market by German authorities and the authorities of other member states<sup>280</sup>.

The Deutscher Apothekerverband association of German pharmacists (representing around 19,000 pharmacies) has therefore brought DocMorris to the Frankfurt tribunal, contesting both the *on-line* offer of medicines and their international delivery by mail, on the basis of national bans which forbid in Germany the distance sale of medicines available exclusively in a pharmacy<sup>281</sup>. According to the acting association, the bans mentioned would not be restrictions to business exchanges forbidden by Art. 28 of the Treaty of Rome and would be compatible with Art. 30 of this Treaty, being aimed at ensuring imperative needs (the protection of life and the safeguard of European citizens' health) and therefore prevailing compared to the principle of the freedom of circulation guaranteed by the Treaty by having an internal market and liberalising the exchange of productive factors (especially goods)<sup>282</sup>. Because DocMorris contested this point, the German judge suspended the main case, deferring to the Court of Justice the solution of a series of extremely important prejudicial questions, which in substance can be summarised as follows: do national bans to the cross-border distance sale of medicines to be sold exclusively in a pharmacy violate the principles of the free circulation of goods found in Art. 28 of the Treaty of Rome? Can the national ban on advertising for the distance sale of medicines to be bought only in pharmacies be extended to the internet site of an established pharmacy in another European Community member state which describes the medicines (indicating name, methods of delivery and cost) and also offers the possibility of buying them *on-line*?

---

<sup>278</sup> See the written interrogation E-3077/00 of the 2<sup>nd</sup> of October 2000 and the answer of the European Commission on the 23<sup>rd</sup> of November 2000, with which this institution announced the beginning of awareness campaigns for European consumers, as well as the promotion of ad hoc codes of conduct (in Guce number C151 of the 22<sup>nd</sup> of May 2001, p. 58).

<sup>279</sup> Case C-322/01, in *Raccolta della giurisprudenza della Corte* (following: *Raccolta*), 2003, p. I-14887. For a first comment about the sentence see R. Manno, Europa: via libera all'e-commerce dei farmaci, in <http://www.interlex.it>.

<sup>280</sup> In particular, DocMorris qualified the medicines as subject to a doctor's prescription according to Dutch law or the law of the consumer's place of residence: in this case, the delivery of the medicine would happen only after the presentation of the original doctor's prescription and the medicine could be collected in person by the customer or by courier.

<sup>281</sup> In particular, they took into consideration the prohibitions present in German law with regards to medicines for human use (Arzneimittelgesetz-AMG) and to the advertising of healthcare professions (Heilmittelwerbe-gesetz-HWG).

<sup>282</sup> Art. 28, 29 and 30 of the Treaty of Rome, pillars of the internal market, prohibit quantitative restrictions to import and export, as well as measures "having equivalent effect" to quantitative restrictions, except national bans and restrictions justified, amongst other things, by reasons of "protection human health and life". These prohibitions shall not, however, constitute "a mean of arbitrary discrimination, or a disguised restriction on trade between member states".

Largely in line with the conclusions of the advocate general, the judges of the Court of Justice established that there is no legitimate reason to justify an absolute ban to the distance sale of medicines that do not require a doctor's prescription. The interest to guarantee correct information and personalised professional advice, asked for by Deutscher Apothekerverband, has not been believed to be enough to justify such a ban and the restriction of exchanges within the European Community that would derive from it: on the contrary, according to the Court, buying *on-line* can have advantageous aspects for European consumers, who can ask the virtual pharmacy, through the *web* pages and *links* offered, any kind of useful or relevant information. The information available on-line, which should be accessed by consumers before a distance buy, has been deemed suitable by the Court to dispel even the potential risks linked or due to the incorrect use of medicines bought *on-line*. According to the Court, therefore, the ban of distance sale could find a legitimate basis only with reference to medicines requiring a doctor's prescription: in this case, in fact, the risks linked to taking these medicines need a stricter control and the observance of eventual bans posed by national laws seems functional to the protection of fundamental and mandatory legal interests.

With regards to the second issue, using again the distinction between medicines needing a doctor's prescription or not (according to the distinction also made by the European Community code relative to medicines for human use in 2001, abovementioned), the Court of Justice noticed that the ban on advertising is justified in relation to medicines needing a doctor's prescription and that in Art. 88 of the European Community code is against national bans on the advertising of medicines that do not need a doctor's prescription (the so-called over the counter medicines or medicines without need of prescription)<sup>283</sup>. Essentially, therefore, the Court of Justice denied that the ban to the distance selling of medicines that can only be bought in pharmacies is a "way of selling", and as such fits into the parameters established by law<sup>284</sup>, clarifying that a ban similar to that under consideration in the national case would bring a more significant prejudice towards pharmacies outside of Germany than to those on German soil. The Court stated, on this point, that "if with regards to... (German pharmacies) it is difficult to contest that this ban deprives them of a supplementary or alternative way to reach the German market of medicines' consumers, nonetheless they still can sell the medicines in their pharmacies. On the contrary, the internet would be a more important tool for the pharmacies that are not on German soil, to directly reach such a market. A ban that affects those pharmacies established outside of the German soil more, could hinder the access to market of products from other member states more than that of national products"<sup>285</sup>.

From the sentence recalled, it appears evident that the Court of Justice favours the internet and, more in general, the application of communication technologies in the health-

---

<sup>283</sup> They are also called OTC (*over the counter*) or NP (no prescription) medicines. These medicines can be sold freely, without the need for a doctor's prescription, but it must be remembered that in Italy the use of the expression "over the counter medicines" seems improper, because the current law demands that the pharmacist gives the medicines and, in the same way, forbids the consumers to autonomously take "from the counter" the required medicines: recurring to his/her famous imagination, the Italian legislator has therefore preferred to create the expression "self-medication medicines".

<sup>284</sup> See in particular sentence *Keck* of the 24<sup>th</sup> of November 1993, Cases C-267/91 and C-268/91, in *Raccolta*, 1993, p. I-6097.

<sup>285</sup> Cf. point 56 of the sentence *Deutscher Apothekerverband*.

care services sector, which seems to be in line with the need to support as much as possible the creation of an internal market and therefore, as mentioned above, the main objective of the integration of the European Community.

We must also clarify that, if the sentence of the Court is mainly effective in the German legislation<sup>286</sup>, it will have significant repercussions also in other member states, like Italy, in which the regulations about the distribution and advertising of medicines seems to be incoherent with the spirit of the sentence examined. In Italy, in fact, the distance sale of medicines is banned tout court: see, about this, the directives in the **1934 Collection of Healthcare Laws**<sup>287</sup>, according to which the sale of medicines must happen exclusively in pharmacies, and Art. 25 of the deontological code of the pharmacist profession, which forbids giving medicines, with or without prescription, via the internet or other informatics systems<sup>288</sup>; only for the so-called self-medication medicines, Art. 3 of Legislative Decree number 541 of the 30<sup>th</sup> of December 1992, allows the advertising to the public in the prescribed forms<sup>289</sup>. Incompatibilities of the Italian legislation compared to the interpretative principle established by the Court of Justice with the sentence *Deutscher Apothekerverband* appear, therefore, with regards to the distance sale and advertising of “medicines without prescription”.

In light of the considerations made, the elaboration of a discipline of the *on-line* sale of medicines for human consumption seems impossible to delay, also to support the positive applications of such a controversial phenomenon<sup>290</sup>. With regards to this, it seems easy to share the trend aimed at supporting, for the internet and its applications, the development of a broad regulatory framework, based on the adaptation of the traditional legal principles and regulations and in part on the elaboration of codes of conduct and self-regulating “good practice” techniques<sup>291</sup>. Resolution WHA51.9 adopted in May 1998 by the 51<sup>st</sup> Assembly of the World Health Organisation, was already going in this direction, as it asked for the Organisation’s Director general to elaborate a guide relative to “**Medical Products and the Internet**” for the purpose of giving the member states a homogeneous model of reference to help internet users to obtain reliable, independent information, comparable on line, on medicines for human use<sup>292</sup>.

---

<sup>286</sup> And in fact the German Ministry for Health announced the inevitable reform of the regulations applicable to the distribution of medicines in Germany.

<sup>287</sup> Cf. R.D. number 1265 of the 27<sup>th</sup> of July 1934, in *Gazzetta Ufficiale* number 186 of the 9<sup>th</sup> of August 1934.

<sup>288</sup> Approved by the National Council of the Federation of the Order on the 13<sup>th</sup> of December 2000.

<sup>289</sup> In *Gazzetta Ufficiale* number 7 of the 11<sup>th</sup> of January 1993.

<sup>290</sup> Think, for example, to particularly rare illnesses and to the related difficulty of identifying and finding the most appropriate medicines for these pathologies, which often, because of the reduced economic perspectives deriving by the small number of interested patients, are not produced or marketed (so-called orphan medicines). In these cases, the internet could be a valid (and cheap) tool to disseminate the relevant information, not only within the scientific community, but also for the benefit of the interested patients.

<sup>291</sup> This is the case of the so-called quality certification, which generally should allow, on the one hand, to assess the organisational and functional efficiency of those subjects offering goods and services on the Web and, on the other hand, to reassure the consumers about the quality, safety, privacy and reliability of the information received and of *on-line* business transactions.

<sup>292</sup> The guide, elaborated on the basis of the contribution given by national authorities, independent experts, consumers’ organisations and representatives of the pharmaceutical industry, is published also in Italian: cf. V. Reggi, *Farmaci e Internet. Guida per la ricerca di informazioni attendibili*, Casalnoceto 2000.

## CHAPTER V: OUTLINE OF ITALIAN LAWS

### 5.1. Pragmatic internet regulations

These are rules dictated by experience, true “norms of good practice”, capable, amongst other things, of adapting more easily than legal regulations to the evolution of the internet. The development of individual behavioural rules and of other forms of private self-regulation, widespread today also in sectors different from telematics (like for example in the biomedicine and biotechnology sector) is then stressed by the globalisation process, to which corresponds the progressive erosion of state sovereignty deriving from consolidating power and transversal dynamics to the states.

The fact that the technical norm has become the rule in the community of Web users – with such committed agreement that it has led to “*considering the internet as a real model of social organisation*” (Rodotà, 1998) if on the one hand allows us to respond with the necessary speed to the solicitations deriving by the application of new technologies, on the other hand it presents articulated and often contradictory possibilities, from which come complex legal problems.

For example, taking into account the universal importance of the global dissemination of the internet as a means of communication, we can say that the phenomenon of retreat of the legal norm described above, poses the premises to state the autonomous status of the person from an international point of view, favouring a sort of re-evaluation of the individual dimension of the freedom of expression, already sanctioned as a fundamental human right by important instruments of international law<sup>293</sup>, but that can have – in some – as already stated in the introduction, general exasperated and maniacal forms of behaviour.

However, it cannot be denied that the globalisation process highlights a distancing between science and society in which science tends to become, cross-nationally, a power devoid of the common foundations of legitimacy. As it is easy to guess, this poses new challenges for the protection of fundamental rights and in particular of the so-called new generation ones, coming from the advent of new technologies. In this framework, the need to assess *cum grano salis* the suitability of the technical rule to overlap with the legal norm, in order to overcome the gaps in the legislation, seems evident, therefore creating a normative fact.

It is important to ask, in particular, if technical rules are able to have a function that is more typically that of the law, with the same efficacy, ensuring to the individual adequate forms of guarantee and safeguarding their effectiveness in a certain social context.

The changes highlighted are so relevant that they have induced those analysing the internet as a global phenomenon to wonder whether the Web is not a new form of law. It is undoubtedly an opinion that can be agreed upon, even though it is necessary to clarify that the development of this new dimension makes the creation of laws for the current process of globalisation of the law even more urgent (Flick, 2000)<sup>294</sup>.

---

<sup>293</sup> Suffice to remember the 1948 Universal Declaration of Human Rights, the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms and the 1966 International Covenant on Civil and Political Rights.

<sup>294</sup> A.M. Flick, *Diritti fondamentali, regole e istituzioni nella prospettiva della globalizzazione*, script of the lectio magistrale at the Università Cattolica del Sacro Cuore in Milan, on the 24<sup>th</sup> of November 2000 p. 23.

## 5.2. The protection of privacy in Italian legislation and the personal data protection code

After this general premise, it is important to recall some aspects of the Italian legislation regarding the protection of the individual in the processing of personal data, amongst which we find – as sensitive data – those about health. These data, in fact, can be processed with IT methods, including via the intranet/internet.

We must recognise that the Italian situation, from a legal protection point of view, is now completely regulated, following Law No.675/1996, the norms deriving from it, the creation of the Guarantor Office and the recurring intervention of the Guarantor for the protection of personal data.

The issuing of the Code on personal data protection completed the framework of reference for the regulations on the public processing also of healthcare data, considered, as we have said, as “sensitive data”<sup>295</sup>.

The *Code* dedicated Title V to the specific problem of personal data processing in healthcare, indicating the general principles (Art. 76) and the methods to access information and consent (Articles 77-84), identifying the aims of relevant public interest and defining the role of the National Healthcare Service (articles 85-86), regulating the form and method for drawing up doctor’s prescriptions (Art. 87), the processing of genetic data with particular reference to bone marrow (Art. 90), the processing of all data to determine the state of health or sex life (clinical records, certificates of care at childbirth, databanks, archives, registers and files) (Articles 91-94). It must be highlighted that, for the purpose of the information to be given to the patient, the “system” is based on assigning this task mainly to the GP or paediatrician of choice (Art. 78), who however can use/or be temporarily substituted by another professional or by another individual who can give specialist care, when requested by the GP or the paediatrician, or can supply the prescribed medicines.

As well as the indirect and generic reference to the possibility of using electronic cards for the preservation of data, it is important to quote subsection 5 to Art. 78, which says:

“The information provided pursuant to this section shall highlight, in detail, processing operations concerning personal data that may entail specific risks for the data subject’s rights and fundamental freedoms and dignity, in particular if the processing is carried out:

- a) For scientific purposes, including scientific research and controlled clinical drug testing, in compliance with laws and regulations, by especially pointing out that the consent, if necessary, is given freely;
- b) Within the framework of tele-aid or tele-medicine services;
- c) To supply other goods or services to the data subject via electronic communication network”.

From these elements we can identify some fundamental principles:

- a) All processing must guarantee the patients’ dignity, privacy and decorum, especially in

---

<sup>295</sup> It is not possible here to recall the Italian doctrinal and legal debate regarding the general protection of personal data, which preceded the issuing of the Code.

Important mentions can be found in Buttarelli 1997; E. Coiera, 1999, Cirillo (in Lo Iodice and Santariello, 2000), Ciacci (in Lo Iodice and Santariello).

case of serious or terminal illnesses and pathologies afflicting minors or people without capacity for discernment (article 2 of the Code);

- b) Information systems and IT programmes will have to be homogenised so that the use of personal data and identification data is kept to a minimum, in order to avoid their processing when the aims in each individual case can be achieved, respectively, through anonymous data or suitable methods that allow the identification of the subject's data only in case of need (necessity principle Art. 3 of the Code).
- c) Personal data must be processed in line with the principles of legitimacy and correctness, that is, respecting the normative framework of reference, without malicious intent or to prejudice the data subject (Art. 11 of the Code).
- d) The transparency, uniformity and suitability of the information must be protected through the promotion, by the Guarantor, of deontological and good conduct codes for personal data processing (Art. 133);
- e) The collection of personal data must also happen in the respect of the principles of pertinence, non-excess and indispensability, which obliges to only collect personal data that are strictly necessary to achieve the aims pursued. With regards to this, we must keep in mind that, according to Art. 11, subsection 2 of the Code, personal data processed in violation of the relevant directive on personal data processing, cannot be used;
- f) According to Art. 13 of the Code, the patient must be clearly informed of the aims and methods of the processing, of the eventuality that it might be compulsory and, in particular, of the identity of the individuals who will have access to his/her personal data, as well as the person or individual they can contact to exercise the rights listed in Articles 7 and following of the Code. With regards to the content and methods with which the information must be passed on to the data subject, we also observe that, given what is stated in Art. 78, subsection 5, letter b) and c) of the Code, the information will have to highlight in detail the processes carried out within tele-aid or tele-medicine and those aimed at supplying other goods or services via electronic communications networks, which can present specific risks for the rights, the fundamental freedoms and the dignity of the data subject;
- g) The data subject's consent must be collected in line with the requirements listed in Articles 23, 26, 81 and 84 of the Code. With regards to the way in which the interested party's consent is presented, it is necessary to highlight that Art. 81 of the Code anticipates that the data to determine the state of health can be documented by a notice written by the healthcare professional or the public healthcare body (the so-called witnessed consent), in which reference shall be made to the processing of data carried out by either one or several entities and to the information provided to the data subject;
- h) Personal data processed with the new technologies mentioned above must be protected by appropriate security measures, in order to reduce to a minimum the risks of destruction, loss, even accidental, of unauthorised access or unlawful processing not in line with the aims for the collection (see Articles 33 and following of the Code and Technical disciplines – annex B) to the Code);
- i) In relation to what said in Art. 37, subsection 1, letter b), of the Code, individuals who collect data disclosing health and sex life, for the purpose of delivering healthcare services on-line relative to databanks or the supply of goods, must notify the Guarantor;
- j) Art. 84 of the Code anticipates that personal data disclosing the state of health must be

made known to the data subject or owner. The second subsection of this regulation states that the owner or the person responsible can authorise in writing persons or healthcare professionals other than physicians who, to fulfil their respective duties, have direct contacts with patients and are in charge of processing personal data disclosing the state of health, to communicate said data known to data subjects;

- k) According to Art. 26, subsection 5 of the Code, the dissemination of data disclosing the state of health of the data subject must never be allowed (for example by the possibility that an indeterminate public of users would access some web pages in which the patient's healthcare data can be viewed);
- l) The processing – also through electronic cards – of data disclosing the state of health or sex life, shall only be allowed if carried out by following the measures and precautions laid down by the Guarantor in a preliminary verification (the so-called prior checking) and respecting the necessity principle (Art. 91 of the Code).

### 5.3 The sanction against illegal behaviour and health protection

The legal framework offered by the Code with regards to personal data protection, stresses the values of privacy and informed consent, linking them to the particular situations brought about by the electronic management of data and by the dissemination of information via the internet through a series of alterations due, in particular, to the necessity principle, which recommends reducing to a minimum the collection of personal and identification data, to the pertinence principle, which allows the acquisition only of the information indispensable and not in excess, and to the principle of mediated acquisition of the right to information, which demands the indispensable mediation of a doctor in the transmission of data to the data subject. We tend to reach a difficult balance between increasingly pressing, detailed, impersonal, mainly centralised information and occasional, personal and mainly individualised services. The protection regards only the acquisition and processing of data and the remedies are exclusively administrative. The guarantor can order the termination of the illegal behaviour (Art. 150), block completely or in part the processing of data (Art. 143), make provisions for a fine for the use of information (Art. 162).

There isn't instead a specific discipline (which was definitely not the task of a Code on personal data protection to issue) on the problem of the quality of information that guarantees an adequate protection for the different profiles of the right to health, which can be prejudiced by an indiscriminate and unchecked offer of information and services. This protection regards both the penal aspects in the case of malicious behaviours likely to cause injury and the civil aspects relative to the identification of the responsibility for a defect in the information.

Currently, *on-line* regulations are the same as those also valid *off-line* and, therefore, a restricted number of completely generic criminal hypothesis, very difficult to adapt to that heterogeneous plurality of data that characterises the dissemination of news on the internet. We often find an inextricable confusion between the communication of data and the supply of the service (Zeno Zenkovich, 2004), scientific dissemination and business advertising, offer of information and offer of advice, offer of services and offer of medicines. The ease and speed of access is, in abstract, a positive data for the users who can utilise, without limitations of time and space, a large number of data, having access to often highly qual-

ified sources that would otherwise be precluded to them. In concrete, there is no chance of guaranteeing the quality of information and relate it to the user's ability to understand problems that could imply delicate choices about his/her health. Together with the unquestionable usefulness, the possible situations of risk increase.

*a) From a penal point of view*

If we examine any site mentioned in specialist publications, we find a wide array of offers: a diagnostic journey to keep in check our health (*Clinics*), a specialist medical advice service for those who want a second opinion (*second opinion*), a web platform to book appointments and tests, receive the results of clinical analysis, consult the medical dictionary (*Internet service provider*) (Munico Park, 2003). These are activities that, *off-line*, would have involved different professionals (doctors, hospitals, laboratories, pharmacies) requiring, both in acquiring the data and in obtaining the services, a whole series of mediations. Each of these mediations requires, in our legal system, a specific accreditation in order to guarantee a preventive protection of professional ability and quality control of the service. The direct and indiscriminate access to the offer of anonymous and generalised medicine could avoid any filter without offering different or alternative forms of protection. As we have observed previously, Art. 84 of the Code on personal data protection tries to create a balance between the impersonal mass of data found on the internet and the individuality and peculiarity of their use, forcing the principle of mediated acquisition of the right to information. The GP should have the central role in guaranteeing control on the quality and methods of the news that are assimilated. It is, however, a norm that has a limited scope and it does not cover a large part of the services that can be obtained on-line. It also presumes a clear professional relationship in which it is possible to identify the individuals responsible and the methods of service. In practice the opposite happens: we have an indiscriminate offer which everyone accesses without any limitation.

All this should impose a specific regulation allowing the repression of frauds and the creation of clear rules to identify those responsible. Instead, in our legal system, we can find, with some difficult adaptations, few repressive legislations (Manno, 2005), linking to Art. 440 of the penal code on the adulteration and counterfeiting of food, Art. 443 of the penal code on the trade or administration of out-of-date medicines, Art. 445 of the penal code on the administration of medicines dangerous to public health and Art. 348 of the penal code on the abusive exercise of a profession. The doctrine tends to broaden their scope, defining them as crimes of danger and not of damage, and therefore putting the moment of crime in the objective beginning of the threat and not in the effective damage. The identification and repression of this hypothetical situation of danger is particularly serious *on-line* for the great amount of people that can be reached immediately, but it is difficult to estimate. The limits of the current regulation, and maybe of any possible law, emerge from at least two points of view: the identification of the regulations to apply; the identification of those responsible.

