

PRESIDENZA DEL CONSIGLIO DEI MINISTRI

SEGRETARIATO GENERALE

N. 7



Italian National
Bioethics Committee

Opinions
2011 - 2012



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

This publication is dedicated to the memory of Prof. Adriano Bompiani, founding promoter of the National Bioethics Committee and passionate scholar for his entire life of bioethical issues. With deep gratitude for his tireless work which blended harmoniously scientific knowledge, the respect for the human person and a deep sense of the Institutions.



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Comitato Nazionale per la Bioetica

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Presidenza del Consiglio dei Ministri



**NOTE ON THE PHARMACIST'S
CONSCIENTIOUS OBJECTION TO THE SALE
OF EMERGENCY CONTRACEPTIVE PRODUCTS**

25th of February 2011



PRESENTATION

The NBC, with the document entitled *Note on the pharmacist's conscientious objection to the sale of emergency contraceptive products*, responds to a question raised by the Hon. Luisa Capitanio Santolini¹ on the conscience clause² invoked by those pharmacists not to sell pharmaceuticals of emergency contraception, also referred to as “morning-after pill”, for which the leaflet does not exclude the possibility of a mechanism of action that leads to the removal of a human embryo.

The Committee pointed out in general terms that conscientious objection, which has a foundation in the constitutional right to religious freedom and freedom of conscience, must still be made in respect of other fundamental rights provided for by our Constitution, which include the inalienable right of the citizen to protect health and receive health care recognized by law.

Different bioethical standpoints emerged within the National Bioethics Committee.

Some members, highlighting numerous reasons, believed it possible to recognize the role of the pharmacist as being akin to those of “health care workers” and therefore, analogous to what happens with other healthcare professionals (Law No. 194/1978 and Law No. 40/2004), the right to conscientious objection must necessarily be recognized also to this category. The fact that the pharmacist has a “less direct” role compared with whosoever clinically practices an abortion was not considered sufficient grounds to invalidate the argument in favour of the moral clause, since the distribution of the product contributes to the possible outcome of abortion in a chain of cause and effect without interruption.

Other members believed, for other reasons, that the figure of the pharmacist and physician cannot be assimilated, since the pharmacist is not responsible for the prescription of the drug, or the personal circumstances

¹ In the Appendix.

² The document will address the issue of conscientious objection without a specific distinction as regards the conscience clause. This reflection will be discussed in detail in another NBC document on conscientious objection in general.

and the health of whoever requests it. The relationship with the user is generic and impersonal: it is the prescription that legitimizes the distribution of the drug and not the identity of the person collecting it. It is entirely the physician's responsibility, while there is no legal involvement on the part of the pharmacist who has no authority to go into the merits of the choices made. It was pointed out that in the event of the pharmacist being granted, in legislative terms, the right to conscientious objection (through the refusal to fill prescriptions for the so-called morning-after pill) he would be conferred a dual faculty. On the one hand, to censure the work of the physician, with consequent risks for the patient's mental and physical health; and on the other, to intervene in the most private and intimate sphere of a woman, preventing de facto self-determination.

Assuming that the legislature acknowledges the right to conscientious objection on the part of pharmacists and pharmacy personnel, the components of the NBC agreed that, in accordance with constitutional principles, the interests of all the parties involved must be considered and guaranteed. An essential and indispensable premise for the possible legal extension of conscientious objection to pharmacists is, therefore, that the woman in question must in any case be able to access the requested drug elsewhere or through different means and that it is for the institutions and competent authorities, in consultation with the professional bodies involved, to provide the most appropriate systems to make explicit the necessary tools and figures responsible for the implementation of this right.

The document was drawn up on the basis of a text prepared by Prof. Lorenzo d'Avack who made use of extensive debate within the NBC, with the written contributions of Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Roberto Colombo, Francesco D'Agostino, Antonio Da Re, Maria Luisa Di Pietro, Riccardo Di Segni, Silvio Garattini, Laura Guidoni, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia.

In the plenary session of the 27th of January 2011 Dr. Andrea Mandelli, President of the Italian Federation of Associations of Pharmacists, and Dr. Antonio Mastroianni, Director General of the Federation were audited.

In the plenary session of the 25th of February 2011 the document received the consent of Profs. Luisella Battaglia, Stefano Canestrari,

Roberto Colombo, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Claudia Mancina, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia.

Prof. Demetrio Neri voted against. Profs. Salvatore Amato and Emma Fattorini abstained. Profs. Adriano Bompiani, Cinzia Caporale, Bruno Dallapiccola, Maria Luisa Di Pietro, Aldo Isidori, Alberto Piazza, Vittorio Possenti, Rodolfo Proietti, Lucetta Scaraffia and Giancarlo Umani Ronchi absent at the voting of the document, have subsequently given their support.

Published along with the document are the personal remarks of Prof. Salvatore Amato, who states the reasons for his abstention, those of Profs. Antonio Da Re, Emma Fattorini and Andrea Nicolussi who propose additional reflection, that of Dr. Riccardo Di Segni, who explains his standpoint in relation to the text and that of Prof. Demetrio Neri who sets out the reasons for his dissent. Prof. Grazia Zuffa, absent at the meeting, subsequently submitted her endorsement to the personal remark made by Prof. Neri.

The President
Prof. Francesco Paolo Casavola

1. Given that:

- under Article 38 of the Regulations for pharmaceutical services (Royal Decree 30th of September 1938, No.1706) every chemist, pharmacist or auxiliary pharmacy, operating as part of a public service, has the obligation to deliver medicinal products to those requesting them and showing the relative medical prescription, and – if the product is not in stock- to obtain it as soon as possible³;

- the obligations provided for by the aforementioned Regulations carry criminal penalties for violation and are valid for pharmacists and auxiliary staff working in community pharmacies, hospital pharmacies, and private and health district pharmacies;

- at the time of the Royal decree of 1938, on the one hand, abortion was prosecuted as a crime and abortive medications were not available, and on the other, conscientious objection was not part of the prevailing sensibility of the legal culture of the time;

- in our pluralistic society, even from the standpoint of understanding the values and fundamental rights accepted by the Constitution, a new sensitivity has developed that allows the possibility, in particularly problematic situations, to raise objection of conscience (understood as an ‘option of conscience’, leaving it up to the individual to choose between alternative legitimate behaviour in legal terms), so that in the most common case of conscientious objection to military service, conscientious objection is legislatively granted in areas that primarily regard the medical and health context;

- currently in the spheres of medicine, health and experimentation our legal system allows conscientious objection in the following regulations:

➤ Law No. 194/1978, Art. 9 (Regulations for the social protection of motherhood and on the voluntary interruption of pregnancy);

➤ Law No. 413/1993, Art. 1 (Regulations for conscientious objection to animal testing);

³ Art. 38 “Pharmacists can not refuse to sell available medicines or refuse to fill prescriptions signed by a physician for medicines present in the pharmacy. A pharmacist with a request for a national medicinal product, which is not in stock, is obliged to obtain it as soon as possible, provided that the requester advances the amount for postage. Pharmacists are required to send the prescription in the shortest possible time in order to masterfully carry out product preparation. All prescription must be signed by a doctor or a veterinary surgeon. Pharmacists must keep copies of all filled prescriptions for a period of five years”.

➤ Law No. 40/2004, Art. 16 (Rules of medically assisted procreation);
- various bills have been presented to both Houses from different political factions aimed at regulating the introduction of “conscientious objection” to pharmacists, in consideration of the new feature represented in particular by the introduction and marketing of drugs commonly referred to as emergency contraceptives;

- the current Pharmacist’s Code of Ethics (2007) Art. 3, paragraph 1, letter c) provides that the professional must act “independently and conscientiously in accordance with ethical principles, and always keeping in mind the patient’s rights and the respect for life”;

- the NBC has directly and indirectly on several occasions dealt with the issue of conscientious objection in health care, recognizing that right whenever the moral decisions of physicians are involved (*Purpose, risks and limits of medicine* (2001); *Advance treatment statements* (2003); *Note on emergency contraception* (2004), *Alternative medicines and the problem of informed consent* (2005); *Bioethics in dentistry* (2005); *Refusal and Conscious renunciation of health treatments in the patient – doctor relationship* (2008); *Alternative methodologies, Ethics Committees and Conscientious objection to animal testing* (2009);

- the question submitted to the Committee identifies as the subject of conscientious objection “pharmaceuticals for which the mechanism of action does not exclude the possibility of eliminating a human embryo, whatever its stage of development”⁴;

- the Committee states from this moment that conscientious objection, which has a constitutional basis in the general right to religious freedom and freedom of conscience, must still be made in respect of other fundamental rights, among them the inalienable right of citizens to protect health and to receive the health care recognized by law;

In consideration of this, the National Bioethics Committee puts forward the following arguments.

⁴ Currently, the drug on sale is NorLevo (levonogestrel) whose leaflet refers to the possible elimination of the embryo. http://www.angelini.it/public/schede/norlevo_gen06.pdf.

The NBC acknowledges that there is wide scientific debate on the subject. The possibility for the interceptive mechanism of action of levonorgestrel was challenged by C. Flamigni, A. Pompili, *Contraception*, Rome 2011, p. 154 that link up with the study of P.G. Laliktumar, *Mifepristone but not levonorgestrel, inhibits human blastocyst attachment to an in vitro endometrial three-dimensional cell culture mode*, in “Human Reproduction”, 2007, 22, pp. 3031-3037.

2. The various arguments concerning conscientious objection

Different bioethical standpoints emerged within the National Bioethics Committee, which are set out below.

2.1 Some members⁵ acknowledge the extension of conscientious objection to pharmacists as regards the sale of so-called emergency contraceptives for the following reasons.

a) With regard to the characteristics of the drug, it is still considered that the experimental and clinical data do not consent the reaching of definite and shared conclusions to exclude a shared mechanism of action, which, at least in a number of cases, prevents the early development or implantation of the embryo in the endometrium, this effect is considered as abortion by those who believe that pregnancy begins from the time of fertilization.

The fact is, however, that the pharmacist dispensing the drug has no discretion to judge the scientific content and must abide by the leaflet, which now accompanies and describes it by law. This, even under the provisions of the Regional Administrative Court of Lazio⁶, contains the aforementioned features; one of the effects also indicated is the prevention of implantation of an embryo which may already be present in the womb. It is evident that if the leaflet of the drug subsequently contained different scientific indications, which exclude such an effect of the product, the objective reasons that support the moral illegitimacy of its sale by the pharmacist would cease.

Should a pharmacist sensitive to the rights of embryonic life, consider the data contained on the current leaflet non compliant with the latest scientific evidence, so as to exclude the “interceptive” mechanism of action of levonorgestrel, he may therefore draw valid personal reasons not to object.

b) Notwithstanding the nature and effects of the active ingredient, among the principle reasons that lead some to question the legal legitimacy of the conscientious objection of pharmacists is the role they play, regarded

⁵ Bompiani, Caporale, Colombo, D'Agostino, Dallapiccola, Da Re, d'Avack, Di Pietro, Gensabella, Isidori, Morresi, Nicolussi, Palazzani, Possenti, Proietti.

⁶ Regional Administrative Court of Lazio, Decision No. 08465 of 12.10.2001.

as not akin to those of “health care workers” as pharmacists are to be considered merely dispensers of drugs to the public. This justification was not shared by the NBC.

The President of the Federation of the Association of Pharmacists, Dr. Andrea Mandelli, at a hearing held at the NBC, purposely made clear that in accordance with current legislation the pharmacist is a healthcare worker⁷ “and that, if there is no obvious intervention in the diagnostic process and indication of therapy, he nevertheless, has his own specific expertise with regard to the drug as regards the citizen, the proof being that he is required to check the prescription”⁸. It is his duty and responsibility not only to sell the requested drug, but also to inform the patient on the correct use of the drug, to point out possible interaction with other medicine taken by the patient, to dissipate any doubts on the active ingredient and excipients, also referring, where appropriate, the client to the physician. As regards a possible “therapeutic alliance”, he stated that: “the pharmacist interacts with the client-patient; in fact he is the health care worker that is closest to the patient and at the service of the people”⁹.

It is clear that the discussion about whether or not the pharmacist can be ascribed the category of “health care worker” has decided implications for the legal possibility that, analogous to what occurs with other health professionals (Law No. 194/1978 and Law No. 40/2004), the right to conscientious objection must necessarily be recognized also to this category.

Nevertheless, the abovementioned question is not conclusive in moral terms. In this sense, even those not belonging to the category of health personnel are entitled to invoke conscientious objection. This is a principle, for example, that the law recognizes those who work in the field of animal experimentation (Cf. Law No. 413/1993). The pharmacist as a

⁷ Cf. R.d. 27 July 1934, n.1265, which at Art. 1999 onwards includes pharmacists and pharmaceutical services in the health professions and arts: Title II is dedicated to the ‘Pursuit of the health professions and arts and activities subject to health surveillance “and inside Chapter II deals with” pharmaceutical services.” Confirmation of this interpretation is also apparent from Law No. 833 of 23 December 1978 on the establishment of the National Health Service in relation to Articles.1, 2, paragraph. 1 No 7; 14, paragraph 3 letter n); 28, paragraph 1.

⁸ In ASCA, 28.01.11 and in the plenary hearing of January 27th 2011.

⁹ Ibid.

citizen in a democratic society characterized by ethical pluralism, has the right not to perform an action, indicated under certain physiological conditions as scientifically capable of preventing the development of a human embryo, when it conflicts with their moral beliefs regarding the respect and protection due to a human being from the beginning of its development. Even more so if one considers that the unborn have constitutional protection (see Constitutional Court No. 27/1975, 35/1997, 151/2009, cf. also Law No.194/1978, Art.1), and that therefore conscientious objection is invoked here in an appeal not only to freedom of conscience but also to the importance of the principle of respect for human life, which in the same way ascends to a good of constitutional significance.

c) The fact that the pharmacist has a “less direct” role compared with whosoever clinically practices an abortion was not considered sufficient grounds to invalidate the argument in favour of the conscientious objection. The distinction between direct or indirect participation has no moral relevance, as both actions contribute to a possible outcome of abortion in a chain of cause and effect without interruption: even the less direct role (the distribution of the drug, after examining and checking the prescription) is still a crucial link in the chain of professionally qualified and informed choices that lead to, as a result of taking the product, the possible chemical elimination of the embryo. Abstention from encouraging (or simply making possible), such practices can therefore represent not only the physician but also for the pharmacist, a moral and ethical¹⁰ duty towards the protection and promotion of human life.

d) Moreover, since in the majority of cases the doctor, consulted shortly after intercourse, is unable to diagnose a real danger to the woman’s health in the case of a hypothetical pregnancy, but can only determine if considered the apparent health conditions of the woman that there are no objective contraindications to taking the drug, the prescription is not a proper indication of treatment. Consequently, as in the case of other products, the role of the pharmacist in the dispensing of the preparation seems no less decisive than that of the doctor.

¹⁰ Pharmacist’s Code of Ethics, 2007, Art. 3, paragraph 1, letter c).

e) Lastly, the possibility that the woman may not immediately and personally use the purchased drug is not a relevant argument against conscientious objection. Otherwise this kind of argument should also apply to the physician prescribing the product, without the certainty of it being purchased and/ or administered exclusively to the person to whom it was prescribed. In order to invoke conscientious objection, it is essential that a law exists which imposes an action that is seriously in contrast with the conscience of those who should respect it: referring to possible circumstances which 'de facto' void of sense, is irrelevant in terms of 'principle'.

Members who put forward these bioethical observations believe, therefore, that the delivery of drugs, which, as mentioned in the leaflet, through their prescribed use bring about even the possibility of preventing the development of an embryo, preventing its implantation in the uterine endometrium, is configured as an activity that can justify the pharmacist and pharmacy employees to avail themselves of conscientious objection.

2.2. Other members¹¹ believe we must recognize the absolute correctness of professional conduct and the ethics of the pharmacist who invokes the conscience clause in order to refuse to sell "pharmaceutical products for which the possibility of a mechanism of action that leads to the removal of a human embryo is not excluded".

In the opinion of those members, the possible *legislative* recognition of the right to object to the pharmacist is nevertheless a much more complex issue, therefore the refusal to fill prescriptions of the so called morning-after pill (NorLevo). In relation to this issue, the role of the pharmacist can not be assimilated to that of the physician. The difficult composition of the contrast between the freedom of conscience of the pharmacist (and / or of the pharmacy auxiliary) - indisputable however in a pluralistic State - and a woman's fundamental right to physical and mental health, do not consent reference to the achievements of the debate regarding conscientious objection of the physician.

The proposal for legislative recognition to the pharmacist of the right to conscientious objection as regards the so-called morning after pill does not appear to be shared, for a multitude of reasons.

¹¹ Battaglia, Canestrari, Garattini, Guidoni, Mancina, Piazza, Scaraffia, Toraldo di Francia, Umani Ronchi.

a) The importance of the scientific nature of the premise must be reiterated. The possibility of the interceptive mechanism of action of levonorgestrel - namely the effectiveness as an abortifacient of the drug NorLevo - has been authoritatively challenged¹².

b) It is highlighted that the role of the pharmacist is very different from that of the physician. In fact the pharmacist is not responsible for the prescription of the drug or the personal circumstances and the health of whoever requests it. It is entirely the responsibility of the physician – who in fact is not obliged to prescribe a particular drug – while there is no legal involvement on the part of the pharmacist, who is limited to ensuring the efficiency of the structure in which he operates, without going into the merits of the choices made and sometimes without even personally knowing the person who will take the drug.

The pharmacist's intervention is limited to cases in which he has doubts, on the basis of his scientific background, regarding the appropriateness of a prescription (and in such cases there is the obligation to immediately contact the physician that wrote the prescription to verify its correctness or authenticity).

c) In the event of the pharmacist being granted, in legislative terms, the right to conscientious objection - through the refusal to fill prescriptions for the so-called morning-after pill - he would be conferred a dual faculty: on the one hand, to censure the work of the physician prescribing the drug, presumably “to the best “knowledge and belief”; and on the other, to intervene in the most private and intimate sphere of a woman, actually preventing self-determination. In both cases, it is to be noted that the rights of others are damaged, - with possible serious risks- to the woman's mental and physical health. The pharmacist, far from occupying a secondary and indirect role, would ultimately take on a decision making role, overseeing the assessment of the physician and the choices made by the woman, without a thorough knowledge of the complexities of the reasons and conditions - both medical and existential - which motivated each one.

¹² See Note 4.

d) An indispensable prerequisite for the possible legal extension of conscientious objection to pharmacists should however be the identification, as a priority, of the appropriate measures to ensure with absolute certainty the delivery of the drug prescribed by the physician. The plenary hearing of the President of the Federation of the Association of Pharmacists, Dr. Andrea Mandelli, confirmed fears that the legal recognition of conscientious objection to pharmacists may undermine in certain situations the fundamental right of the patient to have the drug prescribed by the physician dispensed. The prospect that each pharmacy may be expected to include in its available staff at least one pharmacist that is not a conscientious objector in practice seems very difficult to implement. Legislative recognition of conscientious objection to pharmacists would therefore endorse a kind of conscientious objection to the pharmacy. As such, this is absolutely unacceptable, because the different types of pharmacies perform, in any case, a public service. Lastly, it is noted that possible legislative recognition of conscientious objection to pharmacists may lead to objection on the part of other workers in the cycle of synthesis of drug preparation and distribution, determining at least unavailability.

e) Ultimately, the legal recognition of conscientious objection to pharmacists could lead to an unacceptable impeditive outcome, interrupting the process that leads to the free resolution of the patient, to the next option (still revocable) to take the so-called morning-after pill, under the sole legal responsibility of the physician. This would deny the centrality of the alliance created between physician and patient, the importance of which has been emphasized strongly and clearly in many NBC documents. The pharmacist does not dispose of all the necessary knowledge regarding individual cases to be able to exercise to the best of knowledge and belief and in accordance with the law the right to conscientious objection, to the point of refusing to deal with the physician's request of the drug, sacrificing as a consequence the basic right of the patient to have the so-called morning-after pill dispensed. It is not a question of denying rights to the pharmacist, but to take note of the inability to guarantee with absolute certainty the priority right to physical and mental health of the patient.

3. The right to obtain the drug

Assuming that the legislature acknowledges the right to conscientious objection on the part of pharmacists and pharmacy personnel, the components of the NBC agreed that, in accordance with constitutional principles, already referred to in the premise, the interests of all the parties involved must be considered and guaranteed.

Conscientious objection should be exercised in a responsible manner so as not to interrupt the process that leads to the free resolution of the patient, to the successive options to take a drug, under the moral and legal responsibility of the physician.

A necessary and indispensable prerequisite for the eventual legal recognition of conscientious objection is, therefore, the assertion of everyone's right to get the benefits due by law: only if this condition is established as a priority and with the indication of appropriate measures that ensure that it is not in fact undermined, are the conditions created to avoid a conflict of conscience that could be harmful to the orderly conduct of social life.

The NBC therefore believes that the woman should in any case have the possibility to obtain the prescribed drug and that it is for the legislature to provide the most appropriate systems to make explicit the necessary tools and figures responsible for the implementation of this right.

The NBC recommends that the Institutions and competent Authorities, in consultation with the professional bodies involved, in accordance with Art. 117, letter m of our Constitution, faced with specific regulatory intervention that may provide for the right to conscientious objection to pharmacists and their auxiliaries, will take the necessary steps to provide correct and complete user information and guarantee, for the protection of citizens, to dispense prescribed drugs on medical prescription in a timely manner in relation to their effectiveness.

PERSONAL REMARKS

A personal remark signed by Prof. Salvatore Amato

The legislature does not give us a definition of conscientious objection, but merely identifies some typical situations. It tells us “who” can exercise this right however not “what” it is. The document notes this

and builds its own structure by analogy: the analogy with the professional figure of the physician, the analogy with chemical abortion. I myself was strongly convinced of the basis of both similarities, so I had no doubt about constructing the Opinion “tracing” the *Note on emergency contraception* (2004).

The development of our discussions and the surprising intensity of the ensuing debates showed that this was not the case. The similarities were very subtle and not clear enough to allow us to set aside the right of women to obtain a drug on regular NHS prescription.

At this point, it would have been appropriate to begin clear and direct questioning on the meaning and extension of conscientious objection. Does it have a symbolic value as an expression of freedom of thought? Does it have a political value as an aspect of civil disobedience? Does it have a militant value as an “answer to evil?” Does it have a general and undifferentiated nature, because it addresses the conscience of humanity, or has it a relational and personal value, because it addresses the consciousness of the other party? Does the pharmacist want to induce humanity or the woman to change her mind? And, in the latter case, can we neglect the impersonality of the relationship between the pharmacist and service user? Can we overlook the fact that the conscience of the pharmacist think to abortion, but that woman to contraception? Can we ignore that the pharmacist decides on one way of life, while the woman decides on her life?

All these questions are surreptitiously, or in a Freudian manner, present in the opinion: when we put alongside conscientious objection the “moral clause” or “option of conscience”; when we question the “less direct” or “indirect” role of the pharmacist in the causation of the event (is there a considerable difference in the moral evaluation of the causal link between the physical handing over of the drug and the indicating of the nearest pharmacy where it is obtainable?); when we discuss about the pharmacist (here the figure of the professional comes into play), the owner of the pharmacy (here the organization of the structure comes into play) and the auxiliary staff (here, above all, the sensitivity of the individual comes into play).

It seemed absurd to expect to answer a specific question, if we did not have the total picture completely clear, and without outlining an attempt to provide an answer that covered all these different aspects. Unfortunately,

in the Opinion, it is not clear what we think of the nature and limits of conscientious objection, nor does the identity of the pharmacist emerge from the fog of vague ambiguity. This is why I decided to abstain from voting.

A personal remark signed by Profs. Antonio Da Re, Emma Fattorini e Andrea Nicolussi

A further question - not dealt with in the Response because not object of the specific query addressed to the NBC - deserves to be highlighted regarding the issue of conscientious objection (in the broad sense, i.e. including the so-called conscience clause) of pharmacists to the sale of so-called emergency contraception. We believe that there should be more in depth consideration of the issue as regards vulnerable individuals, in this case minors, who, as all the data seem to confirm, are the largest consumers of emergency contraception (cf. C. Pasolini, *La corsa delle minorenni alla pillola del giorno dopo*, "La Repubblica" dated 10.1.2011). It is a worrying phenomenon, especially in view of the marketing of new drugs with possible abortive effects or preventative effects of embryo development, these vulnerable individuals would then be deprived of even minimal assistance and those procedural rules which are also provided for by Law No. 194 of 1978.

It is hoped that there will be unprejudiced reflection on drug privatization; an eventual *laissez faire* policy in this area could result in conflict with the underlying choices set out as principles in the first articles of that very Law No.194 of 1978. There is special emphasis on the urgency of appropriate instruments for assistance, prevention and education aimed at under age persons; more generally there is reference to the importance of fostering a better and more effective relationship between professionals (physicians and pharmacists) and women who "urgently" request such drugs, in order to ensure a more conscious response to the needs of women – and above all minors – so that they are not left alone to hastily take the drug.

We would like to emphasize the scope of the social and cultural phenomenon which has much wider ranging implications that risk being detracted from faced with the problem of mere conscientious objection of

pharmacists, which, in actual fact, is a final moment in the moral questions and social issues that - especially related to minors – have their origin well before. It is there that they should be addressed.

A personal remark signed by Dr. Riccardo Di Segni

I approved the document agreeing with its conclusions, which in any case, call for the availability of the drug throughout the Country. I have reservations as regards the discussion on the right to conscientious objection that precedes the conclusions, which proposes two different positions: one in favor of conscientious objection, assigning to the State the responsibility to make the drug otherwise available, the other against conscientious objection. I do not recognize myself in either position. On the one hand, I believe that there is a right to conscientious objection; on the other, I carefully evaluate the observations of those who deny this right, but I do not use them, as do their supporters, to deny the right to legislative recognition for conscientious objection, in as much as it is a “weak” right, not absolute, which must yield before a right that I consider stronger, that is the right of the service user to obtain the drug prescribed by the physician. As explained by the representatives of pharmacists, in this Country theory collides with organizational reality, in that in point of fact, in certain areas, the refusal of one or more pharmacists may signify the real unavailability of the drug. I believe at this point that, while recognizing the right to conscientious objection in general, wherever, for reasonable organizational reasons it may be impossible to locate the drug in emergency situations in a specific area, the right of the patient is prevalent and therefore the right to exercise conscientious objection may not be permitted to the only pharmacist in the area.

A personal remark signed by Prof. Demetrio Neri

1. In a letter sent to NBC on November 23, 2010 Hon. Luisa Capitanio Santolini calls upon the NBC “to make a statement regarding the deontological correctness and/or the ethics of the pharmacist who invokes the conscience clause that is however provided for in their Code of Ethics in Art. 3, comma 1 letter c), refusing to sell pharmaceutical products for which the possibility of a mechanism of action that leads to the removal of a human embryo can not be excluded”.