From the first point of view, the structural delocalisation of the mass of news circulating on the internet hinders a clear identification of the legal procedure to apply, so that we don't know if we need to recur to the regulations of the place in which the service is offered or that in which it is required. To understand if the exercise of a profession is abusive or if the sale of a medicine is allowed, we should first of all solve the problem of whether it is the

doctor going, virtually, to the patient or the patient going to the doctor. In the United States, Medical Colleges chose the second solution, stating that what is necessary is the qualification to exercise the profession in the patient's State (Steven et al, 2003). We hope for the introduction of a specific "licence", valid for all the States of the Union, so that it guarantees a uniform protection to those who intend to use the services offered by tele-medicine. This solution, which seems the most obvious, makes us understand how it is extremely complex to be able to create adequate legal regulations valid in all countries, because anyone and anybody can offer cures and services in any part of the world. How can we expect to guarantee a minimum level of quality?

Should the danger or illegality of the service offered be proven, there would still be no repressive or preventive instruments. From the point of view of identifying responsibilities, we must take into consideration that in the dissemination of news via the internet at least four different subjects intervene: the material authors of the content of the data put on-line (so-called *content providers*), the owners of the telecommunications infrastructures (so-called *network providers*), those who offer the possibility of accessing the network and to use certain functions (so-called *access providers*), the suppliers of services that allow the user to link to the network (so-called *service providers*). Even if we could reconstruct it in all of its parts, this complex chain of services operates as much in close connection, because each passage is indispensable to the realisation of the final product, as in absolute autonomy, because the individual *providers* can belong to different countries, operate in different countries, each ignoring the specific work of the other. Without discussing the different forms of responsibility in abstract, it is extremely difficult to prosecute subjects different from the *content provider*, which is also the element that is most fleeting and difficult to identify (Seminara, 1998). In our legal system there isn't a specific duty of the *provider* to check the information disseminated. There isn't a norm like Art. 5 of the German Law of the 22<sup>nd</sup> of July 1997 on information and communication services that explicitly requires the service providers to be responsible for other people's materials when they make them available, but "only if they know their content and blocking their availability is technically possible and can be expected". And it clarifies that "service providers are not responsible for other people's materials if they only supplied the access. An automatic and short retention of other people's materials, following the request of users, is to be considered as supplying access".

Even with a specific regulation of agreement between the content providers and the network managers, it is extremely difficult to determine when a provider has a real knowledge and possibility of intervention. Due to the huge mass of data and their rapid changeability any form of control that is preventive or immediately follows the input of the data on the network seems extremely difficult and it is therefore difficult to hypothesise a repressive action leading both to the identification and incrimination of those responsible, and the immediate cancellation of information dangerous to health, and to deter *network providers*, *access providers* or *service providers* from disseminating this type of news.

#### ***b) From a civil law point of view***

What has been said about the repression of relevant behaviours in penal law is also valid for the eventual solutions in civil law. The need for protection emerges at different lev-

els: we are responsible for the dissemination of erroneous information (*information tort*), the responsibility relative to the telematics marketing of provisions and services and, finally all the vast sector of pharmaceutical marketing (Izzo, 2000).

Also in this case, working out the responsibility is particularly difficult. Tele-medicine, with the plurality of services that it makes available, could be particularly affected by the fluctuation of the law to ascertain the professional responsibility in team medicine. The principle of custody would call into cause each of the healthcare professionals involved within the limits of the specialist contribution to the therapy (in this case also to the informative process overall), but the need to guarantee quick interventions aimed at amending eventual errors would lead to favouring the identification of a care “supervisor”, with powers of control and therefore responsible overall for all the activities carried out. The tendency to the impersonality of the information offered on-line would maybe make it desirable to identify, like in administrative law, someone who is overall responsible for the procedure with the specific obligation to verify both the accuracy of the information and the proper functioning of all the individual passages.

We must also observe that generally, it is believed that the Legislative Decree of the 22<sup>nd</sup> of May 1999, put in place by Directive 97/7/CE, is applicable also to healthcare services offered *on-line*, with it, through the discipline of the so-called distance selling, particularly important obligations of information and specific contractual solutions have been introduced for the consumer’s protection (Pasquino). The importance of these norms must not however be found in the legal protection, maybe even more difficult and complex than penal protection, but in the indirect impact that it could have in prefiguring the fundamental guidelines for the issuing of self-regulating codes allowing the selection of different offers of services. The only practicable avenue to protect the right to health, in fact, seems that of anticipating forms of accreditation, a sort of hallmark, given by scientific bodies recognised internationally, starting with the quality, transparency and reliability of the information. It has been suggested, for example, using PICS labels (*Platform for Internet Content Selection*), requiring for each medical resource the filling of a suitable label including fundamental data (author’s name, creation and updating date, judgement on the quality and extensiveness of the information) (Santoro, 2000). This labelling could be accompanied by *rating* systems giving the different sites quality points on the basis of homogeneous and transparent criteria. It would be desirable that, with time, specialist and accredited “*informediaries*” were created, which users could refer to in order to obtain reliable, selected and highly qualified information. The user should, through this cross system of accreditations and evaluations, be in the condition of making a conscious choice, avoiding with a minimum of caution giving way to false and fraudulent proposals.

It is plausible to imagine that the growth of the level of accreditation and notoriety of some sites will lead to a reduction in frauds. To reinforce this form of self-protection, a network of hot-lines, national and European, could be created, to which any situation that seems dangerous or illegal can be reported, in order to force providers into a specific obligation to suppress news that do not supply adequate guarantees. It would be possible, for national healthcare services or consumers associations, to go even further and organise “*Patient’s advocacy on-line*”: legal agencies specialised in identifying and persecuting anyone who gives health information or services without authorisation, not suitably reliable or even dangerous. Considering the evident limitations of penal repression and the extreme peculiarity of the administrative and civil sanctions, it should be the telematics system itself

to elaborate its own internal corrective measures, fighting the excess of information with the quality of information, through the creation of filters following different strategies (self-regulation codes, quality accreditation, rating systems, hot-lines) so that the evident lack of the one is corrected through the work of the other. If it is easy, in an IT network, to avoid controls and alter quality accreditations, it could become extremely complex, and therefore financially unadvisable, to try and overcome the filters operating at different levels, through a variety of bodies and with particular specialisations.

## CHAPTER VI: SYNTHESIS AND CONCLUSIONS: BIOETHICAL PROFILE OF THE USE OF THE INTERNET IN HEALTHCARE COMMUNICATION

The NBC wanted to present a systematic analysis of the relationship between the ethics of communication and the ethics of health, but suggest some reflections with regards to the use of one of the tools that – in today’s technologically advanced world – have a growing role in ensuring the communication in the healthcare sector, that is, the internet.

This tool – belonging to the traditional classification of the family of synchronic systems of communication<sup>296</sup>, together with ordinary electronic mail (e-mail), mailing lists and electronic conferences (news groups) – although strictly different from the tools of “tele-medicine”, has come to have a growing role of interest and use that the NBC wanted to evaluate with this document.

1. The NBC recognises – generally – that the exceptional development of informatics has greatly increased the communication capabilities of some privileged people or groups, able to use the internet in many sectors of private and public life thanks to their means, professional education and technical knowledge.

The internet can help people to responsibly use science and technology, expand the range of choices available in different aspects of life, broaden their cultural and educational horizons. The growing dissemination of images and words on the global scale is transforming not only the relationship between populations from a scientific, political and financial point of view, but the understanding of the world itself.

This phenomenon offers a variety of possibilities, if based on shared values, rooted in the person’s nature.

Therefore, the intercultural dialogue, made possible by the internet and other means of social communication, can be the preferred tool to build unity and diversity, and from this point of view the NBC cannot but appreciate the growing dissemination of the internet in Italy as well.

However, paradoxically, what leads to better communication can also bring an increase in egocentrism. The internet can be used (consciously or unconsciously) to bring people together, but it can also divide them, both as individuals and as groups suspicious of one other and separate in ideology, politics, passions, race, ethnic origins, intergenerational differences and even religion. It has already been used aggressively, almost as a weapon of war, and there is already talk of the danger represented by “cyber-terrorism”.

From this point of view, the NBC can silence some preoccupations, which have already appeared especially internationally, but that can be shared also amongst unequal economic areas, within the individual nations.

Amongst the most important is what we call today the “digital-divide”, a form of discrimination that divides the rich from the poor, between nations and within them, on the

---

<sup>296</sup> Communication is defined as synchronic when the interlocutors are present and linked to the network at the same time; asynchronous when the messages are exchanged and updated with delays ranging from a few minutes and some days: the interlocutors can participate to the discussion afterwards, according to times and moments more suitable to them (see L. Paccagnella, *La comunicazione al computer*, ed. Il Mulino, Bologna 2000, p. 16).

basis of the access or impossibility of access to new IT technologies. In this sense, it is an updated version of the old gap between the rich and the poor of information.

The expression “digital-divide” highlights the fact that individuals, groups and nations must have access to new technology in order to keep up with the fast use of information, and be penalised in enjoying the benefits promised by globalisation and development. It is necessary that the gap between those who benefit from the new tools of information and expression and those who don’t yet have access to them does not get out of hand, as a further source of inequality and discrimination.

From this point of view, the NBC appreciates the initiatives – national and international – of those governments that facilitate the dissemination of the internet, on the basis of the equality principle.

The Unesco also dedicates a specific Programme to the problem, emphasising that the true challenge is the human dimension of the *digital divide*<sup>297</sup>, rather than the technological aspects. In this sense, it highlights how there cannot be information for all if there’s no education for all.

The “Communication and Information” Programme includes a variety of worldwide and regional projects that have as main strategic objectives: “the promotion of a free exchange of ideas and universal access to information; the promotion of the expression of pluralism and cultural diversity in media and worldwide information networks; the promotion of the access to ICT for all”.

2. If these considerations can be aimed at the competencies and responsibilities of the public authority, others – still from a general point of view – must turn to the same powers as well as the citizens, called to be “user” and “consumer” of internet communication.

Complex and source of further preoccupations – for the NBC – in fact, is the issue of the freedom of expression on the internet, which regards first of all human beings.

The freedom to search and know the truth is a fundamental human right and the freedom of expression is a cornerstone of democracy. All this means that, respecting the moral order and common usefulness, it is possible to freely investigate, examine the truth about public and scientific events, establish also spontaneous groups on the internet for the study of particular problems etc.; in conclusion, to express and disseminate our opinions according to principles that numerous international documents, and the Italian Constitution, dictated for the development of communication in society.

However, also the freedom of expression and communication of thought on the internet cannot avoid the rules that already in oral, written (on paper) or televised communication have been elaborated by civil and penal codes, for the protection of human dignity, honour, public morality and public order.

The individual active network of “users” – that is, those who organise and send messages and select information they believe useful for the community – must take into account that the “public” nature of internet communication, which differentiates it from “private (face to face) communication between two interlocutors who are voluntarily away from the

---

<sup>297</sup> The Resolution of the United Nations Economic and Social Council (July 2000) on the “Role of IT in the context of a global economy based on knowledge” and the Millennium Declaration (September 2000) are two texts that suggest the creation of an international cooperation aimed at overcoming the digital divide.

influence of others (as for example happens in the communication between doctor and patient in the privacy of the surgery). Two interlocutors on the internet can happily, expressly (if they want) give up their “privacy”, but they cannot commit acts that interfere with someone else’s privacy.

We have to highlight, in addition, that the deliberate omission of the name of the writer of the message, or the use of pseudonyms and encrypted contents, is sometimes used on the internet for communications that have illegal aims in the objectives pursued.

In this way, if the objective of sheltering from repression is achieved, remains – at least potentially – the damage to third parties.

Public authorities should be vigilant about the accuracy (in the terms indicated) of the “traffic via the internet and not simply act – on a notification – to repress illegalities, but try and prevent (with methods that the NBC also recognises difficult to identify) the abuses that can happen with this means of communication.

3. These general reflections seem particularly coherent and punctual when the use of the internet is seen as a “service” to the citizen, with the objective of protecting and promoting health.

There is no doubt that also the recurring expectation – advanced by some – of attributing the internet to the “virtual world” (in which often dominates the free expression of feelings, the ideal images of vital situations, the surfacing of profound moods and free thought to share with strangers etc.) rather than to “the real world” (as it’s expressly stated by the extremist positions of internet lovers) collapses necessarily when the tool is used either to obtain scientific news from an informatics library, or to ask a doctor a “clinical opinion”, or finally to buy a medicine.

It is on this aspect of pragmatic usefulness that the NBC has mostly focused, that is, on the use of an “indirect” means of communication between citizens and health workers, in a sector where for centuries there have been specific rules and traditions with regards to “direct” communication, so-called “face to face”, as in the sector of clinical medicine.

In any case, these are rules and habits that – in the evolution of interpersonal doctor/patient relationships<sup>298</sup>, or amongst healthcare organisations and the citizen and/or between auxiliary personnel operating in healthcare and citizens – were established first of all by deontological evaluations, but also legal evaluations, based on some principles, amongst which emerges “the subject’s autonomy” (from which derives the need of an explicit consent to the medical procedure preceded by exhaustive information) and the respect of “professional secrecy”, extended today to the principle of the protection of the patient’s privacy.

If these are the fundamental principles (although not all) regulating “face to face” communication in the healthcare sector, there are some consequences also for the use of the internet, which seems appropriate to explain further:

a) As “information” vehicle on health

No objection – generally – can be made on this use, either in the public or private sector.

---

<sup>298</sup> The concept of “patient” is international and it expresses each individual’s right (independently from being a “citizen” in a certain community) to access healthcare, where there’s the need (ONU Declaration of Amsterdam (WHO) on patients’ rights).

From the point of view of a “social” ethical profile – in which great relevance is given to the initiative, the regulating power and the financial support that the healthcare administrator offers with choices in healthcare policies – the NBC cannot but appreciate those ideas (translated sometimes in concrete initiatives with structures, personnel and means) with which we tend to develop a policy of public information on health, prevention of illnesses, education to healthy behaviours also through the internet.

However, this information has now become redundant in some sectors (for the evident intervention of commercial reasons), lacking in others, and not always reliable.

This information must be “truthful”, it must not be “ambiguous” or “partial” or “vague” to cover, in some cases, the proponent’s unclear interests, that is “triumphalist”, and “falsely reassuring” in other cases, which are a part, most of the times, of the business objective.

The need for accurate internet messages with regards to health – as it has been amply discussed in the text – has been felt for a long time and measures of “quality accreditation” have been suggested (but only partially activated), based in part on the voluntary agreement of those creating the message with behavioural codes shared by the community and in part on the recognition – carried out by authoritative Accreditation agencies – of the quality of the messages.

The NBC recognises the complexity of this activity, not easy to pursue with the necessary range and efficacy. In the same way, it recognises that – from a legal point of view – the various instances called “Privacy guarantees” have, in Europe, created rules for the protection of privacy of internet messages; but we must stress that it is still widespread today the feeling that in some sectors these rules are not taken into account.

But most of all there still is no policy to induce “providers” and in general “active” site users (those who give messages regarding health are not always “experts”) to accept self-regulating codes for the “quality” of the messages, the dissemination of which should be in line with shared “reliability” criteria and subjected to verifications – although occasional – by competent external requests.

This does not mean forcing the producers to exclusively adopt criteria of high scientific content for each message – which would not be fully compatible with the average cultural capability – and it does not mean stopping the dissemination of less elaborate texts, more attuned to the consumer’s understanding (the citizen receiving the message on the internet); but make sure that the consumer can be at least reassured on the “reliability” of the message received and in any case know the date of completion, the name of the organisation and the writer.

It is also true that the “sites’ ownership” – where declared in the messages transmitted as belonging to Scientific Society and Institutions or Hospitals – already operates (at least indirectly) in this effort of transparency, reassurance and “public” effort in the use of the internet; however, from sample surveys (cited in the text), both international and national, the number of sites transmitting health messages where it is not possible to identify the writer is still too high and it can instead be hypothesised, from the content, that the initiative aims at a financial gain.

More rigid regulations should be adopted, therefore, for the qualification of the sites and for the identification of those who write the message.

In this direction go also the documents (reported in the appendix) of the European Community EGE Group and the suggestions of the Council of Europe’s Working Group, which the NBC shares.

b) As a vehicle of healthcare advertising

The NBC, examining the various aspects of healthcare advertising and finding that the internet has been progressively more used, for the vastness of its “target”, like a potent advertising tool dominating in the globalisation of the market – it must highlight a considerable lack of rules expressly dedicated to healthcare advertising on the internet, both in the offer of professional activities, and in the sale of medicines, nutritional supplements, medical instruments and anything else that is part of the healthcare market.

It is also true that we can state that the regulations currently in force in Italy both for healthcare advertising and the repression of the unauthorised exercise of healthcare professions (for example Law No.175 of the 5<sup>th</sup> of February 1992, titles “*Norms on healthcare advertising and the repression of the unauthorised exercise of healthcare professions*”<sup>299</sup>), both for the advertising of medicines for human consumption (for example Legislation Decree number 541 30/12/1992 “*Carrying out Directive 92/28CEE on the advertising of medicines for human use*”<sup>300</sup>) apply – for their general character – also to the use of the internet as an advertising “channel” in our country; however an explicit updating in this sense of both the legislative decrees would help clarity and would strengthen the work of repression of possible transgressions, work that is certainly difficult on the internet because of the facilitations in remaining anonymous, or avoiding what is compulsory by law, offered by making business via the internet. We refer – on the one hand – to ambiguous professional titles, doubtful in nature and reliability, present on the internet, and on the other to the lack of prescriptions for medicines that by law should only be sold with one.

c) As loss of a full communication between doctor and patient

It is maybe this bigger “danger” that the professional activity on the internet is exposed to, real danger and of such potential gravity that it has induced some states to forbid carrying out the medical profession “from a distance” for unknown patients and which the doctor has not examined objectively (except for urgent tele-medicine situations due to the lack of real, different situations: see the case of remote places in Australia, Norway, African Countries, etc. found in literature)<sup>301</sup>.

It has been observed numerous times, in literature, a dual effect:

- A generic one, of all the internet messages, namely, of the loss of a full “interpersonal communication” between users and consumers, as the internet is more an interface tool of progressive messages, than a contextual development of a communication made not only by verbal expressions, but also by visual perceptions of the interlocutors’ attitudes (gesture codes); voice intonations; body language, etc.<sup>302</sup>.
- A specific feature of the art of medicine, relative to the loss of that group of objective signs (general look of the patient, posture, deambulation, objective examination by inspection, palpitation, auscultation, percussion, etc.) which, together with elements of

---

<sup>299</sup> Published on the G.U. number 50 of the 29<sup>th</sup> of February 1992.

<sup>300</sup> Published on G.U. number 7, Ordinary Supplement of the 11<sup>th</sup> of January 1993.

<sup>301</sup> This use finds similar elements with the naval medical service, radiotelephonic, established a long time ago for those sailing.

<sup>302</sup> Read, with regards to this, the analysis of the literature carried out by L. Paccagnella, *La comunicazione al computer*, Il Mulino, Bologna 2000.

emotive perception, guide the diagnostic process in the context of the correct medical semeiotic on the physicality of the person.

With regards to the risk of depersonalising the doctor-patient relationship, various authors have focused their attention on it for some time (for example Evans, 1993; Miller, 2002; 2003 etc.) in particular in those organisations of distance medical consultation services, called “DOT.com”, many of which developed in the USA to satisfy public demand, but are of doubtful safety and financial advantage (Wootton, 2001).

Also, in other situations (for example in subjects with psychiatric disorders or sexually transmitted diseases) the greater anonymity that can be obtained – according to the patient – with an internet consultation seems to encourage reluctant personalities to start tests and treatments and undertake even the use of videoconferences, which would relieve the patient’s uneasiness caused by a “face to face” with the doctor (Mc Laren, et al., 1995).

4. The NBC – finally – stresses the opportunity to intervene, with suitable measures and on the line of the reviewed international Recommendations, and increase the safety factor of the use of the internet in a “sensitive” sector, like that of health, in order to make it easier for the consumer to select, amongst a myriad of information received today, those that are really useful.

We should – from the point of view of public health and the relative “responsibility” of the administrators – ensure not only a greater homogeneity of the “right to be informed” for all citizens, but also a greater ability to control the “quality” of the information exchanged on the internet regarding health problems.

Concluding the review of the issue, the NBC expresses in synthesis the main advantages and problematic aspects (at least potentially) of the use of the internet in healthcare as follows:

#### Advantages

– It can reduce the costs and waiting times of some health services. For example, it is possible to reduce waiting times at the counter, an increased availability of information, the delocalisation of the supply of services, etc.

– It can facilitate the access to treatments and offer higher level advice services to citizens living in areas with poor healthcare services, especially if linked to tele-medicine services.

– It can simplify both the monitoring and control of the patient after being dismissed, once the acute phase has passed (follow-up), maintaining with him/her periodical contact, as well as eventual consultations and further treatments (second opinion and consensus conference). For example, the “electronic slide”, elaborated within the “tele-pathology project” of the National Institute for the Study and Treatment of Tumors in Milan, is significant.

– It can facilitate people’s education to discern – in the current news regarding medicine – what has scientific foundation and what belongs to hopes for the future.

– It can offer an empathic support, link and help to carry out bureaucratic practices for particular categories of patients and their families.

#### Problematic aspects

– Possible depersonalisation of the doctor-patient relationship with an emphasis on the risk of feeling cut off.

Breakdown of the anthropocentric view of medicine as multisensory contact with the patient and – in extreme cases – reduction of the physicality to the network.

Without the doctor-patient direct relationship, it appears extremely difficult both collecting the informed consent and identifying the subject deontologically responsible for the information process.

In the case of medicine sales or any other form of support for forms of self-medication and self-diagnosis, there is a serious risk of abuse or erroneous use of tests and medicines.