2. As for the ethical correctness, regarding the question - as evidenced by the documents attached to the letter of Hon. Santolini - the Order of Pharmacists of Perugia has already answered in a positive sense, on a request from Dr. Maria Lena: and there is nothing to add, except to note that Article 3, paragraph 1, letter c of the Code of Ethics of Pharmacists is formulated less clearly and incisively, concerning the basis of ethics of conscientious objection, compared to the formulation present in the Italian Medical Code of Ethics (Art. 22 version 2006).

3. As to correctness, “however, ethical”, it must be noted that the *moral* right to conscientious objection stems from the value of freedom and integrity of conscience of each individual: anyone who is obliged to perform a service (to which refusal by other means is impossible) has the *moral* right to appeal to his own conscience when the performing of the service is deemed contrary to it. The call for freedom of conscience is, *morally*, entirely unobjectionable, whatever the underlying motivations, it being clear that no one can replace the conscience of another to determine ethical propriety. However, when the objector comes out from the sphere of individual conscience in order to publicly testify his obedience to a duty which he considers greater than that imposed by law, one enters on a different plane from ethics and deontology. Indeed, on this level, it is certainly not permission to disobey that is being requested – although this conduct is still possible, at whatever the cost - but rather authorization to do so without incurring any possible penalties provided by law. It can be said that, by so doing, the objector weakens the symbolic value of “resistance to power” linked to all acts of objection to request, instead, that the regulations leave to the individual the choice between equally legitimate alternative behaviors, within the limits and the most appropriate methods in order to ensure that this area of individual choice is compatible with the orderly conduct of social life.

4. Indeed, in liberal democratic societies respectful of ethical pluralism - which constitute the most favorable terrain not so much to cultivate integrity and inviolability of conscience, but also to see it respected - individuals (and consciences) with different moral orientations must be able to coexist and it is for this reason that the appeal to the conscience of some must never result in the claim to construct coexistence

according to ones' own beliefs, preventing the satisfaction of the legitimate expectations of others: it would be as if they imposed de facto their own moral beliefs on others, in clear contradiction with the very nature of the democratic principle to which they make appeal. If everyone were allowed to break the laws for reasons pertaining to conscience - and as the dictates of conscience are potentially endless – the protection of the law would be undermined and the very fabric of society would become impossible.

5. It is in the light of the aforementioned that the issue must be addressed – it is only hinted at the beginning of the letter of Hon. Santolini, but not the actual subject of the specific question - of a possible law that allows the pharmacist to evade, without incurring the consequences, the legal obligation to fill the prescription: and, by logical consequence and under the principle of equality, anyone else, directly or indirectly, working in the causal chain that leads to the action objected to. The NBC has set up a working group that is examining the general issue of conscientious objection, in view of the increasing number of instances of appeal to conscience in various other areas of social life. Pending the completion of the work, it is to note here that the necessary and indispensable condition for the eventual legal recognition of conscientious objection is the assertion of the right of every citizen to obtain the services due by law: if and only if that condition is established as a priority, and on indication of suitable measures to ensure this, will the conditions be created to avoid a conflict of conscience that could be detrimental to the orderly conduct of social life. In other words, any prospective law should, as a priority, establish everyone's right, on explication of the necessary instruments for implementation and, in particular, of the figures responsible for their accomplishment, and then recognize the right of some (or even of one person) to exemption according to the dictates of personal conscience. A reversal of this order, or the mere reference to general measures, which then - as experience shows - are easily disregarded without any consequences to be paid by those who contravene, is unacceptable. Whoever appeals to the law in order to leave to the individual the choice between equally legitimate alternative behaviour, apparently accepts democratic logic and should not therefore be contrary to the fact that the law establishes procedures for the exercising of conscientious objection to make it compatible with the orderly conduct of social life.

With this purpose in mind, the idea here is to suggest that instead of keeping, as has been done, to the limits of sectoral regulations, uniform regulations on the subject of the rights and duties regarding health should be reached, even considering the variety of professional figures and roles involved in this sector of social life.

Prof.ssa Grazia Zuffa endorses this *personal remark*.

Appendix: Request made by the Hon. Luisa Capitanio Santolini

Hon. Luisa Capitanio Santolini

Rome, 23.11.2010

The undersigned Hon. Santolini Luisa Capitanio, MP

GIVEN THAT

- It is the task of the NBC, as is clear from its decree of establishment, to provide Opinions in view of the preparation of legislative acts;

- Following formal complaints on national territory against pharmacists that appeal to the so-called “conscience clause” to avoid to sell products whose mechanism of action does not exclude the elimination of human embryos prior to implantation in the uterus;

- The Council of Europe in its Resolution No. 1763, “The right to conscientious objection in Lawful medical care”, adopted on 07.10.2010, affirmed that among other things: “No person, hospital or institution shall be coerced, held liable or discriminated against in any manner because of a refusal to perform, accommodate, assist or submit to an abortion, the performance of a human miscarriage, or euthanasia or any act which could cause the death of a human foetus or embryo, for any reason” (see attachment 1);

- The Council of the Order of Pharmacists of Perugia in the meeting of 27.05.2010 adopted the concern of a member who had requested a deontological opinion regarding the matter. (see attachment 2) approving “unanimously the view that gives pharmacists the right to conscientious objection” (see attachment 3);

CONSIDERED THAT

The National Bioethics Committee, already called upon in relation to the possibility for doctors to exercise conscientious objection faced with the request for prescription of so-called emergency contraceptive products, had replied affirmatively to the question with a note approved on 28.05.2004, referring to the right for doctors to appeal to the “conscience clause.”

Given and considered the above, the undersigned

REQUESTS

That the National Bioethics Committee should rule on the deontological correctness and / or ethics of the pharmacist who, by invoking the conscience clause provided for in Article 3 paragraph 1 letter c) of their own Code of Ethics refuses to sell pharmaceutical products for which the possibility of a mechanism of action that leads to the removal of a human embryo can not be excluded.

Thank you for your attention.

Yours sincerely,
Luisa Capitanio Santolini

Presidenza del Consiglio dei Ministri



**PHARMACOLOGICAL TRIALS
IN DEVELOPING COUNTRIES**

27th of May 2011



PRESENTATION

As part of the clinical trials being conducted in developing countries, in the context of increasing globalization of research, it is necessary to pay specific attention to the ethical reference criteria in order to safeguard basic human goods and values.

What emerges - even at an international level – is the concern that the “relocation” of the experimentation is activated to reduce costs and simplify paperwork, to facilitate the rapidity and finding of “bodies” to be used to penetrate new markets. The risk is that commercial interests could hide behind scientific interests resulting in forms of bioethical “colonialism”, unfair exploitation due to the differences in scientific-technological knowledge and socio-economic and cultural inequalities.

The NBC Document, starting with an analysis of documents and international guidelines, highlights some elements of ethical importance. The NBC recommends that research should be oriented according to a single ethical standard, an indispensable prerequisite to avoid any form of discrimination in order to ensure health and global justice, and reduce inequality. It stresses, in addition, how international experimentation should constitute a specific sphere within the context of a broader promotion of the defense of fundamental human rights as a whole, with particular attention to the specific needs of populations in particularly vulnerable conditions. For this purpose, the NBC considers it necessary that research should have adequate justification as regards the clinical importance to the Country in which the trials are conducted, that there should be a consultation process with the community, the establishment of appropriate procedures for informed consent and that the safety and health of participants should be protected. The Committee believes that research should avoid hidden forms of involvement that take “advantage” of a lack of awareness or state of need and should take into account the health requirements of the population, with solidarity, ensuring to the research participants and, hopefully, to the population as a whole, appropriate assistance even after the trial. Particular attention is placed on the use of placebo which as a rule is considered unjustifiable when treatment is available and on the creation of local ethics Committees.

The opinion was drafted by the coordinators of the working group Profs. Salvatore Amato, Silvio Garattini and Laura Palazzani, and contributions made by Profs. Adriano Bompiani, Lorenzo d'Avack, Antonio Da Re, Marianna Gensabella, Laura Guidoni, Demetrio Neri and the participants of the group, Profs. Luisella Battaglia, Assunta Morresi, Monica Toraldo di Francia.

Valuable contributions to the discussion were proposed by the hearings of Profs. Zeno Bisoffi, Director of the Institute of Tropical Diseases of the Hospital "Sacro Cuore - Don Calabria" Negrar (Verona) and Antonio Gioacchino Spagnolo, Director of the Institute of Bioethics, Faculty of Medicine of the Catholic University of the Sacred Heart in Rome.

The document discussed in the plenary session of the 27th May 2011, was approved unanimously by those present: Profs. Amato, Bompiani, Canestrari, Dallapiccola, Da Re, d'Avack, Di Pietro, Fattorini, Flamigni, Forleo, Garattini, Gensabella, Guidoni, Mancina, Neri, Nicolussi, Palazzani, Possenti, Proietti, Scaraffia, Toraldo di Francia. Dr. Di Segni and Profs. Luisella Battaglia, Assunta Morresi, and Giancarlo Umani Ronchi, absent at the meeting, have expressed their approval.

The President
Prof. Francesco Paolo Casavola

1. Premise

The NBC considers it important to focus, within the growing process of globalization, on the ethical principles of transnational or international multicenter clinical studies involving the relationship between so-called “developed Countries” and “developing Countries”.

International documents use the terms “developing Countries” or “Countries of the South” opposed respectively to the “economically developed Countries” or “Countries of the North”. This general and imprecise terminology embraces very different realities which are not simplistically linked to a unique category¹³. However, these expressions have now entered the common lexicon¹⁴ and it is clear to all that the reference is to those Countries or to those populations that are particularly “vulnerable”¹⁵ for several reasons: cultural, social, political, legal, religious, etc., mainly attributable to economic underdevelopment that slows down the progress of science and technology and / or broadly configures a different approach towards scientific knowledge, research and the applications of medicine. This condition can be experienced by some populations in different areas on a regular basis, and by others contingently (due to epidemics, natural disasters, famine). Vulnerability also affects those Countries which are certainly not under-developed economically, but they are not accustomed to testing and unaware of the ethical and legal rules that govern it. This condition exposes some populations, in the context of drug testing, to a substantial risk of exploitation in terms of people, resources and results.

Effective globalization of research would provide a clear quantitative and qualitative improvement of the clinical horizon of reference and would increase the conditions of justice and equality in the distribution of drugs.

¹³ There are Countries, which, despite their falling into the category of “developing” Countries, have started internal testing programmes with scientific and ethical standards of “good clinical practice” comparable to those of “developed Countries”. See, as an example, the extensive and demanding experimentation involving the health facilities of various African nations reported in the journal “Lancet” 2010, vol. 376, November 13th (*Artesunate versus Quinine in the treatment of severe falciparum malaria in African children (AQUAMAT): an open-label, randomized trial*). In contrast, there are “Countries of the North” which on these issues are still “developing” (eg. Countries of Eastern Europe and the Russian Federation).

¹⁴ Cf. final bibliography.

¹⁵ There is no reference to ‘vulnerability’ as an ontological condition or personal situation, but to vulnerability as a particular condition experienced by some populations which, for various reasons, may be exposed to undue manipulation of their autonomy through participation in the trials.

Unfortunately what has emerged with increasing frequency at an international level is the concern that the globalization of clinical studies hides only a “relocation” or “outsourcing” of the experimentation, to reduce costs and simplify paperwork, to facilitate the rapidity and finding of “bodies” to be used to penetrate new markets. About ten years ago (December 2000), “The Washington Post” published a six-part investigation on *The Body Hunters* (Angell, 2005) denouncing the serious ethical shortcomings of some forms of experimentation that would never have been allowed in the United States¹⁶ firstly because of the danger involved, and secondly because of the lack of information: patients were not aware of being treated as “*Guinea pigs*”. This expression has now become part of bioethical jargon to indicate, in its crudity, the emergence of a situation of vulnerability (not limited, however, to developing Countries), which leaves, because of regulatory gaps or institutional contradictions, unprotected the poorest of the poor and the weakest of the weak¹⁷.

¹⁶ The articles were inspired by a serious case which occurred in Nigeria in 1996. Taking advantage of the emergence of an epidemic of bacterial meningitis, Trovan, a new, not yet approved antibiotic to be taken orally was used, which deprived the young patients of the standard intravenous therapy whose effectiveness was certain. A similar exploitation of emergency conditions and poverty had been exposed during the Chernobyl disaster.

¹⁷ It is noted that in recent years the number of Countries involved in the ‘outsourcing’ of clinical trials has increased more than tenfold. It is estimated, to give an idea of the phenomenon that more than one third of the drugs placed on the U.S. market have been tested totally outside the United States (Glickman et al. 2009). UNESCO has also denounced the tendency in Europe to recruit *healthy volunteers* from other Countries, such as tourists for limited periods of time (Report of the International Bioethics Committee on Consent, May 19, 2007, § 43). Appropriate international organizations have emerged, including several *Contract Research Organizations* (CROs), specializing in organizing, on commission, the trial and its recruitment of patients in all parts of the world (Petryna, 2005) within a sort of “economic viability” (Rose, 2008, p. 54), which includes scientific research and marketing, involves multinational pharmaceutical companies, and individual nations, leading to a unique blend of international and national regulations, universal ethical models and local traditions. The phenomenon of relocation of trials is not new. At the beginning of the twentieth century, Europeans used it the natives of the colonies to perform experiments that would not have been permitted in their own country, while the United States resorted to Cuba (Chamayou, 2008). Even in 1956, to hasten the time of marketing, testing of oral contraception was conducted in Puerto Rico, Haiti and Mexico City. In recent years, there have been increasing reports of undisciplined recruitment of ‘bodies’, in very poor Countries, albeit due to a positive increase in cultural sensitivity, or even to a negative intensification of the phenomena of exploitation, caused by a significant increase in the economic interests of all that concerns ‘biocapital’, ‘genetic piracy’ for purposes of patent to collect genetic material for biobanks, the search for organs, the search for ‘bodies’ on which to perform experiments with fictitious or extorted consent due to ignorance or poverty. Recently, experimentation has been carried out mainly in Eastern Europe, Latin America and in Asia.

This leads to the fear, interpreted by the NBC, that commercial interests could hide behind scientific interests and may take precedence over respect for fundamental human rights, resulting in forms of bioethical “colonialism” and “imperialism”, unfair exploitation and manipulation due to the differences in scientific-technological knowledge and socio-economic and cultural inequalities.

1.1. Bioethical and regulatory references

For a proper evaluation of the issue the following documents are to be considered.

In the context of international documents of the United Nations, the *Universal Declaration of Human Rights* (1948) Articles 1 and 2 refer to human dignity regardless of race and the *International Covenant on Civil and Political Rights* (1966) Art. 7 refers to informed consent in medical treatment. In addition, in the *Universal Declaration on Bioethics and Human Rights* UNESCO (2005) there are references to human dignity (Article 3), the direct and indirect benefits for patients participating in the research (Article 4), informed consent (Article 6), respect for human vulnerability and personal integrity (Article 8), equality, justice and equity (Article 10), non-discrimination (Article 11), respect for cultural diversity (Article 12), Solidarity and cooperation (Article 13), social responsibility and health as a fundamental human right (Article 14), international cooperation (Article 24), promoting the international dissemination of scientific information, freedom of movement and sharing of scientific and technological knowledge.

As to European documents one should mention the *European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* of the Steering Committee on Bioethics of the Council of Europe (1997) that emphasizes human dignity (Article 1), and the primacy of human well-being over the sole interest of science and society (Article 2), equity of access to healthcare (Article 3), free and informed consent (Article 5), the protection of the people that lend themselves to research (Articles 16-17) and the *Barcelona Declaration on Policy Proposals to the European Commission on Basic Ethical Principles*

in *Bioethics and Biolaw*, 1998) which proposes four fundamental principles of bioethics and the European biolaw: autonomy, dignity, integrity and vulnerability.

The *Charter of Fundamental Rights* of the European Union (2000) appeals to human dignity (Article 1), the right to personal integrity, the respect of free consent, the prohibition of exploitation of the body (Article 3). The standards of “good clinical practice” that regulate drug testing in the world¹⁸ and represent a scientific and ethical quality standard that ensures the acceptability of the data by regulatory authorities, even with the aim of reducing duplication of experimentation, with the understanding that these involve unavoidable risks for the participants, regulations which have given rise to a specific Directive 2001/20/EC of the European Parliament and of the Council of the 4th of April 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use¹⁹, incorporated under Italian law with the Decree of the 24th of June 2003, No. 211 and No. 184²⁰. The Additional Protocol Concerning Biomedical

¹⁸ These regulations have been implemented in Australia, Canada, European Union, Japan, in Northern Europe and the United States; in 1995 they were gathered together in a WHO guideline (World Health Organization WHO Technical Report Series, No. 850, 1995, Annex 3 Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products).

¹⁹ Law 121/34, Official Journal of the European Communities, L5.2001.

²⁰ Cf. also *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended; Directive 2003/94/EC of the European Commission of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use; Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; Directive 2005/28/EC of the European Commission of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products; Regulation (EC) No 1901/2006 of the European Parliament and the Council, as amended, on medicinal products for paediatric use. Cf. also *Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use (revision 2) as required by Article 18 of Directive 2001/20/EC; Detailed guidance on the European database of Suspected Unexpected Serious Adverse Reactions (EudraVigilance – Clinical Trial Module) (revision 1) as required by Article 11, Article 17 and Article 18 of Directive 2001/20/EC; Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use (revision 1) as required by Article 8 of Directive**

Research (2005) of the Convention on Human Rights and Biomedicine (Article 29) refers to the multi-center research and the duty to apply one standard of ethical evaluation.

In the context of international guidelines the ethical criteria of experimentation with particular reference to developing Countries have been developed (*International Ethical Guidelines for Biomedical Research Involving Human Subjects* 2002, which updated the 1993 guidelines of the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO); *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, in its most recently developed form by the World Medical Association (adopted in 1964, revised in 1975, 1983, 1989, 1996, 2000 and 2008)²¹, Working Party for the Elaboration of *Guides for Research Ethics Committee Members* (CDBI, 2010, Rev. 1. 2); *Barcelona Declaration on Policy Proposals to the European Commission on Basic Ethical Principles in Bioethics and Biolaw*, 1998).

The Reports and Opinions of national bodies that must be reported include: the Report of the Department of Health and Human Services, Food and Drug Administration, *Human Subject Protection; Foreign Clinical Studies not Conducted Under an Investigational New Drug Application*, Federal Register, Vol. 73, No 82, April 28 (2008); Opinion expressed in ethical lines *Ethical Aspects of Clinical Research in Developing Countries* of the European Group of Ethics in Science and New Technologies, European Commission (2003); the ethical concepts

2001/20/EC; *Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial* (revision 2), as required by Article 9 (8) of Directive 2001/20/EC; *Detailed guidance on the European clinical trials database* (EUDRACT Database) as required by Article 11 and Article 17 of Directive 2001/20/EC, CT 5.1 Amendment describing the development of EudraCT Lot 1 for 1 May 2004 and CT 5.2 EudraCT core dataset.

²¹ In 2005 the two organizations created a study group to implement the 'good clinical practice' in drug research being conducted in Countries with limited resources Joint CIOMS/WHO Drug Development Research in Resource-limited Countries: How to succeed in the implementation of Good Clinical Practice Guidelines, Draft CIOMS found on http://www.cioms.ch/activities/frame_drugdeveloprpt14dec2005.htm. See also the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP), Guideline on Clinical Trials in Small Populations, CHMP/EWP/83561/2005; Guideline on Conduct of Pharmacovigilance for Medicines Used by the Paediatric Population (June 2006) and World Health Organization, Operational Guidelines for Ethics Committees That Review Biomedical Research (Geneva, 2000) and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

outlined in the views expressed by national ethics committees (National Bioethics Advisory Commission, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, Report and Recommendations, Bethesda, Maryland, vol. I, 2001, Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries*, 2002 and the Comité Consultatif National d'Étique pour les Sciences de la Vie et de la Santé, *La coopération dans le domaine de la recherche et équipes françaises biomedical entre équipes de pays en voie de développement économique. Rapport 1993*).

In light of these indications, the NBC expresses some ethical considerations and recommendations.

2. The bioethical problem of International experimentation: from general principles to specific criteria

The phenomenon of relocation of trials is not new. In recent years, there have been increasing reports of undisciplined recruitment of “bodies”, in very poor Countries, albeit due to a positive increase in cultural sensitivity, or even to a negative intensification of the phenomena of exploitation, caused by a significant increase in the economic interests of all that concerns “biocapital”, “genetic piracy” for purposes of patent to collect genetic material for biobanks, the search for organs²², the search for “bodies” on which to perform experiments with fictitious or extorted consent due to ignorance or poverty. Much experimentation, as has been said, is conducted in the most backward Countries in order to reduce costs and shorten the length of the research, given the greater ease in recruiting volunteers, reduced bureaucracy and different regulations for the approval of research protocols. Recently, experimentation has been carried out mainly in Eastern Europe, Latin America and in Asia.

The subjective condition therefore must be that experimentation on human beings in these Countries, as well as in the Countries of the North, can be justified in the first place, if it results in real progress in the cognitive ability to cure human beings and, secondly, and simultaneously, if such progress is achieved through a genuine ethical process that

²² Cf. NBC, *Motion on the sale of organs for transplantation*, 13th of June 2004.

minimizes the increased risk of biomedical and pharmacological trials in developing Countries being conditioned by economic policies, related to the market and the profit criterion.

The NBC believes that the general ethical principles of experimentation on human subjects²³ - recognized in international documents - should be applicable everywhere, without making a distinction between more or less developed areas, to avoid unequal treatment, considered ethically unacceptable as detrimental to universal justice. Trials in developing Countries must meet the same scientific and ethical standards of developed Countries: no deviation or modification is justified in terms of principles.

The necessity for the application of general principles to be adapted to the needs of different contexts, should however be highlighted, on the basis that the universally shared principle that experimentation in developing Countries should be primarily oriented to meet the real health needs of the communities or populations on which it is carried out. In the field of experimentation, as, indeed, in that of health, one needs to know how to relate to “the other” and ensure cultural identity when this contributes to social balance and the personal development of that Country. In reality, it is a question of facing the problems of research as well as those related to access to the protection of health, starting from the real needs of vulnerable populations, clearly more affected by certain diseases and therefore with specific health requirements. In some Countries, poverty makes people so vulnerable that often they find it difficult to express their needs, or they do so with resignation, and even humiliation.

In these populations, it is a case of following the “spirit” of general ethical principles, as it is actually practically impossible to follow them “literally”. This does not mean accepting a “double standard” of ethics: on the contrary, it means reiterating that the ethical standard should be “unique” as concerns principles. What is evident in ethical terms, is, that the contextualization and specific interpretation of general principles should not determine a reduction of the fundamental requirements for protection of the human being. This “additional” ethical reflection is necessary in Countries where objective living conditions, such as poverty, lack of access to basic services for survival and

²³ Cf. NBC, *The experimentation of drugs*, 17th of November 1992.

health, also influence the field of development of intellectual capacity, forcing populations into situations of illiteracy, poor education, poor level of scientific-technological knowledge and ethical development.

2.1. Justification for the clinical relevance of research for the Country where the experimentation is conducted

Each drug trial requires scientific justification, as the expected benefits to be gained must outweigh the risks to which the individuals subjected to experimentation are exposed. In the sphere of international experimentation, in addition to the medical and scientific relevance in general, a further criterion must be added, because of the particular vulnerability of the population.

Ethically, the programming of research by a researcher, team of researchers, or research organizations, is fully justified if they cover diseases present only in the population on which experimentation is being carried out, or when these diseases are present in both the promoting Country and the host Country, and in the latter it is generally more widespread, with higher morbidity, mortality and disabling outcomes.

Regulatory powers should not allow experimentation for diseases that are prevalent in other Countries and not in the Country where the testing is being conducted: international testing should be considered as a priority in relation to the specific interests and priorities of the health of the populations of the host Country. A preliminary assessment of the impact of the trial in the host Country is indispensable, as is the direct relevance of experimentation for the acquisition of knowledge that can improve conditions and the specific health needs in the short term or future, or those subjected to it, but also as regards the population in general.

Pharmaceutical companies must first of all carry out trials “for” the populations, which have the right to participate in the experimentation in order to obtain drugs to treat diseases for which they have a direct interest. We can say, together with Kant, that populations whatever their social-economic-cultural condition should be considered “always as an end” and never “just as a means” for experimentation. In this sense, the right to health care as protection of the objective good of a person must be considered a fundamental international right.

2.2. Community consultation

It is essential to establish a dialogue between investigators and participants in the experimentation through “community consultation” with the representatives of the local culture. This allows the acquisition of adequate information on the traditions, cultural customs and habits, the understanding of health and disease, moral values and religious beliefs, the level of scientific knowledge and the social-economic context. This information is necessary in the development and application of the research project.

In this context, the role of the cultural mediator is important. It is hoped that the mediator may be a person from the Country in which the trials are being carried out (or someone with an in-depth knowledge of the culture) and with adequate training according to international standards. This person’s task is to mediate the general ethical requirements of the experimentation and the local issues, and avoid the unification of Western culture recognizing the value of local needs and traditions.

Support can also come from voluntary associations, especially those operating in the sphere of community health, that have lived the reality of the Country for years and know the needs, habits, and customs of life there, and above all the level of information regarding health care.

2.3. Informed consent

As regards the recruitment and selection of participants in the trial, thorough verification of the actual voluntariness and awareness of the participation is essential. With regard to voluntariness and lack of preconditioning, it should be noted that in developing Countries participation in a trial could be an advantage for those who have difficulty in obtaining food and basic health care: the social and economic conditions could push the “volunteers” naively and without adequate awareness of the risks to participate in research. Even due to the fact that often in these populations the concept of research is not clear, and tends to be confusing - but this phenomenon is not unknown also in populations of developed Countries - with care and assistance (therapeutic misconception). In all international documents and guidelines great attention is paid to the search for ways to avoid (in consideration of what will be said in § 2.8) that the

choice of taking part in research is determined solely by the ability to access treatment or basic sustenance that otherwise would be inaccessible, constituting “undue inducement” that would undermine the actual voluntariness of participation.

One must keep in mind that an appropriate level of information and comprehension / understanding of that information is a basic requirement in any trial. The particular difficulty at this level that can be detected in populations living in economic poverty and / or lack of culture and scientific knowledge should not be a reason to exclude them from the trial and the benefits that it can bring: it would be a kind of acceptance and amplification of a disadvantaged condition. The objective difficulties regarding information must be a stimulus to support the activity of experimentation with a contemporaneous intensification of the activities of information and formation (from the fight against illiteracy to health education campaigns as far as the disclosure of scientific and ethical base). Alongside these long-term commitments, it is essential to identify, without delay, suitable methods (however innovative compared to the usual ones) in order to provide appropriate information, apposite to the understanding of individuals, fitted to their educational level and the type of culture. It is never acceptable in any situation, for information to be hasty, ambiguous and unclear, or that it does not take into consideration essential cultural specificities. The ascertainment of informed consent must ensure understanding of the information and responsibility of choice, taking into account local traditions and customs²⁴.