## RECOMMENDATIONS

For the “ambiguities” in the use of the internet mentioned above, the person must be “educated” to understand and evaluate the aspects of the healthcare management of the internet.

Nationally, it seems appropriate to elaborate codes of conduct and guidelines – linked to international experiences – so that explicitly backing them would give reliability to the operators and users in the healthcare sector.

The support action for the patients and their families must be appreciated, when correctly carried out in the spirit of sharing and solidarity, also on the net, by voluntary organisations.

The doctor and in general the healthcare operator must be allowed – since their primary medicine and/or healthcare studies – to use all the cultural and practical potential offered also by this means of communication, without giving up other forms of cultural and professional training, and exercising a critical evaluation of the available information.

In the training of a doctor, specialist and healthcare personnel, it will be important to insist also on ethico-legal problems concerning the protection of “privacy” and caution in the preservation, processing and transmission via the internet etc. of the patient’s health data, according to international and national binding regulations.

The doctor and in general the health operator, when required and interested in professional communication on the internet, must, deontologically, keep sight of the “human” complexity of the doctor/patient relationship and must never give up – in the correct exercise of the profession – the richness of direct communication.

The same deontological rules, aimed at protecting the dignity and professional reliability also with regards to healthcare advertising already in force in other sectors of communication (newspapers, television, etc.) must be applied to the internet; public authorities and professional Orders – in their respective competences – must set up and exercise “adequate control” actions after having – if it is necessary – expressly updated the traditional legal tools regarding advertising also in the sector of internet communication.

In light of the considerations above, the elaboration of a discipline on the on-line sale of medicines for human consumption seems impellent, in order to boost those applications that appear positive even in the context of a controversial phenomenon.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**CAUDECTOMY AND CONCHECTOMY**

5<sup>th</sup> of May 2006



## CAUDECTOMY AND CONCHECTOMY

The National Bioethics Committee received from accountant Alberto Veronesi, President of the Italian Dog Breeders, the request for an opinion on “whether cutting the tail and the ears (*caudectomy* and *conchectomy*) of breeds whose breed standards require it, traditionally, is to be considered legitimate, lecito il taglio della coda e delle orecchie (*caudotomia e conchectomia*) nelle razze canine iconsidered the new legislation on animal welfare, as well as laws regarding animal abuse”.

The NBC has considered the question from different bioethical perspectives in order to define the proper man/animal relationship. Queste prospettive, per quanto diverse, non hanno mai impedito al Comitato di giungere aThese perspectives, however different, have never prevented the Committee from reaching widely shared, if not unanimous, conclusions, when, on other occasions, it has offered its opinion on bioethical issues of great importance as those addressed in the documents: *Animal Testing and Health of living beings* (17<sup>th</sup> of April, 1997), *Bioethics and veterinary science. Animal welfare and human health* (30<sup>th</sup> of November, 2001), *Benessere animale e salute umana* (30 novembre 2001), *Macellazioni rituali e sofferenza*Ritual slaughtering and animal suffering animale (19 settembre 2003) e *Problemi bioetici relativi all'impiego di animali in attività*(19<sup>th</sup> of September 2003) and *Bioethical problems concerning the use of animals in activities linked to human health and well-being* (21<sup>st</sup> of October, 2005). NBC members have in fact always shared the view that animals deserve respect and attention from dell'uomo e che l' *eventuale* subordinazione dei loro *interessi* a quelli degli esseri umani nonman and that the *eventual* subordination of their *interests* to human ones should not be trivially and hastily taken for granted, but carefully and conscientiously reasoned. samente argomentata.The Committee has always been and is unanimous in condemning as bioethically unjustifiable any form of *cruelty* towards all animal life.

Al CNB la caudotomia e la conchectomia appaiono *prima facie* eticamente non leciteThe NBC considers caudectomy and conchectomy as *prima facie* ethically illicit in nome del principio bioetico di *non maleficenza* che sancisce l'obbligo morale di evitarein the name of the bioethical principle of *nonmaleficence*, which establishes a moral obligation to avoid suffering and not to harm any living being that can feel pain. With regards to dogs, the cutting of the tail and ears for purely aesthetic reasons is to be considered harm in the senso proprio, in quanto non giustificato né dal conseguimento per essi di alcun significati-proper sense, as it is not justified either by giving them a significant benefit (as they would, for example, in the case of an operation, such as the amputation of aarto, terapeuticamente necessaria per la sopravvivenza) né dal rispetto di una tradizione, la limb, therapeutically necessary for survival) or by maintaining a tradition,quale (anche se potrebbe apparire in qualche misura consolidata) va riferita a canoni estrin- which (even though it may seem to some extent consolidated) is related to extrinsic aesthetic norms that today certainly questionable, in any case devoid of any relevance from a bioethical point of vista bioetico e ampiamente contestati anche nell'ambito dell'unica professione sanitariaview and widely disputed even within the only healthcare professionche si occupa direttamente del benessere animale e cioè la veterinaria that is directly involved in animal welfare, namely, the veterinary profession<sup>303</sup>.

---

<sup>303</sup> Keep also in mind that, for example, the *Fédération Cynologique Internationale* admits an aesthetic double-standard in consideration of those member states where caudectomy and conchectomy are banned.

In some cases, these interventions are justified to prevent health related problems - mainly linked to the need to correct, in some specific dog breeds, certain defects or pathologies. Né appare priva di spessore l'osservazione contenuta nel Nor does it seem devoid of meaning the observation that caudectomy may, in some cases, eliminate the risk of accidents, quite common among the elderly and children, caused by the very mobile and powerful tails of the Molossoids. These circumstances, however, merely shift the bioethical problem and force us to reflect on several issues: the appropriateness of acquiring as pets dog breeds that are not suitable to a relationship with children or the elderly, or of di selezionare - magari per venire incontro a discutibili richieste diffuse nella collettività -, selecting - maybe to meet questionable requests widespread in the community - razze canine che esigono drastici interventi terapeutici sugli stessi animali al fine di garanti-dog breeds that require drastic therapeutic interventions in order to guarantee to them reasonable conditions of well-being. With regards to this, the NBC believes that the problem of the *suffering razze sofferenti*, cioè di quelle razze i cui esemplari convivono o hanno maggiore probabilità *breeds*, namely those breeds that live or are more likely di convivere per tutta la vita con alterazioni fisiche che ne condizionano sensibilmente lo to live their whole life with physical alterations that significantly affect their stato di benessere, costituisca un questione di ampie dimensioni, meritevole di una trattazio- well-being, is a big issue, worthy of a more in depth study, which the Committee intends to carry out as soon as *ex professo*. Si ribadisce We however reiterate tthat, from a healthcare point of view, avoiding amputations would preserve the dogs from the traumi di un intervento chirurgico. traumas of surgery.

A parere del CNB, in tutti questi casi un elemento chiave è rappresentato dalla figura According to the NBC, in any case a key element is represented by the figure of the del medico veterinario che dovrebbe giocare un ruolo di mediazione e di tutela degli interes- veterinary surgeon, who should have a role of mediation and protection of the interests of the animals, and this especially in the presence of a conflict between animal welfare and human interests, which may appear unavoidable. Come già affermato nel documento *Bioeti-* As already stated in the document *Bioethics and veterinary science. Animal welfare and human health* the veterinary doctor is the guarantor of tthe laws safeguarding animal welfare, and is a spokesman for dei loro bisogni e punto di riferimento per tutti coloro che hanno a che fare con gli animali, their needs and point of reference for all those who deal with animals, either for love or gain. The evaluation of those exceptional cases where caudectomy and conchectomy may be morally justified, therefore always requires the advice of the veterinary doctor who, by virtue of his/her professionalism and the scientific knowledge gained, acts promoting an overall project of "partnership" between man and animal.

Pur non essendo il CNB organo deputato alla formulazione di pareri legali ma soltan- Although the NBC is not the body responsible for formulating legal opinions, but only ethical opinions, it is worth mentioning here, in terms of legislation, the *European Convention for the protezione degli animali da compagnia*, approvata nel 1987 dal Consiglio d'Europa e firma- *Protection of Pet Animals*, approved by the Council of Europe in 1987 and signed- ta anche se non ratificata dal nostro Paese. even if not ratified by our country. Essentially acknowledging the abovementioned "harm principle", art. 10 vieta tassativamente tali interventi 10 strictly forbids such interventions<sup>304</sup>.

Finally, the request of opinion raises the issue of animal sterilization also in the sense of looking at the negative consequences and the significant bioethical relevance compared

to caudectomy and conchectomy. The NBC recognizes that sterilization involves without a doubt a much more severe mutilation than caudectomy and conchectomy: an act that is not only invasive, but likely to lead to behavioral changes, which therefore must be considered extremely carefully for each individual animal involved, and carried out only after examining each case, the advantages and disadvantages of the intervention, always seeking the advice of the veterinary doctor also to assess the possible risk of breast or uterine pathologies<sup>305</sup>. This mutilation, tuttavia, può ritenersi giustificabile sotto diversi profili, in particolare modo nel mutilation however, can be considered justifiable in several respects, especially when dogs don't have an owner<sup>306</sup>. Within an ethics of responsibility, appare infatti doveroso per l'uomo farsi carico dei complessi problemi in-responsibility, it is important that man takes into account the complex problems raised from living with animals and prevent the health and social harm caused by overpopulation. animal overpopulation. Né va dimenticata, in un'ottica sociale, la gravità del fenomeno del *randagismo*, che determina pericoli per la salute umana, un potenziale aumento del fenomeno di *stray dogs*, which causes damage to human health, a potential increase in animal suffering and higher costs which could affect the conditions of life that society can and must ensure to stray and/or abandoned dogs. the living conditions which society can and must ensure to stray and/or abandoned dogs.

L'obbligo della sterilizzazione, previsto per i cani randagi dalla legge quadro Compulsory sterilization for stray dogs under law 281/1991 e dalle successive leggi regionali, è nato proprio dalla necessità di elaborare una politica di controllo delle nascite e di migliore distribuzione delle risorse. policy of birth control and better distribution of resources. The stray dog phenomenon *randagismo* che comunque dovrebbe indurre anche i proprietari o detentori di cani a should also induce dog owners to carefully manage their animals' reproductive life, in order not to increase the number of abandoned dogs due to litters that are unwanted and difficult to place.

---

<sup>304</sup> Article 10 – Surgical operations

1. Surgical operations for the purpose of modifying the appearance of a pet animal or for other non-curative purposes shall be prohibited and, in particular:

- a. the docking of tails;
- b. the cropping of ears;
- c. devocalisation;
- d. declawing and defanging;

Exceptions to these prohibitions shall be permitted only:

- a. if a veterinarian considers non-curative procedures necessary either for veterinary medical reasons or for the benefit of any particular animal;
- b. to prevent reproduction.
- 3.a) Operations in which the animal will or is likely to experience severe pain shall be carried out under anaesthesia only by a veterinarian or under his supervision.
- b) Operations for which no anaesthesia is required may be carried out by a person competent under national legislation.

<sup>305</sup> For the same reasons already expressed with regards to caudectomy and conchectomy, sterilisation can never be justified by trivial reasons.

<sup>306</sup> In the case of owned animals, there are in fact also further considerations regarding wider issues relative to the man/animal relationship of affection and the issue of the informed consent to the veterinary doctor.

These bioethical and social justifications regarding sterilization - except in the above-mentioned exceptional circumstances – do not exist, instead, with regards to cutting the tail and ears, practices that cause unnecessary suffering and are mostly determined by da mode e consuetudini non più tollerabili per chi sia attento al benessere animale e, ad av- fashion and customs that are no longer tolerable for those who are attentive to animal welfare and, according to the Committee, not justifiable also in light of the developing legal-sensitivity on this matter.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**CONFLICTS OF INTERESTS IN BIOMEDICAL RESEARCH  
AND IN CLINICAL PRACTICE**

8<sup>th</sup> of June 2006



## PRESENTATION

Upon proposal of prof. Giovanni Federspil, in the plenary meeting of the 24<sup>th</sup> of June 2005 the National Bioethics Committee unanimously decided to set up a working group on the subject of the conflict of interests in medicine. Various members of the NBC joined the group including Profs. Salvatore Amato, Mauro Barni, Luisella Battaglia, Paola Binetti, Adriano Bompiani, Luisa Borgia, Cinzia Caporale, Lorenzo d'Avack, Maria Luisa Di Pietro, Luciano Eusebi, Angelo Fiori, Carlo Flamigni, Laura Guidoni, Aldo Isidori, Demetrio Neri, Pasqualino Santori, Giancarlo Umani Umani Ronchi. Prof. Federspil was unanimously appointed coordinator of the group. After a year of work with numerous meetings of the group, Prof. Federspil delivered the draft of the Document agreed upon by the group to the NBC. The Committee, greatly appreciative of the work carried out by Prof. Federspil and the results achieved, expressed its unanimous approval in the plenary meeting of the 8<sup>th</sup> of June 2006, with a slight but appropriate change in the title.

The delicate nature of the subject dealt with in this Document hardly needs to be stressed. The crisis of Hippocratic medicine, the spread of a reductively contractualist vision of the doctor/patient relationship, the influence that utilitarian models of thought (often not well understood and above all badly applied) has on most contemporary public opinion, the exasperated technisation characterising the most recent and most efficient diagnostic and therapeutic methodologies cannot but exasperate issues that were well-known to traditional medical ethics, but which have now become such as to require new rigid forms of approach. One must not be eluded that bioethics alone can adequately deal with problems of such dimension, without further forms of biojuridical and above all biopolitical support. It can however – and therefore must – take on the task of judging and reporting the new forms of alteration in the professionalism of the researcher and medical practice, which have specific ethical repercussions. By publishing this Document, the NBC is certain that it has opened up the road to reflection and commitment in this field which will be exemplary, at least in the short and medium term.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## INTRODUCTION

Medicine is a complex polymorphous science, having relations of different types, with society and the institutions produced by it. These relations involve both biomedical research and clinical medicine, that is to say, the applied medicine practised daily in surgeries, x-ray departments, laboratories and in hospital wards and teaching hospitals.

Modern biomedical research can be carried out, overall, only with the use of huge capital. While it is in fact true that some research can be done with the use of relatively inexpensive equipment and materials, it is just as true that many other types of research – especially of an applicative nature – need extremely sophisticated instruments and a complex structured organisation which often goes beyond the boundaries of single states and has to be kept operational for years, with great expenditure of human and economic resources.

Similarly, clinical medicine is today practised with the use of elaborate equipment and investigation techniques and treatment of patients which weighs heavily upon social expenditure. In order to have a real idea of the economic resources that are taken up by medicine, it suffices to think of the huge radiological equipment, the computerised axial tomography, the nuclear magnetic resonance, modern microscope techniques, transplant surgery and the widespread use of costly drugs.

It is therefore easy to understand how the use or non-use of a technique, a piece of equipment or a drug can move considerable sums of money in one direction or another.

This situation, which is strictly linked to the quantity and quality of the investigations and therapies available to citizens today, is the origin of an evident bioethical problem. The doctors who deal with applied research and the actual problems of the patients are obviously social subjects, who work in the human community and who therefore have desires, plans and ambitions like all the other members of such a community. Hence, working in a world where the economic interests coming into play are often huge, they are greatly exposed to possible conflicts of interest.

Over recent years this argument has been the subject of numerous articles in international scientific journals and, in some of its aspects, of normative measures aimed at guaranteeing the correct carrying out of research and experimentation activities<sup>307</sup>.

Very recently a number of scientific organisations have dealt with the issue and have introduced some practical norms in an attempt to make the possible conflicts of interest of the various researchers explicit<sup>308</sup>.

Despite the attention paid to the conflict of interest in the world of medical research, the problem has not yet been analysed in any depth or satisfactorily by the bioethical world. Without claiming to deal with all the aspects of such a complex subject, it seems opportune to dedicate a number of reflections to the question of the conflict of interest, which might be the starting point for further in-depth studies.

---

<sup>307</sup> With regard to this see *Jama* 2000, 284, pp. 2234 - 37; *Jama* 2003, 290, pp. 2521 - 22; *Jama* 1998, 279, p.1067; *Lancet* 1997, 348, p. 627; *Lancet* 1997, 349, pp. 327 - 31; *Br Med J* 1994, 308, pp. 4 - 5; *N Engl J Med* 1989, 321, pp. 86 - 92; *N Engl J Med* 1997, 336, pp. 1666 - 67; *N Engl J Med* 1989, 321, pp. 464 - 66; *Nature* 1992, 360, p. 205.

<sup>308</sup> As for example, the SIMI made a declaration obligatory for its members concerning the possible personal interests of a speaker in the field of research in which he is publishing a piece of work or giving a paper at a conference.

The phenomenology of the possible conflicts of interest is vast and highly polymorphous, the very concept of 'conflict of interest' not always being clear and univocal. According to one widely accepted definition, 'there is a conflict of interest when one finds oneself in a condition in which the professional judgement concerning a primary interest (the health of a patient or the truthfulness of the results of research or the objectivity of giving information) tends to be unduly influenced by a secondary interest (economic gain, personal advantage)' (Bobbio 2001).

### The problem of the 'false facts' in science

Modern science is presented as objective knowledge, which sets out to describe and explain natural reality just as it is. This aim was repeatedly challenged during the XX Century and contemporary epistemology has demonstrated how scientific knowledge is partial knowledge, approximate and always open to being corrected – that is, reformable – rather than incontrovertibly true knowledge. In other words, an absolute realism of science is presented more as a regulatory ideal than as a definitive achievement.

Despite these intrinsic limits, there is no doubt that modern scientific knowledge is presented as objective, reliable and rationally founded knowledge. These general characteristics of naturalistic knowledge are founded on the objectivity and truthfulness of factual records that are carried out by scientists. Even if scientific assertions cannot aspire to absolute completeness and neutrality, there can be no doubt that the scientific code of ethics establishes, as a fundamental and minimal duty of the researcher, the obligation to make one's own observations in such a way that they are as faithful and complete as possible.

Despite these ethical imperatives, the history of science bears witness to how in the last Century numerous conspicuous false facts were claimed<sup>309</sup>.

In reality, the phenomenon of 'false' scientific facts is not easy to interpret. While in many cases there can be no doubt with regard to the will of the researcher to deceive the scientific community, in others the boundaries between the authentic 'false fact' and imprecision or the poor methodological rigour of the research certainly appear more unclear.

### Scientific 'false facts' and methodological distortions in medicine

In a discipline like medicine, in which the subject being studied – healthy and ill people – is extremely complex and very often observations lack the precision and objectivity that are more easily obtained in the sciences of the inorganic world and in the other branches of biology dealing with organisms that are more simple than the human one. Furthermore, the points of view from which a specific biomedical problem can be looked into are very often so numerous in medicine that it is not easy to establish what the best approach is in the different circumstances.

---

<sup>309</sup> It suffices to mention the cases of William T. Summerlin, John Darsee, Soman and Felig, John Long (Kohn, 1991) to have the proof that researchers do not always observe the rules that should constitute the ethical basis of their profession.

It therefore appears evident how in biomedical research – and particularly in research more closely connected to clinical problems – the approaches of a researcher can be directed and motivated not only by cognitive problems or by the exclusive desire to find a remedy to morbid problems, but also by personal problems or by those linked to the institutions where the researcher works.

This complex situation in which biomedical researchers often find themselves, and above all those working with therapeutic problems, has aroused the suspicion that a more or less relevant amount of the research carried out today is not as neutral and objective as it should be<sup>310</sup>.

In a parallel way, medical practice can also be easily influenced by the world of industry which operates in close contact with doctors practising in healthcare structures<sup>311</sup>.

There is no doubt that today the industrial world finances a very considerable part of clinical research in one way or another. According to some assessments, about  $\frac{3}{4}$  of biomedical research currently carried out in hospitals and clinics (and in a lesser way also in non-clinical research), is backed by industry. Of course, the contribution by industry is not limited to financing the research that comes into the production interests of the companies, but is extended to supporting studies of purely theoretical interest that are conceived and carried out as a result of the interest and initiative of researchers belonging to public facilities.

In a Document published on the 22<sup>nd</sup> of March 2005, an ad hoc committee set up by the House of Commons of the UK Parliament declared that: “the influence of industry has spread to such an extent that now numerous activities move against public interest....”.

In Italy, as in other countries, single scholars have maintained that research and clinical practice are considerably influenced by industry and that clinicians are exposed to the danger of taking decisions that are not always linked to the patient whose interest they have the duty to take care of.

Even though a prejudicial attitude is manifest in many of the reports made, hostile to the world of industry where every intervention is seen as a potential danger for the neutrality of research and good clinical practice, there is no doubt at all that the situation that has come to be raises serious bioethical issues to which it is indispensable to try and give an answer and for which general rules of conduct must be outlined.

---

<sup>310</sup> With regard to this, see the international and Italian regulations on clinical experiments. The principle references of the Italian regulations for the trials relative to drugs can be found on the site of the Agenzia italiana del Farmaco (AIFA). Among these is highlighted the Ministerial Decree of 15.07.1997 which sets down a series of indications on instruments of protection (known as Good Clinical Practices) and which set up the Ethics Committees for clinical trials, and the following M.D. of 18.03.1998 – Reference guidelines for the setting up and functioning of the ethics committees. See furthermore Legislative Decree No. 211 of 24.06.2003 – Implementation of the directive 2001/20/EC relative to the application of Good Clinical Practices in the carrying out of clinical drug trials for clinical use, which foresees a series of applicative decrees.

<sup>311</sup> In confirmation of all this, a recent survey in the US carried out by the Health Partners Research Foundation of Minneapolis, conducted on 3,247 researchers, highlighted how a considerable number of those interviewed admitted having put forward incorrect interpretations of the data obtained and how about 15% confessed to having modified their own study upon pressure from the commercial sponsors (Corriere della Sera 14-6-2005).

## Ethics of research and conduct in clinical medicine

Since medicine is made up of two parts, distinct but closely connected – research and clinical activity – it is opportune to keep the treatment of the first separate from the second here too.

Biomedical research is made up of two parts – the research that is carried out on parts of living organisms or on laboratory animals or on healthy or sick subjects with the aim of describing or explaining normal and pathological biological phenomena, and the research that is carried out on ill human subjects, with the aim of deciding on diagnostic and/or therapeutic treatment that will improve the course of the illness and the prognosis of morbid processes affecting the patients. The first constitutes the sector of medicine which is generally called experimental medicine, while the second is called *clinical research*.

The question of the conflict of interests arises in most cases in clinical research since it is in this sector that considerable economic resources and sophisticated analytical instruments are usually used.

The general ethics of research requires the application of clear standardised rules: researchers must refer the results of their observations and experiments in full, scrupulously and faithfully, without eliminating the data that do not agree with their initial hypothesis. They must fully describe the techniques used to carry out their research and the type of data analysis used to highlight the phenomena that appear to be most significant. If the slightest doubt exists that something did not work as it should have done during the experiment, the scientific observations must be repeated until the results obtained have become constant and superimposable. The results and techniques of their studies must not be kept hidden and, when published, no parts of the results must be left out, thereby favouring some conclusions rather than others. Lastly, they must not be influenced by personal interests of any kind whatsoever: economic, social, personal prestige, etc. The basic mental approach of researchers must be inspired by a fundamental humbleness before nature and its laws; they must recognise, in fact, that they are simple disciples asking questions in order to learn and can never think that they can superimpose their own ideas onto nature. A sociologist has summed up the values that must inspire the ethos of the researcher in an acronym – Cudos – which unites Communitarism, Universalism, Disinterest and Scepticism as methodological approach.

These general rules are sufficient for an honest practice of studies in many naturalistic disciplines. They are, for example, adequate and sufficient for a botanist as they are for an astronomer or a palaeontologist. For biomedical sciences, on the other hand, the ethical problem immediately becomes more complex since experimental medicine already poses the morally relevant problem of the use of laboratory animals to acquire greater knowledge of the living world. It is in fact evident how a lot of research carried out by biochemists, physiologists, embryologists, pathologists, etc. has no immediate consequence of a practical nature and is only carried out with the aim of checking a specific biological hypothesis.

In clinical research the issue becomes more complex and difficult since the researcher, in carrying out his own studies intervenes and works on other men and can more easily modify their organism and lifestyle or, even their fate.

In reality, a more detailed investigation can show how the conception of an ethics of science that identifies with an ethics of knowledge and neutral impartial truth (Gismondi 1997), is today clearly insufficient to deal with the many issues raised by modern research.

With regard to medicine, the ethical problem of human experimentation has already been dealt with by this committee (The experimentation of drugs. 17<sup>th</sup> of November 1992), nevertheless this problem goes beyond the solutions already discussed and takes other issues into consideration.

With respect to the problem already dealt with, which concerned above all the rules and procedures of clinical trials, informed consent, the protection of patients, pharmacovigilance, etc., the present one can appear to be totally banal since it seems obvious to say that the behaviour of a researcher should not be influenced by external factors for the intrinsic ends of science. Nonetheless, the question will not appear to be so foregone if one considers that the problem being debated is presented as *a problem of ethical limitations* rather than of ethical principles. From this point of view it is no different from other bioethical issues – for example, from the question of persistent therapy – in which it is easy to accept the basic principle, but it is extremely difficult to identify the limits within which that principle is valid and must be applied.

### Contemporary clinical research and industry

Today the world of clinical research is closely connected with the social production reality constituted by industry and the presence of the institutions, represented by universities and healthcare facilities.

When a result of basic research (explicative hypothesis, technological instrument, diagnostic procedure, drug or clinical trial) leaves the closed environment of the laboratories and goes on to be used, it comes into contact with a much bigger environment than the one where it was born and had lived, and finds itself exposed to very strong pressures of different types.

A drug for example is evaluated for its therapeutic possibilities that it may have in the various social contexts of the same country and in different countries of the world. At the same time, it is also evaluated for the several other factors: the possible side effects, the cost of transforming it from a potentially effective molecule with therapeutic effects into a marketable drug, the possible return and profits that it can make, the similar drugs with which it will have to compete, the foreseeable length of its presence on the market, and the reception it will receive in the medical world, etc.

As the pharmaceutical companies have to make a profit in order to stay in the market, they need to try to promote the sale of their own drugs (or, for companies not producing drugs, the sale of their own products: diagnostic kits, surgical devices, diagnostic equipment like scans, stents, bone density measurers, etc.). If one considers that the average cost of putting a drug onto the market amounts to hundreds of million euros, it is easy to understand what the entity of the product must be to be able to amortise the expenses sustained.

Before the industries come the doctors, who inevitably become the terminals of pressure made by the industries to realise their own economic ends.

Between the industries and the healthcare world are the public institutions, which take various measures to contain drug spending, adopting different measures: regulation of drug prices, stratification of drugs into different categories, specific packaging of products containing the pharmacological principle, but without brand name at a lower price, prescription control, exclusion of ineffective products or ones that have been substituted by other more effective ones, etc.

The strategies used by industry to lead doctors to prefer their products are several and differ from each other. Some of these appear to be completely licit, while others, which will be looked at more in detail in the conclusion of this document, are clearly debatable from an ethical point of view.

### **The conflict of interest of the doctor researcher and the clinician**

In Italian society today, as in all the other countries of the Western world, the pharmaceutical industry and the other companies producing materials and instruments for the healthcare service, powerfully interact with such system. It is certainly no mystery that a considerable amount of applied medical research is carried out upon initiative or even upon commission of the industries that are very keen on the success of new drugs or new technological products. In this way a relationship is created of the 'researcher/client' type between the doctor carrying out the research and the industry that conceives, plans, organises, finances and lastly, edits the publication of the research itself.

It appears evident that in some cases the doctor-researcher figure can become subaltern to that of the client: in fact, while an interest of the industry consists in valorising the product in which it has invested its resources to the maximum, the aim of the doctor-researcher should be that of describing how things are without being influenced by different ends. It is just as clear, furthermore, that even a researcher with no contacts with industry has a personal interest in concluding his research positively: in fact, studies demonstrating the effectiveness of a drug or the clinical usefulness of an instrument are usually more appreciated and more rapidly promote the career of a researcher than studies giving a negative result. However, in the case of a sponsored trial, the interest of the financier is added to the personal interest of the researcher, thus creating conditions that facilitate the creation of a conflict of interest.

Conflicts of interest can be of two different types: direct and indirect. The first type takes place when the doctor-researcher receives direct payment for his work from the industry. The indirect conflicts are when the doctor-researcher doing the research involving a product of an industry, receives various forms of fringe-benefits from this industry (for example, free participation at congresses, trips, grants for himself or for his collaborators, giving of scientific equipment 'on gratuitous loan', etc).

It is easier for these conflicts of interest to take place in those fields of pathology in which morbid alterations are particularly widespread, the pathogenetic mechanisms very long or even indefinite. Examples of these 'at risk of conflicts' spheres of study are the anti-hypertensive, hypolipidemic or anti-osteoporosis therapies.

It is inevitable that the medical world is sensitive to the economic backing that industry offers research and/or professional refresher courses. A doctor's gratefulness clearly conceals a considerable danger for the intellectual independence of the clinician. The choice and prescribing of medicines (like diagnostic tests or instruments or equipment) can be widely influenced by the doctor's state of mind, which could be led into preferring one drug instead of another, not because of the pharmacological or therapeutic features of the molecule, but owing to the relations that he has with a certain industry.

This situation, with dangers on all fronts, has been compared to the porcupine dance,

or rather to a situation in which the two sides are obliged to dance together without however getting too close for fear of hurting one another.

### The possible remedies

The American scientific world has become aware of the situation that has come to be in the last decade and in 1990 the American Medical Association included the Opinion expressed by its Ethical and Legal Commission into its Code of Ethics for the medical profession. In Italy only two medical-scientific associations have dealt with the problem of the conflicts of interest until now<sup>312</sup>.

In 1999 FNOMCeO included an Article (Art. 73) on conflicts of interest in its Deontological Code. This article however concerns the conflict that can arise between the clinical activity of a doctor employed in the healthcare service and free-lance clinical activity.

Different approaches can be used when dealing with this phenomenon. On the one hand, there is the standpoint defended by the British Medical Journal<sup>313</sup>, according to which the conflict of interests would in itself be morally reprehensible and it is therefore to be hoped that a separation of the medical world from the industrial one may be achieved. On the other hand there is the standpoint described in the work of a number of sociologists<sup>314</sup>, according to whom it would be opportune to overcome the definition of 'conflict of interests'. The conflicts going under the name of 'conflicts of interest' are not real conflicts, but 'social interactions with a strong speculative nature'. The social relations as such would not be dishonest but only the behaviour of the single persons: pharmaceutical representatives, publicists, doctors prescribing medicines, etc. What all these subjects have in common would be the deliberate diffusion of false information or the distortion of facts leading to conduct for the purpose of guaranteeing personal gain. The conflict of interest would therefore be a form of agiotage that would come under the sanctions foreseen by the Penal Code (Art. 501) and the Civil Code (Art. 2628), and the 'physical evidence' would be the dishonest information.

Both positions appear extreme and lead to undesirable consequences: the first would

---

<sup>312</sup> These societies are the Associazione Nazionale Medici Cardiologi Ospedalieri and the Società Italiana di Medicina Interna. At its 102nd National Congress (2001) the latter held a Round Table entitled "The neutrality of science. Conflicts of interest" and resolved that in the papers presented at their congresses and in those published on their official journal (*Annali Italiani di Medicina Interna*) the authors must declare the presence or absence of conflicts of interest\*. In reality, such a declaration, praiseworthy as it may be, does not seem to constitute an adequate instrument to check such a widespread phenomenon as the conflict of interest is today. \**The compulsory declaration is the following: "The author denies having any connections of an economic or professional nature with industries or organisations, as a result of which a conflict of interests may arise concerning the matter discussed in this presentation"*.

<sup>313</sup> See R. Smith, *Medical journals and pharmaceutical companies: uneasy bedfellows*, in "Br Med J", 2003, 326, pp. 1202-05. R. Smith, *Conflict of interest and the BMJ*, in "Br Med J", 1994, 308, pp. 4-5. R. Smith, I. Roberts, *An amnesty for unpublished trials, send us details on any unreported trial*, in "Br Med J", 1997, 313, p. 622.

<sup>314</sup> See Ivan Cavicchi, *Il medico tra due conflitti: l'economia che determina e la società determinante*, in "Ann Ital Med", Int 17 (Suppl 1), 2002, pp. 143S-149S. Ivan Cavicchi, *Implicazioni della neutralità tra scienza ed economia*, in "Ital Med", Int 18 (Suppl 1), 2003, pp. 203S-206S.

greatly harm applied biomedical research as a whole, and would slow down any therapeutic progress; the second would hit only the conduct whereby wrong information is given. This obviously implies that it is possible to clearly distinguish true scientific statements from false ones and disregards the fact that scientific claims are usually characterised by more or less high degrees of credibility (Hempel, 1968).

Instead, as often declared by a number of sources, it must be recognised that the conflict of interests tends to arise as a condition that could give place to or even promote ethically reprehensible conduct. In other words, conflict of interests is not a conduct, but a 'condition' and, therefore cannot be reprehensible in itself: in fact, in every man's life he finds himself in conditions of conflict of interests on numerous occasions and this status cannot be eliminated from human life. Big advantages are to be obtained from an industry and an absolutely upright conduct can be equally maintained, just as one can have weak conduct before someone who can give us an insignificant gift. Nobody can deny however that the first condition is ethically much riskier than the second, and therefore it seems ethically important to recognise the limit beyond which a conflict of interests increases forms of ethically censurable conduct with great probability.

What bioethics can do is to set out a limit that makes reprehensible conduct difficult to practise or that establishes where a status of conflict generates reprehensible conduct. Of course, the idea of being able to fix this kind of limit in such a precise and definitive way appears rather naïve since the conflict of interests, for the very reason that it is a condition and not a conduct, becomes morally reprehensible only when it causes reprehensible conduct.

It is evident how the context of scientific research and clinical practice, intentionally not dealt with in this document, are closely connected by the methodological and ethical correctness with which scientific data are produced. A clinical trial and/or its corresponding publication, which contains partial data will heavily condition the correct use of a drug in clinical practice, since the prescription of a pharmacologically active substance is substantially founded on results published in scientific literature. A distinction must be made however between the conduct of a researcher facing a scientific problem posed by a drug, studying its effects on a sample of subjects and that of a clinician who finds himself treating a single person.

In the first case the general interests of the patients must be assessed above all and any conduct will censurable which describes the advantages of a drug with respect to other similar drugs in a way that is basically false, or which conceals its drawbacks or dangers.

In the case of clinical activity, the solution to an extremely difficult problem like this one can only be found in the reference to a principle which, in all circumstances, is superior to the one caused by the conflict of interests. This principle can be no other than the welfare of the patient: every time that a conflict of interests produces clinical conduct in which the interest constituted by the well being of the patient is put after a different interest, that conflict must be judged as being ethically censurable.

In other words, the ethically censurable conduct will first of all consist in a decision which, on the basis of his general knowledge or the experience that a single doctor has of a single patient, chooses a drug or opts for diagnostic treatment that is the least suitable for the individual pathology of that patient<sup>315</sup>.

---

<sup>315</sup> Of course insofar as in this opinion pharmacological therapy is dealt with in particular, similar considerations are true for all types of therapy and diagnostic procedures.

In this case, the ethically censurable conduct does not derive from the breach of the general rules of research, but from not adequately considering the most reliable knowledge existing at a certain moment and by not giving the well being of the patient priority<sup>316</sup>. In fact, in clinical practice, only the doctor that is acquainted with the pathological condition of the single patient, his/her personality, existential situation and the desires expressed, can recognise what is good for that person.

### Final considerations

Recently some of the situations that frequently arise have been described, in which the objectivity of research and that of the scientific information given to doctors can be jeopardised:

- 1) industry does not always give doctors information that is complete and neutral, but targeted information, created in its own offices;
- 2) the drugs produced are often duplicates of other already existing medicines (the so-called me-too drugs) which present no advantages with respect to the latter and which are sold at a higher price. The industry usually promotes the most recent and expensive drugs and for this purpose lavishes various types of 'gifts' on the doctors leading to an attitude inclined to hyper-prescription by the same or to the prescription of the most expensive drugs;
- 3) industry controls and directs research by means of funding given to universities;
- 4) industry sometimes interrupts non-favourable research or hinders its publication. In other cases it distorts on-going research, substituting the primary end points with surrogate ends;
- 5) the rough data of clinical-pharmacological trials often remain in the hands of industry and are never put at the disposal of the researchers who produced them. They are given the data only when they have been reprocessed by the statistics offices of the companies;
- 6) being the 'owner of the results', the industry does not publish the negative ones;
- 7) scientific journals do not publish articles containing negative data since it is of little scientific or commercial interest;
- 8) the industry conditions, by means of publicity, the big medical journals, whose referees often have relations of economic dependence with the companies;
- 9) the doctors who draft the reviews or guidelines are very often not truly independent of industry.
- 10) even the public administrations are often not independent of industry.

This incorrect conduct – which is moreover not extended to all industries – does not exclude the fact that a correctly interpreted and regulated free market regime has had and may have a central role in the progress of biomedical research and in the development of

---

<sup>316</sup> It is therefore hoped that the professional associations carry out controls on their members, assessing the clinical conduct of doctors and attempting to highlight those situations in which the conflicts of interest have generated ethically unacceptable clinical conduct.

technologies relative to it. This conduct however can create conditions of conflict of interest on the part of biomedical researchers and doctors towards the companies with which they are in touch.

Given the complexity of the real situation, the possible remedies do not appear to be without difficulties and can certainly not lead to definitive solutions. The role of the ethics committees seems to be fundamental in this field, in checking experimental protocols put to their approval, evaluating any possible risks inherent in the research, in the light of the benefits which could in fact be obtained for the single patient and the whole community.

Moreover they could promote the diffusion of knowledge gained from clinical research, asking for commitment in the diffusion and/or publication of results by the experimenters, in the respect of the laws in force on the privacy of data and patent protection. In the case of clinical trials not sponsored by industry and carried out in accordance with the so-called 'no profit' decree (M. D. 17.12. 2004: Prescriptions and conditions of a general nature, relative to the carrying out of clinical drug trials, with particular reference to those for the improvement of clinical practice, as an integral part of healthcare), the ethics committees also have the task of verifying that trials with commercial ends are not carried out in this capacity. In this case the ethics committees are explicitly called upon to verify that a declaration is signed on the conflict of interests, foreseen in detail in an attachment to the decree.

The ethics committees themselves can perform the task of 'guarantors' only if they are set up and organised in such a way as to ensure their independence from any form of hierarchical subordination by the structure in which they work. Even in the ethics committees the absence of any form of conflict of interests of the voters with respect to the research protocols proposed must be guaranteed.

As far as concerns the problems linked to research, the first measure should regard the transparency of the various situations. Each sponsorship and each link, be it direct or indirect, existing between industry and the single researcher or the institution in which he works, should be declared publicly and described without concealing anything in its real terms when the results of the research are made known or used to support therapeutic choices. The sponsoring industries should always give all the rough data obtained to all those who have taken part in a study. The interpretation of such data should be discussed together among the company representatives and the those of the various research groups that carried out the study. The final paper should be approved by all those who participated in the investigation and, in the case of contrasting interpretations, should include the different opinions.

Since the failure to publish the results of a non-favourable or little favourable trial to a specific treatment represents a factor that distorts the overall knowledge of the scientific community, the ethics committees should make every possible effort so that the outcome of all clinical research begun is published. This should be true also and above all for the studies that are interrupted owing to the obvious poor efficacy of the therapy being tested or owing to the presence of considerable side-effects. In fact the absence of the publication of the negative effects of research in literature produces a very serious information gap, both in the experimental context (allowing useless duplications of similar research, with an unacceptable waste of economic resources which could be used for other sectors), and in the clinical context (not permitting the doctor to know all the information necessary so as to guarantee each patient the due combination of "best therapeutic result/least exposure to the risk of adverse events").

It is important to point out that a piece of research, at a moral level, belongs to all those who, together, conceived and carried it out and who drew and demonstrated their conclusions, independently of their juridical position (employees of the public sector, private companies, individual professionals, etc) or professional one (biologists, chemists, doctors, statisticians, physicists etc.) in which they found themselves at the moment of carrying out their work. Therefore, it must be stressed how the role of researchers who work for the PA must in no way be less important than that of those who financed the research.

Lastly, the increased use of revealing the results of an experiment by means of mass media seems unethical, before the results have been published in scientific journals and thus submitted to the scrutiny and judgement of the scientific community. Such conduct can in fact lead public opinion to have false hopes or dangerous alarmism, even before the results have had the necessary confirmations or denials.



*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**BIOBANKS AND RESEARCH ON HUMAN BIOLOGICAL MATERIAL**  
**Opinion of the NBC on a Recommendation of the Council of Europe and**  
**on a Document of the National Committee for Biosecurity and Biotechnology**

9<sup>th</sup> of June 2006



In the meeting of the 16<sup>th</sup> of December 2005, the NBC examined the work carried out by the Steering Committee for Bioethics of the European Council (SCB) on the topic: “Draft Recommendation on research utilising human biological material”, concluded in the plenary meeting of the Committee which took place in Strasbourg from the 17<sup>th</sup> to the 21<sup>st</sup> of October 2005 and transmitted to the Delegations of the Ministers of the European Council.

This Document was accepted by the Committee of the Ministers of the European Council on the 16<sup>th</sup> of March 2006, without modifications.

In the plenary meeting of the 6<sup>th</sup> of June, the NBC has examined the document of the National Committee for Biosecurity and Biotechnologies (NCBB) “Guidelines for the creation and certification of biobanks”, developed on the 19<sup>th</sup> of December 2005 and received by the NBC, courtesy of Professor Leonardo Santi.

Taking into account that the two Documents come from independent sources but fully coincide in time, the NBC deems appropriate to express the following considerations:

1 – The “Project” developed by the EBC has become necessary for the recent passing of the “Additional Protocol to the Convention for the Protection of Human Rights and Human Dignity in the application of Biology and Medicine regarding Biomedical Research” (adopted by the Committee of Ministers on the 30<sup>th</sup> of June 2004 and published as STCE No. 195, 2005), as the aforementioned Protocol does not take into consideration the treatment of biological material involved in biomedical research, but simply determines the principles and regulations the contracting States need to put in place for the protection of people and their rights in the different general conditions that could arise in exercising biomedical research.

This protection is now extended to the conservation and to the availability, given specific conditions for research even by third parties, of the biological samples and of the data deriving from the people participating in the research and donating biological material, taking inspiration from the principles of the Convention of Human Rights and Biomedicine (STE No. 164, 1997) and of the Convention for the Protection of People with regards to Automated Use of Personal Data (STE No. 108).

The NCBB Document was born out of the necessity to offer – to the Italian legislator – guidelines for the correct definition of “biobank”, to establish criteria for the founding and organisation of it, to determine the necessary conditions for the correct management and certification of this activity, and it finally dwells on the ethical and legal criteria effective in ensuring respect for the rights of the donors of biological samples, the activities of coordination between biobanks, between biobanks and researchers, and their exact function with regards to public opinion.

The NBC takes note primarily of the convergence in the inspiration underlining the two Documents, which cover largely comparable ethical and legal areas.

In fact, although the two documents start from different points of view (taking as model and route, the first, the protection of personal rights; the second, the biobank’s capability and potential of service), the point of arrival for both is common under many aspects. Furthermore, both documents are interested in the same area of applications, which is well defined and excludes trespassing into fields which are differently regulated or are currently being regulated.