Forms of verbal consent or consent expressed by others (the community leader or a family member) are highly questionable. The choice of methods of expression of consent must verify the actual voluntariness and awareness of individual participation (as well as the opportunity to refuse or withdraw participation at any time), the absence of coercion or indirect external

²⁴ The problem of verification of the real understanding of the information received from participants in research is particularly pressing in the case of some experimentation in developing Countries, but it is not a solved problem in trials in developed Countries. In order to verify the actual understanding of information, it is from some time that many international documents call for a more active involvement of the ethics committees in the stage of recruitment of participants, and the next stage of monitoring the conduct of research (Cf. specifically the Italian National Bioethics Committee, *Guidelines for Ethics Committees in Italy*, 13th of July, 2001).

pressure on the subject entering the trial. The involvement of other figures in the procedure of obtaining informed consent is acceptable and understandable, but they can never replace free personal expression. Oral consent is acceptable only for the illiterate in the presence of a witness. In some cultures where the role of women is subject to various forms of family and / or social²⁵ authority, third party involvement can be accepted as ‘additional assent’ in as much as it is essential to the cultural context. The important thing is that research, to the extent that it needs women²⁶, should protect - in every way possible – a woman’s autonomy. In this context, the intervention of international organizations, devoted to the protection of women, is hoped for.

2.4. Confidentiality

A further issue that emerges contemporaneously to that of consent is confidentiality. Confidentiality is inevitably weakened (if not obliterated) given the family’s possible permission to research, as well as the fact that in some cultures there is a lack of the very concept of “privacy”. This raises an ethical problem because the mere act of participating in research for vulnerable populations means risking the stigma of being sick. It is hoped that cultural associations may play a supportive role to those who undergo experimentation, helping the patient to be seen as a person and not to be ghettoized. This, in the context of experimentation, highlights the importance also of solid culturally formative intervention in this direction.

2.5. Protection of the health and safety of participants

The balancing of risks/benefits, a preliminary for access to experimentation, should be commensurate with the basic conditions of the population (including nutritional, epidemiological and health conditions),

²⁵ The same is true for men in matriarchal cultures.

²⁶ On the issue of experimentation on women see NBC, *Drug testing on women* (2008). It should be noted that as regards experimentation on women special attention should be paid to women who are pregnant or breastfeeding. It is to be reiterated that within the *Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Medical Research*, Italy expressed the following position: “The government of Italy will not allow that a research which does not produce direct benefits to the health of the research participants be carried out on persons not able to give their consent and on a pregnant or breastfeeding woman”.

in reference to each individual, but also to the community, i.e. the population of the host Country as a whole. Commensuration of risk for the individual and the population in relation to the benefits for “third parties” (with reference to the Countries performing the trials) is ethically unacceptable. Research is ethically justified if it provides reasonably direct benefits to participants and indirect benefits for the overall population, and minimization of risks to people participating in the research, but also for the vulnerable population as a whole.

Consideration and management of risk should be commensurate with local conditions and in relation to the selection of individuals (also considering the difficulty in knowing medical history), both for clinical monitoring (given the inadequateness of medical facilities) and the problems in the relationship between participants and research group (there being, at times, difficulties in transport and communications. The compensation of direct and indirect damage to health should be assessed with particular attention in relation to local conditions and the weak (children, women, and the elderly). Appropriate treatment is to be ensured during the trial, with attention to the guaranteeing of emergency services.

With regard to the risks that the individual runs concerning current and future physical integrity, a system of “liability without fault” should be established: so-called responsibilities of an objective nature, which exempts the injured party from the need to prove that the investigator departed from the model of diligent service. A solution that shifts, on the one hand, from the assumption that the danger is not applicable to the conduct of that individual nor to the structure holder of the activity of experimentation, but rather that it is immanent in the activity of research, and on the other hand from the need to ensure full protection to patients during and after the experimentation.

It is a system that would avoid forms of neglect once the trial is over and can ensure the individual has effective social care facilities, able to provide care even in the long-term regarding the possible negative consequences of the experimentation. Protection should be provided through arrangements for automatic mandatory insurance in view of the payment of possible damages, where the premium is assessed in relation to the local economic state. It therefore seems natural that the same research group agrees to bear the economic consequences and the risks inevitably associated with such testing. It would probably be beneficial to establish

independent organizations that are non-profit and internationally accredited to monitor the implementation of international multi-centre trials, and in particular those carried out in developing Countries (Kelleher, 2004)²⁷.

2.6. Communicable and non-communicable diseases

The evaluation of the scientific relevance of research in developing Countries must take into account the differences between communicable diseases and non-communicable diseases in relation to the various stages of experimentation.

Communicable diseases include all types of bacterial, viral, fungal and parasitic diseases; non-communicable diseases include acute and chronic non-infectious diseases. In the past, the attention to developing Countries was addressed primarily to the first category, but in more recent times, since the increase in life expectancy is a global phenomenon, the second category is becoming important.

It should be noted, in general, that the clinical trial is divided into four phases, which are in continuity and are distinguished as follows: Phase I is represented by the first administration of the drug in humans based on adequate documentation of pre-clinical investigation on animals in order to ascertain the tolerability of the product (most often performed on healthy volunteers, except for toxic drugs, such as anti-cancer chemotherapies, which are assessed directly on the sick); Phase II covers the effectiveness and serves mainly to assess in advance whether the product carries the desired pharmacological effects; Phase III compares the drug with other products of reference or, failing this, to placebo in a randomized manner, and if possible, double-blind (this is a comparative study in which you define the benefit-risk ratio and determines the position in the arsenal of drug treatment available); Phase IV is to control, even after the marketing of the new drug, the side effects and / or possible problems that have escaped the previous clinical trials, because they occur very rarely or in the long / very long term, or only under specific conditions.

²⁷ Currently in the United States two such institutions are already operating: the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) and the Partnership for Human Research Protection (PHRP).

In the context of communicable diseases, the initial testing of all four phases must be done on site for obvious reasons, since it is difficult to find a sufficient number of persons who live outside the Countries in the developing world. It should also be borne in mind that the testing could involve people with severe nutritional imbalances and comorbidities. The ethical problem in phase III is very delicate because if there are other effective treatments, these should be provided free by the sponsor²⁸. There is also a school of thought that believes it is important that the control group receives the treatment that is used locally, even if lacking in scientific evidence.

In the context of non-communicable diseases, the initial testing, seeing as it regards diseases that are widespread in industrialized Countries should not only be carried out in developing Countries. This may suggest that the various stages will be carried out even in Countries that promote experimentation, but only subsequently, after receiving information on the tolerability of the drug. In any case, before entering Phase III, there should be at least one study for “dose-finding” to take account of any high frequency polymorphisms that affect the metabolism or the target of the drug evaluation.

2.7. The use of placebo

One of the most delicate ethical issues concerning experimentation in developing Countries concerns the use of placebo²⁹ that is generally opposed to the assessment of “best current therapeutic methods”³⁰.

In fact, the term “best current therapeutic methods”, easily applicable to developed Countries, has sparked a heated debate in relation to developing Countries, because it can be understood both in the sense of the best treatments available in the world or best existing standard, and also in the more restrictive and less guaranteed sense of known and normally applied treatments at the local level (Errico, 2004, 2007)³¹.

²⁸ Cf. § below.

²⁹ NBC, *The improper use of placebo* (29th of October 2010) and *Bioethical problems in clinical trials with non-inferiority design* (24th of April 2009).

³⁰ Cf. the *Declaration of Helsinki* (2000): “The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo or no treatment in studies where no proven prophylactic, diagnostic or therapeutic methods exist”.

³¹ The discussion on the issue of the use of placebo in developing Countries has become particularly evident since 1997 because of testing on pregnant women with HIV of a new method to pre-

Some believe, in the context of a pragmatic view inspired by the idea of satisfying the real needs of local health, that the use of placebo may be legitimized under certain conditions by the balance between costs and benefits: seeing as locally, because of the differences in economy and health, these alternative treatments of proven efficacy that are found in other parts of the world are never available, the deviation from the requirement of “best current therapeutic methods” could be offset by the fact that at least half of the study population obtains the drug the other half is still subject to health surveillance. To the general advantage of more rapid testing is, on a local level, greater availability of care and treatment. To prevent experimentation, because there is no guarantee of the best therapy in the world for everyone, would mean to reduce even this small opportunity to enjoy a much better form of care than the one that is in point of fact practiced, even if this is not optimal at all.

This argument is rejected by others, according to which, in any form of experimentation, the aspect of solidarity must prevail over every other consideration, in order to prevent that economic and social inferiority may justify exploitation, creating irreversible situations of vulnerability. For these reasons, when there is a best proven treatment that is effective and efficient, it must be made available to the population by those conducting the experimentation, considered that the use of placebo is always unjustified. The prospect of possible future benefit to others does not justify the rejection of an effective treatment to research participants, whose dignity must be at the center of ethical reflection. The use of placebo

vent HIV transmission from mother to child, already approved by the Food and Drug Administration (FDA) and used in developed Countries. The first trials conducted in the U.S. (also not without controversy) had actually proved that the drug (known by the abbreviation AZT) could reduce HIV transmission from mother to child by two thirds, but the high cost and the methods of administration made it prohibitive to use this medicine in developing Countries. Subsequent trials conducted in several African Countries, South-East Asia and the Caribbean, under the sponsorship of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) were designed to evaluate the effectiveness of reduced doses of the drug and using application methods best suited to local conditions. The study design included a placebo control arm, the justification given being the consideration that high costs would have prevented, in any case, the administration of these therapies, which cost around one thousand U.S. dollars, the average income in these Countries amounted to few dollars, and just as low was government expenditures for the protection of health. A criticism of the trial emerged from those who drew attention to the fact that testing should be done first in developed Countries (where the disease was widespread) with a study based on the comparison between taking the full dose and half dose, and not half-dose and placebo.

is subject to the same ethical standards of developed Countries: placebo can not be used in view of speeding up the length of the experimentation or for the reduction of costs. The admission of the use of placebo would legitimize a “double standard” of experimentation with a difference between rich and poor Countries, resulting in discrimination.

The range of positions on this matter, and arguments in support, is much larger than it is possible to give an account of here and this is reflected in the different positions expressed papers by international documents and guidelines³².

The NBC believes that the general ethical principle must always apply which states that placebo is usually unjustified as part of experimentation when there is already available treatment, therefore, even in trials in developing Countries. Where, for exceptional reasons, the use of placebo is deemed necessary, it is essential that the reasonableness of this is scientifically demonstrated, and never due to economic and / or organizational reasons and it should always take into account the primary health needs of the local population.

Specific attention should be placed on providing exhaustive information to individuals and the obtaining of their consent, and on the reasonable expectation that the temporary suspension of an active

³² During the discussion on the revision of the *Declaration of Helsinki* (version 2000), the World Medical Association refused to change Art. 29 in order to make it more permissive, as some demanded. Instead, in 2002, the position of the CIOMS was less steadfast against the possible use, in some cases, of placebo and the following year this position was endorsed by a large majority, by the EGE, in an Opinion in which, in reaffirming that the use of placebo in trials in developing Countries should be regulated, in principle, but the same regulations in force in European Countries, provides the possibility to derogate from the rule of “best proven treatment” “when the primary purpose of the clinical trial is the attempt to simplify or reduce the cost of treatment in Countries where the standard treatment is not available for logistic reasons or is inaccessible because of the cost” (§ 2.10). It should also be noted that the latest version of the *Declaration of Helsinki* (2008). Art. 32 affirms that “The benefits, risks, burdens and effectiveness of a new method should be tested by comparing the best proven intervention in use, with the exception of the following circumstances: the use of placebo, or no treatment, it is acceptable in studies where no proven intervention exists in use or where compelling reasons and scientific methodological reasons for the use of placebo is necessary to determine the efficacy and safety of an intervention and the patient who is receiving the placebo or no treatment is not subject to any serious or irreversible risk. Extreme care must be taken to prevent abuses in this area”. The danger is that this opening up in more permissive terms to experimentation and the use of a lower standard of care or placebo may be introduced for economic and not scientific reasons only in order to exploit the state of vulnerability of those Countries. The ethical ‘double standard’ denies the equal dignity of human beings by increasing the gap between developed and developing Countries.

treatment does not have serious and irreversible clinical consequences and also to the balance between exposure to minimum damage and consistent future benefit for the individual.

This reasonable scientific justification should be expressed in the research protocol and evaluated by the Ethics Committee of Research and the local Ethics Committee. It calls for a unified regulation that is also harmonized between the different Countries involved in the experimentation and research, since - as mentioned - the strict application of general ethical principles in different contexts may hinder development in Countries that are already disadvantaged.

2.8. The duty of solidarity during and after experimentation

The Countries that carry out experiments in developing Countries should avoid increasing inequalities and contribute to the reduction of inequalities. It is within this perspective that assistance should be guaranteed to developing Countries during the experimentation without inflicting on them the burden of the “indirect costs” of the trial (on an already precarious local health system) and helping them to become full partners in international research, stimulating the improvement of the local health system and transferring technical and scientific skills, involving also doctors and representatives of the host Country, to monitor compliance with ethical standards and avoid abuse. As a result there should also be specific training for doctors and the medical staff conducting this experimentation as well as formation of the local doctors and health personnel, often in particularly fragile conditions, so that the care becomes a “*collaborative partnership*” and consents to develop in the host Country the skills to be able to independently conduct clinical trials and ethical assessments.

It is an ethical requirement of experimentation that the investigators assume responsibility and solidarity - in the framework of international cooperation - which continues even after the trial, so that research participants do not feel abandoned. In this sense, experimentation is considered justified to the extent that the product - if it proves effective - can be made available to the entire population. There is considerable international debate, even as regards the ways in which this ethical requirement can in actual fact be accomplished.

The NBC considers it a duty to guarantee access to new treatment – should it be necessary - and privileged assistance to volunteers, taking into account the risk to which they are subjected during experimentation. It is certainly possible that the “post-trial benefits” - which especially in the case of certain diseases may be continued indefinitely - constitute improper incentives to participation in research, but the alternative would be that, due to the cost of the drugs, those who have actually contributed to their experimentation would be excluded from treatment.

More controversial is the question on how to access the new drug by the population. The NBC considers it worthwhile to ensure access to the drug for the entire population, although in view of the complexity of the problem, many international documents suggest dealing with this through the preliminary negotiations between the sponsors and representatives of the community, in order to find a balance between economic sustainability and respect for local needs. It is hoped that pharmaceutical companies may concede the experimented drug to the entire population at affordable prices. It is not possible to provide general rules and proof of this comes from the language, marked by caution, used in international documents on the subject, even those from developing Countries.

The inequalities in wealth and resources on a global level and inequality among men in accessing treatment and health care are of such magnitude that it would be unrealistic to expect that those who want to conduct experimentation in developing Countries should shoulder the burden of resolving them alone. However having stated this, it should not be overlooked that experimentation is part of a general political context regarding the environment (health, nutrition, education, the fight against illiteracy).

2.9. “Social ecology”

A balanced development of research and experimentation, a development that does not create conditions of vulnerability and exploitation, determines an improvement of the overall epidemiological picture. A factor that is not to be underestimated is, in fact, the correct assessment of the influence on the results of the research both of the different genetic profiles and the economic and social diversity. Regarding

the former, there is an ever increasing number of studies that highlight the impact of genetic profiles in response to drugs therefore one can not disregard consideration of the ancestry (African, Asian, European ancestry) of the individuals subjected to experimentation (Glickman et al. 2009). Similarly, as regards the second aspect, one can not ignore that there is a profound difference in the clinical assessment of the individuals subjected from birth to multiple drug regimens and those who have never or almost never had access to systematic and constant therapies. In addition, a correct study can not even ignore, cultural differences, education levels, the relationship with disease and suffering, and social expectations.

All these elements help to understand how operating in unilateral conditions, which do not take into account the “specificity” of the populations tested, may, in addition to often bringing about serious damage to these very populations, may also provide unreliable results, which could lead to new and unexpected situations of risk. The immediate utility in terms of cost saving and rapid results is often only apparent when one considers the elements of uncertainty that in the long run, could emerge. Only a balanced social relationship can provide optimum conditions for the correct assessment of the possible advantages of a trial. From this point of view, the issue of vulnerability³³ assumes particular ethical importance and plays an increasingly central role in the protection not only of those who are particularly weak, but as regards the international community as a whole, directing it towards policies that take into account the different weights of vulnerability and power, in a view that emphasizes the ties of interdependence

³³ In the *Barcelona Declaration* (1998) vulnerability, included in the four fundamental principles of bioethics and the European Biolaw (autonomy, dignity, integrity and vulnerability), is defined as follows: “Vulnerability expresses two basic ideas. (a) It expresses the finitude and fragility of life which, in those capable of autonomy, grounds the possibility and necessity for all morality. (b) Vulnerability is the object of a moral principle requiring care for the vulnerable. The vulnerable are those whose autonomy or dignity or integrity are capable of being threatened. As such all beings who have dignity are protected by this principle. But the principle also specifically requires not merely non interference with the autonomy, dignity or integrity of beings, but also that they receive assistance to enable them to realise their potential. From this premises it follows that there are positive rights to integrity and autonomy which grounds the ideas of solidarity, non-discrimination and community” (*The Barcelona Declaration on Policy Proposals to the European Commission on Basic Ethical Principles in Bioethics and Biolaw*, adopted in November 1998 by Partners in the BIOMED II Project, reprinted in the *Final Project Report - two volumes - on Basic Ethical Principles in European Bioethics and Biolaw*, Institut Borja de Bioètica, Barcelona & Centre for Ethics and Law, Copenhagen, 2000).

not only between individuals but also between communities and peoples. In this perspective it becomes clear that the perpetuation of situations of marginalization and exploitation of some individuals or some populations may not reflect on us all. Morally “suspicious” situations that occur in many clinical trials conducted in populations that are particularly vulnerable (Hawkins, Emanuel 2008) are not only unacceptable in themselves from the ethical point of view, but they reflect negatively both on the relations between populations and on the ‘scientific reliability of the data to be analyzed. It is common interest of all Countries to develop an ethic based on the awareness of the mutual bonds of interdependence, an ethic of solidarity, which ensures not only the respect of fundamental human rights, but which also preserves the particularity of individual social contexts.

2.10. The role of Ethics Committees

Research must be approved by the Ethics Committee of the health facility of the Country or Countries that undertake experimentation. If a trial is undertaken by a pharmaceutical company, it must refer to an ethics committee that consists of medical and bioethical experts with appropriate formation, who are independent from the promoters of the research.

The experimentation project must also be approved by the ethics committee of the host Country of the reference health care facilities. In the absence of an ethics committee, it is possible to refer to the WHO regional committees for research on medicines, present in many regions of the world. If the host Country has not yet established an ethics committee, it is important that its establishment is prompted, by stimulating also appropriate training for this purpose. The establishment of a “Joint Ethics Committee” composed of doctors, independent bioethical experts and local representatives, is foreseeable. It is hoped that in the local committee or joint committee a representative of the local associations and a cultural mediator will be present. Currently, the subordination of the authorization to the introduction of the tested drug to the registration of the trial is mandatory (e.g. on the database of the WHO Register WHO International Clinical Trials Registry Platform), as a guarantee of visibility, transparency and controls³⁴.

³⁴ ICTRP www.who.int/ictcp.

The primary goal is to guarantee a “double check” (ethical review) on the ethicality of the research, both by the Country carrying out experimentation and also by the Country hosting the trial. A double check that fosters communication and integration between the different needs of Countries³⁵.

3. Recommendations

1. Research in developing Countries should not be discouraged, on the contrary it should be encouraged, but oriented according to ethical criteria considered essential to avoid all forms of exploitation and discrimination in order to ensure health and global justice, and reduce inequality. Different standards of ethical assessment can not be applied in other Countries: ethical criteria must be unique, common and shared.

2. International trials must constitute a specific area in the context of a more extensive promotion of the protection of fundamental human rights. In this sense, experimentation can be an opportunity for development if properly supported by suitable campaigns regarding information and scientific and ethical training.

3. Special protection should be ensured as to the specific needs of developing Countries because of the socio-economic-cultural context in order to contribute to the improvement of their conditions and prevent that needs constitute an undue influence on the choice of participation and ways of participating in the research.

4. The direct scientific importance of the experimentation for the Country in which it is conducted should be determined in advance (both for communicable and non-communicable diseases), the balance of risks and benefits for participants, the obtaining of consent, avoiding hidden forms of involvement in research which ‘takes advantage’ of the lack of awareness or the condition or need.

³⁵ In the field of experimentation on communicable diseases, especially AIDS, the experience of UNAIDS is to be recalled, from which a very detailed document originates, proposed as a guideline for the development of HIV vaccine. The document examines the main aspects of development and testing of this type of medicine in populations with different exposure to infection and poor access to care, taking into account the unique aspects of local cultures and scientific infrastructures. Cf. *Ethical considerations in HIV preventive vaccine research*, UNAIDS guidance document - May 2000, available on the website <http://data.unaids.org/publications/>.

5. The experimentation must take into account in a supportive manner the health needs of the population as part of international cooperation, providing the research participants and hopefully the population as a whole with adequate assistance even after the trial, with reference to the availability of drugs which have proved effective.

Presidenza del Consiglio dei Ministri



**ORPHAN DRUGS FOR PERSONS AFFECTED
BY RARE DISEASES**

25th of November 2011



PRESENTATION

The document “Orphan drugs for persons affected by rare diseases” describes the difficulties faced by people affected by rare diseases which still pose a challenge as regards diagnosis, the limitations of aid and therapy, which, in most cases, is non-existent. The text focuses on the statistical data currently available regarding rare diseases and orphan drugs on a national and international level, in order to highlight the problematicity of the issue also on a bioethical level.

The rarity of the disease does not, in actual fact, allow for investment by pharmaceutical industries, on account of the scarcity of economic returns. The problem can not be tackled only nationally but must also encompass a European and international dimension.

The NBC, while recognizing the difficult solution of the problem, proposes some measures in order to limit it and ensure - as far as possible - the conditions of justice; promotion and economic support of research, by public and private structures, for a better knowledge of rare diseases, and the development of orphan drugs; the careful control of expenditure so as to avoid wasting resources or speculation; greater coordination in the search for genetic abnormalities with the appropriate development of genetic counseling and genetic therapies; the reduction of the threshold that defines the rarity of disease to ensure the sustainable promotion of research, development, and the marketing and delivery of truly innovative drugs.

In addition, request is also made to provide aid for families, as often these are diseases that affect children. It is also recommended that a European fund be created to support the discovery of diagnostic tools and new drugs by giving impulse to trials (both international and multi-centre trials), in full respect of the ethical rules. Finally, it highlights the need to consider orphan drugs for rare diseases a priority in the research programmes of public bodies, *charities* and private individuals.

The document was prepared by Prof. Silvio Garattini, with the collaboration of Profs. Salvatore Amato, Adriano Bompiani, Antonio Da Re, Bruno Dallapiccola, Marianna Gensabella, Laura Guidoni, Laura

Palazzani, Monica Toraldo di Francia, Grazia Zuffa, together with the members of the working group Profs. Luisella Battaglia, Maria Luisa Di Pietro, Carlo Flamigni, Assunta Morresi, Andrea Nicolussi, Giancarlo Umani Ronchi.

The opinion was approved by those present: Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Francesco D'Agostino, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Carlo Flamigni, Silvio Garattini, Marianna Gensabella, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Vittorio Possenti, Rodolfo Proietti, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa. Prof. Demetrio Neri expressed his negative vote. Profs. Adriano Bompiani, Roberto Colombo, Maria Luisa Di Pietro, Romano Forleo, Laura Guidoni, absent at the session, subsequently expressed their assent Prof. Cinzia Caporale outlined her non-adherence to the document.

The President
Prof. Francesco Paolo Casavola

INTRODUCTION

When one speaks of rare diseases we refer to a large and heterogeneous group of pathologies characterized by a low rate of frequency in the population³⁶, whose criterion of classification is in general purely epidemiological. Not well known and poorly researched, these diseases often have a chronic and debilitating outcome, and/or premature mortality, they strike in general and considering only the population of Europe, roughly 30 million people, half of these develop the disease already at the age of childhood. As regards the scope of the term rare disease, in Europe, “the entity of rare disease appears as a concept of a health and social nature, thereby meaning not only the diagnostic and therapeutic aspects, but also those inherent to activities of prevention, rehabilitation and socio-economic support”³⁷.

From a regulatory perspective, the first public recognition of the importance of the problem of rare diseases, dates back to the 80’s of last century, and this coincides with the launch in 1983, of the National Organization for Rare Diseases and the simultaneous enactment, always in the U.S., of a specific law on ‘orphan’ drugs (Orphan drugs Act). In the 90’s the European Union too began to study the problem, so that in 1999 orphan diseases were identified as a priority area for Community action in the context of public health (Decision no. 1295/1999/EC of the European Parliament and Council). With this decision, the Union’s aims: to improve access to information, to stimulate the training and retraining

³⁶ In Europe, the threshold is less than 5/10.000 (Regulation (EC) No. 141/2000).

³⁷ Cf. D. Taruscio, *Rare diseases as an example of contrasting marginality*, in “Rivista delle Politiche sociali”, 2004, 4. In Regulation (EC) No. 141/2000 rare disease is defined as: “a life-threatening or chronically debilitating diseases which are of such low prevalence (less than 5 per 10000) that special combined efforts are needed to address them so as to prevent significant morbidity or perinatal or early mortality or a considerable reduction in an individual’s quality of life or socio-economic potential”. These criteria, which refer to other factors, additional to the mere epidemiological criteria, are not adopted by other Countries with different organisation of health care from the European ones, e.g. in the U.S. the recognition of rare disease is dependant exclusively on prevalence. It should also be noted that even in epidemiology there is an absence of uniformity in the definition of rare disease, the established threshold for inclusion as a rare disease may vary, depending on the country and the relevant legislation, and that the same prevalence criterion is not always certain, given the objective difficulty, for many diseases, to be diagnosed and consequently that cases be detected.

of health workers, to promote transnational collaboration of voluntary and professional associations and, together, the epidemiological surveillance of rare diseases and the creation of a network of experts. In 2000 the Regulation of the European Parliament and the Council on orphan drugs was drawn up (Regulation No.141/2000) - establishing a Community procedure for the designation of orphan drugs by establishing incentives for research, development and the placing on the market of those products – this was followed by a series of initiatives aimed at implementing the points of the program. In this way an increasing role is recognised to the contribution of knowledge and proactive activity given by the patients' organisations³⁸, reiterating the `added value` derived, in the complex field of rare diseases, from the coordination of action on a European level as well as transnational collaboration. As regards this aspect, there are at least two initiatives among the most recent to be reported: the 2009 Recommendation of the Council of the European Union, which called on Member States to adopt, by 2013, national plans and strategies for rare diseases, to identify centers of excellence and to promote participation in networks of European experts; the Directive of March 2011, concerning the implementation of patients' rights in cross-border healthcare³⁹, which “supports Member States in developing reference networks of healthcare providers and centers of excellence, especially in the field of rare diseases” (Art. 12), “in particular in order to make health professionals aware of the tools available to them at Union level to help them make a correct diagnosis of rare diseases” and “making patients, health professionals and agencies responsible for financing health care aware of the possibilities offered by the (EC)

³⁸ The most important European organization, which has had a leading role in the dialogue with the European Commission as well as the promotion of national plans and strategies in favor of rare diseases, is Eurordis (European Organization for Rare Diseases); established in 1997, today it is the reference point of more than 500 associations of patients affected by rare diseases. Eurordis, among its many initiatives, also organizes an annual International Day of Rare Diseases (February 28th), with the aim “to raise public awareness, the European health authorities, national and local, and the political authorities, health professionals, researchers, academics, pharmaceutical and biotechnology industries and the media “on the issue of rare diseases. In 2011, the Day had as its motto “Rare but Equal”, with an emphasis on health inequalities in Europe and within individual states, while for 2012 the chosen theme is solidarity. See: <http://www.eurordis.org/it/content/giornata-delle-malattie-rare-2011-focus-disparita-sanitarie>.