2 – With regards to the content, the NBC in particular has taken note that both Documents have clearly identified the principles that should preside over the correct behav-

ious of the researchers in utilising biological material and the data deposited in the different typologies in which the structure of conservation is classified, in the interest of each donor of the biological material and in the interest of society, but also of those very same researchers. It deals with principles that are well known in bioethics, regarding primarily the duty to evaluate risks/benefits, which must precede any participation to the research protocol and the privilege generally given to anonymity, in different forms, of the samples and data, towards a clear strengthening of the protection of privacy, provided that the non-anonymous (therefore identified and codified) use of the biological material or of the joined data, is in the interest of the subject and freely accepted by him/her.

Completely comparable are – in addition – the proposals contained in the two Documents – regarding the specific information and the consequent agreement or disagreement by the donor of the biological material, with regards to the typology and extent of the use of the biological material itself, and/or the data deriving from it; the principle of the gratuitousness of the donation; the exclusion of remuneration to the donor; the prohibition of interference with his/her private life and of personal discrimination or of the group he/she belongs to, with regards to the participation to the research or to the knowledge of the data deriving from the preserved samples; the right of the interested party to access and control his/her own information, within a sensible but strictly regulated frame – when it comes to genetic data – even with regards to sharing with his/her family information absolutely indispensable to other people's health.

3 – On the basis of the aforementioned details, the NBC agrees with the recommendations, contained in both Documents, regarding the correct procedures for the collection of the material, its preservation and use, in conformity with a criteria of information and agreement as much as possible “specific”, but that – where necessary and agreed upon by the donor – is not limited to immediate uses but extends also to future uses, coherent with those for which the collection has been carried out.

Furthermore, the NBC deems appropriate the distinction made in the EBC Document, between “collections” of biological material and the respective storage of the data, and “tissue banks”; the first ones (collections) in accordance with criteria of particular specialization in the collection of material, the second ones (banks) with a wider aim of “service” offered to researchers, even external to the body that promotes and manages the bank.

Moreover, such distinction is also present in the NCBB document, which anticipates, within the tissue banks, different typologies in the collection as well as different aims and dimensions.

Both “models” for the collection and preservation of the material and/or of the data, should include explicit validation and procedures for the management of the different activities.

The NBC is in favour – consequently – of timely defining, in legal terms, the responsibility of the management, including the periodical publication of their activities, particularly with regards to the tissue banks and to the data open to researchers, according to principles of transparency and of monitoring of the effectiveness/efficiency of the administration.

The NBC, finally, deems appropriate the recommendation contained in both Documents, so that every research project – even if conducted on biological material that does not involve the physicality of the person and has been made available for research by that same person (through a donation without lucrative purpose) according to well defined

protocols, which guide the procedures of information/consensus – should be the object of an independent examination regarding both the scientific pertinence and the ethical acceptability.

4 – In concluding the analysis of the two Documents; the NBC – agreeing with the appropriateness of elaborating norms directly applicable in the national legislation which would complete the outline of the protection of every human being, expected by the Convention on Human Rights and Biomedicine (Oviedo 1997) and respective Protocols – hopes that in a topic in rapid technical evolution, like the one regarding biobanks, we will proceed in establishing principles that will direct the behaviour of those who will manage them and of those who will use them, without however imposing regulations too rigid and detailed, which would be ignored or rapidly overcome by concrete needs. The NBC hopes for a preliminary census of the collections of biological material and of the tissue banks already existing today within state and private institutions in Italy and the possible founding of a National Register. The NBC stresses, furthermore, that the future outlook of biobanks – whether collections or tissue banks – is to grow in scale, from local to national, and from national to European, and these changes in scale might have an effect on ethical issues and on their elaboration, in the sense of directing them towards less individualism and a new sense of solidarity. More than in the rights of the individual, and within the respect of private life, biobanks could become tools in a new form of solidarity between groups and generations, based on a voluntary sharing of samples and information, for a common resource that must be available on a basis of rules of democratic participation.





*Presidenza del Consiglio dei Ministri*  
NATIONAL BIOETHICS COMMITTEE

**NANOSCIENCES AND NANOTECHNOLOGIES**

9<sup>th</sup> of June 2006



## PRESENTATION

On Prof. Luca Marini's suggestion, in the plenary meeting of the 23<sup>rd</sup> of April 2004, the National Bioethics Committee has decided to create a working group dedicated to the bioethical problems arising from the spread of the nanosciences and by the consequent establishment of new, and often hard to imagine by the general public, nanotechnologies. Prof. Salvatore Amato, Prof. Demetrio Neri, Prof. Adriano Bompiani, Prof. Paola Binetti, Prof. Isabella Coghi and Prof. Renata Gaddini immediately decided to join the group and afterwards Prof. Silvio Ferrari and Doctor Laura Guidoni also joined. From the 27<sup>th</sup> of May 2004 to the 16<sup>th</sup> of March 2006, the group met fourteen times and also invited precious contributions from external experts. In fact, Doctor Renzo Tomellini, chemist, head of the nanosciences and nanotechnologies unit for the European commission; Prof. Paolo Milani (Physics Department at the Università degli Studi di Milano – Centre of excellence in Nanotechnologies); Prof. Enzo di Fabrizio (Università Magna Graecia in Catanzaro, member of the Area Science Park in Trieste); Doctor Guido Rasi (CNR); Prof. Mauro Ferrari (Ohio State University – Institute of nanotechnologies and microtechnologies for biomedical application – and Università di Pisa) collaborated with the Committee, and therefore are dutifully thanked for their great generosity and the sincere friendship they showed us.

The Document's draft, drawn up by Prof. Marini (warmly thanked by all the Committee for his efforts in drawing up a considerably complex text), was brought to the NBC's attention during the plenary meetings of April and May 2006. With some variations, born through intense group discussions during the plenary meetings, the text was finally unanimously agreed upon on the 9<sup>th</sup> of June 2006.

Those who will read this Document, will immediately perceive its most apparent characteristic, which is its in depth and full introduction to a long and subtle series of cutting-edge bioethical issues that are mostly not yet known by the wider public. From this point of view, it is fair to believe that, with this Document, the NBC has been truly pioneering in this field. However, behind this informative role, which the NBC has always felt necessary to undertake, the document precisely highlights numerous and thorny bioethical issues, the solution of which (if not final, at least possible) will be made possible only by further experiences and by even richer scientific reflections. We must in fact assess data that many bioethicists' impatience disregards: that is, that not all bioethical issues (and in particular the most recent ones) are such that they can have, in a short space of time, solutions so convincing that they can be considered consolidated. The bioethicists' task, in many cutting-edge cases, like the ones discussed in this Document, is not to offer ethical certainties to the general public, but to exactly and precisely describe the problematic importance of issues that are destined to stay unresolved maybe for a very long time. It is for this reason, maybe, that more than naïve leaps forward, what suits bioethicists is careful and cautious evaluation.

*President of the National Bioethics Committee  
Prof. Francesco D'Agostino*

## INTRODUCTION

Having been introduced a few decades ago<sup>317</sup>, “nanosciences” and “nanotechnologies” apply to particles whose size is measured in nanometres, equivalent to a billionth of a metre (or, if preferred, a millionth of a millimetre), a dimension that is tenth of thousand of times smaller than the width of a human hair<sup>318</sup>.

The term nanosciences is used to indicate the numerous and varied scientific fields (physics, chemistry, biology) that have an interest in nanotechnologies. These should allow original industrial and commercial applications in a variety of sectors, from medicine to information technology and communication, from energy production to the production of new materials. A branch of nanotechnologies, the one most known in the biomedical field, is dedicated to the construction of devices on a molecular scale, through the transferral of the laboratory of synthesis on the nanometric scale (molecular nanotechnologies). Then there are the nanostructures, which today constitute the cutting-edge of miniaturisation and have applications especially in the field of electronics. Finally, nanostructured materials are being developed, which involve the introduction of materials whose size is only a few tenths of a nanometre, in products such as ceramic or steel, with the purpose of improving their characteristics.

As nanotechnologies have as their object the manipulation of materials at the atomic and molecular level, the nanometric dimension of the manipulated material opens applicative horizons that were unthinkable in the past, because the properties observable at this level can be used, even on a different level, to develop procedures and products characterised by new functions and performances, in a possibly unlimited number of sectors<sup>319</sup>.

We must consider, as examples, the diagnostic and therapeutic possibilities (in particular the miniaturised devices to be implanted in the human body for diagnostic purposes or a material capable of improving the biocompatibility of transplanted organs), the applications in the information technology and communications fields (as in the case of the support in storing data with a very high density of registration), the electromagnetic molecular devices and, more in general, the new “nanomaterials”, characterised by extremely original and diverse properties, like being anti-scratch and self-cleaning or extra-resistant to a variety of situations. Some of the aforementioned products, in addition, have already been introduced into the market: bandaging and cardiac valves, electronic components, anti-crease and anti-stain fabrics, anti-scratch paint, sun creams and cosmetics are becoming part of the European citizens’ consumption habits and have reached a market value estimated at around 2.5 billions of euros<sup>320</sup>. Less known are, instead, some applicative possibil-

---

<sup>317</sup> Cf. R.Feynman’s predictions at the end of the 1950s: *There’s Plenty of Room at the Bottom*, in “Eng. And Sci”., 1960, number 23, p.22. Possibilities of development in the application of such technology have been presented a few years later, by K.E. Drexler, *Engines of Creation. The Coming Era of Nanotechnology*, Anchor, New York, 1986 and ID., *Nanosystems: Molecular Machinery, Manufacturing and Computation*, 1992.

<sup>318</sup> In the international measurement system, the prefix “nano” indicates  $10^{-9}$ , that is, a billionth of a unit (0,000000001).

<sup>319</sup> We must clarify that what has been said also applies to nanosciences and to the scientific principles that can be inferred on the basis of the study of phenomena that can be observed at the nanometric level.

<sup>320</sup> Reliable estimates predict, by 2015, the development of a volume of business in the hundreds of billions of euros each year: cf. the document of the DEPARTMENT OF TRADE AND INDUSTRY, *New Dimensions for*

ities of the nanotechnologies in the food sector (with particular reference to the tracing of food through the use of miniaturised labelling systems), in energy production and conservation (the new fuel cells or the new light nanostructured solids, able to guarantee efficient systems of hydrogen accumulation), in environmental protection (photocatalytic techniques based on nanotechnologies) and in security (selective surveys systems of chemical or bacteriological agents and techniques, like the marking of banknotes, able to increase the protection of goods)<sup>321</sup>.

From a conceptual point of view, the interdisciplinary (or “convergent”) approach to nanotechnologies focuses around two alternative methodologies: the first, based essentially on assemblage procedures, consists of the miniaturisation of materials or devices (the so-called top-down approach), whilst the second, based on synthesis procedures, tries to create new structures starting at the atomic and molecular level (the so-called bottom-up approach or “atomic technology”). It is especially the second methodology, although still at the embryonic state, that seems destined to “revolutionise” current production processes, significantly contributing to the saving in raw materials and to the reduction of the emission of polluting substances during the entire life cycle of the new products.

The variety and multiplicity of the aforementioned applications make nanotechnologies into true “horizontal technologies” or “enabling”, because they can, as it has been mentioned, permeate all technological sectors. This requires and includes an interdisciplinary approach, necessary to combine a variety of knowledge and competences to aid scientific research and the development of the relative technological applications: from chemistry to physics, from engineering to biology, from computing to genetics. It is therefore easy to understand why the entire scientific community (and also especially industry and, more in general, the wider public) looks at nanotechnologies as the “technologies of the future” and asks for the highest economic, financial and, not least, political/institutional support for them.

Next to the enthusiasm of many, and although agreeing with the idea that the ability to work at “nanoscale” level constitutes a triumph of human ingenuity, we also point out the caution of those who believe that they can identify some criticisms for nanotechnologies. For these technologies, as for many others, we feel the need to assess not only the advantages that they will be able to bring to the improvement of the quality of life, but also the risks (especially for the environment and human health) connected and consequent to the development of nanotechnological applications. On the other hand, the public perception of the nanotechnologies’ real or perceived risks seems widespread, also because it has been recently fuelled by some newspapers and by literature, which have represented with success, apparently without distorting available scientific data, narrative situations in which issuing invisible nanoparticles in the environment turns into existential threats for mankind’s sur-

---

*Manufacturing: a UK strategy for nanotechnology*, London, 2002, p.24. Currently, the global expense for research in this sector is 7 billion euros per year (source: La Repubblica, 27th of March 2006, p. 14). Only in the European Union, the financial support offered by the European Community’s Frame Programs of scientific research and technological development, will go from 1300 million euros for the period 2002-2006 (VI Frame Program) to about 4800 million euros for the period 2007-2011 (VII Frame Program).

<sup>321</sup> For an outline of the variety of applications of the nanosciences and nanotechnologies, we firstly refer you to the European Commission’s documents *Verso una strategia Europea in favore delle nanotecnologie e Nanoscienze e nanotecnologie: Un piano d’azione per l’Europa 2005-2009*, on which we’ll return later.

vival<sup>322</sup>. It therefore appears clear that there's a need to promote, with regards to nanosciences and nanotechnologies, an open and constructive debate between science and society, in order to distinguish between scientific data and sensationalism or unfounded fears about the effects of these new technologies on health, safety, environment and society. As well as providing a first organic and systematic study on the bioethical implications of nanotechnologies and "nanobiotechnologies", with this Opinion the NBC intends to promote a wider circulation and an easier understanding of these issues even by a non-specialist public, in accordance with its institutional aims. For this purpose, the Opinion first of all describes the nanotechnologies' most important applications (immediate and hypothetical) in biomedicine (paragraph 2), and then evaluates some critical profiles of the nanobiotechnologies (paragraph 3) and the adequacy of the existing methodologies to assess the risks – in particular those of a toxicological and ecotoxicological nature – associated with nanotechnological products (paragraph 4). In addition, both international and European normative policy trends will be examined (paragraph 5), whilst the concluding paragraph (paragraph 6) will summarise the document and its bioethical recommendations.

## 1. Nanotechnologies and health: the "nanobiotechnologies"

### *Potentially "positive" aspects of the applications of nanobiotechnologies*

The application of nanotechnologies in biomedicine has the objective of achieving a complete and constant monitoring of the human organism and of contributing to health-care, working at the molecular level to achieve medical and clinical benefits through the use of nanodevices and nanostructures. In particular, the February 2005<sup>323</sup> report on nanomedicine by the *European Science Foundation*, identifies three main areas in the development of the research on the production of nanomaterials and nanodevices: the optimisation of already existing devices for a wider application in the medical sector; the development of new multifunctional systems for the diagnosis of illnesses and the focused administration of drugs; an increase in the competences and knowledge which would allow the production of increasingly more reliable, specialised, renewable materials, increasing their efficiency and lowering costs.

According to statements we have found in literature on this topic, statements that are often still completely futuristic and at the level of conjecture, the development of the ability to use nanoparticles in medicine opens new horizons. An important example, from the ones cited, regards the gold nanoparticles, as it has been proven that they can act as heat "concentrators", causing the selected area to overheat, which is lethal for the surrounding cells<sup>324</sup>.

Through the use of biolinkers, the nanoparticles can be designed to act on precise tar-

---

<sup>322</sup> For all, look at M. Crichton's *best-seller*, *Prey*, Milan 2002.

<sup>323</sup> Cf. European Science Foundation Policy Briefing, number 23, February 2005.

<sup>324</sup> In recent literature refer to V.P., Zharov, M. Everts, D.T. Curiel, J.W. Kim, *Integrated Photothermal Nanodiagnosics and Therapy with Gold Nanoclusters*, *Nanomedicine*, 2005, K. R. Visaria, R. J. Griffin, B.W. Williams, E. S. Ebbini, G. F. Paciotti, C. W. Song, and J. C. Bischof, *Enhancement of tumor thermal therapy using gold nanoparticle-assisted tumor necrosis factor- $\alpha$  delivery*, in "Molecular Cancer Therapeutics", 2006, n.5, pp.1014-1020.

gets. The idea of using, as transporters of anti-tumour drugs, vesicles or viral particles coated with molecules able to direct the vector towards the cells that need to be selectively eliminated is not new. The biolinker molecules are absorbed or incorporated in the nanoparticles and are able to bind themselves to specific cells or tissues, directing in such a way the nanoparticles and their contents to the target organs. Up until now few clinical studies exist on this topic, however they are destined to a rapid increase.

Besides strengthening, as in this case, already existing techniques, nanobiotechnologies should allow the construction of multiple sensitive devices of *in vitro* analysis and measuring, the production of new tissues and artificial organs, the training of biological systems to repair other biological systems in support of regenerative medicine<sup>325</sup>, the conception of “3-D displays” for biomolecular signals emission, sensors and mechanisms for the mobile and *in vivo* telemetric control, the elaboration of multifunctional diagnostic systems in connection with the intelligent administration of drugs, the refining of bioanalytic methods in order to understand the functioning mechanisms of cellular and molecular systems.

We presume that, in a short time, we could be able, through instruments of analysis that use nanoimages, to know the beginning and the progression of an illness, monitoring in real terms and *in vivo* the cellular and molecular processes. A biotechnological marker to identify the stress of the neurons is in phase of elaboration by an international net of researchers, according to a study recently published on *The Journal of Experimental Medicine*. According to this study, the mutation of a gene that regulates the protein *Eaat2* indicates the reduced presence of the neurotransmitter that, if in low concentration, is often a sign of the possibility of nervous cells becoming ill. If applied on a large scale, the marker could support the prevention of illnesses of the central nervous system, often followed by just as serious cardiovascular syndromes, which reduce the amount of nutrients and oxygen reaching the tissues.

In addition it will be possible to identify new biological objectives for analysis and therapies, a more rapid passage from experimentation on animals to clinical application for human beings, the closing of the gap between molecular and cellular technologies and clinical diagnosis. In the long term, we should be able to design nanoinstruments of analysis *in vivo* and non-invasive, with a high level of sensitivity, reproducibility and reliability, in order to use them to identify the symptoms of illnesses, in the design and synthesis of new molecules, in the analysis of all sub-cellular components at the molecular level, and in the development of cellular functions in support of the immune system. Particularly precious seem to be the indications we could obtain to identify the profiles of genic expression responsible for specific differentiating trends in multipotent stem cells.

These new therapeutic and pharmacological perspectives will be possible through the setting up of nanocapsules with a particular composition that, overcoming the biological

---

<sup>325</sup> A nanotechnological “bridge” that would allow torn nervous tissues to reconstitute and start carrying out their original physiological functions again is the basic idea of the project, by a team of MIT researchers, whose positive results have recently been published in Proceedings of the National Academy of Sciences of the United States of America (Dynamic reassembly of peptide RADAI6 nanofiber scaffold. H. Yokoi, T. Kinoshita, and S. Zhang (2005). PNAS 102: 8414-841). The group identified a peptide that reorganises itself, assuming its original form of nanofibers “bridge”, in length and width, even after having been fractured by ultrasounds. The procedure has been successfully repeated four times. This work allows us to hypothesize important developments, for example in the creation of new structures for 3-D cellular cultures, for the repairing of tissues in regenerative medicine, for the therapy in serious plegic and neurodegenerative pathologies.

barriers, will be able to transport the drug and to release it in a focused manner. In the long term, we can hypothesize the conception of bioreactive synthetic systems able not only of intercellular transport of macromolecules for a therapeutic purpose, but also able to self-regulate, creating nanostructures made by biosensors joined with transport mechanisms.<sup>326</sup> The design of nanostructured sensitive supports (for example, artificial biological tissues) could, in addition, allow the immediate identification and the control in time of the manifestation of degenerative phenomena, preventing the spreading of cancer, of neurovegetative, cardiovascular, pulmonary, ocular diseases, and others.

#### *What do we know about the health risks associated with nanotechnological products?*

Despite such inviting possibilities, there's no lack, in literature, of more cautious reflections. The high surface/mass relationship, the "atomic" dimensions and the ease with which nanoparticles can absorb and carry other substances: the same characteristics that make nanomaterials attractive, also suggest a certain caution in their use in biomedicine. In fact, if the extreme penetrability of nanoparticles is the secret of their potential, we must not underestimate the risks connected with their nano-dimensions, seen as a variety of sources highlight how the possible interactions between nanoparticles and the human body are still unclear. Little known, until today, is the effect that materials of atomic dimensions can have on the human organism: the little we know, although extremely promising with regards to the possible applications, seems not completely reassuring with regards to the possibility of even serious undesired collateral effects.<sup>327</sup>

We must stress that the use of substances of submicronic dimensions in the pharmaceutical industry has long shown a level of interaction with biological systems and has allowed us to establish the first safety rules in the field. However, especially most recent studies on ultrafine powders (those of dimensions smaller than a tenth of a micron), and in particular those relative to the smallest fractions of these classes of aerosol, arouse the greatest worry and direct the course of the first specific investigations. Ultrafine powders derived from carbon combustion, carbon black, diesel engine particles and soldering fumes: these are the materials containing significant fractions of nanometric dimensions which, as we already know, have adverse effects on health (even if some of these materials, mostly considered undesirable pollutants, are often not subjected to specific tests). To the listed substances, considered dangerous, we must then add materials specifically produced and already on the market: sun protective creams with titanium dioxide, self-cleaning and insulating glass (also with TiO<sub>2</sub>), materials supporting and prolonging catalytic processes,

---

<sup>326</sup> On this point, it is possible to imagine situations like the ones described by A. Diaspro, *Nanobiorobot. Oltre la fantascienza*, in "Darwin", 2005, p. 54 ff. In scientific literature, see O. M. Koo, I. Rubenstein, H. Onyuksel, *Role of nanotechnology in targeted drug delivery and imaging: a concise review.*, in "Nanomedicine: Nanotechnology, Biology, and Medicine", 2005, n. 1, pp. 193-212; E.S. Kawasaki, A. Player, *Nanotechnology, nanomedicine, and the development of new, effective therapies for cancer*, in "Nanomedicine: Nanotechnology, Biology, and Medicine", 2005, n.1, pp 101-109; K. Donaldson, C.L. Tran, *An introduction to the short-term toxicology of respirable industrial fibres*, in "Mutat Res.", 2004, Sep. 3, p. 553 (1-2): 5-9.