³⁹ 2011/24/UE Directive of the European Parliament and Council of 9th March 2011.

Regulation n. 883/2004 for the transfer of patients with rare diseases to other Member States, for diagnosis and treatments that are not available in the Member State of affiliation” (Art. 13).

As regards Italy, even though in the last decade several measures have been taken to for the setting up of suitable structures to the dictates of the community and in order to improve the condition of patients suffering from rare diseases, the legislative reference point remains the Ministerial Decree of 2001 (DM 279/2001), which regulates the establishment of the national network for rare diseases and gives the list of rare diseases for which there is recognition of the right to be entitled to exemption from participation in the costs related to health care⁴⁰.

It should however be noted that despite growing awareness in recent years towards the issue of orphan diseases, their lack of individual epidemiological importance makes them to this day still not very appealing for industries, that are not encouraged to seek and develop remedies that would not find an adequately remunerative market. On the other hand, when available, these treatments are very expensive, despite the fact that, in most cases, their efficacy and safety has not been sufficiently documented. For these reasons, orphan interventions are often less efficient than the more simple and less expensive ones, of sure - even if sometimes limited - efficacy, which are used on larger populations of patients.

The NBC believes, however, that the latter consideration, mainly based on the criterion of cost-effectiveness, and directed at protecting public health, can not and should not be detached from a specific attention to the suffering of people affected by rare diseases and to a united commitment to the promotion of their health status.

The NBC has already examined, in the opinion on Drug experimentation (1992), the economic problems faced by pharmaceutical companies in the study and production of orphan drugs for rare diseases, hoping, however, on the basis of ethics that transcend the mere logic of economics, that orphan drugs may be “adopted”⁴¹.

⁴⁰ For the situation of rare diseases in Italy, see the Istisan Report 11/20. The National Registry and Regional/Interregional Registers of rare diseases, the 2011 Report.

⁴¹ A recent ruling by the Swiss Federal Court (23 November 2010) sets a limit on the management of certain drugs. <http://www.tsr.ch/emissions/36-9/3264987-trop-cher-tu-meurs.html>.

The patient suffering from a rare disease is primarily a person who has the right to health care: the right that, in this case, is expressed as a right to receive treatments with proven efficacy but also as a right to hope in the development of possible new treatments thanks to advances in pharmacological research. The two rights are implicit in the Preamble of the Constitution of the World Health Organization (WHO), which states that “the possession of better health that you are able to achieve is a fundamental right of every human being.

As noted by NBC in the opinion bioethical guidelines for equity in health (2001), there is introduced here the notion of “possible health” which opens, among other things, “one of the major issues of health justice, namely the ‘impossibility of deciding matters concerning distribution, allocating to everyone the same amount of resources. Such a solution does not take account of the tension introduced in the health field from different natural and social distribution of disease and psychophysical deficits, and therefore the different degrees of intervention necessary to ensure possible public health”⁴².

One should add that in the context of the difficult and sometimes tragic choices⁴³ imposed by the scarcity of health resources, it often happens that the person suffering from a rare disease feels even more emarginated, if not abandoned, for several reasons: on account of the many difficulties encountered regarding health care and because of the lack of real hope, in the near future, in the possibility of availability of effective treatment for their disease, which, due to its very rarity, is in actual fact neglected.

In addition, the research, development, and marketing of therapeutically effective drugs would seem to require investment on behalf of society of such magnitude as to be perceived as contrary to the interests and the right to health care of all other citizens suffering from common diseases. However, in a just society, an appropriate resolution should be found to solve this contrast. In order to deal with distributional issues related to health, there must be a justified and shared policy, for the allocation of resources which does not penalise any type of patients.

⁴² NBC, *Bioethical guidelines for equity in health*, 2001.

⁴³ G. Calabresi, P. Bobbitt, *Tragic choices* (1978), tr. it. *Scelte tragiche*, Milan 1986.

This NBC document intends to consider the problems raised by rare diseases and by orphan drugs in particular, for those who govern intervention and spending within public health care.

Rare diseases: on the patients' side

Rare diseases raise a number of problems, both for the person who is affected, often burdened by serious or extremely serious disability, both for the family, and for the community.

The problems of the individual and the family concern mainly:

- the difficulty, or the impossibility, to access the correct diagnosis - due to the absence of identification of a clinical reference centre specialized in the pathology in question - with the consequent worsening of the patient's psychological condition and state of health;
- the delay in diagnosis adversely affects prognosis;
- the isolation and lack of scientific knowledge and information about both the disease, as well as existing laws and rights;
- the lack of adequate medical care and the necessary rehabilitative and psychological therapy, considering the chronic and debilitating nature of the majority of rare diseases and the disruption and destabilization that experience of the disease entails for the patient and family;
- the difficulty of access to treatment and care, that concerns both the obtainability-availability of innovative drugs, at a high or very high price, used specifically for a particular rare disease and already marketed in Europe as well as, when there are no specific etiological therapies, and the access to other treatment options;
- the strong inequalities that exist at regional and local level, in the access to diagnosis, to innovative therapies and, more generally, health care and social services;
- the high costs of treatment, overall, and the lack of support measures that meet the needs of daily and ongoing assistance determined by the disease, this burden falls almost entirely on the family, and often causes its impoverishment and exclusion from the world of work;
- the precarious conditions, that are often serious or very serious, of those affected, even after having obtained diagnosis;

- the heavy social consequences for the patient (stigmatisation, isolation at school and occupational activities, the difficulty of building a network of social relations).

A study sponsored by Eurordis (Rare Disease Europe⁴⁴) has identified a number of problems related to the diagnosis of rare diseases:

- 25% of patients wait 5-30 years to obtain confirmation of the diagnosis;

- 40% initially receive an incorrect diagnosis;

- 25% must move to other regions in order to obtain diagnosis;

- in 33% of cases the diagnosis is communicated in an unsatisfactory way (12% in an unacceptable manner);

- in 25% of cases it is not reported to patients or their families that it is a genetic disease;

- Genetic counseling is offered in only 50% of cases.

Besides all this, the *Dossier on the subject of rare diseases 2008*⁴⁵ (by Cittadinanzattiva, Tribunal for Patients' Rights, National Coordination of associations of the chronically ill), in pointing out the difficulties in actually enjoy the benefits provided by law and the considerable differences that exist between regions, states that over 40% of patients do not often have access to essential drugs, or drugs for the treatment of complications. Even more serious is the difficulty in taking advantage of innovative drugs. To overcome these difficulties several measures were proposed including the simplification in the marketing of to drugs for the treatment of rare diseases, for example by reducing, the time for publication in the Official Journal, a more rapid implementation on national territory, of the decisions taken at European level, effective and timely availability after the approval of the AIFA. Cost and inconvenience lead to renunciation to medical care by 1 out of 4 patients to which there should be added a further 37% for those who abandon due to bureaucratic impediments⁴⁶.

Other studies have found, that 57.9% of patients are forced to personally bear the costs of therapy with an annual cost that ranges from a minimum of 800 Euros to a maximum of 7,000 Euros and this leads to

⁴⁴ <http://www.eurordis.org>. The voice of 12.000 patients, 2009.

⁴⁵ http://www.cittadinanzattiva.it/files/approfondimenti/salute/malattie_croniche_rare/dossier_tema_malattie_rare_nov_2008.pdf.

⁴⁶ *Focus sanità*, in "Il Sole 24 ore", 11-17 November 2008, p. 14.

renunciation to medical care by 1 out of 4 patients to which there should be added a further 37% for those who abandon due to bureaucratic impediments (2008 study by the Tribunal for patients' Rights⁴⁷); that for many parents to meet their care needs means to worsen their work situation, or to interrupt it completely (Pilot Study ISFOL⁴⁸); Among the families participating in the study many live on a very low income, 35.1% are below the poverty level, or at high risk of poverty; almost 20% are forced to resort to loans, to cope with management of the disease.

Rare diseases: on the community's side

Rare diseases affect a limited number of people individually. In relation to the different definitions used, each of them affects less than 1 person in every 2,000 in Europe, 1/1.250 in the United States, 1/2.500 in Japan, 1/15.000 in Australia. The following are some examples:

| Rare diseases with the highest estimated prevalence | |
|---|--|
| | Estimated prevalence per 100,000 ⁴⁹ |
| Brugada syndrome | 50 |
| Erythropoietic protoporphyria | 50 |
| Guillain-Barré syndrome | 47 |
| Familial melanoma | 46 |
| Genetic Autism | 45 |
| Tetralogy of Fallot | 45 |
| Scleroderma | 42 |
| Transposition of the great vessels | 32,5 |

⁴⁷ http://www.cittadinanzattiva.it/files/approfondimenti/salute/malattie_croniche_rare/dossier_tema_malattie_rare_nov_2008.pdf.

⁴⁸ A. Spagnolo, *Difficult to to stay afloat. The needs of families and patients affected by rare diseases: a pilot study IAS*, in "About Pharma", 1/March 2011, p. 35 ff.

⁴⁹ Prevalence of rare diseases: bibliographic data, Orphanet Reporter Series. www.orphanet, May 2011, Number 1 and Number 2. Overview of rare diseases activities in Europe and key developments in 2010. Joint Action to Support the Scientific Secretariat of Rare Diseases Task Force, European Union Commission of Experts on Rare Diseases, 20082291.

| | |
|----------------------------------|------|
| Focal dystonia | 30 |
| Marfan syndrome | 30 |
| Malignant non-Hodgkin's lymphoma | 30 |
| Retinitis pigmentosa | 27,5 |
| Narcolepsy | 26 |
| Multiple Myeloma | 26 |
| Alpha 1-antitrypsin deficiency | 25 |
| Congenital diaphragmatic hernia | 25 |
| Juvenile idiopathic arthritis | 25 |
| Neurofibromatosis type 1 | 25 |
| Esophageal atresia | 25 |
| Polycythemia vera | 25 |
| Source, "Lancet", 2008 | |

However, the number of these diseases is very high (at least 6,000 according to the WHO). Consequently, the total number of patients suffering from rare diseases is enormous: an estimated 30 million in Europe, of which there are about over 1 million in Italy (although the absence of comprehensive data on the population of the rare patients makes it difficult to make a precise estimate), 25 million in the USA.

The treatments available for rare diseases vary in kind and are not restricted only to pharmacological treatments⁵⁰. This document, however, refers exclusively to pharmacological treatments.

⁵⁰ See the following table:

| Examples of treatments available for rare diseases |
|--|
| <ul style="list-style-type: none"> • Limitation of a substrate in the diet (eg. Phenylalanine in phenylketonuria) • Elimination of drugs (eg. Barbiturates in porphyria) • Gene therapy (eg. In adenosine deaminase deficiency) • Transplants (eg. Marrow in thalassemia; liver in biliary atresia, heart in dilated cardiomyopathy, etc.) • Removal of pathological tissues (eg. Neurofibromas in NF1; colectomy in familial polyposis of the colon) • Reparative surgery (e.g. Congenital heart disease) • Neuropsychomotor therapy (eg. Various types of psychomotor retardation) • Prostheses (e.g. Deafness, intracerebral electrodes in dystonia) • Robotics (eg. Exoskeleton for deambulation in diplegia) |

Since 2000 (Regulation (EC) No. 141/2000⁵¹) to 2010, there have been approved in Europe little more than 60 orphan drugs that treat around forty rare diseases. If we consider the availability of orphan drugs for disease groups, the most available are those for metabolic diseases (64%) and rare tumors (59%), while there is a lower availability in other fields such as, for example, cardiology, neurology or hematology, and it is the drugs that treat the rarest of conditions that are not available.

It should be stressed however that, given the few approved drugs, there are over 800 products designated by the regulatory authority (COMP) as potential orphan drugs. These products are not developed because of lack of funds. Hence the necessity of establishing an appropriate European fund for translational research on orphan drugs, privileging research for the rarest of conditions.

According to the Italian Drug Agency (AIFA), the use of these drugs in 2010 amounted to 6,839,423 DDD (daily doses) for a cost of 661,709,750 Euros.

Instruments to meet needs and limit their impact

The picture briefly represented here renders the idea of the size of two problems: the first is the disparity between needs and their satisfaction, that is, between the number of rare diseases and the people affected by them and the number of genuinely effective treatments available; the second is the current and future burden arising from this problem, and therefore the need to promote research and development of orphan drugs and, thereafter, to make them available to patients.

Several international initiatives seek to provide a solution to these problems. The International Rare Disease Research Consortium (IRDIRC⁵²),

⁵¹ Data were collected by Eurodis and the National Federation of Rare Diseases (UNIAMO), starting in September 2010, the survey, which examined the question of access to 60 orphan drugs with marketing authorization in Europe, has shown that it is precisely the drugs that treat the rarest of conditions that are not available

<http://www.uniamo.org/it/news/news-europa/190-indagine-eurordis-sullaccesso-ai-farmacifani-in-europa.html>.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:018:0001:0005:en:PDF>.

⁵² <http://www.geneticalliance.org/irdirc>.

for example there is the ambitious project to develop, by 2020, 200 new therapies for rare diseases and diagnostic tests for all rare genetic diseases, together with advisory and family support programmes.

Instruments to measure the effectiveness and efficiency of intervention

Two problems of great importance concerning the choice of the resources to be allocated for the treatment of rare diseases, regard the effectiveness and efficiency of these interventions and the possibility of their measurement⁵³. The QALY (Quality-Adjusted Life-Year) is the most common instruments used to determine the value of a drug. The QALY measures the survival and quality of life of the patient in reference to a treatment. For example, a vaccine used at a pediatric age, which prevents death or ensure decades of life without that disease, is credited with many QALYs, an anticancer drug, which allows increased survival of just a few weeks, moreover, burdened by a poor quality of the remaining life, will have a very modest QALY. The cost of treatment, in relation to the QALY, represents, in general, a measure of cost-effectiveness to determine the value for money of one intervention in relation to another.

In a system with fixed financial resources (each year a budget for health spending is established, with a set percentage cap for drug expenditure) the cost for QALY could in future be the instrument by which the choice of priority intervention is determined: in the context of forecast expenditure only the most efficient interventions are reimbursed. This would make it possible to purchase more public health with the available budget.

The criterion of QALY, however, is not free from critical consideration, in general and especially when it comes to rare diseases It is purely statistical, which leads to a single social factor in the evaluation of a specific health intervention spread across multiple subjects, based on an overall calculation that does not take into account the different conditions of the people involved. It should be emphasized that QALY should not be

⁵³ As already noted by the NBC the search for just and shared policies in selecting priorities “requires the assignation of a higher value to the criteria of quality and effectiveness of medical services”. (*Bioethical guidelines for equal access to healthcare*, p.32).

the physician's clinical reference, as it is a tool for the allocation of resources. Its application, as an exclusive criterion therefore, runs the risk of not meeting up to the requirements of fairness in the allocation of scarce resources based merely on a question of efficiency.

Although a criterion of efficiency such as the one based on the cost/effectiveness of interventions, ensures an efficient allocation of resources for the purchasing of the greatest possible amount of public health, it does not promise to adequately safeguard the individual rights and needs of marginal patients', consequently, additional or alternative instruments of policy must be identified in order to meet them. Therefore, the (ideal) primary objective to achieve must be the improvement of standards and the quality of life for every patient, without discrimination based on the nature of the disease or the cost of therapy. All the energies of researchers, health professionals and those who manage the public health, supported by the actual patients' associations should be directed towards this aim. Therefore, the NBC maintains reflection on this debate open to contributions from new evaluation criteria.

Sustainability of pharmaceutical expenditure

Except in rare cases of clear disproportion between the cost and effectiveness, the Italian National Health Service has for now guaranteed to cover not only interventions at low cost and high yield (think of a few tens of Euros for vaccines administered in childhood, allowing decades of life of a good quality), but also interventions at a very high cost and modest yield (e.g. the tens of thousands of Euros paid for innovative medicines that lengthen only by a few weeks the life of cancer patients in the terminal stage).

Some worrying signs (such as the exceeding in 2010 of the cap of hospital pharmaceutical expenditure) are the signal of an imminent breakdown in the balance maintained for years by a careful policy of management of drugs and their prices. Consequently, there could be in the future, a change of choice, mortifying for the right to health of certain groups of patients, contrasting with the ethical and legal principles that inspired our Constitution (equality, solidarity, personal development, the right to health).

The case of orphan drugs

Orphan drugs - generally, very expensive, and to date reimbursed on the basis of different criteria from that of cost effectiveness - could be affected by the above-mentioned situation. As well as being expensive, they often have little documentation regarding their actual clinical effectiveness⁵⁴.

| Orphan drugs and their approximate cost | | |
|---|-------------------------------------|--------------------------|
| Drug | Rare disease | Cost/patient/year (Euro) |
| Imiglucerase | Gaucher disease type 1 | 104,000 ^a |
| Alfa-agalsidase | Fabry disease | 145,500 ^a |
| Idursulfase | Mucopolysaccharidosis | 462,500 ^b |
| Alfa alglucosidase | Pompe disease | 300,000 ^a |
| Sapropterin | phenylketonuria | 115,000 ^a |
| Eculizumab | Paroxysmal nocturnal hemoglobinuria | 280,000 |
| Cost calculated using unit prices obtained by the British National Formulary UK for such patients and, where necessary, according to body weight: a 70 kg b 48 kg Exchange rate sterling/Euro used:: 1,1192 (28.06.2011) | | |
| Source, "British Medical Journal", 2010 | | |

The uncertainty regarding the real clinical efficacy of some orphan drugs and the limited capacity of the system to ensure free availability for the patients affected by rare diseases could lead to restrictions on the reimbursement of drugs and/or the accentuation of the already ongoing

⁵⁴ An example is the demonstration of the modification of the biochemical parameters in the short term, such as glycolipids in Fabry disease the Insulin-like growth factor-1 in acromegaly, glycosaminoglycans in the mucopolysaccharidoses, etc. is not sufficient to ensure a greater and/or better survival in the long term (Joppi et al. "*Br J. Clin. Pharmacol.*", 2006 and 2008).

trend, for policies and measures to differ from region to region, and consequently, for some patients, there is non-recognition of the equal right to treatment of the disease and their being treated in a discriminatory manner depending on the location⁵⁵.

At the same time it is unthinkable that a gradation of interventions, based on an evaluation of the cost-effectiveness, can be completely set aside for orphan drugs: investing too high a share of resources to make available more and more drugs for rare diseases would considerably decrease the quota allocated to the treatment of diseases that are not rare. Therefore, it is necessary to address the problem of the choice of distribution criteria for scarce resources, such as those of their health system, without opposing the protection of public health to the right to treatment of the ‘disadvantaged’, such as those suffering from rare diseases.

A Question of Justice

The basic ethical question concerns the possibility of identifying univocal and transversely valid criteria in order to guarantee fairness in meeting the needs of the individual and the community in the distribution of public resources.

It is evident that the limited resources available in health care make it impossible to have a model of justice capable of guaranteeing “everything to everyone”, although, as already noted by the NBC in an earlier opinion, we must strive - at least in principle - to ensure “all that is effective for all those in need”, as each patient has the right to be treated equally, regardless of solely economic calculations. This is a postulate (equal consideration being due to every person) which is the reference point for any reflection in this area.

In addition, it should not be forgotten that a fair distribution of resources, in order to be so, must take into account also difference. The lack of consideration of individual differences can in fact produce

⁵⁵ On policies and measures that differ from Region to Region, cf. I. Giancaloni Bartoli, Regions in random order, in “About Pharma” 1/marzo/2011, p. 33 ff. and, in the same issue of the journal, A. Spagnolo, *Hard to stay afloat. The needs of families and patients affected by rare diseases: a pilot study IAS*, cit.; See also Cergas-Bocconi, *Analysis of regional policies on access to innovative drugs, the final research report*, September 2008 http://www.celgene.com/downloads/SINTESI_RAPPORTO_BOCCONI.pdf.

profoundly anti-egalitarian effects and this for the obvious reason that the equal consideration of everyone may entail 'unequal' treatment in favour of those who are in a disadvantaged position. It is therefore necessary to ensure justice while respecting the equality of human beings regardless of the existential conditions (e.g. the disease or incidence of the disease) and - at the same time - the different needs of each, relating in this case to the different states of health/disease. It is precisely this interpretation of the concept of justice which is at the basis of equity. It follows, as noted in the introduction, that, in the face of health issues, a distribution policy should be found - moving from the concreteness of human reality - offering to all individuals an equal opportunity to achieve their full health potential permitted by their condition⁵⁶.

Following this ideal regulative principle, although not hiding the difficulties, the NBC believes it possible to search for a solution, albeit partial, to a very real problem.

Resolutions aimed at limiting the problem

The guidelines for the protection of the right to treatment of people suffering from rare diseases also include measures to restrict the size of the problem. Possible areas of intervention include:

- The promotion and economic support of both research aimed at achieving a better understanding of rare diseases and the causes of their occurrence (under the label of a specific syndrome, e.g. very different diseases, that share similar symptomatologies, whose cause is still not known, could be grouped together), as well as research and development of orphan drugs, enhancing the contribution of numerous patient associations especially active in this area. Currently there are about 800 active ingredients that have received orphan drug designation, but which can not be developed due to the lack of economic resources. More specifically, a European (or even international) fund should be established, for the creation of orphan drugs, to draw attention to the problem on behalf of the national health policies, and to encourage private investment in this sector using appropriate strategies.

⁵⁶ See the aforementioned NBC Opinion, *Bioethical guidelines for equal access to healthcare*.

- Close monitoring of expenditure on orphan drugs, in order to avoid wasting resources. A drug originally recognized as an orphan drug should not be considered as such when alongside the indication for this rare disease there are added other indications for common diseases. The cost, sustainable for a niche area, should not remain the same for interventions which apply to large populations⁵⁷. Therefore a cap must be imposed on expenditure for these drugs, so as to ensure an adequate return on investment for research and development, but also in order to avoid speculation by virtue of the fact that the market in gradual expansion does not affect the initial price of the product⁵⁸. Indeed often certain drugs that have been designated as orphan drugs and, as such, authorized for sale, may subsequently be clinically developed also in other pathological areas and obtain for these new clinical indications, marketing authorization. The price agreed upon with the drug regulatory authority for an initially restricted market, in these cases, is applied to trade on a large scale, with a heavy cost burden for the NHS.

- The promotion of research directed at ensuring clinical effectiveness and quality control of orphan drugs, when addressed to neglected areas, benefit from concessions and privileges. They should offer real benefits to patients, that are certain and measurable in terms of increased survival and/or better quality of life. Today, this rarely happens⁵⁹. It is important to encourage international multicentre experimental research to overcome the problem of the scarcity of patients and facilitate the planning of alternative designs for clinical trials⁶⁰. In this respect, it is required that Governments put pressure on the European Commission and on the European Regulatory Agency (EMA, European Medicines Agency) in order to increase the rigour in the evaluation of new drugs, and particularly orphan drugs, so they respond better to the needs of patients and the NHS.

- A more coordinated investment: for research of genetic anomalies and their markers, in the development of diagnostic tests, the pharmacological treatment of inherited rare diseases, in the formation of

⁵⁷ N. Hawkes, D. Cohen, *What makes an orphan drug?*, in "BMJ", 2010, c6459, p. 341.

⁵⁸ For example, imatinib is an orphan drug, but it requires an investment of 145 million Euros only in Italy.

⁵⁹ See Joppi et al., "*Br J. Clin. Pharmacol.*", 2006 and 2008.

⁶⁰ S. Gupta, M.E. Faughnan, G.A. Tomlinson A. M. Bayoumi, *A framework for applying unfamiliar trial designs in studies of rare diseases*, in "Journal of Clinical Epidemiology", 2011, pp. 1-10.

medical, nursing and laboratory expertise, to transfer and make available the new knowledge. In fact about 80% of rare diseases have a genetic origin and the number of conditions for which genetic tests can be performed is constantly increasing (about 100 in 1993, over 2,200 in 2010, GeneTests database). These developments have not been matched by the number of adequate facilities for genetic counselling and appropriate pharmacological therapies⁶¹.

- The reduction of the threshold that defines the rarity of a disease (currently 1/2.000 in Europe) to ensure a sustainable promotion of research, development, marketing and delivery of truly innovative drugs. It is important to introduce serious reflection on the possible reduction of the threshold considering the consequences that this might entail. The threshold to be adopted should be sufficient to define a market situation capable of ensuring to industries - without reducing patient protection - satisfactory economic returns, and the promotion of their commitment to the research and development of effective orphan drugs. For example, if a prevalence of 0.5/10 000 (that is 5/100.000) were adopted, instead of the current 5/10.000, the industry would however still have a potential market of about 25,000 patients for that rare disease in the EU. This is an area of action of a significant size, especially in consideration of the chronicity of the majority of these treatments. In fact, assuming a drug cost that is even much lower than average for the present effective orphan drugs, for example, 6,000 Euros/patient/year, there would be an annual turnover of 150 million for the EU alone, therefore able to guarantee to pharmaceutical companies significant economic returns. The high prices of orphan drugs, however, allow for, higher revenues than those prefigured here, even for diseases that are even rarer than those identified by the above-mentioned threshold⁶².

⁶¹ This document does not intend to address the question of the use of genetic tests in the prenatal sphere; the document only deals with the issues of those already born and suffering from a rare disease.

⁶² For example, at a cost of more than 50,000 Euros per year per patient agalsidase for Fabry disease, which has a prevalence of 1/40.000, would have a market well in excess of 600 million Euros in Europe. Imiglucerase for Gaucher's disease (prevalence of 1/30.000) costs about 230,000 Euros per year for each of the over 16,000 patients in the EU, a potential market of approximately 3,800 million Euros.

Obviously the new threshold applies only to the use of the European fund for the development of orphan drugs and does not affect the social care providence carried out in various European Countries including Italy.

The NBC Guidelines

Pending further contributions on the identification of appropriate assessment criteria, the NBC reiterates that, particularly in the case of rare diseases, the right to health care for people affected by rare diseases can not be called into question by the contraction of economic resources and choices of allocation of funds driven by the sole criterion of cost-effectiveness. However, being aware of the scale the financial commitment required by research and therapy in the context of rare diseases and the difficulty that this commitment creates in the choice of priorities that guarantee the right to health for all, the NBC suggests adoption of certain measures able to limit the onus. These measures are general measures and guidelines of principle, which do not allow us to propose concrete solutions, that are specific and immediate, but they delineate the reference values for health policy choices in this area. These measures include in brief:

1. the recommendation, to the European and national legislators, to adopt a new definition of rare disease, based on more restrictive epidemiological criteria, and to establish a cap on the revenues for orphan drugs, over which to revoke the designation of orphan drug and their privileges and incentives in order to discourage speculative policies based on the extension of the clinical indications of very expensive products;

2. the promotion taking charge and treatment, pharmacological and non pharmacological, of rare diseases, both hereditary and non-hereditary even reducing the number of undiagnosed cases, reducing the time of diagnosis and increasing the availability of genetic counselling for hereditary diseases;

3. the promotion of clinical trials on a multicentric, national and international level, in full respect of the subjects on which the testing is done (children or other conditions of particular vulnerability) and the criteria of ethics (informed consent, confidentiality of information, etc...); for this purpose the establishment of a European fund for the translational research of new orphan drugs is advocated;

4. the promotion of the transfer of research results in the treatment of rare diseases and the simultaneous adoption of more rigorous criteria for assessing the degree of innovation of orphan drugs before they are placed on the market, ensuring the best national and international clinical practice to all patients, without exceptions or regional differences;

5. the monitoring of the effectiveness and tolerability of drugs granted for compassionate use or used in an off-label form;

6. the recovery of resources capable of sustaining the onus of orphan treatments through the redistribution of the burden of expenditure for some classes of drugs, that are widely used and low cost, by the NHS to patients, but also by promoting campaigns so that large companies, both pharmaceutical and producers of consumer goods, are encouraged to 'adopt' one or the other orphan diseases, considering that the 'ethics' of a product, once advertised, may represent an added value.

Glossary

CHMP: Committee for Human Medicinal Products, this committee evaluates the documentation supporting the request for authorisation to market human medicinal products, including orphan drugs. The CHMP assessment is summarized in the opinion which the European Commission takes into account before granting the definitive drug marketing authorisation for the EU market.

COMP: Committee for Orphan Medicinal Products, the committee is responsible for awarding the designation of the status of “orphan” drugs to developed drugs or to the development of drugs for the treatment of rare diseases, the designation is granted on the basis of the request made by a sponsor, meaning a person or company; designation is granted on the basis of epidemiological data (prevalence of the disease to be treated $<5/10.000$ inhabitants), the criteria of clinical plausibility and the potential benefit to the patients to be treated.

DDD: Defined Daily Dose the assumed *average maintenance dose per day* for a *drug used for its main indication in adults*.

Orphan drugs: are medicines that treat or cure rare diseases and, as such, are “orphans” in an extensive market, such as the market for drugs that treat highly prevalent diseases (real or supposed).

Rare diseases: according to European legislation, are diseases that have a prevalence of up to $5/10.000$ inhabitants in the European Union.

Off label: with reference to what is foreseen in the Summary of Product Characteristics (SPC) of a registered drug approved by the Ministry of Health, the off-label use refers to its being prescribed in a non-compliant manner as regards disease, population or dosage (e.g. used differently to the therapeutic indications, means, and the expected method of administration, in different doses compared to those required by the SPC dosage, overriding the contraindications referred to in SPC, in contrast to the uses authorized by the Ministry of Health, and the list prepared by the National Drug Evaluation Board.

QUALY: Quality Adjusted Life Years is a unit of measure used in cost-utility analysis that combines duration and quality of life. It is used as an index weighting in the evaluation of increases in life expectancy related to health care. One QALY equal to 1 corresponds to life expectancy of one year in normal health; the value 0 corresponds to death. The measurement scale is continuous and to some years of life there can also be given values less than 1 in relation to a non-optimal quality of life or even negative values, in the case, for example, of a serious condition of immobility or acute pain.

Translational Research: Translational research is the pre-clinical biomolecular research that produces results that are quickly transferable to clinical activity and, vice versa, that clinical research proposes that in-depth insights and solutions be verified through basic testing. Research of a translational kind is, therefore, integration between experimental research and clinical practice. One example is pharmacogenomics, whose aim, in oncology, is to construct a genetic map of the tumors to obtain a predictive test to determine the response to therapy. More generally, translational research includes:

- The basic scientific studies which define the biological effects of treatments in humans;

- Investigations in humans that outline the biology of the disorder and provide the scientific foundation for the development or improvement of new therapies;

- Non-clinical studies or animal studies conducted to improve clinical therapy.

Clinical studies: experimental studies in humans which through successive stages aim to establish the pharmacokinetic properties of a drug (absorption, distribution, metabolism, excretion), its mechanism of action, effective and safe doses, tolerability, efficacy and safety. Phase I Study: conducted on a small group (a few dozen) of healthy volunteers (or patients who have no therapeutic options) to study pharmacokinetics, mechanism of action, ideal doses. Phase II studies: conducted on a larger group (several dozen or a few hundred) people, preferably patients, designed to confirm the active doses and to determine their effectiveness more often based on surrogate outcome measures (blood pressure levels, blood sugar, cholesterol levels, volume of a tumour, etc.). Phase III studies: conducted on hundreds or thousands of patients, are intended to establish the actual efficacy and safety of the drug through clinical outcome measures, that is, events that affect the duration and/or the quality of life of the patient (death, myocardial infarction, stroke, bone fracture, physical or mental disability, dependence on others, hospitalisation, etc.). Phase IV studies: conducted on large populations, when the drug has already been approved for the market, designed to establish the efficacy and safety in real conditions of use in clinical practice, or to evaluate specific aspects of toxicity revealed through time, or new clinical indications, or the risk-benefit profile of vulnerable population groups (pregnant women, children, the elderly, etc.) or combined with other drugs.

Presidenza del Consiglio dei Ministri



**KNOWING ONE'S BIOLOGICAL ORIGINS
IN HETEROLOGOUS MEDICALLY ASSISTED
PROCREATION**

25th of November 2011



PRESENTATION

The National Bioethics Committee (NBC) has approved the opinion ‘Knowing one’s biological origins in heterologous medically assisted procreation’.

The NBC does not go into the ethical evaluation of MAP and its juridical regulations in Italy. It limits itself to considering the ethical problem of the offspring’s right to know the truth about their conception and biological origins in its general aspects, given the importance that this issue has taken on at international level, also on the basis of provisions permitting heterologous procreation, unlike the situation in Italy.

In these cases the document advises against the parents not revealing the way their child was conceived; it is considered opportune that the information be given by means of filters and suitable criteria (proportionality, sustainability, relevance, bearing, etc) and with the aid of counselling, should it be necessary. Furthermore, it is recommended that the offspring be always recognised the right to access the registers where the genetic data and medical record of the donors of the gametes are kept, as this information can at times be indispensable for their health.

The question remains, to which the Committee has not yet been able to give a unitary answer, of whether the search for one’s origins can justify the child’s right to know the personal data of the donors of the gametes in the sphere of artificial fertilisation.

Some members of the NBC consider it more opportune to maintain anonymity with regard to personal data, given that the offspring has a genetic but not a relational connection with the ‘biological procreators’. The main concern is that the disclosure of personal data might alter the existential balance of the original family with possible external interferences in the plan and privacy of the family. Within this sphere the risk has not been excluded of facilitating forms of market, given that it is easier to ask the person supplying genetic material upon payment for absolute transparency or other forms of possible serious consequences, than the real ‘donors’ whose gesture is supposed to be based on the philosophy of voluntary free donation, mainly characterised by altruism and solidarity.

On the other hand, other members recognise the offspring the right to full information concerning the donor of the gametes. Information about one's origins is considered indispensable for the reconstruction of the offspring's personal identity; the offspring's fundamental right to know their origins is therefore recognised, in contrast with any possible interest on the part of the parents to maintain secrecy and of the donors to keep their anonymity. Moreover, this knowledge is motivated by reasons of parity and non-discrimination, as it is not legitimate either from the ethical or juridical point of view to stop only the offspring born by such technique from seeking information about their biological origins. It has also been highlighted how evading the request to know the truth implies a specific form of violence: the violence of whoever knows the truth that regards another person and is in a position to disclose it and refuses to do so, maintaining an unjust position of power towards that person.

The NBC has stressed the need to direct the information modalities in both options according to the real circumstances (considering the difference between minors and adults) and possibly with the help of psychological counselling that can give the necessary support to all the parties involved in the phase leading up to the 'disclosure'. Should the care and protection of the minor's health then make it necessary, it is indispensable that the doctor and/or medical facility, informed of the ways the child was conceived, and the parents having been informed too, or subject to the authorisation of the latter or, in the case of their refusal, of the competent judicial authority, always have the possibility to request the access to the records and the use of the data necessary for the diagnostic and therapeutic treatment of the under-age patient. With a similar aim it is hoped that there will be an ongoing relationship between the medical centres and donor/giver in time.

The opinion was drafted by Prof. Lorenzo d'Avack, with the contribution of Profs. Adriano Bompiani, Luisella Battaglia, Stefano Canestrari, Francesco D'Agostino, Marianna Gensabella, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Lucetta Scaraffia, Monica Toraldo di Francia and Grazia Zuffa.

In the plenary sitting of the 25th of November 2011 the opinion obtained the consensus of those present (Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Francesco D'Agostino, Lorenzo d'Avack,

Bruno Dallapiccola, Antonio Da Re, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Vittorio Possenti, Rodolfo Proietti, Laura Palazzani, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa), with vote against of Prof. Carlo Flamigni. The Profs. Adriano Bompiani, Roberto Colombo, Romano Forleo, Laura Guidoni, Aldo Isidori, Carlo Piazza, Lucetta Scaraffia, were not present at the sitting but nonetheless expressed their adhesion to the document. In order to give the reasons for their dissent, Profs. Maria Luisa Di Pietro and Carlo Flamigni have respectively drafted their annotations. These annotations have been published together with the opinion.

The President
Prof. Francesco Paolo Casavola

1. The reasons for the Opinion

- Law No. 40/2004, which sets down the rules on medically assisted procreation in Italy, in Arts. 4 and 12 prohibits MAP with donors/givers⁶³ of gametes (so-called heterologous MAP⁶⁴), without however sanctioning the couple requesting and obtaining it, but only the medical staff carrying it out. In Art. 9.3 of the law it is established that in the case of heterologous MAP, carried out *against the law*, the donor of the gametes can acquire no juridical parental relationship with the offspring⁶⁵. Nothing however is said by the law with regard to the problem of the protection of the offspring's right to know the truth about their own conception and the advisability or not to inform them of their biological origins.

- Furthermore, the existence of offspring born by means of fertilisation with gametes outside the couple must be taken into account before the coming into force of Law No. 40/2004, when such technique was not prohibited⁶⁶. Even at present different situations can arise which affect the issue being dealt with: Italian citizens born in Italy following fertilisation practised in breach of the law in force, or in clinics of foreign Countries where the technique is permitted⁶⁷.

⁶³ In the continuation of the text, according to current use, the term 'donor' is mainly used, even if the NBC is aware that the giving of gametes does not always take place free of charge, but upon payment expressly foreseen by the legislations, even in the shape of indemnity. In particular, with reference to the problem of the commercialisation of gametes, the NBC refers to its *Motion on the trade of oocytes* (2007).

⁶⁴ The NBC uses the term 'heterologous' as it is widespread in legislations and bioethical and scientific literature. However, it is aware that this is an improper terminology, insofar as 'heterologous' in medicine and biology is used for an organ, tissue, organic substance coming from animal species different from the one considered.

⁶⁵ In this context, the concept of 'offspring' is not applied to a particular stage in time of the life starting from birth (as for example the concept of the newborn baby) but extends its general effects over the course of their existence.

⁶⁶ For those born in Italy before Law No. 40/2004 there is the risk that the centres may not have kept track of the donors. The first centres in Italy in the 70s to carry out the insemination with gametes from outside the couple, before the decree by the then Health Minister Degan (1985), were few, also because there was a certain tendency not to publicise their existence, given that it was not clear whether it was legal or not to carry out this kind of insemination in Italy. At a later date, following the Degan decree which prohibited public medical centres from carrying out artificial insemination with gametes from outside the couple, the private centres felt authorised to do so. Nonetheless, standard protocols were lacking with regard to the obligation to keep medical records or registers of the operation.

⁶⁷ It must be considered that the Italians born from MAP with gametes from outside the couple, conceived abroad, can know more or less completely their origins according to different regulations governing the technique in those Countries.

- It must also be considered that the MAP techniques, especially those with donors of gametes, do not exhaust their juridical effects only in the phase of direct application, but are extended to the offspring and family in time.

Therefore, even if in Italy these situations are not subject to any specific norms from a juridical point of view at present, the bioethical issue which arises for the offspring is the same as the one that exists in those Countries where MAP with donors is permitted and where the right to know one's origins is hotly debated, with the legislation regularly evolving.

The Steering Committee on Bioethics (CDBI)⁶⁸ of the Council of Europe also recommends those states prohibiting fertilisation with donors of gametes to set down norms to be applied for the protection of the offspring's identity, independently of the modalities of conception.

In the light of this reasoning, the NBC considers it right to not evade such complex issues. Therefore the objectives of this Opinion are to offer the Italian legislators a set of arguments that might help in drafting legislative acts to deal with the questions of an ethical and juridical nature which arise before the request of the offspring born by means of the assisted fertilisation technique with gametes from outside their social parents to know the modalities of their birth.

In formulating the opinion the NBC does not intend to deal with the ethical evaluation of MAP nor its legislation in Italy. This is also bearing in mind that in this Committee, as in the past⁶⁹, a consensus in the bioethical stances concerning the subject of MAP has not been reached. Some members⁷⁰ are in favour of the prohibition imposed by Law 40/2004 on fertilisation with donors of gametes, maintaining that such practice

⁶⁸ See the Document *Draft opinion of the CDBI on the draft Recommendation on the rights and legal status of children and parental responsibilities*, Strasbourg, 22 November 2010, CDBI (2010)21. The CDBI with regard to the 'access to origins' (Art. 4), puts forward the following formula: "*Children shall have access to recorded information concerning their origins. Where the persons who procreated the child have a legal right not to have their personal information disclosed, it shall remain open to the competent authority, to the extent permitted by law, to determine whether to override that right and disclose relevant non-identifying information in particular medical information, having regard to the circumstances and to the respective rights of the child and the persons involved*".

⁶⁹ Opinion of the NBC on assisted procreation techniques synthesis and conclusions, 17 June 1994 and Assisted fertilisation, 17 February 1995.

⁷⁰ Amato, Bompiani, Colombo, D'Agostino, Da Re, Di Pietro, Gensabella, Isidori, Morresi, Nicolussi, Palazzani, Possenti, Scaraffia.

lacks ethicality, fosters the donor's irresponsibility, alters the statute of medicine and comes into conflict with some fundamental human and inviolable rights referring to the dignity of the person and the rights of the unborn child as well as with the parental responsibility foreseen by Art.30 of the Constitution. Others⁷¹ do not share the opinion that the absolute prohibition of such technique, in itself not ethically reprehensible nor prejudicial of rights or legal interests of constitutional relevance: consequently they consider that heterologous MAP must be allowed in some hypotheses strictly foreseen by the law.

2. The problem

The access to MAP in its different forms is sought after not only by heterosexual couples, united or not in marriage, but also by homosexual couples or by single persons of both sexes. By dissociating sexuality and procreation, MAP tends to transform our centuries old concept of filiation. The child is no longer necessarily conceived in the womb of the legal mother: hence the possibility of both surrogate maternity and of using gametes from outside the couple, involving more than two subjects in the generative process, not necessarily a father and a mother according to traditional roles. 'New' filiations are thus created which are characterised *ab origine* by the mingling of biological and social elements.

All this gives rise to a complexity of ethical, medical, psychological and juridical questions and involves a comparison between a plurality of interests and rights that can even result conflicting among those involved in the generative process: those of the parents, the child, the donors of gametes and the members of the family.

Within the sphere of these situations, questions are increasingly asked the advisability to regulate the access to personal information about the procreation modalities. Various options are at stake with regard to filiation: secrecy, partial anonymity and the complete knowledge of the information regarding the donor.

⁷¹ Battaglia, Canestrari, d'Avack, Forleo, Garattini, Guidoni, Piazza, Toraldo di Francia, Umani Ronchi, Zuffa.

3. Secrecy

A first reflection stems from the fact that ‘secrecy’ and ‘anonymity’ are not always superimposable. Secrecy in MAP concerns the conception modalities. Anonymity refers to the genetic/personal identity or other information that regards the donors.

Only once the secrecy has been dropped can the question of anonymity be posed. It is evident that the request to know one’s origins can only be put forward by the person informed of the modalities of their own conception.

It must be remembered that the secrecy/anonymity problem can present different aspects according to the sexual identity of the donor and for the various subjects involved, the offspring, the donor and the pregnant mother. While in fact, biological paternity has always been uncertain, maternity – until MAP – represented the only certainty owing to cultural and psychological reasons therefore, it is possible for it to be easier to accept to not know the biological father than to be ignorant of the genetic mother. To this disparity is also added the diversity of the donation mechanisms: for women, in fact, the donation of the ovum can require prior to a regimen of hormonal stimulation, followed by an invasive operation, which is far more complicated than the way male donation is carried out. Instead, the donation of the female gamete to the woman who will carry the child does not change the bonding relational experience between mother and unborn child represented by the pregnancy. This is the main reason why the legal systems attribute a position of pre-eminence to the pregnant mother with respect to the genetic one, legally recognising her as the child’s mother.

The principle of secrecy, which on the one hand concerns the child and on the other the external environment, comes into autonomous choices and is generally left to the parents to decide (if, when and how), also because any obligation foreseen by the state, besides being hardly coercible, would weigh upon the private sphere of the persons and the dynamics of family life⁷². The problem therefore arises of the legitimacy or

⁷² In adoption, a different situation but often referred to in MAP questions, Law 184/1983, amended by Law 149/1999 in Art. 28 foresees that: “the adopted minor shall be informed of his/her condition and the adoptive parents shall take measures to do this in the ways and terms they deem to be most appropriate”. This is a “soft” formulation, with no intervention by the state, which leaves the parents a wide margin for decision making on the time, the modalities and the contents of the informa-

not of parental behaviour that prefers to maintain secrecy, impeding the offspring from asking themselves about their own existence in a complete way, with possible negative repercussions on family relations, particularly on the primary relationship of trust between children and parents. The reasons put forward in support of the choice to remain silent are many and can be summarised as follows⁷³:

- to protect the privacy of the parents in the procreative choice, also by reason of the possible stigma of sterility and to guarantee the 'imitative' desire of the social family towards the natural family⁷⁴;

tion. Nonetheless, it is evident that with such formulation the legislator intended to call to mind and stress the 'duty' of the parents to inform the adopted minor of his/her condition, or rather of an important part of their personal history. A duty that is reiterated by the social workers at the moment in which they verify the psycho-physical suitability of aspiring adoptive parents.

Even the foreign legislations allowing MAP with gametes from outside the couple are limited to regulating the principle of anonymity (protected in an absolute or partial way or not protected at all) and not that of secrecy. And it can be seen how in no Country in which the partial or full transparency has been adopted has a system been formalised to oblige the social parents to the truth (to verify in particular for Australia). Even if a transparency policy can obviously contribute to creating a climate in which the social parents are more greatly driven to tell their children about the modalities of their conception.

⁷³ These and other observations on the moral reasons leading to certain choices by the persons involved in this procreation need to be substantiated with empirical studies. Nonetheless the NBC must take cognisance that at the present time there are no scientifically exhaustive studies, and shared opinions on their needs, interests, and life experiences. The gathering of this data is particularly uncertain, confused, inhomogeneous and often superficial and just as often invalidated by preconceptions of various types (C. Flamigni, *Il secondo libro della sterilità. La fecondazione assistita*, Torino, 2008, p. 466). The Ethics Committee of the American Society for Reproduction Medicine (in "Fertility and Sterility", 2004, 81, pp. 527 ff.) discovered as new statistical data a greater propensity by parents with a child conceived by MAP to inform him/her on the modalities of their conception. But there are also contrasting data that show a percentage contrary to revealing the truth of the circumstances of their conception to their children and this happens also in the Countries that foster value-truth (V. Raditsky, *Donor conceived individuals' right to know*, in "Human Reproduction", 2010). A great number of children born from assisted insemination with donor however whose parents have never revealed the modalities of their conception are left out of the research. An insurmountable limit to the study sample is thus created which is usable in any research on the needs and experiences of life particularly of the offspring of the donor. Secondly, the recruitment strategies of the participants in the research by means of 'support networks' can lead to a significant partial selection of the study sample, insofar as it is probable that the individuals are members of these networks, for the very reason that they have problems of identity or because they have specific interests. Lastly, it must be considered that the persons conceived by donated or given gametes are still relatively few and young from the numerical point of view, and that therefore studies have not yet been completed that have ideally followed the individuals for their whole life and recorded the impact of their particular condition on the various phases of their lives.

⁷⁴ It must also be considered that in the hypothesis in which the oocyte is donated, the genetic data can be more easily kept secret within the family if the donor remains anonymous. Nevertheless, before the difficulty posed by the collection of oocytes, the possibility is not always excluded, as in the case of the use of blood or kidney donation, that it is the future recipient mother that indicates the

- to avoid any possible negative repercussions in the sphere of the couple on the child/social parent cohesion, in certain cases the latter being placed in a condition of asymmetry with respect to the other genetic parent;
- to guarantee the autonomy, stability and the interest of the family, including also the offspring in this, given that knowing without the due precautions may not always be the child's best interest and cause traumas and psycho-social distress.

These arguments deserve special attention owing to their delicate nature and the importance of the interests at stake, and by way of the particular vulnerability of the centre of such interests: the offspring and the harmonious development of their identity. Nevertheless, in the balancing of the various interests and points of view, in the costs/benefits evaluation and the consideration of the 'best possible good' for the offspring – the primary subject of parental responsibility – the Committee does not consider that secrecy on the conception modalities is an advisable option to guarantee the stability of the family and the right to the respect of the private life of each of its members, nor to safeguard the offspring's serenity.

Furthermore, secrecy is difficult to maintain over time and could constitute 'harm' for the child. Genetic tests are increasingly diffused and accessible to obtain information about genetic origins with the possibility of identifying the risks of illness and actual illnesses, and condition the reproduction choices on the basis of the knowledge of the biological parent's clinical data. This involves the need for a relationship that will continue in time between the donors of gametes and the medical centres operating in the sector, given the possibility that the donor is the carrier of genetic mutations with the possible late appearance of an unexpected and unsuspected illness, the knowledge of which could be important for the offspring in prevention and/or therapy.

woman who is available to give her ovocyte, who is often found within the sphere of the family nucleus. In these cases the presence of a genetic mother and a carrier for the child, meeting inside the family could generate friction with the questioning of the maternal role.

Other situations also exclude any secrecy for the most part. Undoubtedly in the so-called 'pro-creation on behalf of others' an almost automatic 'domino effect' of transparency is to be found in consideration of an involvement of different categories of persons: the pregnant woman and her family, the intended parents and the offspring, all with their own rights and duties. Lastly, it is taken for granted that the offspring ask about their origins in the case in which the family is made up of a single parent or composed of a homosexual couple.

In such context it is always less advisable that secrecy be maintained. A secret that, once disclosed late or by chance, could become even more serious, arousing unforeseeable reactions and generating a sense of betrayal and damaged identity and negatively influence family life, making all relations of trust based on truth difficult. Instead, information given to the offspring by means of filters and appropriate criteria (proportionality, sustainability, relevance, bearing, etc) on the modalities of their birth can make it possible to avoid such risks and to guarantee them the condition of knowing their genetic identity.

For this purpose the parents must be given complete and detailed information by the doctors during the consultancy phase preceding the access to reproduction technologies on the risks linked to the choice of secrecy. A number of studies have highlighted the loneliness of the parents at the moment of their decision and their poor preparation before the possible psychological distress of the children who get to know the truth. Adequate counselling during the entire 'disclosure' period, which takes into account also the psycho-physical maturity of the minor, is therefore necessary in order to make the users of the technique better prepared to take on their responsibilities and to fulfil the commitments connected with the procreation modalities they have chosen.

4. The search for one's biological origins

The donation/giving away of gametes implies the birth of a child on the one hand, and on the other enables the aspiring parents having recourse to the technique to realize a family plan.

In the 90s there was a propensity by the legal systems to establish that total anonymity were kept between the donor/recipient/offspring, except for cases linked to medical reasons. This solution was introduced for the same justifying reasons as secrecy, but above all in the name of the juridical protection of the social family and for the purposes of excluding the possibility of the donor expressing their own parenting project with the rights and claims connected to it. The choice of anonymity is analogous to the choice made in other juridical situations, like in the adoption of minors not recognised at birth, in which case one tends to clearly separate the natural family from the social one and to maintain the secrecy on the biological origins of the offspring when the mother claims anonymity.

Following an increasingly widespread use of MAP in its various forms and different social contexts, an inversion in the legislative tendency can be seen in the European Countries and also outside Europe: that of taking preeminent account of the claim of the minor or of whoever has become of age, once acquainted with the modalities of their conception, to be able to access the data concerning the donors⁷⁵.

These claims are frequent and tend to become a real right for many persons. Claims that find a multitude of reasons (psychological, social and religious). The importance of the awareness of one's own history is above all stressed for the construction process of their personality and for a harmonious psychological development.

It must also be remembered that claims have also been made to international conventions dealing with adoptions, to support the existence of a right of the offspring to know their own roots also in MAP in a similar way⁷⁶.

5. Partial anonymity and knowledge of the donors' personal data

5.1- As mentioned above, only once secrecy has been lifted, whether spontaneously or by chance, does the offspring have the possibility to ask for more complete information with regard to their origins. This request can be limited to information connected to health⁷⁷ or other queries about the donors or be extended also to the knowledge of their personal data.

⁷⁵ The Countries that have lifted anonymity are: Austria (1992); Germany (1998); Switzerland (2001); Holland (2002); Norway (2003); Great Britain (2004); Sweden (2006), Finland (2006). Outside Europe: New South Wales (2007); Western Australia (1999 and 2004); Victoria (1995 and 2009) and New Zealand (2004).

⁷⁶ Reference is usually made to the statements contained in the *Convention on the rights of the child* (1989) and in particular in art. 7 of such Convention that states that "The child shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by his or her parents". This provision is at times interpreted as an imposition on the states adhering to it to attribute to each minor the right to find their biological parents, even if the recommendation was made following the abduction of minors in South America and the irregular adoptions linked to this. A more substantial pretext to confirm the existence of a right to "one's origins" of the adopted minor can be found in the *European Convention on the Adoption of Children* (2008), which in Art. 22, para. 3, states that the competent authorities may, having regard to the circumstances, override the right of the child to know his or her parents of origin with respect to the right to the anonymity of his or her biological parents.

⁷⁷ The reasons most frequently put forward are of a health and psychological nature. For the former it must be taken into account that the donors undergo screenings to ascertain the existence or

This is nonetheless a psychologically delicate path to face considering the strong emotional impact that it can cause in the sphere of the persons involved in this search, which should be accompanied by the support of a multi-disciplinary body with a competent role of mediation, interacting with and speaking to those concerned.