<sup>327</sup> We report the results that have emerged from the first international Symposium on the implications of nanomaterials on the workers' health, organised by the British Health and Safety Executive and by the National Institute for Occupational Safety and Health, which took place the 12<sup>th</sup>, 13<sup>th</sup> and 14<sup>th</sup> of October 2004 in Buxton, in the United Kingdom.

semiconductive metal nanotubes, pigments and carbon black toner, fillers containing amorphous silicones, organic nanoparticles used in the pharmaceutical industry and others. There's no evidence that these materials are considered dangerous.

We must also however report other statements. The nanomaterials already in mass production (or "bulk NP, where NP stands for Nano Particles), are already known and tried (also with regards to the potential adverse effects) in comparison to the "engineered NP". However, the knowledge regarding nanotubes, originally considered as a variety of fullerene, but also revealed as morphological curiosities in the area of natural carbon particles, is very advanced<sup>328</sup>. It's especially the nanotubes, and their potential applications (even as equipment to operate in the ultrafine), to generate less known and potentially dangerous risks. The main preoccupation is that, as has already been demonstrated in other fields, materials that are not toxic when in sufficiently big particles can be harmful when in nanometric dimensions. That the dimension of the inhaled particles is to be taken into account is by now a known fact. From the notorious fine powders, deriving from the combustion of petrol and diesel oil, which are one of the main elements of urban pollution, we already know that the smallest they are, the more dangerous they are. The PM 2.5 (where PM stands for "Particulate Matter"), with a diameter smaller than 2.5 micron, produce worse effects than the PM 10: in fact they reach the lungs' deepest parts and seem able to cause tumours. If, as it appears, the biological effect depends on the exposed surface, in equal doses the more the particles are small, the more they are dangerous. A NASA toxicologist, Chiu-Wing Lam, studied the effect of carbon nanotubes, molecules discovered at the beginning of the 1890s, which are predicted to give us materials a hundred times more resistant and six times lighter than steel, and are today produced only in small quantities. Instilling in mice's lungs a suspension of aggregated nanotubes, an operation which is not exactly considered equivalent to inhalation, the animals had the same reaction of irritation caused by the powder. Instead, when the nanotubes were administered as separate particles, lesions appeared in the lungs. Nanotubes are long and thin particles. In the case of asbestos, one of the most critical factors is its fibrous form. Could it be the same for nanomaterials? Some investigations conducted in past years – and, according to Green Peace, ignored by the media – give us worrying results: inhaling a 5 milligrams dose of nanotubes per kg of body weight, 15% of animals died, but not because of the substance's toxicity. Nanotubes aggregated to the point of obstructing the rats' bronchial tubes: the rats were suffocated<sup>329</sup>. The biological damage therefore can depend, with different effects, both on the nanoparticles' dimensions, and on the nanoparticles' state of aggregation.

Other studies look at the molecular systems used to take drugs over the hematoencephalic barrier or inside cells. Up until now, no harmful effects have been observed, but there's very little research in this field. The Center for biological and environmental nanotechnology at Rice University (USA) is one of the main laboratories with regards to the study of environmental impact. There, it was observed how the *buckyball*, molecules made

---

<sup>328</sup> Unlike diamonds and graphite, solids at infinite lattice, fullerenes are the only finite form of carbon. In October 1996 the Nobel Prize for Chemistry was given to researchers Harold Kroto, Robert F. Curl e Richard E. Smalley for discovering fullerene (also called by some "buckyball"), which takes its name from the American architect Buckminster Fuller, known for his projects of habitation modules in geodetic dome shape based on pentagons and hexagons.

<sup>329</sup> See what is reported by C. Palmerini, *Nanoinquinamento*, in "Panorama", 26<sup>th</sup> of September 2003.

up of 60 carbon atoms<sup>330</sup>, “travel” on the ground: it appears that, if they can aggregate, they are absorbed like any other organic compound, but that, left free to disperse, they penetrate the ground without being absorbed. One of the fears is that such molecules could join in this way to other contaminants, like pesticides, and maybe penetrate in the organism of worms or other animals, entering the food chain.

#### *Prevention in working places and for the environment: current state of knowledge*

For now, the only subjects at risk of inhaling nanotubes are those who produce them: researchers in sixteen companies around the world. Some Japanese companies have already announced that they want to start producing them in large quantities and experts think that there’s a potentially large relevant market. The objections to the criticisms regarding their safety is that laboratories take the necessary precautions and that, in any case, nanotubes are not made to be breathed in.

In work hygiene is by now consolidated the distinction of powders according to their granulometry (or, more precisely, according to their “equivalent diameter”) on the basis of their ability to reach various parts of the respiratory tract and to get stuck there. Particles whose dimensions are between 5 micron and 0.5 micron are part of the so-called “breathable fraction”. Particles with a smaller diameter and especially extremely fine ones, until about a decade ago were considered inert substances: it was believed, that is, that they were inhaled and exhaled without interfering with the structure of the pulmonary epithelia. In particular, the reduced interaction of these particles with the typical mechanisms for the removal of the respiratory tree (mucociliary, macrophage and lymphatic) led us to think that their participation to the pathogenesis of pulmonary damage was insignificant.

Physics has long since shown that ultrafine powders are kept in suspension by the Brownian motion: therefore, they are not subject to inertial fall or to sedimentation and they tend to stay suspended in the air indefinitely, from which they are removed only by currents or by rain. In addition, because of the Brownian motion, the distribution of these powders in space depends only from the way in which they are diffused. From this derives that the environmental hygiene and the technical normative that regulates the sampling of confined air and defines its classes (UNI-EN 481) has in effect neglected (and, indirectly but substantially, underestimated) ultrafine fractions. The European Normative Committee, aware of all this, has long since warned analysts, highlighting the particular difficulty of applying the regulations of the “sampling convention” when sampling and characterising soldering fumes. We refer to the points following in this document for the evaluation of the adequacy of existing methodologies in assessing the risks associated with nanotechnology products. We must stress that particles smaller than 0.5 micron, whose absorption is regulated almost exclusively by their diffusion, should be evaluated using, instead of the “equivalent diameter” criteria, the so-called “diffusive diameter”.

Only in more recent years, and especially in the field of the studies on atmospheric pollution of urban areas, epidemiological and experimental data have called the attention back

---

<sup>330</sup> The *buckyball*, the basic component of the fullerene, is made up of 60 carbon atoms arranged in 20 hexagons and 12 pentagons, like a football. When this structure is forced to stretch, through a variety of chemical-optical-electrical procedures, a nanotube is formed.

on fine powders: the by now known PM 10 and in particular the smaller fractions (the PM 2.5 – which represent about 60% of the PM 10 – and the PM 1)<sup>331</sup>.

There are two critical points of the respiratory apparatus through which, essentially by diffusion, nanoparticles penetrate in the organism: during turbulent air movements at the nasal coana level and at the alveolar level, where instead air is in “flat calm”. Easily going through the alveolar epithelium and the endothelium, ultrafine powders go into the blood where, probably due to a mechanism of oxidation, they actively participate to atherosclerotic processes: from this derives an increase of cardiovascular pathologies (heart attack, thrombosis, etc.), which has been observed in epidemiology and experimentation. In addition, because of the emetic distribution, it can potentially affect all organs: in fact, the organs that appear particularly affected are those that have a tight vascular net, like liver and spleen, as it has been shown with regards to the workers in the carbon industry, especially if already affected by pulmonary pathologies. However, the accumulation of particles in the liver and spleen does not seem to lead to particular pathologies, with the exception of a possible procoagulatory action at the hepatic level.

Instead, the nasal absorption seems to be associated with a peculiar tropism (maybe through the cranial nerves) with the encephalic tissue: in particular, the powders’ small dimensions would allow them to overcome the so-called hematoencephalic barrier, with the consequent increase in toxic neuropathies. The passage of radioactive nanoparticles, administered to rats by inhalation, to the olfactory lobe has been experimentally demonstrated. However, the differences between the various types of powders are not negligible: essential is the particles’ chemical composition, because of the relative toxicological properties linked not only to their structural components (essentially carbon), but also to the presence of pollutants (dangerous are the metals) even in traces. Rats exposed to soldering fumes show clear evidence of neurological illnesses caused by manganese.

The skin penetration of NP has been experimentally studied, but with controversial results. Only the smallest particles – but a very small percentage of them – seem able to go through the corneal stratum, and this happens especially when the skin is subjected to a trauma. The nanoparticles’ coalescence through the forces of Van der Waals tends to generate particles of a diameter of tenths of micrometers. In the case of nanotubes, particles of dishomogeneous dimensions can be generated. Such particles tend to be stringy (with a diameter of around 20 nanometres and a length up to one mm) or flat in shape. The same can be said of semiconductive metal nanotubes.

Some experimental data (intratracheal administration of multi-wall nanotubes to rats) highlight inflammatory responses and fibrotic pulmonary reactions similar to the ones due to the inhalation of asbestos. Other experimental studies have demonstrated the possibility of the passage of nanoparticles into the pulmonary interstice. The inflammatory response of the pulmonary parenchyma, measured in quantity of neutrophils present in the liquid of the bronchoalveolar wash, seems to be linked to the superficial area of the inhaled particles and, if the surface is equal, it is emphasised in the case of ultrafine particles. Titanium dioxide and *carbon black* particles are known causes of fibrosis and tumours in rats. Moreover, all chronic inflammatory pathologies of the lung seem to be linked with a higher

---

<sup>331</sup> G. Oberdorster, E. Oberdorster, J. Oberdorster, *Nanotoxicology: an emerging discipline evolving from studies of ultrafine particles*, in “*Environ Health Perspect*”, 2005, Jul., n.113(7), pp. 823-39. Review.

occurrence of neoplasia and maybe the only licit conclusion is to admit that there's still not enough knowledge of the chronic effects and/or pulmonary neoplasia of nanoparticles.

Finally, we must mention two other difficult aspects of the risks involved in the production processes. The quantity of energy used to bring the reagents (generally graphite) to a plasma state and the need to use metal catalysts (especially aluminium), as well as the dimensions of the nanomaterials so obtained, make the electric risk and the risk of explosions particularly critical and difficult to manage. Because the powders' capability to explode is linked to their mass-surface relationship and to their concentration, it is clear that the risk of explosion (especially high for metal powders) is always present. The use of technologies in inert atmosphere have so far prevented big accidents, but it is the little knowledge of these particles' explosive behaviour in their ultrafine state, which makes this a problem deserving of attention and deeper study. Similar considerations can be made with regards to the validity of protective equipment and devices in the industrial manipulation of nanomaterials. For the protection of the respiratory system it seems that class 3 (FFP3) anti-dust facial masks can offer sufficient protection, at least for powders with a diameter bigger than 2 nanometres.

## 2. Nanobiotechnologies' critical profiles

### *General aspects*

It must be taken into account that the problems we will discuss in this paragraph, should we go beyond the phase of research and strictly controlled experimentation, are mere hypothesis (or "*Apocalyptic Nightmare*")<sup>332</sup>, which at the moment appear difficult to verify because of the lack of specific studies and official information. Many of these critical profiles are typical or common to any technological innovation, but, in this case, we are faced with a sector with extensive scientific and social potential, which could redefine the traditional barriers between biology, physics and chemistry, so that according to some<sup>333</sup> it is indispensable to elaborate a new ethics in support to the science of the future, anticipating and preventing the consequences of certain choices. The USA Senate, in approving, on the 18th of November 2003, the *21st Century Nanotechnology Research and Development Act*, has highlighted the risks of "self-replicating nanoscale machines or devices; the release of such machines in natural environments; encryption; the development of defensive technologies; the use of nanotechnology in the enhancement of human intelligence; and the use of nanotechnology in developing A.I. (Artificial Intelligence)". Similar doubts on the possible negative outcomes have been put forward, more cautiously, and then immediately put aside in the document titled *Social and Economic Challenges of Nanotechnology*, published in July 2003 by the *UK Economic and Social Research Council*. For these reasons, the NBC believes that it is appropriate to examine some of the most uncertain aspects of nanotech-

---

<sup>332</sup> As in B.Gordijn, *From utopian dreams and apocalyptic nightmares towards a more balanced view*, in "Proceedings of the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)", Third Session (held in Rio de Janeiro from the 1st to the 4th of December 2003), p. 115 and following.

<sup>333</sup> *Ibidem*.

nologies, making no claim to having exhausted the issue and wanting to avoid alarmism, with the only aim to accept the invitation made in the document of the *Economic and Social Research*, point 27: “We need to have rational and mature public dialogue informed by good science. This will explore the acceptable uses of new technologies, and processes whereby the outcomes of dialogue help to shape the policies introduced by the Government”<sup>334</sup>. In particular we will examine the following profiles: the combination between inorganic and organic molecules (the problem of self-replication); the social and economic fallouts (nanopoverty); the control of the individual and the protection of privacy; the military or terrorist uses; the repercussions on human identity.

#### *A singular aspect: the combination between organic and inorganic molecules*

It seems appropriate to dwell on the problems that nanotechnologies could give in the form that is called “advanced”<sup>335</sup>. In this case, nanotechnologies do not only give us new technological opportunities for the production of materials or plastic and chemical substances (fullerene, nanotubes, nanoparticles, nanocapsules, nanopores, *nano dots*, *nano wires*), but combine inorganic nanomaterials and organic molecules, intervening in the cellular metabolism to affect molecule production or the transmission of information, or to create new cellular structures or supports for the construction of new complex molecules or atom assemblers to create new molecular orders. Therefore we have the intentional alteration of living organisms through DNA manipulation to create moleculesize machines, devices that synthesize a variety of macromolecules piece by piece, penetrating and integrating into the cells of living organisms. The already mentioned work by Drexler calls these biological devices “assemblers” and describes them as “living machines” capable of self-reproducing, hypothesizing that “with assemblers, we will be able to remake our world or destroy it”<sup>336</sup>. These are mere suppositions, capable of suggesting the scientifically questionable adventures of the novel *Prey* by Crichton, but absolutely futuristic in relation to the current development of this technology. Futuristic, but not unfounded, because research is studying in more depth the idea of creating nanomaterials, applying the “bottom up” model of construction of cellular structures. There’s a very subtle (although not only semantic) difference between “construction bottom up”, for “self-assembly of DNA to sort carbon nanotubes”, and self-replication.

#### “Nanopoverty”

If in reality nanotechnologies should keep their promises to increase the length and quality of life, to improve physical conditions, to reduce pollution and the cost of energy and

---

<sup>334</sup> “Engagement of the scientific community in regular dialogue with the general public in order to discover likely public concerns early, and continuation of dialogue to address and alleviate public concerns by the presentation of clear facts” is also the anxiety expressed by the *ESF Scientific Forward Look on Nanomedicine* in “European Science Foundation Policy Briefing”, February, 2005, n. 23, p. 5.

<sup>335</sup> J. P. Dupuy, *Complexity and Uncertainty. A Prudential Approach To Nanotechnology* prepared for the March 1-2, 2004 meeting of the Directorate-General for Health and Consumer Protection of the European Commission, “Mapping Out Nano Risks”.

<sup>336</sup> Cf. K. E. Drexler, *Engines of Creation. The Coming Era of Nanotechnology*, cit., p. 174.

raw materials, the differences between rich and developing countries could become even more apparent. Even now, many of these countries have an extremely limited access to electricity, information, education, drugs; the introduction of even more sophisticated technologies which are even more connected to one another, presents the risk of turning the current differences in development into discrimination, an intolerable form of “poverty of poverty”: the “nanopoverty”. On this subject, as on the economic effects of biotechnologies, there’s a profound divergence of opinions and some even think that only nanotechnologies could help developing countries to overcome some of their pressing needs, as the investments of India Thailand, Chile, Argentina, Mexico in this sector, seem to show.<sup>337</sup>

### *Biosurveillance and privacy*

We have already mentioned that one of the most promising uses of nanobiotechnologies in medicine regards the possibility of preventing the arising of illnesses through miniaturised cybernetic laboratories (*lab on a-chip technology*). Diagnostic nanospheres are already being trialled on humans. It is also believed that these chips would make genetic tests simpler and more immediate. Everyone could keep him/herself under constant medical observation. Nanoparticles could be used also as support for the release of drugs aimed at annihilating or repairing individual cells. Materials of nanometric dimensions can constitute the substrata in which viruses or DNA molecules can be encapsulated or ordered. The interaction between biomolecules and nanoparticles, nanotubes or nanometric surfaces can be used to identify specific proteins or viruses, as well as to carry the molecules to the target. The extraordinary advantages of these techniques in prevention and aimed care, let us hypothesize the possibility to eliminate, essentially through prevention, the incidence of deadly diseases, like cancer, during the current generation. However, we must take into account the complex problem of the enormous psychological pressure that this potential self-monitoring could create. Is the idea of being constantly under observation tolerable? How would it influence the relationship between health and illness? How would it be possible to continue to guarantee the privacy of sensitive data? The same technology that allows the introduction of “DNA chips” in the organism to carry out medical screenings or to release drugs, also allows the building of nanosensors, nanocameras and nanomicrophones. A functional and mobile telemetric control with sensors and devices *in vivo*, could be used both for diagnostic purposes as well as political purposes, in order to achieve an integral control of the whole population without it realising it (not even partially)<sup>338</sup>. We stress that all this is already possible without the use of nanotechnologies. The so-called *smart tags*, based on RFID (*Radio Frequency Identification*) technology, are currently used to control access to ticket offices or in transport. These are objects that are much smaller than a tenth of a millimetre and therefore completely invisible. There is no technological difficulty in further reducing their dimensions and in widening their functions to control, integrally and inadvertently, every aspect of private life. Nanotechnologies could increase this risk, because it would be extremely difficult to prevent the same nanochip that releases a drug to

---

<sup>337</sup> For the opposite point of view: F. Salamanca-Buentello, D.L. Persad, E. B. Court, D.K. Martin, A.S. Daar et Al., *Nanotechnology and the developing world*, in “PloS Medicine”, April 2005, n.2, p. 4.

<sup>338</sup> A. Grunwald, *Nanotechnology - A New Field of Ethical Inquiry?*, in “Science and Engineering Ethics”, 2005, n.11, pp. 187-201.

also be programmed to carry out other functions. These are futuristic possibilities, but technologically possible.

Some go even further and hypothesize the creation of a nanochip able to condition the nervous system from a distance. The same mechanism that allows us to overcome the cerebral barriers to interact with specific molecules or to release a drug could be used, maybe with a judge's authorisation, to repress certain violent impulses or to control certain forms of sexual perversions. Crichton also wrote about this problem, a long time ago and without yet thinking of nanotechnologies, in another novel, *The Terminal Man*, in which he hypothesized the use of a system of electrodes to control from a distance crisis of homicidal violence caused by a strange form of epilepsy. In the Introduction Crichton reported statements by James V. McConnell of Michigan University: "Listen, we can do these things. We can control behaviour. Now, who's going to decide what's to be done? If you don't get busy and tell me how I'm supposed to do it, I'll make up my own mind for you. And then it's too late"<sup>339</sup>. We must not transform novelistic hypothesis in bioethical issues, however we also cannot ignore that the problem of control and eventual conditioning from a distance becomes extremely current as an effect of the biometric measures of identification and examination, which are increasingly more invasive and sophisticated, and also as an effect of the extreme miniaturisation of the possible monitoring instruments. If the electronic tag is considered a licit way to control subjects on probation, what would stop us from using the much more refined and safe nanotechnologies? If chemical castration is invoked to prevent certain sexual crimes, why not ask, if the technology is available, the inhibition of any violent behaviour through a nanochip? Even if these are mere hypothesis, or even novelistic suggestions, a reflection on the ethical limits of bio-surveillance, on the relationship between freedom and safety, does not seem to be deferrable: when does control become conditioning and when does conditioning become a violation of personal integrity?

#### *Terrorist and military uses*

We point out that a nanochip capable of operating in the human body can be more easily programmed to destroy than to cure. The ability to interfere with the cellular metabolism would open, to those interested in bacteriological war or terrorism, enormous destructive capabilities. If then these nanomachines could self-replicate, the instrument would be even more dangerous than the atomic bomb, but more precise, less costly, simpler to build and to use but harder to identify. The very small size would make their transportation and release in the environment extremely simple. In this case the risks would be worsened by the fact that nanoparticles can reproduce and can easily penetrate both the skin and the hemato-cerebral barrier. The nanoparticles' ability to interact with sub-cellular structures is not very known and the scientific community is far from being unanimous in excluding its potential dangers<sup>340</sup>. On the other hand, if it's possible to hypothesize the strengthening of immunity barriers (mosquito nets) to reduce the incidence of infectious diseases, it is just as possible to hypothesize the elaboration of opposite systems that would inhibit the immuni-

---

<sup>339</sup> New York, Harper Collins Publishers, 1972, p. XV.

<sup>340</sup> C. Zardonella, *The Tiny Toolkit*, in "Nature", 1st of May 2003, n.423, p. 11.

ty defences. The biotechnological mechanisms of the two operations are the same. In abstract, terrorists could easily get relatively innocuous forms of toxins or chemical substances and with a small manipulation make them into instruments of death, through the possibility of making them interact with the organism, altering the metabolic processes. This is a simple technology, much simpler than the one needed to create traditional chemical or bacteriological weapons. For example, it is theoretically possible, through a nano-machine, to build in great quantity, molecule by molecule, the anthrax toxin without having access to the *Bacillus anthracis*<sup>341</sup>. The same technology could be used to attack mechanical or electronic systems, blocking nuclear plants, power plants, airports, information systems. The self-replicating nanoparticles could act in the same way as computer viruses: automatically activating themselves and spreading until the destruction of the basic functioning elements. What measures can we adopt against these dangers? Clearly the issue is not stopping research, but causing an awareness of the profound ambivalence of certain developments<sup>342</sup>, supplying information and feeding public debate. To minimise the risks and highlight the advantages could, in the short term, have a reassuring effect, but would end up, in the long term, creating a void of conscience and therefore of democracy. In ethical choices it is not always possible to guarantee everybody's good, but it is certainly important for everybody to participate in the decisional process.