From a general point of view it must be considered that in the donor/recipient/offspring relationship, anonymity is also always relative with regard to sperm centres and banks. Even if the information and collection system of biological data varies enormously⁷⁸, it is usually foreseen that in the records are kept, according to the recommended modalities, the names of the users, the gametes used, specific information on the ethnic group, cultural extraction, state of health, medical, personal and family history and other additional data given voluntarily and knowingly by the donors. On the one hand this data and information make it possible to identify certain physical characteristics of the donor that do not distance him/her too much from the recipient couple, and on the other to carry out the necessary controls and inspections, so as to avoid situations at risk such as multiple donations by the same person who in fact would increase the risk of genetic pathologies among the offspring of donors unaware of being consanguineous. Recently some legislations have established the need to obtain a wider range of information pertaining to the privacy of those donating gametes⁷⁹.

It is also not ruled out that the register includes the donor's 'desiderata' concerning the use of their gametes. For example, their consent or dissent regarding the use of their genetic material only to resolve a problem of sterility of medical origin of heterosexual couples and not to help in the

absence of a variety of common transmittable and inheritable illnesses. Therefore, screenings are presumably the most efficient method early on in the process to spare the child certain illnesses or the susceptibility to develop them during his or her life. Nevertheless, the data contained in the medical record of the single donor on their family medical history can be useful and any information given at a later date too.

⁷⁸ Registers can be foreseen with "identifying" and "non-identifying" information or "voluntary" registers.

⁷⁹ In the most recent legislation in Great Britain where the person supplying the gametes is asked the number of children born as a result, marital status, successive medical interventions; new identifying information, a possible good wish message to the future child.

desires of single persons or homosexual couples. Furthermore, the period of validity of consent given by the donor must be recorded in the register along with their will to be informed every time that their gamete is used. If not motivated by unacceptable reasons of discrimination, such recommendations and requests can be ethically legitimate and are even more justified in the standpoint of those who consider even the personal identification of the donor preferable, who in various cases could enter into contact with the offspring.

5.2 - The presence of these records therefore makes it possible to access the data by the person born from gametes outside one or both legal parents, in person if of age or through a legal representative if a minor and with the prior authorisation of the competent bodies. As mentioned beforehand, the offspring's search for their own biological origins can be limited to partial anonymity (allowing extensive information on the donors of different nature, without however revealing their personal data) or to including the knowledge of the donors' personal data. These different solutions are to be found in the legislations that have tackled this issue in MAP with donors of gametes, as said above.

It must also be considered that besides the two options outlined above, there is also the one that theorises the possibility of offering the donors of gametes the decision between partial anonymity and the possibility of being identified, and a similar possible choice to the beneficiaries between gametes obtained with anonymity or gametes with the possibility of identifying the donors. This is a solution that to date has been rejected by the European regulations to avoid falling into forms of discrimination of the offspring, placed in conditions of knowing their own origins in a more or less extensive way according to the 'single' and 'combined' desire of the parents and of whoever supplies the gametes. Hence this might result in the possible original discrimination between those who know and do not.

Lastly it must be pointed out that many of the psycho-sociological reasons for caution with regard to the minor's interests are no longer valid once the person born by heterologous fertilisation becomes of age: a structured solution to the problem is therefore necessary that takes such difference into account.

5.3 - The two remaining options, partial anonymity or complete truth are each supported by some of the Committee members, who back them up with different ethical considerations.

a) According to the members of the NBC⁸⁰ who consider it opportune to keep the anonymity of the donors of gametes, the reference to the offspring's interest to become acquainted with the information surrounding the donor is modulated and balanced with regard to other interests and rights, which are just as worthy of attention and protection, and cannot be automatically turned into a claim to know the personal data of the supplier of the gametes. The present possibility to dissociate genetic from social filiation poses the need to identify the best and most reasonable interest of the minor that cannot set aside a preeminent connection to the 'ethics of responsibility' in the sphere of any parenting project, whether it be natural or social. It is with reference to the 'best interest' of the minor that the reflection must be made on the so-called biological 'truth'.

Apart from the single cases, it necessary to ask whether the knowledge of the donor's personal data is generally a real advantage for the offspring, such as to be able to represent that *favor minoris* prevalent in family relations. Studies on this never fail to underline the importance for the child or adult, if this is their desire, to acquire information about their personal history, rather than their genetic origins. The offspring's need is to belong to a family as a child and to have the conditions for a proper psycho-physical development that can and must be guaranteed first and foremost by means of the solidity of the relations within the family nucleus. It must be furthermore considered that in the psychic development of the child, interpersonal processes are central, particularly the fusional experience with the mother, this remaining such when the social mother coincides with the woman carrying the child, despite the fact that the biological contribution is of another woman.

It is true that the desire to know one's roots exists, but this 'curiosity about one's origin' (as often called in literature) once again refers to the relational dimension rather than to the biological fact. This search is driven

⁸⁰ Battaglia, Canestrari, d'Avack, Forleo, Guidoni, Neri, Palazzani, Piazza, Toraldo di Francia, Umani Ronchi, Zuffa.

by the questions: Was I a wanted child? One seeks one's origin in order to verify the existence of a meta-biological as well as a biological bond with the donor. The search for the donor however cannot offer a real contribution to the construction of one's personal history: the donor is a stranger who has 'given' their gametes, with which the child has a merely genetic (and moreover partial) connection but certainly not relational or parental.

The search for the donor can perhaps be explained on the basis of the lack or inadequate handling of those fundamental affective phases of the parents/children relationship that push the latter to idealize imaginary unknown parent figures, in the identification of whom are based the hopes of finding a remedy to questions with no answer, and to the voids not filled by the family.

However, according to an ethical concept drawing on parental responsibility and the primary interest of the minors, cases of this type are not sufficient to justify the protection of the biological truth in an absolute way. So much so that, even in this case, the failure of family relations cannot be mitigated by the knowledge of the biological procreator, who in the case of the donor, has never had a parenting project.

It must also be considered that the legislations that support the truth principle are often led to put adoption and MAP on equal terms, whereas they are profoundly different. While in the case of the adopted child one can speak of a family 'history' before being given up for adoption, it is misleading to use this term for the simple genetic patrimony deriving from the offer of gametes. The access to one's roots has therefore a very different meaning for the adopted child: in some cases this knowledge could be of help for a better psychological elaboration of their refusal by the natural parents, a condition which instead is completely lacking in the birth by MAP.

Therefore, to speak about family 'history' for the MAP child or even of paternity/maternity with reference to the donor with reference to the genetic contribution, risks reducing genitoriality to the merely biological dimension.

Furthermore, a choice in favour of limited anonymity to the personal data of the donors is not in contrast with the Italian and international legislative panorama. The general principles of many foreign legal systems

have not represented the *favor veritatis* as an absolute right on the subject of filiation, for the purposes of not compromising the delicate work of balancing with the potentially colliding rights of the other persons involved. In the Italian system the *favor veritatis* finds many exceptions with regard to the interests of the minor, also irrespective of the legitimizing adoption of minors and the mother's right to maintain anonymity at the birth of her child. Reference is made to the normative hypotheses in which the best interest of the minor can determine – according to the phase in which it is taken into consideration – a reassessment of the biological data in the ascertaining of state.

The very prohibition, just and necessary, of the disclaimer of paternity in MAP with donors of gametes, set down also in the Italian legislation is also oriented in this direction. Moreover, this MAP technique finds its justification in a desire for procreation and in an aspiration to assume the social and affective role of parents. In such a perspective the principle of parental responsibility, regardless of the modalities of conception of the offspring, guarantees the constitutional provision of article 30, decreeing the duty of the parents to support, instruct and educate their children.

Relationality is therefore the supporting element of genitorality. In this sense the child is overridingly a son and a daughter, whose identity is progressively constructed, from the original fusionality to the detachment, within the parental coordinates.

Lastly, to establish the possibility of some kind of relationship of the offspring with the donors would turn into a complex of risks with effects on various persons, which would be much greater than the psychological harm that might be caused by the anonymity on the donor's personal data:

- alteration of the existential equilibrium of the original family with possible external interferences in the planning or privacy of the family⁸¹;

⁸¹ This is in breach of Art. 8 of the *UN Convention on the Rights of the Child* (1989) which guarantees the right to the respect of private and family life. A number of important observations can be made on the risks that the children and family run from the experience gained in France, where the legislation (2002) on adoption allows the minor, who has reached the age of discernment and through the legal representative, to have the identity of the woman who did not recognise him/her at birth to be revealed, on the condition that the latter renounces the secrecy of the birth. A detailed study carried out by the *Conseils National pour l'Accès aux origines personnelles* (CNAOP), that is the ministerial body appointed to deal with such practices, puts forward the proposal that the claims for access be

- absence of protection for the *status* of the mother who is the woman who carried the child in her womb and who in the legal systems, with the exception of the case of the maternity contract, is always considered the legal mother to the detriment of the genetic one;

- traumatic effects on the psychological balance of the ‘rediscovered’ donor and on their family dynamics;

- facilitation of forms of market, given that it is easier to ask the person supplying genetic material upon payment for absolute transparency or other forms of possible serious consequences, than the real ‘donors’ whose gesture is supposed to be based on the philosophy of voluntary free donation, mainly characterised by altruism and solidarity.

Therefore, in stressing the importance of the affective dimension and social filiation, one part of the Committee considers it ethically and juridically advisable that the anonymity of the personal data of the parents/donors/offspring be maintained, even though allowing the latter to access those data that, according to the circumstances, may be necessary for their psycho-physical health and for a deeper knowledge of the reasons and modalities of their origins.

b) The members of the NBC⁸² who deem it opportune that the offspring have the right to access information on their biological origins and therefore also the personal data of the donor of the gametes, depart from other ethical and juridical assumptions.

The basic standpoint, common to ethics and law, is marked by the connection between genitoriality and responsibility: or rather between the act with which one brings a human being into the world and the taking of responsibility for its life. Such connection is recognised as the principle of parental responsibility by the Italian constitution in art. 30, which – in line with the most advanced international juridical culture – places the duty of

allowed only to people of age, given the “strong emotional impact” caused by the “early sudden appearance” of other parental figures in the life of the adopted child, that risks having negative effects on the solidity of his/her affective ties with the adoptive parents, fostering damaging intrusions in their education process: “to search for the natural parents, when the child is still a minor is like letting a ghost into his/her family” (CNAOP, *Les demandes d'accès aux origines personnelles émanant de personnes mineures: l'âge de discernement*, 31 March 2010, in www.cnaop.gov.fr).

⁸² Amato, Bompiani, Colombo, D’Agostino, Di Pietro, Garattini, Gensabella, Isidori, Morresi, Nicolussi, Possenti, Scaraffia.

the parent to support, instruct and educate the children, even if born outside marriage. This duty generally concerns the biological parent, the so-called natural filiation being sufficient: the source of responsibility is therefore the very biological derivation and not the will to be or not be parents, nor the affection that can develop only within the relationship not in the constituting of it. Without this objective element the specific sense of filiation would be lost, which has direct effects on the person's identity and is different from any other personal relationship (love, friendship, etc.). To link parental responsibility to biological fact, to treat it as an irreversible relationship, voluntarily irrevocable, is coherent with the principle of the superior interest of the child, as laid down in many legal systems and international charters of rights.

It follows that in the relationship between the third party who has given their gametes and wants to remain unknown behind anonymity – a desire expressed by the legislations of some Countries in order to not discourage the donation of gametes – and the offspring from heterologous fertilisation who needs to know their biological origins for the development of their person, the interest of the latter should always prevail. Otherwise there would be a complete disruption in the protection of these two persons: in fact heterologous fertilisation already constitutes a derogation from the principle of parental responsibility, since it imposes a family *status* on the offspring that is different from the one they would have a right to, a *status* in which filiation is dissociated by the biological derivation on the basis of the choice of the adult subjects involved.

It is therefore opportune to take into account the tendency in many Countries to lift anonymity and introduce *favor veritatis* and to allow a right to knowledge – which as such can be exercised or not – rather than imposing the rule of concealing the identity of the genetic parent. Since the offspring born from heterologous fertilisation are discriminated against with respect to all the others, insofar as the artificial separation of the biological and family dimensions leads to a derogation from the right of every child to grow and be educated in his/her own family (Art. 1, L. No. 189/1983), a minimum of equity and the criterion of the prevalent interest of the minor should suggest recognizing the offspring at least the right to have access to the data relative to the identity of their biological parent.

The arguments in favour of the offspring's right to the truth are therefore based on the principles of equal social dignity and of non-discrimination, fundamental for ethics and the law: this is to avoid the offspring born by means of these techniques being represented as the only group of individuals who are legally prevented from having access to their biological procreators. An unexplainable discrimination would also arise with regard to adopted children who are instead recognised – in line with the legislative evolution on the subject of adoption which has stood back from the fiction of the *imitatio naturae* – the right to access information on their biological origins in adulthood.

This tendency to grant the right to know one's origins finds its foundation from the ethical and anthropological point of view in the principle of the respect of the autonomous development of the human being, which can be hindered by a removal of the past imposed *ab externo*. The notion of personal identity, linked to that of origin, earns a inevitable relational dimension, relating the person giving origin and the one taking origin: the idea of being born of someone cannot be absorbed in that of being educated by someone, even if the latter can generate significant solid relations. Furthermore, while it is not true that the claim to know one's biological origins necessarily turns into an imbalance of the relations with the family in which one has grown up, the risk of such imbalance appears more evident should the offspring find it impossible to satisfy the need to know their origins in order to better understand themselves.

As is well known, the relational structure of the person is such that the knowledge of oneself cannot be of a self-referential type: our identity is built by means of a continuous reference between the knowledge of ourselves and that of the others with whom we live. The biological connection with the person who contributed to our birth is not excluded from this interweaving, but constitutes a significant part of it, considering the inseparable connection between body and mind, bios and psyche.

Those facing heterologous MAP recognise the meaning of the biological connection between parents and offspring, and such recognition is at the root of their motivation in turning to this practice: it is nonetheless a partial recognition and contradictory to a certain extent. On the one hand a child is desired that will develop in the body of the woman who will be recognised as the 'legal' mother, who is born to her and who might possibly

have the genetic patrimony of one of the two members of the couple; on the other hand, it is assumed that the offspring will give no importance to the biological connection, imposing on them a ‘genealogical void’, which can have no ethical value, given that it is not in their interest.

Even though it is clear that it will never be possible to completely fill such void by having knowledge of a biological parent who has only donated their gametes – given that it will hardly become authentic interpersonal knowledge – it must however be recognised that the right to know one’s origins cannot stop at the threshold of knowledge of the procreation modalities or of the donor’s genetic data. For every human being the question about origins is in fact a question about identity, which cannot be sated by anything but the knowledge of ‘who’ has given origin to their life.

Lastly, it must be stressed that to evade the request to know the truth implies a specific form of violence: the violence of who, acquainted with the truth about another person and in a position to convey it, refuses to do so, maintaining towards that person an undue position of power. This argument has further importance when this subject is the state: the subject of the supreme principle of public law identified by Kant must be remembered, which cannot be that of publicity, of the abolition of the *arcana imperii* in any form at all. The state does not have the right and should never have the right to preclude the access to truth not only to its citizens, but to any human being, in particular when the subject of this truth is personal identity.

Nevertheless, the legal system must not assume the principle of truth in an abstract way, predetermining it in obligatory forms, but foresee it with reference to the only subject that can be existentially concerned by it, that is the offspring, and only when they and they alone vindicate their right to knowing the truth: a right that the legal system cannot and must not censure under any profile at all and least of all under that of the psychological motivations that might support it. In line of principle, a legal approach that corresponds to what characterises all medical practice: every subject has the absolute right to be acquainted with the conditions of his/her own health and to be informed with regard to all medical treatment that he/she may have to undergo in the present time or had to undergo in the past. The need remains to direct the information modalities according to the actual circumstances and possibly with the help of a counsellor able to

give the necessary support. Whereas when the offspring has come of age there is no reason to limit the possibility of exercising the right to know their origins, a certain amount of caution in the case of the minor seems opportune. During this period the prevalent interest of the minor, that is theoretically oriented in favour of the knowledge of his/her origins, could actually call for caution, time, the ascertainment of the psychological conditions of the minor, the identification of the best ways to obtain non-traumatic knowledge for himself/herself and the equilibrium of the family in which he/she lives.

The responsibility of whoever allows such forms of procreation is nonetheless recommended and which should at least manifest itself in the possibility of giving the legal parents the information and consultancy necessary to suitably start the relationship with the offspring born by means of this procedure, so as to avoid situations being created such as to make the knowledge of the truth more traumatic.

6. Recommendations

The Committee is in agreement with recommending the following:

1. To avoid harming the dignity of the person with discriminatory attitudes by society in consideration of the modalities of his/her conception.
2. To consider that when the offspring born from heterologous MAP is a minor, it is the moral responsibility of the parents to inform them of their origin through appropriate filters and criteria: proportionality, sustainability, relevance, bearing, etc.

This responsibility must be exercised with generosity and loyalty towards the minor, in the full respect of the principle of the superior interest of the same and the autonomous development of his/her person, expressed by the socio-cultural values, juridical traditions of Italy and by the international conventions safeguarding him/her.

3. To recognize, according to the modalities to be entrusted to the legislator, the right of the offspring, when coming of age, to access information concerning their origins, should they request it.

4. To foresee, should the care and protection of the health of the minor make it necessary, that the doctor and/or medical facility, being acquainted with the modalities of procreation of the child, the parents having been

fully informed of this, or upon their authorization or in the case of a refusal on their part, of the competent judicial authority, have the possibility to ask to access the records and the use of the necessary data for the diagnostic and therapeutic treatment of the underage patient.

To encourage the possibility for there to be a continuative relationship in time between the medical centres and the donor, for health reasons.

5. To foresee the setting up of multi-disciplinary bodies able to guarantee suitable counseling and support for all the subjects involved in the ‘search for their origins’.

6. To keep a register of the identity of the users in the sperm banks or in the authorised centres, with a record of the gametes used and the information obligatorily and/or spontaneously given by the donors and in the respect of the modalities set down by the European directives⁸³.

PERSONAL REMARKS

Personal remark signed by Prof. Maria Luisa Di Pietro

In expressing my vote against the document ‘Knowing one’s biological origins in heterologous medically assisted procreation’, I shall now briefly give the reasons for such dissent.

The recourse to Medically Assisted Procreation (MAP), even in the heterologous form, has led to a profound distortion of the meaning of generating and genitoriality. Expanding the parental roles – the biological parents (the ‘donors’ of spermatozoids or egg cells), the carrier or surrogate mother (according to whether she has given only her womb or ‘donated’ also the egg cell), the social parents – MAP in the heterologous form breaks this fundamental bond for every human individual between biological identity and social identity.

Notwithstanding the desire for a child by the intended parents, the endorsement of society and the improper equivalence with the institute of adoption, in the heterologous form MAP in fact deprives the offspring of the guarantee of being desired and brought into existence within an exclusive

⁸³ At present: Directives 2004/23/EC; 2006/17/EC and 2006/86/EC.

interpersonal relationship, violates their right to knowing their family identity and introduces elements of social disorder that are not easy to handle. It suffices to think of the hardship in reconstructing a family medical history in a context in which the parental relationships have been overturned.

The fact that with this document some of the members of the National Bioethics Committee want to put a limit to the grave injustice of being deprived of the knowledge of one's genetic roots, recognising the right to access this information is without any doubt positive, but it is absolutely not sufficient. In fact it is not taken into account that such violation is the mere consequence of the recourse to MAP in the heterologous form. And it is somewhat singular to debate on the consequences without dealing with the cause generating them.

In Italy where Law No. 40/2004 prohibits the recourse to donors of spermatozoids and egg cells or to the borrowing of the womb in a MAP process, a deeper reflection on the issue would have been expected. This is also in the light of the recent sentence by the European Court, which establishes that to prohibit MAP in the heterologous form in no way whatsoever constitutes a violation of the rights of men, indirectly endorsing the same Italian Act.

In my opinion, by reducing all reflection on MAP in the heterologous form to the mere knowledge of one's biological origins, the opportunity has been lost to analyse a problem which, apart from the different and often irreconcilable ethical positions, calls to account the responsibility of each one of us for the difficulties that this creates for the unborn child, society and also those social parents that very much desired and sought after it from the start.

Personal remark signed by Prof. Carlo Flamigni

The specific and systematic reasons for my vote against

A short introduction is necessary to make the reasons for my dissent more understandable. The donation of gametes is prohibited in Italy by Law No. 40; to get around this prohibition every year thousands of couples go to Countries where the donation of gametes is legal, preferring those that

guarantee secrecy. I have asked about one hundred couples over the last year, who told me about having decided to leave Italy to obtain a donation (above all of female gametes), what their intentions were and nobody answered that they had already decided to inform the child that would be born as a result of their choice of their conception modalities; most of the couples told me that they wanted to take time over their decision, taking into account the child's character and sensitivity, and numerous others openly declared that they wanted to keep it to themselves.

There are no foreign Countries in which the 'donation' of gametes exists but they are almost always purchases, more or less covered up. In Italy, in the period running up to the approval of Law 40 this was not the case as the donations of oocytes were all made using the supernumerary gametes of women who had done MAP and to my knowledge none of them ever received any payment (or favour) at all in exchange. This could be reproduced, but female donors would certainly not be found if a law existed forcing them to be transparent, as maintaining secrecy was the thing that they were all so keen to do in particular. But those seeking fortune in Europe do not just have to worry about the high costs but also about the lack of guarantees (the recent scandal of the MAP laboratories in Cyprus should be a demonstration of this) and an indefinite number of cases of abuse of power, great and small, like having to undergo laboratory tests which are just as expensive as they are useless. It is practically impossible to protect these couples and this is a scandal nobody wants to tackle, least of all the NBC. In the cases that I have referred to I can see many reasons that could justify an intervention by the Bioethics Committee; the NBC has chosen to ignore them all and to write a document that concerns only biolaw, filling it furthermore with highly debatable arguments. As recently reported in a newspaper by one of our best known sociologists, the subject dealt with has nothing to do with bioethics but concerns only the complex problems of family relations and should be dealt with by true experts (who do not exist in the NBC) and with great compassion (of which I do not seem to have seen any trace).

My most specific criticism starts from the title of the document, in which the word 'heterologous' appears. I quote the meaning of the word according to a number of Italian dictionaries:

Sabatini-Coletti: 'of organ, tissue or organic substance coming from a species different to the one in question';

Sapere.it: ‘of a different species, presenting diversity in its structure’;
Treccani: ‘of organ, tissue or organic substance that comes from an animal species other than the one considered’.

Et cetera.

I asked not to use this word, which was introduced to superimpose an element of bestiality on the donations of gametes, but the only answer I was given is that the word is present in the text of Law No. 40: that is, it is used in the most indecent act (I am speaking from a lexical point of view) that I have ever had occasion to read, the same one that considers sterility and infertility synonyms, which was thrown out by the Constitutional Court, and which was put together with the precise aim of not lasting. For the love of peace, I shall avoid judging those who intended to take it as an example.

1. The aims of the opinion do not come into the institutional competences foreseen and the ethical analysis is lacking

I have something to say with regard to the aims of the document that are as follows:

‘to offer the legislator of Italy a series of arguments that might help *to create legislative acts to deal with the problems of an ethical and juridical nature which arise before the request of the offspring born by means of the technique of assisted fertilisation with gametes from outside the social parents to know the modalities of their own birth.*

In formulating this opinion *the NBC does not intend to go into the ethical evaluation of MAP* nor into its legal regulations in Italy. This is also considering that in the Committee, as in the past⁸⁴, agreement on the bioethical stances concerning MAP has not been reached. Some members are in favour of the prohibition set down by Law No. 40/2004 on the fertilisation with donors of gametes, maintaining that such practice lacks ethicality, alters the statute of medicine and comes into conflict with some fundamental human and inviolable rights, regarding the dignity of the person and the rights of the unborn child. Others do not share the absolute

⁸⁴ NBC Opinion on assisted procreation techniques. *Synthesis and conclusions*, 17 June 1994 and *Assisted fertilisation*, 17 February 1995.

prohibition of such technique, in itself not ethically reprehensible: consequently they consider that in some hypotheses expressly foreseen by the law, heterologous MAP must be allowed’.

First of all the *declared aim* is not foreseen by the NBC’s competences, at least with those declared in the official site which reads as follows: ‘The Committee carries out the functions of consultancy ... and functions of information ... on ethical issues arising from the progress in research and technological applications in life and healthcare sciences’. Its help is not foreseen ‘in drafting legislative acts’ which is a task of a technical-judicial nature and very different from ethical analysis. Perhaps the NBC aspires to substituting or influencing the Parliamentary Committees or other organs in charge of this, but in this way steps out of its specific mandate: something that alone divests the opinion of foundation.

On the other hand one can see that the ‘legislative acts’ in question concern issues of an ethical kind and it is a question of examining which ones they are, so as to formulate a more exactly ‘ethical’ analysis.

The opinion states that the issues of an ethical nature are generated by

1. the request of the offspring;
2. by assisted fertilisation;
3. wanting to know the ‘modalities of one’s birth’;
4. when this takes place ‘with gametes other than those of one’s social parents’;
5. practice to be considered irrespective of the ethical evaluation of MAP as a new reproduction technique;
6. and irrespective of the ethical evaluation of Law No. 40/2004;
7. since there is dissent on the ethical evaluation of MAP as such;
8. for some the prohibition of the donation of gametes in Law No. 40 is i) lacking in ethicality, ii) alters the statute of medicine [with an operation similar to that of witches who faked reality?], iii) violates fundamental and inviolable human rights;
9. while for others i) the absolute prohibition cannot be shared [foreseen only by Catholic morals, which does not preclude that there might be concurrences on a prima-facie prohibition], ii) they can grant that it is not reprehensible [not that it is good and can represent moral and civil progress!], iii) and therefore in some specific cases ‘strictly foreseen by the law’ it is even benevolently allowed.

This list was necessary to immediately highlight four aspects:

First: there is a claim (in No. 5) to disregard the *ethical* evaluation of MAP as practice, an ethical evaluation which furthermore (with considerable confusion) seems to be equivalent to the one given by Law 40/2004, where we pass from No. 7 to No. 8 giving the ethical motivations which are assumed to underpin Law No. 40.

Second: the asymmetry between the strong concrete reasons of those against the prohibition foreseen by Law 40 against the donation of gametes – which are in general valid against MAP – and those weak and hesitant reasons of those in favour, who anyway limit themselves to granting the practice only within *strict* provisions!

Third: the claim to avoid any evaluation is a promise that is not kept, something that arises from the first points of the list. In fact it would be necessary to understand why the ethical problems arise only when the children ask:

1. to know ‘the modalities of their birth’
2. when they were born by assisted fertilisation
3. by means of the help of ‘gametes coming from outside the social parents’.

It could be asked why the opinion limits the problem to only this modality of birth, and does not consider others like the cryopreservation of gametes, the places in which the conception happened (on the beach rather than on the back-seat of a car), or the positions of the coitus, or the reasons leading the parents to plan that birth (granted that there were any, and with particular regard to the sobriety of the couple or to the existence of particular motivations, like the existence of a first child that is ill and to whom the second one could donate marrow or organs). In other words the document is concerned about making it clear from the very beginning that a problem exists, which means that it is not true that it sets aside its ethical evaluation. From the start it is assumed that the donation of gametes creates particular difficulties with respect to other ‘modalities of birth’. The ethical evaluation therefore exists and it is implicitly already present in the way in which it is stated and in the definition of the problem, that is, in the form in which it is presented. And the difficulty would be determined by the fact that the birth takes place thanks to the presence of ‘gametes coming from outside one’s social

parents', where the adjective 'outside' indicates the *rift* created right within the social relations. The term is only apparently neutral, but in reality it indicates the existence of an 'intruder', 'someone that has nothing to do with it', and who instead is present on the scene. This confirms that it is not true that it disregards:

A) the ethical evaluation of the specific content of Law 40, or the prohibition of the donation of gametes;

B) the ethical (and social) evaluation of the *consequences (even social ones)* of the prohibition foreseen by Law 40, considering that the problem to be dealt with was created by the prohibition to donate gametes foreseen by Law 40, as the opinion itself recognises in its opening lines: even having prohibited the donation of gametes, 'nothing however is said by this act with regard to the issue of the protection of the children's interest to know the truth about their conception and the opportunity or not to inform them about their biological origin'.

Having passed a law which, prohibiting the donation of gametes, creates a stigma around the practice, lets it be understood that the problem will be examined *in vacuo*, or regardless of the ethical and social context that has been created and that any evaluation of the law will be avoided.

Apart from the initial error of wanting to help in 'drafting legislative acts' to resolve the issue, (something that does not come into the NBC's competences), 'to deal with the questions of an ethical and juridical nature which arise before the offspring's request by means of the assisted fertilisation technique with gametes from outside the social parents to know the modalities of their conception', this cannot be done without first having specific knowledge of the historical circumstances (or social context) in which the problem arose and without giving a social and ethical *evaluation* of this situation. For example, it will be necessary to begin to establish whether the prohibition has reached the objective foreseen or whether instead it has basically failed, and on the basis of this first evaluation to analyse its social effects in order to give a positive or negative judgement of it. This involves the clarification of an evaluation *criterion* that the NBC does not give. To claim to deal with the problem *as if* were possible regardless of the knowledge and evaluation of its context, means to distort the ethical analysis that one sets out to carry out from the start.

Even granted that the opinion is a bioethical one (a false premise considering the explicit declaration of purpose), the ethical analysis of the problem is lacking and unacceptable since it claims to be able to do without the analysis of the historical context and its indispensable evaluation. This initial error is reflected in the whole opinion. The presumed ethical ‘neutrality’ is manifested in giving as implicit what instead should be made explicit, analysed and discussed. It cannot be understood how a Committee of ‘experts’ can produce an opinion of such modest cultural profile, which repropose the same banalities repeated over and over again in our terrible pseudo-cultural talk-shows.

2. The definition of the general problem of the access to MAP: where the negative evaluation lies

Once again I shall begin with the analysis of the text with which the NBC sets out the general problem to be dealt with, which is presented as ‘innocent’ in order to show how instead it is full of prejudices. The access to MAP in its different forms is sought after not only by heterosexual couples, united or not in marriage, but also by homosexual couples or by single persons of both sexes. MAP, dissociating sexuality and procreation, tends to transform our centuries old concept of filiation. The child is no longer exclusively conceived in the womb of the legal mother (given also the possibility of surrogate maternity) and the persons involved in the generative process can be more than two, not necessarily a father and a mother according to traditional roles. ‘New’ filiations are thus created which *ab origine* are characterised by the mixture of biological and social elements.

This gives rise to a complexity of ethical, medical, psychological and juridical questions and requires a comparison between a plurality of interests and rights that can result even opposing among those involved in the generative process: the interests and rights of the parents, the child, the donors of gametes and the members of the family.

Within the sphere of these situations, the question is increasingly asked regarding the advisability to regulate the access to personal information on the procreation modalities. Various options are at stake with regard to filiation: secrecy, partial anonymity and the complete knowledge of the information regarding the donor.

The first point to stress concerns the underlining of the *dissociation* between sexuality and procreation created by MAP, which ‘tends to transform our centuries old concept of filiation’. Various elements must here be considered.

1. From the start it is peremptorily stated that MAP tends to transform something that should instead be part of our tradition, our culture and that ‘common sense’ which religion has contributed to creating within each one of us, something proposing this technique as a source of ‘subversion’, leaving one to imagine it as something reprehensible.

2. There is not much more said about the donation of gametes in a heterosexual couple (as it seemed to be inferred from the initial assumption), but the least common cases are immediately highlighted, like those of homosexual couples and single women, to finally stress the already mentioned transformation of ‘our centuries old concept of filiation with the creation of new social roles and above all with the increase in the number of ‘parents’ (who are no longer only two but increase continuously in number). This presentation in itself is not ‘neutral’ considering that it stresses the concern (if not the sense of ‘panic’) about the profound changes taking place. A more ‘neutral’ presentation of the problem would have chosen as starting point the importance of the difficulties many have with reproduction, and which are for the most part resolvable thanks to the donation of gametes, a solution that already existed (with quite peculiar modalities) even in the traditional concept of filiation and which is now extended to new situations and should be carefully considered.

3. The negative evaluation of the donation of gametes already clearly presented at the beginning of the document is shown and clarified in the reasoning that follows, in which the NBC states that, by creating ‘new’ filiations which ‘*ab origine* are characterised by the mixture of biological and social elements’ the new practice gives rise to ‘a complexity of ethical, medical, psychological and juridical questions’ owing to the presence of ‘a plurality of interests and rights that can result even opposing among those involved in the generative process: the interests and rights of the parents, the child, the donors of gametes and the members of the family’. This representation of the problem is misleading and wrong since it presupposes – at anyway leads one to believe – that the *conflicts* (those due to the plurality of interests and contrasting rights) between the interested parties

arise exclusively in the case of donations of gametes and do not exist or are irrelevant in *natural reproduction* in which the contrasting interests would disappear in favour of peaceful harmony.

Despite the claimed ‘neutrality’ and the intentions to avoid any moral evaluation with regard to the donations of gametes, this strongly negative (and catastrophic) formulation of the approach to MAP allows the identification of the problem arising from the fact that ‘Within the sphere of these situations, the question is increasingly asked regarding the advisability to regulate the access to identification information on the procreation modalities. Various options are at stake with regard to filiation: secrecy, partial anonymity and the complete knowledge of the information regarding the donor’.

The error in this formulation lies in supposing that an analogous problem is absent in the so-called natural fertilisation, which is absolutely not true nor likely.

3. Why the formulation given by the NBC to the problem of knowing one’s origins is misleading

In order to develop the argument on the specific subject of the knowledge of one’s origins the opinion introduces a number of terminological distinctions among which that of ‘*secrecy*’ (which ‘in MAP concerns the modalities of conception’), and ‘*anonymity*’ (which instead refers to genetic/personal identity or other information about the donors). The differences existing with regard to anonymity are stressed according to the different ‘sexual identity of the donor’, underlining that ‘it is easier, owing to cultural and psychological reasons, to accept to not know the biological father than to be ignorant of the genetic mother’. In reality, my long experience teaches me that it is exactly the opposite, and I could even try to explain the reasons for this, but nobody in the NBC has taken the trouble to ask my opinion. However, continues the opinion, notwithstanding this and despite the greater invasiveness involved in the donation of oocytes, ‘the donation of the female gamete to the womb of the carrier does not change the relational bonding experience between mother and unborn child represented by the pregnancy. This is the main reason why the legal systems attribute a position of pre-eminence to the carrier of the child with

respect to the genetic mother, legally recognising her as the child's mother (and thus belittling the genetic aspect!). In fact magistrates have made different choices in many Countries, and even in many American states the judges have delivered contradictory verdicts. Furthermore, there are Countries that entrust the choice of the 'real mother' to the existence of a contract between the two women and to the contents of the same. In any case it is not clear why more attention was not paid to this obvious contrast between cultural tradition [only one? Which one?] and the recent legal decisions as well as the many contradictions of the courts...

After the theoretical and conceptual analysis the opinion goes on to discuss the normative hypotheses, stating that 'The principle of secrecy, which on the one hand concerns the child and on the other the external environment, comes into the autonomous choices and is generally left to the parents to decide (if, when and how), also because any obligation foreseen by the state, besides being hardly coercible, would weigh upon the private sphere of the persons and the dynamics of family life. The problem therefore arises of the legitimacy or not of parental behaviour that prefers to maintain secrecy, not letting the offspring ask themselves about their own existence in a complete way, with possible negative repercussions on family relations, particularly on the primary relation of trust between children and parents. The reasons put forward in support of the choice to remain silent are many and can be summarised as follows'.

Deferring the analysis of the reasons for and against, here it can be seen that the opinion could have paid greater attention to the clarity of language, seeing that this part of the document is somewhat contracted and a little unclear and would have benefited from some comprehensible definitions.

First of all *the principle of secrecy* is the normative criterion that grants a person the right to keep their personal data reserved, forcing third parties to comply with their request. In the sense referred to here, the principle of secrecy concerns licit and legitimate practices that have nothing to do with occult schemes capable of blurring social relations. And in this sense too, the principle is applied, for example, in the case in which I were diagnosed with an illness or had to have an operation, guaranteeing me the right to maintain secrecy and obliging the people taking care of me to help me keep it.

In the case of the donation of gametes this right can have consequences for the offspring and the external environment, but it is not clear in what way this ‘might concern’ these aspects more than what happens in the case of an illness or a bank account, unless the practice in question is considered socially non-transparent or illegitimate: an ethical evaluation that the NBC has stated it does not want to go into. The problem should at least have been examined.

In second place, the principle of secrecy, in the sense understood above, is not something to include ‘among the (possible) autonomous choices’ which the subject is granted, so that ‘usually it is left to the parents to decide (if, when and how)’ also because any intervention by the state is ‘hardly coercible’ and would then weigh ‘upon the private sphere of the persons and the dynamics of family life’. This way of representing the problem is at least less debatable, since the principle of secrecy is not something marginal, but is a central principle which establishes very personal rights which must be respected not because they ‘hardly coercible’ on the external level, but because they affect the nucleus of the personality and identity. In other words they are part of personal autonomy.

I understand that the reference to autonomy and self-determination may arouse some degree of concern, but I do not think that I am alone in reasoning in this way. I therefore find the formulation given to the problem misleading that poses the principle of secrecy as something extrinsic and as a possible option among many, since this formulation overturns the ethical order of the question that should collocate the legitimate requests deriving from the principle of secrecy at the centre of moral life and make it one of its cornerstones. This obviously does not mean that it is a question of *absolute* claims as even the duties deriving from the principle of secrecy, in some specific circumstances, can be suspended or subordinate to needs of a higher order. In order to do this however the burden of proof falls on the person asking for the exception, who will have to advance concrete reasons to justify such request. In the other case, instead, when the principle of secrecy is one of the possible options, it seems almost that the other needs are prevalent and that it is the job of the person concerned to give reasons to support the legitimacy of secrecy in their particular reproduction situation, inverting the burden of proof.

This inversion of the burden of proof presupposed in the formulation of the NBC's opinion is confirmed when it states that there arises 'the problem of the legitimacy or not of parental behaviour that prefers to maintain secrecy, impeding the offspring from asking themselves about their own existence in a complete way, with possible negative repercussions on family relations'. As can be seen, it is up to the person that wants secrecy to give the reasons to justify their own choice and not the other way round. It is an uphill battle to their disadvantage, since the opinion immediately highlights the fact that secrecy impedes 'the offspring from asking themselves about their own existence in a complete way, with possible negative repercussions on family relations', whereby the principle of secrecy appears as being socially dangerous and such as to impede the 'complete' development of one's children: this is undoubtedly inappropriate if not despicable and aberrant.

Apart from the reversal of the principle regarding the normative level, two considerations are needed to demonstrate the fallacy that is implicit in the formulation given to the problem. The first one regards the fact that the request to declare the 'truth' to the offspring to allow them 'to ask themselves about their own existence in a complete way' is *only* and *exclusively* valid for the children born by assisted fertilisation with donation, and not for *all children*. Equality is not taken into account at all and is put aside as it is taken for granted that the very 'assistance' in reproduction creates difficulties and problems and is not a question of a simple extension of 'natural' reproduction. The second observation concerns the very generic character of the presumed 'harm' caused by secrecy, insofar as it is limited to mentioning two seriously negative effects: 1) the fact that secrecy would impede 'the offspring from asking themselves about their own existence in a complete way'. But is this really so serious and important? And what does 'asking themselves in a complete way' mean? Is it not true that during religious education one can find oneself before a similar obstacle? And what about the children born from adultery? Or from incest? And what about those children born from a legitimate marriage by the woman's calculated interest, to secure some kind of benefit, or to be guardians for a disabled sibling? As can be seen, as soon as one reflects on the presumed 'tragedy' implicit in the maintaining of secrecy, the entire construction becomes blurred. 2) The other negative

effect would consist in the ‘possible negative repercussions on family relations’, an aspect that undoubtedly contains an element of truth, but which – once again – must be considered at the same level as other secrets (for example, bank accounts) which also have negative repercussions on family life.

The very formulation of the problem thus appears to be misleading. We can now move on to the examination of each single point.

4. Analysis of the reasons for and against secrecy

According to the NBC the reasons in favour of the principle of secrecy are the following:

1) ‘to protect the privacy of the parents in the procreative choice, also by reason of the possible *stigma of sterility* and to guarantee the ‘imitative’ desire of the social family towards the natural family’;

2) ‘to avoid possible negative repercussions in the sphere of the couple on the child/social parent cohesion, in certain cases the latter being placed in a condition of asymmetry with respect to the other genetic parent’;

3) ‘to guarantee the autonomy, stability and the interest of the family, including the offspring in this too, given that knowing one’s origins, without the due precautions, may not always be the best interest of the child and be the cause of traumas and psycho-social distress’.

The opinion states that ‘these arguments deserve special attention. Nevertheless, in the balancing of the different interests and points of view, in the costs/benefits evaluation and the consideration of the ‘best possible good’ for the offspring, the secrecy on the modalities of their conception is not considered a recommendable option by the Committee to guarantee the stability of the family and the right to the respect of the private life of each of its members’.

It must be noted that the NBC recognises that the arguments in favour of secrecy ‘deserve attention’: an important and generous recognition that shows the broad mindedness of the Committee itself, and for which I express my gratitude since I expected worse. Unfortunately what follows seriously betrayed my expectations: in fact, the NBC simply states that in ‘consideration of the ‘best possible good’ for the offspring, the secrecy on

their procreation modalities is not considered a recommendable option by the Committee to guarantee the stability of the family and the right to the respect of the private life of each of its members'. One cannot help but detect the apodicticity of the statement, since the Committee takes on an oracular tone by means of which to guarantee that, in consideration of a vague and elusive 'best possible good' for the child, 'secrecy on the modalities of their procreation' would not be recommendable. If the NBC's proposition were to be taken literally it would be acceptable, as it would concern any form of 'procreation modalities', including the natural one: but unfortunately it is evident that the NBC intends to refer only to the assisted reproduction modalities.

The two reasons adopted appear to be somewhat little comprehensible. In the first place they refer to a standpoint of the consequentialist type which is nevertheless left indefinite and seems plausible only on the strength of costs/benefits, in turn only evoked by allusion and not specified as would be necessary. To be more precise, with regard to the first one it is not at all clear either in which sense the elimination of secrecy might guarantee in itself the stability of the family, or least of all in which sense this stability is so important for the 'best possible good' of the children, unless to suppose that also divorce is seriously reprehensible or that it must be prohibited in view of this 'best possible good' (which at this point would become an unbearable pall: but is it really true that parents must lead their lives in view of the 'best possible good' of the offspring? The second reason becomes even less clear, since the right to the respect for private life would seem to be in favour of secrecy, should this be requested by the person concerned.

In order to complete the analysis it is opportune to examine the other reasons put forward, which are also of an empirical/factual type. The first is that secrecy is 'difficult to maintain over time and could constitute 'harm' for the unborn child. Genetic tests are increasingly diffused and accessible to obtain information about genetic origins with the possibility of identifying the risks of illness and actual illnesses and condition the reproduction choices on the basis of the knowledge of the clinical data of the biological parent'. As a corollary of this appears the recommendation to medical centres in this sector (which are prohibited in Italy, the reason why the NBC seems to want to dictate the rules to the world, being a little guilty of

presumption) to maintain the relations with the donors, 'given the possibility that the donor is the carrier of genetic mutations with the eventual late appearance of an unexpected and unsuspected disorder, the knowledge of which could be important for the child in a preventive and/or therapeutic sense'. The second reason is that a secret 'revealed with delay or by chance, could become even more serious, arouse unforeseeable reactions, generate a sense of betrayal, of damaged identity and negatively influence family life. Instead, information given to the offspring by means of appropriate filters and criteria (proportionality, sustainability, relevance, bearing, etc) on the modalities of their birth can make it possible to avoid such risks and to guarantee them the condition of knowing their genetic identity'. As corollary of this consideration is the provision of 'complete and correct information by the doctors during the consultancy phase before the access to reproduction technologies on the risks linked to the choice of secrecy. A number of studies have highlighted the loneliness of the parents at the moment of their decision and their poor preparation before the possible psychological distress of the children who become acquainted with the truth. Adequate counselling over the entire 'disclosure' period, which takes into account also the psycho-physical maturity of the minor, is therefore necessary in order to make the users of the technique ready to take on this responsibility and fulfil the commitments linked to the procreation modalities they have chosen'.

Apart from the fact that the difficulties in maintaining secrecy and the relation between the appearance of these difficulties and the availability of simple genetic tests to everyone is an extraordinary lie (I can barely avoid the term 'ridiculous' which none of the members of the Committee like), the two reasons adopted do not add anything significant to the previous oracular discourse, of which they have the same generic character and the anti-technical prejudice that leads to idealising the idyllic climate of the 'natural family'. In fact the observation on the genetic tests is also valid for occasional partners, an aspect that is neglected and the due consideration of which changes the framework of the situation. With regard to the additional problems of the delayed revelation of the truth, they are presented in completely hypothetical and evocatory ways, following well-known forms of 'psychological terrorism', also because other numerous hypotheses of revelations are certainly possible that could be welcomed

with fondness, interest or pleasure. The only new aspect lies in the two corollaries: the first, which expresses a certain tendency to omnipotence leading the NBC to the claim to give advice beyond its limits too; the other one, instead, behind a kind form of ‘help’ to the (poor) parents who have recourse to assisted fertilisation, conceals a subtle form of stigmatisation, insofar as they would implicitly become class B parents who would need suitable counselling to eliminate the ‘harm’ deriving from recourse to a dangerous technique and is made ‘necessary in order to make the users of the technique ready to take on their responsibilities and to carry out the commitments linked to the procreation modalities they have chosen’.

As far as concerns the reasons that the NBC considers ‘worthy of attention’, it must be noted that the first one pertains to the protection of the ‘privacy of the parents in the procreative choice, also by reason of the possible stigma of sterility and to guarantee the ‘imitative’ desire of the social family towards the natural family’. It is very strange that the only argument in support of the right to privacy is, once again, of a factual and empirical nature, and regards the need to avoid any possible harm to the dignity and social prestige and the ‘imitative’ desire of the ‘natural’ family. It seems that should the extrinsic factors be eliminated (completely negative), the right to privacy would have no reason to exist and the ‘natural family’ model could shine in all its brilliance. An inversion of the argument is made in this way, since the right to privacy is fundamental and – at most – the empirical considerations can strengthen the argument.

To tell the truth there are also other considerations to be made. The first is ‘to avoid possible negative repercussions on the child/social parent cohesion in the sphere of the couple, in certain cases the latter being placed in a condition of asymmetry with respect to the other genetic parent’: once again a consideration of a psychological nature about the possible (generic and vague) negative repercussions on the child/social parent relationship. Also here there is no denial that these difficulties might exist, but it is astonishing that the negative repercussions existing between offspring and biological parent are never mentioned, and which are often a lot more serious: is everything perhaps idyllic and harmonious in the natural family?

A further consideration is ‘to guarantee the autonomy, stability and the interest of the family, including the child in this too, given that knowing one’s origins without the due precautions may not always be the best

interest of the child and can cause traumas and psycho-social distress'. It is interesting to observe that here the pivot of the argument is addressed to the *family*, which also includes the offspring whose best interest must be given priority. Once again a thesis of an empirical and consequentialist nature, which moreover concerns the family without considering the individual and their rights.

Conclusion: the NBC does not appear to have understood the reasons of the supporters of secrecy and represents them inadequately and partially.

5. The new 'social attitude' to the donation of gametes and 'ethically legitimate' guidelines on their destination

Having outlined its reasons for the disclosure of secrecy, the NBC acknowledges that in the 90s the tendency was almost everywhere in its favour 'above all in the name of the juridical protection of the social family and for the purposes of excluding the possibility of the donor advancing any parenting project with the rights and claims linked to it'. The choice of anonymity was therefore analogous to the choice made 'in other juridical situations, as in the adoption of unrecognised minors, where one tends to clearly separate the natural family from the social one'. Nonetheless, in the following years, 'as a result of an increasingly widespread use of MAP in its various forms and a different social attitude' 'an inversion of the legislative tendency' would be seen, which led 'to taking into account the minor's request or that of the adult, once acquainted with the modalities of their conception, to be able to access the information about the donors. Frequent requests, which for many tend to turn into a true right. Requests that find a number of reasons (psychological, social and religious). The importance is often stressed of the individual's awareness of their history for their personality construction process and harmonious psychological development. Furthermore, it must be considered that various references were made to international conventions dealing with adoptions, in order to support in an analogous way the existence of the offspring's right to know their roots also in the sphere of MAP'.

Rather than by ethical reasons, here the opinion reports a change in the *social attitude* that took place in other Countries and which

would have led to a change in the legislation. Moreover, the generic nature of the allusions to the most varied of reasons is quite striking, such as to the 'harmonious psychological development' and international conventions.

After having established the need to prohibit secrecy, as a fundamental part of the whole debate the NBC goes on to analyse the specific problems that can arise, like the ones relative to the possible extension of anonymity. It is a question of knowing whether the knowledge of the donors 'can be limited to information linked to health' or if on the other hand it can be 'extended also to the knowledge of personal data'. In any case the opinion does not fail to stress that 'This is nonetheless a psychologically delicate path to face considering the strong emotional impact that it can cause in the sphere of the persons involved in this search, which should be accompanied by the support of a multi-disciplinary body that carries out a competent role of mediation, interacting with and speaking to those concerned'. In short, assisted fertilisation is a dangerous practice to be handled with great care!

This aside, it is interesting to see how the opinion states that 'anonymity in the donor/recipient/child relationship is also always relative with regard to the sperm centres and banks. Even if the information and collection system of biological data is extremely varied, it is usually foreseen that the records contain, according to the established modalities, the names of the users, the gametes used, specific information on the ethnic group, cultural extraction, state of health, medical, personal and family history and other additional data given voluntarily and knowingly by the donors'. There are other problems that the NBC considers to the point of observing that according to some 'It is not excluded also that register includes the donor's 'desiderata' concerning the use of their gametes. For example, the consent or dissent so long as their genetic material is destined only to resolve a problem of sterility of heterosexual couples of medical origin and not to aid the desires of single persons or homosexual couples. Furthermore, the period of validity of consent given by the donor must be recorded in the register along with their will to be informed every time that their gamete is used. *If not motivated by unacceptable reasons of discrimination, such recommendations and requests can be ethically*

legitimate and are even more justified in the standpoint of those who consider even the personal identification of the donor preferable who in various cases could enter into contact with the offspring.

Two considerations need to be made. The first is that the NBC is describing an activity that concerns the sperm banks prohibited by Law No. 40, so that it seems quite strange that the National Committee expiates upon the examination of the modalities of an illegal practice. The second, even more peculiar, is that it recognizes that the ‘*instructions and requests*’ left by a donor ‘*can be ethically legitimate*’, above all in the case in which the personal identification is also foreseen. It appears to me that by saying this the NBC presupposes that the donation of gametes is *ethically* legitimate, since it becomes difficult to sustain that only the specific instructions and requests are ‘ethically legitimate’ of a practice that *in itself* would be reprehensible.

6. Partial anonymity or the whole truth about the donor?

The document, apparently somewhat little concerned about the implications of its previous affirmations and unaware of the existence of a law in Italy prohibiting the donation of gametes, with the intention of ‘helping in drafting legislative acts’ and without giving ethical judgements, goes on to examine the different standpoints relative to the anonymity of the donor distinguishing between the one in which ‘the offspring’s search for their own biological origins can be limited to partial anonymity (allowing extensive information of different nature on the donors, but omitting to make their personal data known) and the one that can stretch to the knowledge of the donors’ personal data. These different solutions can be found in the legislations that have dealt with this issue in MAP with donors of gametes’. Once the different solutions proposed concerning this have been clarified, the Committee goes on to opportunely consider only two alternatives, partial anonymity and absolute truth. The opinions differ with regard to this.

For some members it is ‘opportune to maintain the anonymity of the donors of gametes with regard to personal details’, owing to the following reasons: once again the reference is to ‘the interest of the child to know the information surrounding the donor in the MAP context’, and this interest is

modulated and balanced with regard to other interests and rights, which are just as worthy of attention and protection, and cannot be automatically turned into a claim to know the personal data of the supplier of the gametes'. Even considering that 'it is with reference to the 'best interest' of the minor that the reflection is made on the so-called 'biological 'truth', when it is a question of going into the specific case 'it must be asked ... whether the knowledge of the donor's personal data is generally a real advantage for the child'. Empirical research demonstrates that people search for 'information on their biological origins, rather than on their genetic ones'. In fact, 'in the psychic development of the child, interpersonal processes are central and in particular the fusional experience with the mother, this remaining such when the social mother coincides with the carrier, despite the biological contribution being of another woman'. Even if 'the desire to know one's roots exists', this really refers to the need 'to verify the existence of a meta-biological as well as biological bond with the donor', a connection that cannot be valid insofar as 'the donor is a stranger who has 'given' their gametes'. For this reason, those who maintain 'an ethical concept drawing on parental responsibility and the primary interest of the minors' can say that the presence of cases of the searching for one's roots 'are not sufficient to justify the protection of the biological truth in an absolute way'. This thesis is corroborated at a legislative level too since 'a choice in favour of limited anonymity to the donors' personal data would not be in contrast with the general principles of many foreign legal systems'. Also those who maintain that 'relationality is the supporting element of genitoriality, just as the identity of the offspring 'is progressively constructed, from the original fusionality to the detachment, within the parental coordinates by virtue of the importance 'of the dimension and social filiation' can consider it 'ethically and juridically advisable that the personal anonymity of the parents/donors/child be maintained, though allowing the latter to access those data that, according to the circumstances, may be necessary for their psycho-physical health and for a deeper knowledge of the reasons and modalities of their own origins'.