### *Human identity*

We state that nanotechnologies, in conjunction with biotechnology, electronic and medicine, will allow us to radically intervene on the human body to repair it or to develop its abilities. It is possible to think about the construction of organs or tissues for transplants but also to repairing or widening compromised sensorial functions, for example widening the electromagnetic spectrum of visual perception. The connections between electronic and the nervous system are already being studied, through *nanoelectronic neuro-implants (neuro-bionics)*, which would allow us to correct sight or hearing defects. If it was possible to connect cerebral activity to systems of data elaboration, what would open up, which is suggestive as well as futuristic, is the possibility of *uploading*: extracting the information contained in a human brain and replicating it in a calculator. Specialised nanomachines should pass cerebral tissue through the scanner, atom by atom. Then the information should be digitalised and implemented through appropriate software that would allow for it to be preserved and transferred. Looking at this same issue from the point of view of the machine rather than the man, attempts at building "organic computers" that use "flash memory chips", integrated with cellular structures or transistors assembled with carbon nanotubes and DNA fragments, have already been made. The construction of these biological hybrids, from nanomachines to *labs on a chip* and up to organic based computer, profoundly alters the distinction between biology, chemistry and physics, but also the distinction between material and immaterial, material and device. As well as nano-ethics, nano-philosophy has also been mentioned, to highlight the need to rethink all the conceptual categories of human

---

<sup>341</sup> J. Rothstein Wolfson, *Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies*, in "Biotechnology Law Report", August 2003, n. 4, 376-22, p. 381.

<sup>342</sup> K. Geiser, *Nanotechnology and Environmental and Public Health Considerations*, in "New Solutions", Vol 14(1), 2004, pp. 8-18.

identity “bottom up”, starting with the idea that what exists is not man but the nano-particle, with all of the possible ways to assemble it. Even without going that far, facing the purely hypothetical problem of how to qualify, ethically and legally, the content of the brain once it has been scanned and preserved in a nano-chip, it is easy to guess the profound changes that the notion of human identity and personal integrity could undergo<sup>343</sup>. For example, could the development of neurological, mnemonic or visual capabilities be indiscriminately allowed? Who will decide the limits and the possibilities of use? Will the technological domain allow the “production” of biologically superior beings, feeding new forms of racism?

### 3. Adequacy of existing methodologies in assessing the risks associated with the products of nanotechnologies

Several documents, in recent years, have tried to identify and describe the potential risks linked to or due to the development of nanotechnological applications<sup>344</sup>. In 2005 the European Commission set up the basis for further studies on this issue, asking the independent experts of the Scientific Committee on Emerging and newly Identified Health Risks (SCENIHR) to elaborate a scientific opinion on the adequacy of existing methodologies in assessing the potential risks associated with engineered products or products incidentally derived from nanotechnologies<sup>345</sup>. This opinion, which at the moment is the most exhaustive study on this issue and which we take into account in this paragraph, was elaborated on the basis of acts adopted by the European Commission because of the increasing importance of nanotechnologies in the context of European industrial research and economy, like the conclusions of the European Union Council on the European strategy on nanotechnologies<sup>346</sup>,

---

<sup>343</sup> R. W. Berne, *Towards the Conscientious Development of Ethical Nanotechnology*, in “Science and Engineering Ethics”, 2004, n.10, pp. 627-638.

<sup>344</sup> Cf. on this topic, as well as the report *The Social and Economic Challenges of Nanotechnology* approved in July 2003 by the British Economic and Social Research Council, which started the public debate on the argument, also the results of the workshop organised in Brussels by the European Commission in March 2004 (cf. *Nanotechnologies: A Preliminary Risk Analysis*); the document *Nanosciences and Nanotechnologies: Opportunities and Uncertainties*, adopted on the 29th of July 2004 by The British Royal Society and by The British Royal Academy of Engineering, in <http://www.nanotec.org.uk/finalReport.htm> (which, although it excludes the existence of valid reasons to worry about the potential risks of nanotechnology applications, highlighted the need to study the issue in more depth and recommended to apply the same caution to nanostructured materials imposed by law on new chemical products); the document elaborated in October 2004 by the Health and Safety Executive of the British Government (in <http://www.hse.gov.uk/research/rrhtm/rr274/htm>); the report *Down on the Farm* drawn up by the Action Group on Erosion, Technology and Concentration (ETC Group) in November 2004; and the report titled *Characterising the Potential Risks Posed by Engineered Nanoparticles*, adopted in December 2005 by the British Department for Environment, Food and Rural Affairs. This last document identifies three main areas that need to be studied more in depth to create an effective management system for the potential risks linked to or due to the spreading of nanoparticles: a) nanoparticles characterisation, definition and measurement; b) assessment of the nanoparticles’ impact on human beings and the environment; and c) understanding of the nanoparticles’ origins and of how they move in the environment, also through the human body.

<sup>345</sup> In [http://europa.eu.int/comm/health/ph\\_risk/committees/04\\_scenihr/04\\_scenihr\\_en.htm](http://europa.eu.int/comm/health/ph_risk/committees/04_scenihr/04_scenihr_en.htm)

<sup>346</sup> Cf. the Commission’s communication towards the European strategy in favour of nanotechnologies [document COM92004] 338 def. of the 12th of May 2004], approved by the European Union Council on the 24th of September 2005.

which highlights the importance of the “analysis of the potential risks during the vital cycle of all products that are created starting with nanotechnologies”, and the European Union’s Plan of Action on nanotechnologies<sup>347</sup>. These documents will be examined in the following paragraph.

The SCENIHR’s Opinion first of all describes the properties of nanomaterials, then identifies the sources of nanoparticles and examines the suitability of existing procedures in collecting and measuring such structures. In addition, the opinion deals with the toxicological and ecotoxicological profiles of nanoparticles and the potential effects due to an eventual exposition to them, with the purpose of defining, on one hand, the most efficient methods of measuring such exposition, to identify and characterise the risk linked to it and to integrally assess the mentioned elements; and, on the other hand, to fully appreciate the possible interactions between nanoparticles and living systems. The Opinion, finally, identifies the most significant gaps in the scientific knowledge necessary to correctly evaluate the risks associated with nanotechnologies and defines the relevant normative profiles on this issue.

To fully appreciate the potential negative effects of nanotechnologies on human health and the environment, the SCENIHR first of all suggests a distinction between two typologies of nanostructure: those in which the structure itself is a free particle and those in which the nanostructure is an integral part of a bigger object. Nanoparticles can be naturally generated, or they can be the accidental product of an industrial process, or they can be specifically created to develop applications based on their particular properties<sup>348</sup>.

The first problem we encounter in assessing the risks of the spreading of nanoparticles for human beings and for the environment comes from the difficulty of collecting and measuring structures and materials that are below the threshold of being “visible to the naked eye”. In fact, referring to the sector under consideration, the SCENIHR believes that using the criteria of the mass concentration is insufficient, and suggests integrating this criteria with other, more suitable criteria (like the concentration number and the surface area), which currently are not taken into account by the applicable laws. In addition, according to the opinion under examination, existing methods for the analysis of the environmental impact of nanoparticles are inadequate in determining the nanoparticles’ distribution and persistence in a variety of environmental systems. According to the group of experts from the Commission, from this derives the need to opportunely change the current exposition assessment methods and, in particular, to develop methodologies and instruments that would allow us to *routinely* measure the representative exposition to nanoparticles.

Examining nanoparticles’ toxicological and ecotoxicological profiles, the SCENIHR first of all highlights that only some conventional toxicology and ecotoxicology tests have been proven useful in assessing the risks associated with nanoparticles, whilst taking into account the fact that, at the moment, scientific data capable of identifying systematic rules about the toxicological and toxicological properties of nanotechnology products, are not available. From this, according to the SCENIHR, derives that the assessment of the toxico-

---

<sup>347</sup> Cf. the document *Nanosciences and Nanotechnologies: A Plan of action for Europe 2005-2009* [document COM92005] 243 def. of the 7th of June 2005].

<sup>348</sup> These properties will be influenced primarily by the nanoparticles’ surface (in relation to the volume) and by the quantum effects that occur at nanometric level. A careful identification of their physicochemical properties is essential for the purpose of making routinely available adequate risk assessment methods.

logical and ecotoxicological risk should be made case by case, with specific reference to the nanoparticles' ability to affect pre-existent clinical conditions or to increase the predisposition to certain illnesses. A corollary of what has been stated is the need to base the assessment criteria of the toxicological and ecotoxicological risks associated with the spreading and distribution of nanoparticles, on profiles different from the "equivalent material: the correct assessment of the potential risks deriving from nanotechnologies, therefore requires the development of new investigative techniques that will take into account, also in itinere, the possible uses of the products under consideration and the potential exposition, both for man and for the environment.

With regards to the possible interactions between nanoparticles and living organisms, the SCENIHR's opinion first of all highlights that, if the nanoparticles interact with living organisms because of their size and properties, we cannot however exclude that bigger structures (e.g. the nanotopographic characters of medical devices) could also present specific risks for human and environmental health. Therefore, in considering the specific risks deriving from nanoparticles, what seems important is not only their size, but also their shape and composition, as well as the amount of absorbed surface; equally important are the modification, aggregation, dissolution or degradation phenomena of the nanoparticles' surface, from which the release of nanoparticles can occur. Given that the immediately soluble nanoparticles lose their specific properties in the physiological environment, it is important to verify if they dissolve into harmful molecules or not. With regards to essentially insoluble nanoparticles, there's a chance of biopersistence, arising from the long term exposition and from specific effects associated to nanoparticles. In addition, the nanoparticles' movement can happen at a more extensive level and in different places in comparison to what happens with bigger particles: therefore a systemic distribution and accumulation of such particles could happen. It has been proven that nanoparticles are able to move from their entry point in the human body and reach other areas, including the blood and the brain, although the amount and the importance of this movement is not clear and few studies have been carried out on this issue. In particular, it is uncertain whether nanoparticles can reach the foetus, even though the systemic distribution seems probable in medical applications requiring the parenteral administration of nanoparticles.

In current research, the proof of the toxicity for man of the systemic exposition to nanoparticles intentionally produced is minimal: however, states the SCENIHR, the current guidelines on experiments identifying and characterising the risk of chemical substances and products, do not yet require the identification of the nanoparticles' systemic distribution, despite the existence of some potentially suitable methods<sup>349</sup>. It is different for nanoparticles of natural origin and those generated unintentionally by human activity: they have an exposition risk which potentially extends to an individual's entire life. Their main form of contact with man is inhalation, but the increasing use of nanoparticles in high consumption products (like cosmetics, pharmaceutical preparations and food) means that the exposition surface of the skin, the gastro-intestine and the parenteral surfaces, are acquiring an increasing importance. With regards to the environment, nanoparticles' release and propagation can instead happen through air, water, soil, with the consequence that a vari-

---

<sup>349</sup> According to the SCENIHR, a toxicity mechanism for some particles consists of the emission of a type of reactive oxygen and of the consequent oxidation process of the cells under consideration.

ety of species can be affected by the exposition: therefore, the need to obtain data on human exposition (with specific reference to workers and consumers) and on other species', including micro-organisms, is even more urgent.

In conclusion, the SCENIHR's opinion highlights that, in current research, there's no sufficient data able to identify systematic rules to assess the toxicological and ecotoxicological risks of nanotechnology products. In fact, if the existing toxicological and ecotoxicological methods allow us to assess the majority of the risks in theory, it is also true that the scientific uncertainty about the seriousness and the amount of possible negative effects deriving from the spreading of nanoparticles, should lead to elaborating of new methods or to changing those available today. In any case, whether existing assessment methods need adapting, or whether new methods of analysis, where available, have not reached a normative consent, the SCENIHR points out the need to: assess the risks case by case; set up adequate methods to define the physicochemical properties of nanoparticles; develop methods and instruments that will allow us to carry out the *routine* measurements of the representative exposition to nanoparticles; modify toxicity and ecotoxicity tests and introduce new tests aimed at optimising the risk assessment process; put in place suitable methodologies to assess the nanoparticles' systemic distribution. In particular, the hoped-for new assessment methods should give us information regarding how nanoparticles spread in human tissue and in environmental areas.

For the aforementioned purposes, the SCENIHR states the need to fill the gaps in the scientific knowledge regarding the nanoparticles' characteristics and the understanding of the impact and persistence of these structures on man and on the environment, with specific reference to the risks of a toxicological nature. In fact, despite the growing number of scientific publications about nanosciences and nanotechnologies, there's still a significant *gap* in the knowledge of relative data, in particular with regards to the characterisation of the mechanisms and the kinetic of the release of nanoparticles, starting with a wide *range* of nanoparticles' processes and products; with regards to the current levels of exposition to nanoparticles both for humans and for the environment; to the possibility of extrapolating toxicological data relative to nanoparticles of different sizes and shapes; to the study of the levels of exposition to nanoparticles through the analysis of the response of "*target organs*"; to the exposition levels and to the effects on the health of the workers employed in the making and the treatment of nanoparticles<sup>350</sup>. In this perspective, the issues regarding the movement of nanoparticles within the human body and the interaction mechanisms at the sub-cellular and molecular level have particular importance. Therefore, the monitoring of occupational exposition and the epidemiological data relative to the potential impact of nanoparticles on human health are a priority of future research and will lead to normative and risk management implications, for example in the elaboration of suitable guidelines for toxicological tests, in the definition of *standard* of occupational and environmental qualities and in the revision of the legal classification and labelling of industrial products.

---

<sup>350</sup> The cognitive gaps include the characterisation, the collection and the measurement of nanoparticles; the response dose, the impact and persistence of nanoparticles in the human body and in the environment; and all the aspects relative to nanoparticles' toxicology and ecotoxicology.

#### 4. Normative policy trends

First of all we must highlight, from a general and introductory point of view, the lack of International and European legal regulations to expressly control nanotechnologies applications, even though there are general principles that can find useful application with regards to the issues under discussion, like, for example, the prevention principle, of early assessment of the impact on the environment, and the precaution principle. In addition, in International law, there is a pactional source, the Cartagena Protocol on biosecurity (signed in Montreal on the 29th of January 2000), in addition to the Convention on biological diversity (Rio de Janeiro, 5th of June 1992), which has a certain importance for the purposes of this investigation.

The precaution principle, in the formulation accepted by multilateral treaties on the protection of the environment, takes for granted, as it's known, a sort of inversion of the probationary responsibilities, giving those who want to carry out a dangerous activity (and not the potential victims) the responsibility to show that the activity does not threaten a "serious and irreversible" damage for the environment and the human habitat, as well as the responsibility to adopt suitable measures to dispel the potential risks linked to or consequent to the activity under consideration. Intended in this way, the precaution principle could be cited (also in national regulations) if the spreading in the environment of nanoparticles and other nanostructured materials, which tend to bioaccumulate in organisms and in the food chain, was expected. It is true, however, that any discussion regarding this, is still at the embryonic state: in the document *Nanosciences and Nanotechnologies: Opportunities and Uncertainties*, adopted by The Royal Society of Engineering on the 29th of July 2004, scientific data that would justify requesting a moratorium in the release of particles in the environment, formulated by some environmental associations (ETC Group and Greenpeace)<sup>351</sup>, are refuted, but at the same time governments are invited, in line with the precaution principle, to adopt normative measures adequate to the risk that nanoparticles could present from a toxicological and ecotoxicological point of view<sup>352</sup>.

The Cartagena Protocol, "in conformity with the precaution approach ratified by Principle 15 of the Rio Declaration", aims at "contributing and ensuring an adequate level of protection for the safe transferral, manipulation and use of living modified organisms resulting from modern technology, which could have negative effects on the sustainable preservation and use of biological diversity, also in consideration of the risks to human health, with particular attention to transfrontal movements" (cf. art. 1). To this end, the Protocol regulates the transfrontal movements of living modified organisms, foreseeing the recourse to risk assessment procedures in order to ensure, on one hand, the sustainable preservation and use of biological diversity and, on the other hand, the protection of human health. It is clear that, to understand the level of useful application to nanotechnologies of the regulation introduced by the Protocol, we need to correctly appreciate the significance of the definitions used by the pactional instrument, and in particular those of "living mod-

---

<sup>351</sup> The request of a moratorium was formulated during the Johannesburg summit on sustainable development, held from the 26th of August to the 4th of September 2002. In paragraph 6, we will discuss the reactions about this proposition, which in the ETC Group intentions should have been about nanotechnological research as well as nanotechnological applications.

<sup>352</sup> Cf., p. 77.

ified organism”<sup>353</sup> and “modern biotechnology”<sup>354</sup>; in any case, beyond an assessment of merit, it is clear that the Cartagena Protocol only incidentally touches the issues posed by nanobiotechnologies and does not give them any specific consideration<sup>355</sup>.

The policy and normative trends taken up by the European Union are instead more focused, as they can help in identifying the main legal problems caused by nanotechnologies, not just from the point of view of the protection of health and the environment: in fact, next to the mentioned profiles, the European Union’s documents raise peculiar aspects, regarding the protection of privacy and of the right of intellectual property or, more in general, the international cooperation in this sector<sup>356</sup>.

A certain favour of the European Union towards nanotechnologies is stated by the title of the first document dedicated to them, the communication *Towards a European Strategy in Favour of Nanotechnologies*, adopted by the Commission on the 12th of May 2004. This communication, in short, identifies as the main objective of the European Union policy in the sector under examination, the strengthening of the competitive “supremacy” achieved in this sector by Europe and suggests, to this end, an integrated and responsible strategy, capable of joining the aspects connected to industrial development to the aspects more directly linked to the aforementioned needs of environmental and health safety<sup>357</sup>. After expressing the hope that the knowledge acquired by the European Union in the field of nanosciences will be fully used through the realisation of adequate research infrastructures and the allocation of adequate levels of investment (public and private), essentially for the purpose of allowing the development of commercially sustainable products and processes, the Commission’s communication highlights how, facing by now a rapid evolution of nan-

---

<sup>353</sup> That is, the “living organisms characterised by a new combination of genetic material obtained through modern biotechnology”, where for “living organisms” we must intend every “biological entity able to transmit or replicate genetic material, including sterile organisms, viruses and viroids” (cf. art. 3, letters g and h).

<sup>354</sup> That is, that the “application of *in vitro* techniques of nucleic acid, including the re-combination of the deoxyribonucleic acid (DNA) and the direct inoculation of the nucleic acid in cells and organelles”; or “the fusion of cells outside of the taxonomic family, which would overcome the physiological barriers of reproduction or re-combination and which are different from the traditional techniques used in breeding and selection” (cf. art. 3, letter i).

<sup>355</sup> It is important to highlight that the notion of LMO accepted by the Cartagena Protocol, coincides only partially with the one elaborated in the European community. Art. 2, number 2, of directive number 2001/18, in fact, it defines the OGM as “an organism, different from a human being, whose genetic material has been modified in a different way from what happens in nature” (intending as “organism” any biological entity able to reproduce or to transfer genetic material: cf. art.2, number 1, in the directive). It therefore seems clear, on one hand, the explicit exclusion of the human being from the field of application of the European community, and on the other hand, the clear reference to the use of modern biotechnology in the Protocol. The genetic modification techniques relevant for the Protocol purposes, do not find exact correspondence in those relevant for the purposes of the number 2001/18 directive, which excludes from its field of application the “conventional” genetic modification techniques listed in the attachments IA, part 2, and IB. The Protocol, finally, includes in the notion “living organisms” every “biological entity able to transmit or replicate genetic material, including sterile organisms, viruses and viroids”, which therefore is able to regulate the emission on the market also of those LMO containing the sterility gene (for, example, the so-called terminator seeds), which instead are excluded from the application field of the European Community.

<sup>356</sup> Also, take into account the problems, mentioned in paragraph 3, regarding the fair access, at a reasonable cost, to nanotechnologies and to the imbalance between regions and individuals in the preparation and in the ability to use the technological innovations brought by nanotechnologies, which could cause, in the medium term, a “nano divide”.

<sup>357</sup> Cf. the document COM(2004) 338 def. of the 12th of May 2004, also in *Guce* number C222 of the 4th of September 2004, p.7.

otechnologies, it is indispensable to identify and resolve the security problems, real or perceived, from the beginning, at the same time promoting a dialogue based on trust with the public. From this point of view, the Commission also deems necessary to elaborate a new approach to assess and manage the risks, one that would allow the adaptation of consolidated and traditional procedures used for this purpose<sup>358</sup>.

The basic content of the Commission's communication, which was the object of a wide public consultation<sup>359</sup>, has been favourably received by the European Union Council, gathered on the 24th of September 2004, and has also received the approval of the Economic and Social Committee, which gave its opinion about it on the 10th of November 2004. In the light of such confirmations, the Commission adopted, in June 2005, a specific Action Plan on the issue of nanotechnologies, titled *Nanosciences and Nanotechnologies: a Plan for Europe 2005-2009*, which defines a series of articulated and interconnected interventions aiming at carrying out the main objectives identified by the communication<sup>360</sup>. In fact, the Action Plan, after stressing the progress in nanosciences in a wide range of sectors and highlighting the need for dealing directly and early with the health, safety and environmental risks connected to the development of nanotechnologies, analyses the priorities of the proposed strategy, pointing out the desirable actions<sup>361</sup>.

In particular, the Action Plan expresses the Commission's will to increase the allocation of funds in favour of nanotechnologies in the future VII Program, research, technolog-

---

<sup>358</sup> For the initiatives proposed on this issue, see further on, the 2005 European Union Action Plan. Instead, for the lines of action (or "dynamics") aimed at promoting the progress of nanotechnologies, the 2004 communication stresses the strengthening of investments, the coordination of research and technological development activities, in order to raise scientific excellence, interdisciplinary and competition in this sector, as well as industrial valorisation; the development of a high quality and competitive research infrastructure; the promotion of interdisciplinary education and training for research personnel, as well as a stronger entrepreneurial spirit; the creation of favourable conditions for industrial innovation in order to guarantee a translation of research in products and processes that bring wealth, are safe and have acceptable costs; the respect of ethical principles, the integration of social consideration in the initial phases of the research process and on the promotion of the dialogue with the public; the early consideration of the risks to public health, safety and health at work, environment and consumers, caused by products derived by nanotechnologies; the integration of the aforementioned actions through cooperation and other adequate initiatives at the international level.

<sup>359</sup> For the outcome of such consultation, ended on the 15th of October 2004, cf. the report *Nanoforum*, on <http://www.nanoforum.org>.

<sup>360</sup> Cf. the document COM(2005) 243 def. of the 7th of June 2005, also in *Guce* number C172 of the 12th of July 2005, p. 22. It is important to stress that the new document by the Commission finally puts on the same level of interest, starting with the title, nanosciences and nanotechnology, thus satisfying not only elementary methodological and conceptual needs, but also the observations of those who highlighted, in the May 2004 communication, a focus centred more on the technological-industrial and commercial applications, than on scientific research: suffice to think that in the communication's text the term "nanosciences" appears only once.

<sup>361</sup> With regards to the nanobiotechnology sector, the Commission clarifies that the Action Plan is a complement of the European strategy on the sciences of life and biotechnology, adopted by the Commission in 2002 [cf. the document COM(2002)27 def. of the 23rd of January 2002, also in *Guce*, number C55 of the 2<sup>nd</sup> of March 2002, p.3]. Some uncertainty is caused by the opinion expressed on this issue by the European Commission, which simply vaguely refers to the precaution principle, limiting its application to "realistic risks of a certain severity". This field of application differs from the one recognised by the communication on the precaution principle adopted by the Commission in 2000 [cf. the document COM(2000)1 of the 2nd of February 2000], according to which the precaution principle "is applicable in all cases where a preliminary scientific assessment indicates that there are reasonable reasons to fear that the potential risks could have negative effects on the environment or on human, animal and plant health, but the scientific data do not allow a detailed risk assessment" (italic added).

ical development and demonstration, relative to the period 2007-2013<sup>362</sup>, reinforcing interdisciplinary research during the whole cycle of creation, transferral and use of knowledge, and suggesting specific support for the nanoelectronic sector. In addition, the Commission intends to reinforce the support given to research concerning the potential impact of nanotechnologies on human health and the environment (with specific reference to nanoparticles and to the so-called nanotubes), through the carrying out of toxicological and ecotoxicological studies, as well as the development of methodologies and instruments adequate in monitoring and reducing the exposition to potentially harmful agents, in particular in the place of work (like research laboratories). To these priorities, finally, is added the promotion of the support to nanotechnologies in those sectors considered fundamental for European Union's competitiveness, like medicine, chemistry and space. For these reasons, and taking into account that the infrastructure for scientific research and innovation in the nanotechnology sector presumes a critical mass of resources that at times can be beyond the possibilities of single governments, the Action Plan hopes for the promotion and development of excellence through the institution of appropriate university networks, the integration of transnational resources, as well as the cooperation of small and medium businesses.

Because the Action Plan's underlying strategy mainly aims at boosting industrial and commercial development, in accordance with the European Union's mercantilist objectives, the Commission's document also discusses profiles relative to the promotion and support of businesses' technological innovation and the protection of intellectual property rights, also through the institution of a monitoring system for patents in this sector, the harmonisation of the practices overseeing patents' requests at an international level and the reaching of an agreement on the adoption of a European Community patent<sup>363</sup>. With regards to international cooperation, finally, the Commission proposes the adoption of a binding act, like a declaration or a "code of good conduct", for the responsible use and development of nanotechnologies, which would be the basis for an open and shared system of nomenclature, metrology and risk assessment, that will allow the creation of a toxicological, ecotoxicological and epidemiological databases, as well as a European electronic archive of scientific publications on nanotechnologies. In addition, the Commission invites the member States to reinforce the support given to scientific research and to promote cooperation from less developed countries in this sector, highlighting, at the same time, the contribution of nanotechnological applications in achieving the objective of sustainable development<sup>364</sup>.

Finally, assessing the activity of the so-called normative bodies on this issue, we can refer to the fact that, at the beginning of 2005, promoted by the British Standard Institution (the United Kingdom's national normative body), the International Organisation for Standardisation (ISO) asked its members to assess the opportunity of discussing a new set of regulations relative to nanotechnologies (ISO/TS/P199). This initiative, basically, aims at instituting a technical committee (ISO/TC229) to look into regulations in the field of nanotechnology, with specific reference to classification (including calibration and certifica-

---

<sup>362</sup> Cf. COM(2005)119 of the 6th of April 2005, in *Guce*, number C125 of the 24th of May 2005, p. 12.

<sup>363</sup> Another priority indicated in the Action Plan is the development of education, training and interdisciplinary learning, which would involve exact, human and social sciences.

<sup>364</sup> The Commission clarifies that this is with regards to water purification, healthy and safe diet, more effective administration of vaccines, cost reduction of health checks, preservation and more efficient energy use.

tion), to environmental aspects and to risk management. From this point of view, the relative trial methods should include procedures to determine the physical, chemical, structural and biological characteristics of those materials and devices whose performance, in their expected use, depend on one or more parts being smaller than 100 nanometres.

It is easy to observe that the ISO's proposition takes into account the predictable growth of the industrial applications of nanotechnologies and of their probable spreading also in the domestic environment. The consequent impact of these applications, in sectors that vary from communications to health and from the manufacturing and materials industry to information technology, persuaded the ISO to gain the necessary instruments, on one hand, to give researchers, the industry and politicians, regulations able to sustain the technological and commercial development of products using nanotechnologies; and, on the other hand, to offer to civil society the appropriate instruments to assess the risks and protect health and the environment. Also moving in the same direction is the European Committee for Standardisation (CEN), which, at the beginning of 2004, instituted a working group on nanotechnologies within its Bureau Technique (CEN/BT/WG166). This working group has the task of consulting the interested parties and putting in place a strategy able to identify the possible responses to market expectations; in addition, it intends to be the coordinating and connecting point for other initiatives on nanotechnologies by other individual European countries (like in the case of the National Body of Unification in Italy).

## 5. Synthesis and bioethical recommendations

From nanotechnologies we expect interdisciplinary and very different applications: extra-resistant and light materials, drugs capable of hitting only the right "target", efficient and extremely fast computers. The production of nanomaterials (the leading sectors are electronics, pharmaceuticals, energy production and "intelligent" materials) is beginning to have an important place in industry and the production costs are constantly being reduced: it is therefore certain that the application of nanotechnologies will increase, starting with electronic devices in cars. Scientists, industry and the Government anticipate that the manipulation of matter at the nanometric level will produce enormous benefits and will open possibilities of applications unimaginable until recently, but even the strongest supporters of these new technologies agree that such small structures could hide considerable dangers. In fact, what we still don't know about atomic or molecular technology, could generate potentially serious risks, that could have negative effects on the health of living creatures, the environment, the protection of privacy and even the construction of new weapons of mass destruction.

This is, in synthesis, what has been analytically discussed in previous pages. This document does not mean in any way to question the benefits that can derive (and have in part already been derived) by the progress of nanotechnologies. But, facing developments that are necessarily open to ambivalent outcomes, it seems appropriate to stress the issues we need more information and more public debate about, in order to clarify all their bioethical implications.

We therefore suggest the following reflections:

1) To avoid the shallows that have characterised the debate on biotechnologies or on GMOs, mostly dominated by the sterile confrontation between scientists and technophobes,

it seems urgent not only to promote the coordination of disciplines (from material engineering, to biology, to social sciences etc.) that contribute to form this sector of scientific knowledge, and of the subjects (universities, research centres, businesses, government agencies) at the centre of the nanotechnological revolution, but also to facilitate the understanding of the relevant problems by the civil society, to stimulate society's participation in crucial decisions, to accompany the apparently unavoidable emission of nanotechnological products on the market through democratic and transparent instruments of information, revision and control<sup>365</sup>.

In this perspective, it has been stressed in particular that the specificity of the applications based on nanotechnologies could require the adaptation of the traditional and consolidated risk assessment methods, especially with regards to biomedical technologies and nanobiotechnologies. The European Commission's documents examined earlier state how the study of the potential risks for public and environmental health, linked to nanotechnologies, as well as presenting peculiar profiles because of the nanoparticles' extremely reduced dimensions, could become a challenge for classic physics and chemistry. In fact, some nanotechnological applications generate new toxicological and ecotoxicological data and require particular adaptations in the processes of product production, manipulation, preservation, transport and disposal, ending up extending the risk assessment procedures to the entire life cycle of these products.

If, in the current state of scientific research, it seems difficult to predict which properties and characteristics of nanotechnologies' derived products will have favourable market conditions (and therefore the potential risks linked to them), it is however necessary that the application of these technologies respect the standard of protection of public health, consumers, workers and the environment, established by the Treaty of Rome and by the Nice Charter on the fundamental rights of the European Union, as well as the fundamental ethical principles recognised by numerous legal instruments both European and International, like the Oviedo Convention on biomedicine.

The regulatory dimension of nanotechnologies, in particular, should ensure the most suitable preventive measures to neutralise the possible risks, as well as resorting to measures of a different nature if there are still relevant margins of scientific uncertainty regarding their existence or the assessed risks and the damage that could derive from them, especially in the long term<sup>366</sup>.

As well as through an adequate change to the existing regulations and the introduction of ad hoc codes of conduct, the new challenges imposed by this technological revolution could be faced at the institutional level too, for example through the creation of ad hoc ONU

---

<sup>365</sup> On this topic, see the conclusions reached in the document titled *Mind the Gap*, published in February 2003 in the journal *Nanotechnology* by a group of researchers of the Joint Centre for Bioethics at Toronto University.

<sup>366</sup> In this conditions, the application of the precaution principle seems therefore unavoidable, taking into account the uncertain character of the scientific data relative to the potential risks of the nanotechnological applications, the European Commission's trend could provoke some perplexity, which, in the 2005 Action Plan examined earlier, simply vaguely refers to this principle, confining its application to the "realistic risks of a certain gravity". This field of application is different from the one recognised by the communication on the precaution principle adopted by the Commission in 2000 [cf. the document COM(2000)1 of the 2nd of February 2000], according to which the precaution principle "is applicable in all cases where a preliminary scientific assessment indicates that there are reasonable reasons to fear that the potential dangers could have negative effects on the environment or on human, animal and plant health, but the scientific data do not allow a detailed risk assessment" (italics added).

offices and bodies, able to pick up the inheritance of organisations dissolved at the beginning of the 1990s (*UN Centre on Transnational Corporations e UN Centre on Science and Technology for Development*)<sup>367</sup>.

In conducting this first reflection, we can state that the bioethical considerations regarding this wide sector, which goes under the name of “nanotechnologies”, are still limited, and they seem mostly directed to (overly) “exalt” their positive potential; or to warn against the fearfully negative potential that this economic-industrial field of development presents. These reflections appear to many people to be “reductive”, preconceived and far from factual reality. In addition, there are also those who request a more “balanced” discussion (e.g. BERT GORDIN, 2003) and a stronger adherence of the judgement on nanotechnologies to the reality of current developments, with regards to a variety of initiatives that are part of this industrial sector (DETERSON, 2003).

2) Therefore, the NBC deems useful to formulate wider considerations, as follows.

a) In consulted literature, the question of whether it is legitimate to intervene on atoms and molecules to build functional structures of nanometric dimensions is not asked; for the purpose to both replicate those already existing in nature, or to design and create new ones in order to give them (or recognise in them) particular properties, not found in the natural order of things.

The basis of the ethical justification is the fact that chemistry – in itself - already operates at the atomic and molecular levels to recognise and manipulate matter; so that – consequently – to use scientific knowledge deriving from more in depth studies on organic or inorganic matter, in order to produce nanostructures, would not be – in itself – an ethically relevant fact. It is thought that nature’s changing action is an innate tendency in man, and we must simply accept that we are able, at this moment in time, to dominate also this sector for different purposes, although with evident industrial and commercial pitfalls, exploring new combinations of atoms and molecules.

But - as it is known – not everyone acritically accepts this reductive interpretation of human development, which has other dimensions – including those of a spiritual nature – that are not exhausted in the manipulation of matter.

Linked to this problem is the notorious ethical discussion on the danger of “autonomous”, autopoietic development of technology, which increasingly tends to be detached from humanity’s reality. We could therefore ask ourselves if nanotechnologies correspond to this model of exaggerated industrial development.

From a bioethical point of view – the answer can only be the traditional one: technological development must be directed towards very clear objectives of personal and social value, compatible with the individual and collective safety and good, promoting in the democratic context a social participation in defining the objectives and in controlling the results. The nanotechnological industry should also abide by these requirements.

b) However, a strange aspect of this sector – which concerns more closely the bioethical questions we are discussing – is connected to the possibility of creating structures composed of organic matter (for example proteins) and inorganic matter (for example metals) in manufactured goods of nano dimensions, proposed as nanomotors, or nanoconductors

---

<sup>367</sup> In this way, also see the ETC Group document mentioned in note 26.

or nanosensors etc., to obtain a wider range of possibilities of use for this technology in the field of communications as well as healthcare (diagnosis and therapy).

It seems apparent that – in some cases – organic matter that joins in new combinations with inorganic matter represents a bio-chemical component that has particular capabilities, because of its intrinsic structure, with regards to fulfilling the possible properties of the manufactured good, and would not in itself represent an ethical problem, if it was non-living matter. The bioethical problem however is at the start, and can at times involve the “living status” of the organic matter used, but always – in any case – has something to do with the origin and the methods of acquisition of the organic component. Whilst there would be no problem, for example, about a so-called cellular reactor in a culture of living *Saccharomyces cerevisiae*, genetically modified to create drugs, encapsulated in a polymer with molecular permeability, ethical problems would instead occur, for some, about the hypothetical derivation from human embryo cells for the cellular reactor; or – at a different level of legitimacy and problematic – about the production of reactors with human living cells, carried out without the informed consent of the tissue donor. Obviously, these are only examples indicative of the ethical-legal problems.

Should these situations occur, there would be, for similar applications of nanotechnologies, bioethical questions to carefully consider, but not dissimilar (in their intrinsic nature) from ethical reflections already discussed about these problems in applications at the microscale or at the larger level.

Particular bioethical “sensitivity” should be applied with regards to the possible production – for example – of nanotechnological manufactured goods that include human genes (for example artificial chromosomes; nanocapsules of polymers enclosing and supplying genetic human products) with regards to the “instructions” for their use, and not only about their adherence to the international patenting rules in their production.

In the same way, there would be ethical questions regarding the presentation to the consumer of such manufactured goods in advertising and placing on the market, because there would be a duty to inform the consumer of the origin of the biological material in the manufactured good, and to allow him/her to exercise his/her freedom of choice in accordance with his/her personal ethical sensibility.

In conclusion, under these profiles, it seems possible to refer to – also for nanomanufactured goods – well known “principles” protecting human rights, already experimented in bioethics and codified by private, public, commercial, penal etc. law, national or international, when using devices and inventions in response to various human needs, and operating at the normal current scale dimensions.

3) These general bioethical considerations on the social “acceptance” of techniques included in that very wide and varied sector, known under the name nanotechnologies, after all, are very similar to those already discussed about the extraordinary development of “biotechnologies and genetic engineering” (for example genetically modified organisms), a development that strongly posed the question of the moral “legitimacy” of the modification of the genome of living beings (vegetable, animal, human), but also of the “justice” in the enjoyment and in the wider access to the (eventual) benefits. These questions gave rise to a variety of responses, which were influenced by the positive or negative contributions offered by these technologies to the solution of problems, especially economic and social, emerged in the different environmental and social contexts in which the human population lives.

In our ethical judgement, matured within western society, the answers given do not cover every need; but even in sectors where “positive” judgement on nanotechnologies is more uniform (e.g. the case of biotechnological production of drugs) the benefit offered by such technologies is still completely unbalanced.

Some authoritative voices who participated – during international encounters – to this initial bioethical reflection on the social “falls” of nanotechnologies, have already expressed the opinion that few individuals and industrialised countries will be the ones to mostly benefit from them, whilst the distance between rich and developing countries will increase (see for example J.C. Tealdi, 2003); others have stated that this is an opportunity to start a new chapter of particularly profitable industrialisation, especially for developing countries (Salvaterra, 2003). This opinion does not appear – at the moment – to go beyond the petition of principle.

In any case, the ethical profile of the “justice principle” in the potential benefits is certainly strongly felt in the international discussion on the issue of “nanotechnologies”, as it is with regards to genetic “biotechnology”.

4) In the sector that particularly interests the NBC, we must list the bioethical considerations on the issue of using nanotechnologies in medicine, which demand particularly careful consideration.

The possibility to define a competitive and “winning” “nanomedicine” in contrast with currently practiced medicine, which is also technologically advanced (obviously this is only a prospect, at least in many cases) is supported by two trends:

- the first, considered as a development coherent with medical tradition, for the improvement of diagnosis and treatment in some morbid forms (Alivisatos, 2001; Bachmann, 1998; Chemla et al, 2000; Jordan et al., 2000; Randal, 2001; Reichert et al., 2000; West e Halas, 2000; Wolfe, 2002; DiasproI, 2005);

- the second, innovative but susceptible to many ethical reservations – aimed at increasing some intellectual human “capabilities”, already existing and considered to be within the range of normality, through the boosting action of microchips compatible with the organic matter in the nervous and sensorial systems (Drexler, 1986; Freitas, 1988 b; Kaku, 1997; Kurzwei, 1999).

What is put forwards again is a “scheme”, already discussed, for a genetic intervention of “enhancement” (the realisation of which, probably, should be more easily allowed by the nanotechnological “vector”).

The desirability of this second line of development for future medicine must be ethically contested, and rightly Gotjn (2004) states that – if this was the predominant thought in society – the continuation of research in this direction should appear as devoid of meaning from an ethical point of view.

Instead, any reasonable effort in the first direction is not contested, provided that research and expected outcomes are motivated by substantial benefits for the patient, and are also in proportion to the investment of resources that – necessarily – are taken away from other sectors of health care.

Without a doubt, in the literature produced so far, it is stated that considerable results can be expected – with the use of the nanotechnologies’ criteria – with regards to a better identification of the drug’s target (Alivisatos, 2001; Bogunia-Kubik and Subisaka, 2002; Davis, 1997; Mehner and Mader, 2001; Moghiari et. al, 2001; Randal, 2001; Taton, 2001;

West and Halas, 2000; Woolley, 2001; Wusthoff, 2002); in diagnostics (Alivisatos, 2001; Chemla et. al., 2000; Randal, 2001; Relchert et. al., 2000; West and Halas, 2000; Wolfe, 2002); in prosthesis and implants (Alivisatos, 2001; Bachmann, 1998; Murphy and others 2001; Taton, 2001); in cancer therapy (Alivisatos, 2001; Jordan et. al., 2000; Randal, 2001; Schattenfrom, 2000; Diaspro, 2005).

It seems justified, at the moment, to give credit to these statements as they come from serious researchers, although we are still waiting for proven documentation of practicability and efficacy in the use of nanovectors, or nanosensors, etc., as it is hypothesised in literature.

5) Finally, we must discuss the bioethical problem that today appears fundamental and on which there is not enough information: the risk linked to experimenting with and using nanotechnologies, in particular in medicine.

Given that it is not justified to “globally” examine the “risk of nanotechnologies” as if they were a homogeneous category – it seems clear that we still badly lack information about the effects of each type of nanotechnological device on living matter, cells, tissues, organs and organisms.

In current society prevails the idea (highlighted also in the recent NBC’s Opinion on the precaution principle; 2004) of “risk acceptance”; but such risk should be strictly checked not just by traditional criteria and methods of experimentation and before its biological and clinical applications, but also by training, monitoring of sensible parameters, awarding of responsibility to individuals, preventive and not merely repressive control by the Control Authority, etc.

There is no doubt – in any case – that still too little is known about the biological dynamics between organism and “guest” to allow reliable predictions about the organic reaction to the use of artificial micro-nanostructures proposed in medicine. Currently, we are reasoning by analogy; but our notions on the action – at the molecular level – of microparticles already produced by the industrial society and dispersed in the biosphere, are just as episodic and fragmented.

A very serious program has been put into place by the British government, which promotes a series of investigations on the biological effects of nanoparticles, with research conducted on animals too; in addition, research funds have opportunely been allocated by the European Community and by a variety of OCDE countries.

As long as we don’t know the reactions at the cellular and tissue level - acute and chronic – of the “grafting” of foreign or genetically modified material (although protected by capsules of permeable polymers), or of the effects of miniaturised “analytical robots” inserted in the digestive tract or of other devices (for example implants of miniaturised cerebral stimulators) in animals, it will not be possible to move on to the trial phase on humans.

This pre-clinical process seems necessary, and it involves protracted observation (long term effects).

6) Still with regards to the ethical and legal profile, we cannot forget the possible interferences with private life (see the case of bugs and what has already been described on information nanotechnologies) but we also cannot underestimate the positive aspects offered by the storing and transmission of data, hypothesised by nanotechnologies (F. Galembeck,

2003) in less dangerous sectors and maybe their easier social control, in comparison with the biomedical sector, with regards to the safety of use.

It must be remembered that, in relation to the environmental risks and the “trespassing” of them during the production of nanodevices, “guidelines” have been issued (Forsight, 2000), which require limiting production to not self-replicating devices with a controlled duration of action and in any case adding – in every program of production and use – an assessment of the effect on the environment.

It can seem pleonastic to state that these “guidelines” – although minimal – should be imposed by the Supervising Authority.

Rationality and moral sense of responsibility must also guide development in this sector, as it is expected in every human activity.

Inalienable premise to the ethical evaluation is also the need for the expected benefits to be accessible by the needy, independently from social factors of discrimination or economic obstacles, which the community will have to avoid with appropriate forms of solidarity.



---

Editing

*National Bioethics Committee*

---



---

Published by PRESIDENCY OF THE COUNCIL OF MINISTERS  
The Department of Information and Publishing *Head of Department Ferruccio SEPE*

---

Printed by Stab. Tipolit. Ugo Quintily S.p.A.