On the other hand, others depart from 'differing ethical and juridical assumptions', considering that 'the offspring has the right to access information on their biological origins and therefore also the personal data of the donor of the gametes'. In fact, on the basis of the fact that 'there is a widespread idea that the possibility of knowing one's origins is indispensable

in order to fully elaborate the child's identity', stating that 'the right to regain the biological connection recomposes the person's identity ... in the form ... of the simple knowledge of one's biological origins'. In fact, according to them, 'the children born by assisted fertilisation with donors of gametes undergo the sacrifice of this fundamental right which discriminates them with respect to everybody else, insofar as the law deprives them from the very start of a status resulting from the biological and family dimensions that are artificially separated'. Therefore, 'a minimum of equity, together with the criterion of the prevalent interest of the minor should suggest recognising the offspring at least the right to know their origins and therefore to have access to the date relative to the identity of the donor of the gametes. The arguments in favour of the offspring's right to the truth are therefore based on the concepts of equality and non-discrimination: the aim is to avoid the children born by means of these techniques representing the only group of individuals that is legally prevented from searching for or accessing information about their biological procreators' (my bold). This is also because there is a 'psycho-physical need to know one's origins to have a better knowledge of oneself. One cannot exclude that the internal rift suffered by those aware of the cognitive void around their own biological origins, can turn out to be the herald of relational difficulties, which are increasingly manifested when the person tries to create their own family'. Those 'who are born in this way' must be spared the discrimination 'of not being able to answer the Homeric question 'who are your parents?'. The knowledge of oneself cannot therefore be of a self-referential type, as in a mirror in which only our own image is reflected: our face and features will be more recognisable to ourselves if we can refer to other known physiognomies. The mirror in which we look to know ourselves better must be able to return the image of the community of belonging, which in the first place can only be that of whoever has contributed to our birth'.

For all these reasons 'the offspring's right to know their biological origins is prevalent and superior to the interest of the parents in maintaining secrecy and of the donors in keeping anonymity. Contrarily, to evade the request to know the truth implies a specific form of violence', the violence of whoever 'knows the truth that regards another person and is in a position to disclose it and refuses to do so, thus maintaining an unjust position of power towards that person'.

Now that the various standpoints are clear I can move on to my criticism of them. The first is that, once again, the proposed stances do not represent the framework of the debate. In fact, both standpoints share the same basic assumptions, like the thesis of the reference to the ‘child’s best interest’ as a principle criterion, only that in some cases this leads to the exclusion of the knowledge of personal data, while for others these are also necessary in the light of the widespread idea that ‘the possibility of knowing one’s origins ...[would be] indispensable in order to fully elaborate the child’s identity’. I am not going to check the plausibility of this widespread idea: it is very surprising that a National Committee gives credit and voice to a simple ‘widespread idea’ without evaluating the plausibility of it, since this is the attitude that exists in other very different places where empiricism and the lack of specific culture are justified. Nor can it be understood which evidence has been used to support the thesis that ‘the internal rift suffered by those aware of the cognitive void around their own biological origins’, can ‘turn out to be the herald of relational difficulties’ without specifying which and of what type these may be. In fact, it is clear that this cognitive void does not exist only in the case of assisted fertilisation, but also in numerous cases of natural fertilisation. It is nevertheless inexact that ‘the children born by these assisted techniques’ represent ‘the only group of individuals who are is legally prevented from searching for or accessing information about their biological procreators’: it is not the only group at all, as these children are in good company. It cannot be understood how the NBC can have neglected this fact. A further criticism concerns the offspring’s supposed right to know their genetic origins. There are various hypotheses, and just as plausible, according to which the essential information that all offspring should receive and to which they certainly have every right, regards the name of the people who have fought and suffered to have them. It is the principle of genitorality based on responsibility, which if correctly applied should create family relations that are not lacking in knowledge and curiosity, according to the principle whereby the history of each one of us begins where it is possible to record an act of love, the search for our ancestors derives from feelings that are too stupid to be able to imagine that they have anything to do with morality.

7. Analysis of the ‘recommendations’ proposed in the synthesis

At the end of the opinion, without any preamble or link, the NBC proposes 6 specific recommendations on which an apparent convergence exists and which constitute the equivalent of the ‘purview’ put forward to ‘draft legislative acts’ with regard to the issues taken into examination. In fact, the final ‘recommendations’ are the ones that are more carefully examined by the press and make up the synthesis of the opinion. They deserve to be carefully examined for this reason.

The first is the following: ‘1. To avoid harming the dignity of the person with discriminatory attitudes by society in consideration of the modalities of their conception’.

These words are all very nice and persuasive, but if they were taken seriously (or if the Committee knew their meaning), they would make the opinion superfluous (insofar as assisted fertilisation would be equated with the ‘natural’ one) and would perhaps press for another to highlight the real discriminations created by Law No. 40/2004. They represent therefore the declaration, deliberately constructed to evoke what is then denied in practice by facts.

The second recommendation confirms that one must ‘consider that when the offspring born from *heterologous* MAP is a minor it is the moral responsibility of the parents to inform them of their origin through appropriate filters and criteria: proportionality, sustainability, relevance, bearing, etc.’ (my italics), a thesis maintained by the need imposed by the ‘full respect of the principle of the higher interest’ of the minor ‘expressed by the socio-cultural values, juridical traditions of Italy and by the international conventions safeguarding him/her’.

The use of the term ‘heterologous’ shows once again the superficiality in the use of words or the implicit will to create subtle discrimination. Apart from this, it is not clear what the reasons are supporting this recommendation, if not the respect for general socio-cultural or juridical traditions. It is not clear where the ethics lies and one goes back to the beginning.

Furthermore, I would like to point out that the words quoted refer directly to the specific paragraph of the text in which ‘adequate counselling’ for the parents so as to give them ‘complete and correct information’ aimed at preventing their ‘loneliness’ and ‘poor preparation’. I hope that the

recommendation being examined is limited to the ‘advice to the parents to inform’ alone and does not foresee also the opportunity to set up ‘counselling centres’ to give the parents ‘complete and correct information’, a thesis that in itself not only raises numerous issues and which – if approved – would strengthen the deep inequality already highlighted for the different modalities of conception.

The third recommendation is an invitation to ‘recognise the offspring’s right, when coming of age, to access information concerning their origins, should they request it’.

While the previous one is a piece of ‘advice’ to the parents, here it states the offspring’s ‘right’ ‘to access information concerning their origins’, a thesis that can take on an appearance of credibility only owing to the vagueness of the words ‘information’ and ‘origins’. It is in fact a question of knowing what the ‘relevant information’ and the ‘origins’ are that are being referred to: whether only the biological ones (and in what sense) or another type too. The NBC avoids any kind of explanation demonstrating a generic character that does not befit a scientific body: if it had done so, the inequality existing between the offspring from assisted fertilisation and the others would have been immediately obvious, in open contrast with the declaration of principle of the first recommendation.

The fourth recommendation is even more astonishing insofar as it invites one to ‘foresee, should the care and protection of the minor’s health make it necessary, that the doctor and/or medical facility, having knowledge of the modalities of procreation of the child, the parents having been fully informed of this, or upon their authorization or in the case of a refusal on their part, of the competent judicial authority, have the possibility to ask to have access to the records and the use of the necessary data for the diagnostic and therapeutic treatment of the underage patient. To encourage the possibility for there to be a continuative relationship in time between the medical centres and the donor, for health reasons’.

The surprise at this recommendation arises from the fact that the specific subject has never been discussed in the text: this directive springs from nothing and ‘is slipped in surreptitiously’ as if taken for granted.

For obvious reasons I cannot go through the specific content of the recommendation here: I shall just say that from a grammatical-syntactic point of view it does not seem that the formulation reaches the level of clarity

that should characterize the National Committee. I must nonetheless point out that it is not clear what the ‘doctor and/or medical facility’ is that ‘having knowledge of the modalities of procreation of the child’ should have the possibility to ask to have access to the records, nor least of all since this is foreseen only for the *artificial* modalities of procreation, and not for any type.

The fifth recommendation invites one to ‘foresee the setting up of multi-disciplinary bodies able to guarantee suitable counseling and support for all the subjects involved in the ‘search for origins’. Here there is a return to what was already stated in the second recommendation, and that is the idea of setting up ‘multi-disciplinary bodies’ which would end up stigmatizing those making recourse to artificial techniques even more.

The sixth recommendation is ‘To keep a register of the identity of the users in the sperm banks or in the authorized centres, with a record of the gametes used and the information obligatorily and/or spontaneously given by the donors and in the respect of the modalities set down by the European directives’. It is once again astonishing how the NBC gives precise directions on how to regulate institutes that are outlawed in Italy, without giving ‘ethical judgments’ on the law itself.

8. Conclusions

Immediately following the approval of the opinion a well-known newspaper reported the following declaration given by the deputy president: “An important statement, put forward and approved, adds d’Avack, ‘unanimously with only one vote against’”. I shall pass over the considerations with regard to the evaluation given to the importance and progressiveness of the opinion, because there are more serious aspects to be looked at. The first is of a procedural nature and concerns the fact that the relations with the press have not been kept by the president for some time, but are referred to others. This creates an institutional problem as one cannot understand how it is that it is not the President who conducts an opinion as important as the one approved on the 25th of November.

I say this also and above all because I am certain that the President would not have deprived me of a soul (if my interpretation of ‘unanimity’ is right), a deliberately intended oxymoron, meant to underline the scant or non significance of my opposition.

I shall not go to the point of saying that this upset me, but I certainly did not like the fact that none of the NBC members considered it opportune to highlight this incivility.

As far as I am concerned I only tried to demonstrate what the serious shortcomings of the opinion seemed to be.

I have asked myself on various occasions the reasons why a document was chosen as subject of debate that has nothing to do with bioethics and which seems absolutely useless to me; I have also asked myself the reasons for the choice to approve it before the end of the year, despite a voice of dissent being raised from time to time in the debates. I believe that the Committee – which despite having said very little has nothing more to say now – is concerned that a government decision might put it among the ‘useless bodies’ and that for this reason it is speeding up the conclusion of documents that would deserve different attention (or, as in this case, of not deserving attention).

If this were the case, it would be a mistake: there is nothing more useless than a useless body that does not know it is.

Presidenza del Consiglio dei Ministri



**BIOETHICAL ASPECTS OF AESTHETIC
AND RECONSTRUCTIVE SURGERY**

21st of June 2012



PRESENTATION

In the first part of the document, the NBC reflects on the limits of the legitimacy of requests for aesthetic surgery – which are ever-increasing in number - and in particular on the physician-patient relationship, in the context of the discussion on the many ethical, social and cultural factors that affect the change of attitude towards the body and an expansion of the concept of health in the subjective sense.

Since this intervention is not for strictly therapeutic purposes, the NBC reiterates application of the deontological standards that govern medical practice, which are - in this specific field - sometimes disregarded in favour of an accommodating compliance with the request expressed by the individual; it emphasises the unacceptability of disproportionate intervention, as it is excessively invasive or unnecessarily risky and inappropriate in relation to the possible benefits requested by the patient. In addition, the Committee believes that the licitness of intervention should be proportional to the balancing of risks and benefits and commensurate with the psycho-physical condition of the patient and the functionality of the affected organs, and the comprehensive information given to the patient, with the provision of adequate counselling, including also psychological advice.

As regards operating on minors and those lacking the capacity to consent, the NBC believes that there must be limits to licitness, except when this intervention is in their exclusive and objective interest in terms of health, especially in consideration of the period of adolescence. In particular, the NBC does not consider aesthetic surgery on children with Down syndrome to be legitimate, when its aim is the conformity to the social canons of ‘normality’, especially if it is invasive and painful, even considering that it is unlikely that these operations may be beneficial to individuals, frequently instead, it is possible that they accentuate rather than reduce personal uneasiness.

The Opinion calls for the provision of appropriate social information and education regarding the risks and benefits of aesthetic surgery and greater rigour in the formation and professionalism of plastic surgeons, also aimed at including the understanding of the psychological and ethical issues related to this specific medical practice.

The second part of the document tackles the emerging bioethical issues in reconstructive surgery. This is a sector in continuous expansion and development which requires appropriate ethical reflection. With particular reference to face and limb transplantation - due to the experimental nature of these procedures and the fact that they are not essential for survival, the NBC recommends a careful assessment of the risks and benefits, in relation to general considerations of the improvement of the quality of life for the patient. Furthermore, appropriate counselling is considered necessary in advance of the surgery, and for a prolonged period (extended even to the family), because of the complex issues that affect the risks and benefits, accompanied by constant psychological monitoring of the recipient. Patients must be informed accurately and comprehensively of the risks to health and the severity of the anti-rejection therapies and the fact that in any event they lead to a dependency on these drugs (with possible negative outcomes) that could even last a lifetime.

It is hoped that in the implementation of appropriate informed consent there will also be use of new information technologies, so as to promote the collection of information and knowledge through access to sites accredited by the competent public institutions, as well as the national and international registers in which the most recent studies in this field are published and where scientific publications generated from the study can be found. In addition, the NBC encourages public awareness campaigns for the donation of external organs and tissues, as normally takes place for the donation of internal ones. It also calls for, in this context, the possibility of integrating legislation providing for “partial” consent or dissent to external organ donation.

The subject was proposed by Prof. Umani Ronchi during the plenary session on 27th January 2011. The opinion was drawn up by Profs. Lorenzo d’Avack, Laura Palazzani and Giancarlo Umani Ronchi, with written contributions from Profs. Salvatore Amato, Antonio Da Re, Riccardo Di Segni, Marianna Gensabella, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Monica Toraldo di Francia.

In the drafting of the Opinion valuable contributions were provided by the auditions in the plenary session by Prof. Nicolò Scuderi (Director of the Department of Plastic Surgery, University “La Sapienza” of Rome), by Dr. Francesca Romana Grippaudo (Plastic Surgeon Sant’Andrea Hospital

in Rome) and by Dr. Anna Contardi (National Coordinator of the Italian Association of People with Down Syndrome) for the field of aesthetic surgery and by Prof. Giorgio Iannetti (Professor of Oral and Maxillofacial Surgery at the University of Rome “La Sapienza”) and Prof. Marco Lanzetta (Director the Italian Institute of Hand Surgery) for the field of reconstructive surgery.

The Opinion was voted in the plenary session of 21st June 2012 and published 5th July 2012.

Profs. S. Amato, L. Battaglia, F. D’Agostino, A. Da Re, L. d’Avack, E. Fattorini, M. Gensabella, A. Morresi, D. Neri, A. Nicolussi, L. Palazzani, V. Possenti, G. Umani Ronchi voted in favour. Prof. Claudia Mancina voted against. Profs. A. Bompiani, S. Canestrari, B. Dallapiccola, R. Di Segni, M.L. Di Pietro, R. Proietti, L. Scaraffia, M. Toraldo di Francia absent at the plenary session voted in favour.

The President
Prof. Francesco Paolo Casavola

1. Introduction

In the field of plastic surgery aesthetic surgery can be differentiated from reconstructive surgery.

Aesthetic surgery comprises operations that modify, correct or improve the aesthetic and functional aspect of the body. It is aimed at those who request medical intervention for the modification of parts of their body for purposes which are not always strictly therapeutic and that, more often than not, are motivated by desires and subjective needs to conform to a corporeal ideal.

Reconstructive surgery corrects malformations that are congenital or caused by trauma or demolition. These operations have the primary objective of restoring function and improving the appearance of patients with serious impairments, victims of significant trauma (car accidents, workplace accidents, animal bites, burns, ballistic injuries, etc.) or destructive pathologies. Autotransplantation can be performed on the outcomes but when this is not possible healthy tissue donated from cadavers can be implanted. It is technically a composite tissue allotransplantation of skin, bones, muscles, blood vessels and nerves. In reconstructive surgery there is an overlap of both aesthetic and therapeutic needs.

The issue of transsexualism will not be dealt with here, (which requires more extensive references to issues regarding sexual identity - regulated in Italy by Law No.164/1982), scarification and the request for limb amputation (which leads to a more complex treatment of psychiatric problems), the activities of skin *piercing* and tattooing and acts of self-creation (*body art* or *carnal art*).

From an ethical and juridical viewpoint, the issue of aesthetic and reconstructive surgery intersects on one hand with the vexed question of the status of the human body and on the other with the actual activity of the physician aimed at protecting the health of the patient.

2. Aesthetic surgery

2.1. Regarding the request made to the physician to modify one's body

The body as subjectivity, “the lived body” is what we are and carries on it the signs of what we have been: it is the body that bears the years that pass and the signs of the emotions that have marked and mark our existence. In this sense, our identity is always the identity of an ‘incarnate being’.

We inhabit the world and relate 'to' others as a body-subject. The body which we are projects outwardly and this projection has a dual significance. It places us in contact with others, in an inter-subjective/inter-corporeal dimension, which allows us to build our identity. At the same time it is a vehicle of meaning that communicates what we want / would like the world to perceive about us. It 'is especially in this second function, that the body can be perceived differently in its outward manifestations, to the eyes of others, from what is experienced within our subjectivity: not an incarnate identity, but a "mask" that overlaps with that identity, sometimes altering it, with consequences on the same experience that each person makes of himself and herself and their own sexed corporeal dimension, and at the same time with negative consequences on intersubjective relationships. In these cases there may emerge the 'need', a more or less induced need, to work on the external aspect of the body, that body as 'object' which 'appears' to the eyes of others: a process of 'objectification' of the body begins, in order to make it manageable, modifiable, malleable according to the desire for an identity which the body should reflect, according to the models accrued within intersubjective relationships, often based on social conditioning.

It should be borne in mind that there are multiple social factors that have influenced the new imaginaries that accompany the changing attitude towards the body and an increase in requests for aesthetic surgery. Among these one should mention: the tumultuous development of bio-technological innovation that always offers new possibilities for manipulation of the body opening up future scenarios of 'cosmetic genetics'; the profound changes in the interpersonal and professional relationships which impel towards external representation in social life and attention to 'appearance'; the emphasis on beauty that tends to become increasingly synonymous with well-being, youth, increased sexual pleasure and the subsequent need for this to last over time⁸⁵.

Supporting, these fantasies of freedom from the constraints that our being incarnate imposes on us is today's media culture (advertising, television programs, films, articles in newspapers and magazines, internet), allied with

⁸⁵ Take 'aesthetic surgery on private parts' (vaginoplasty, hymenoplasty, cosmetic vaginal tightening, plastic phallus), widely advertised on many websites (female genital cosmetic surgery or FGCS).

an increasingly pervasive business of beauty and fitness. The growing number of offers on the web for aesthetic surgery, capable of arousing clearly unrealistic expectations should be noted. These messages, influencing tastes and aesthetic canons convey the idea that it is on the body and its aesthetic dimension that social and economic interests converge. Those operating in this sector should be made aware of the risks that their messages can transmit.

It is possible then that men and women today turn to the aesthetic surgeon more and more often due to physiological and psychological needs, and even unconscious ones, but above all out of a desire for social integration in accordance with certain stereotypes. And it can not be denied that the relationship between aesthetics and emotional, social and family life can be very close, so much so that after an operation that has solved serious physiognomical problems, it can not be excluded that patients re-elaborate their own internal image in order to gain confidence in relationships with others as well as with themselves.

But the activation of models of beauty with their cultural and consumerist imperatives can also create negative effects, especially in the most vulnerable: growing insecurity in the face of the ageing process or simply somatic aspects that create individual differences compared with the dominant and uniforming aesthetic criteria.

Therefore, the increase in requests for aesthetic surgery stimulates and makes necessary the bioethical discussion on the limits of legitimacy of such a request especially in the relationship between the patient and the physician.

In this context, inevitably, the theme of beauty intersects with that of health as the individual's request for body modification to the physician can not be detached from direct or indirect reference to the therapeutic dimension. There is, today, a trend towards the expansion of the concept of health with the accentuation of the subjectivist dimension, even following the definition of health of the World Health Organisation as a state of "complete physical, mental and social well-being"⁸⁶. In this perspective,

⁸⁶ It is the definition of 1948, subsequently revised by the Ottawa Charter in 1984 ("the process that allows people to increase control over and improve their own health). Also the Charter of Fundamental Rights of the European Union (2000) believes that the interest in "physical integrity" must be measured, more generally, in all the decisions that relate to the modification of the body, with the widest integrity of the individual (Art. 3).

aesthetic surgical intervention would come under therapeutic treatments, in so far as a specific physical condition - regardless of objective pathological considerations - is perceived by the person concerned, on the psycho-social level, as the source of uneasiness and discomfort. Therefore those who ask the physician to transform their body to make it more beautiful (according to their ideal of beauty and health) believe they have a right to freedom and self-determination in the implementation and development of their personality, considering 'aesthetic health' as a good not only to preserve and replenish, but to some extent, also to promote as a fundamental element of the identity of the individual, according to their own subjective desires and social relations⁸⁷.

The NBC, while noting that the current bioethical debate tends to question the clarity of the distinction between 'healthy / normal' and 'pathological / abnormal' and to welcome the co-existence within the context of health of subjective and objective dimensions, it intends to highlight in the specific area of aesthetic surgery the risks of an excessive relativisation and subjectivisation of the concept of health.

In this context, it is not possible to define a priori in a specific, exhaustive and definitive manner the limits of licitness of interventions (requested by the patient and carried out by the physician), to rigidly outline the distinction between the spheres of acceptability and unacceptability: nevertheless the need to reiterate the deontological obligations governing medical practice, at times annulled - in this specific area - in favour of a compliant implementation of the individual's request. Therefore, the NBC believes that in casuistry both the patient and the physician must respect the principles of proportionality and accuracy (assessment of physical and psychological condition of the patient, comprehensive information, informed consent, risk/benefit assessment-

⁸⁷ In Italy the right to self-determination over one's body, within the limits of Art. 5 Civil Code was claimed under Articles 2, 13 and 32 of the Constitution. The Court of Cassation already in 1994 recognised that aesthetic surgery had a precise position, stating that "the typical function of medicine, identified in the care of the patient in order to cure disease, to reduce the injurious effects or, at least, alleviate the suffering it produces, safeguarding and protecting life, does not exclude the legitimacy of cosmetic surgery, whatever the psychological disorders that may result from an expanded view of the unpleasant aspects of one's body, it tends to improve only the aesthetics" (Cass. civ. No. 10014/1994, in "Foro it.", 1995, I, 2913). See also Cass. Civil. No. 9705/1997.

expectations). It is through these policies that it is possible to justify the licitness of the request and the resulting surgery as it is in the patient/physician relationship that a therapeutic aim is reached, in the broad sense. There must be exclusion of other requests for intervention distorted by the logic of ‘desire’ which may backfire on the same individuals who ‘desire’ them and which represent a sort of ‘aesthetic persistence’ or mere exploitation of the body or dictated by psychiatric disorders (so-called *dismorfofobia*).

The specificity of these interventions means that public institutions are generally reluctant to contribute financially to the exercise of the right of patients to change their physical appearance for aesthetic purposes⁸⁸. Moreover, it can not be forgotten that while the private system responds to a logic strictly related to insured risk and to the type of service provided (ratio which determines the premium paid, subject to the profit margin), the public system responds to a broader logic that must take into account, and mitigate, natural, social and economic inequalities and the need to ensure fundamental rights (right to protection of health), despite their inseparability from evaluations of an economic nature, given that resources are still limited.

2.2. The responsibility of the physician and informed consent

The responsibility of the surgeon in legal terms in aesthetic surgery has some peculiarities with respect to general professional liability. In reality, in so far as the aesthetic purpose differs from common therapeutic purposes, there can be a change in the importance of responsibility in the relationship with the patient and the sense of distribution of the risk inherent to the intervention and consequently also a change in the extent and method of informed consent.

In the analysis of the obligation that the doctor takes towards the patient it is an established principle that, in addition to having to comply with the rules of professional conduct, it includes the performing of

⁸⁸ In Italy, the National Health Service has introduced, with effect from 1 July 2002, the “essential levels of assistance (LEA)” defined by Decree (DPCM) of 29.11.2001 establishing essential minimum services guaranteed in all the Country. The LEA have comprised among the categories of the excluded services/benefits also aesthetic surgery not resulting from injury, disease or congenital malformation.

professional activity necessary and useful to the specific case, according to criteria of appropriateness and medical expertise. Consequently the result, measured according to objective parameters, does not always and necessarily coincide with the satisfaction of the patient, since the satisfaction of the patient - may not be obtainable only and directly through the professional's behaviour - think of the recovery from an illness. Therefore, in medical practice in general, this result should be evaluated so as not to discourage intervention for which there is a socially felt need and which, moreover, aims to achieve the protection of a fundamental value such as health itself. In addition, the particular significance of the activity carried out by the physician may advise us not to heighten his responsibility to the extent of his being made guarantor regarding risks extraneous to his actions.

Notwithstanding that even when the physician acts for aesthetic purposes he must measure his behaviour in relation to expertise and deontology, the given result could be assessed in a different manner. The moment that the operation is merely or mainly for aesthetic purposes the need to encourage these interventions may fall short or be less valuable socially. Consequently, a possible reduction in the physician's responsibility, arising from consideration of the correct behaviour comprehensive of the requested result, or by less serious evaluation of technical error in cases of special difficulty, should not be extended to services performed for merely (or mainly) aesthetic purposes, burdening the risks on the patient. In these cases, the interest of the professional to carry out his activity - for strictly economic reasons (in the case of a contractual tie with the patient) or indirect economic reasons (in the event that he is employed by a hospital) - is not offset by an objective need to protect the health of the patient/client.

The specificity of aesthetic surgery, which, as mentioned, is not an indispensable therapeutical intervention makes even more necessary the informed request (informed consent) of the patient, which includes each aspect of the justification for the intervention, together with the professional autonomy of the physician and his deontology.

As a result there is a need for special rigour and attention regarding the information given by the doctor. The NBC considers it necessary - in order to ensure the principle of non-maleficence - that the information

must be complete and comprehensive, not only as regards the techniques of the operation, but also the consequences on health, possible benefits and risks, the expected results of the medical act in relation to the subjective expectations of the patient, verifying in a particularly scrupulous manner which part and how much of the information provided has been fully understood by the patient⁸⁹. In this context, it could be useful to indicate to the patient to obtain information online through accredited sites or by using means of verification (including questionnaires) of the understanding of information directed also at highlighting the real reasons that lead to the request for surgical intervention.

What is certain is that the physician should not only have the role of a technician who works on imperfections and improves them, but he must also have the sensitivity and the psychological preparation to understand when and if operating is essential. The aesthetic surgeon should therefore not neglect, even indicating to the patient the possible need for an extended consultation, considering the personality of the applicant, evaluating, even in this respect, the feasibility of the treatment.

In addition, despite the capacity of aesthetic surgery to significantly reduce dysmorphia, it is not always able to remove the condition of malaise that underlies it, so that the problem can recur after even a short period of time with the claim to additional, unnecessary operations. It is in this way that the risk/benefit relationship is broken or, more exactly, it is altered and becomes unbalanced - within the context of the therapeutic alliance - which is the deontological and ethical foundation of the

⁸⁹ A recommendation endorsed the Court of Cassation: "In terms of surgery, so the patient is able to exercise their right, that the Constitution gives him to choose whether or not to undergo surgery, it is incumbent on the doctor of a specific duty of information about the benefits and procedures of the transaction, as well as any foreseeable risks in the post-operative stage; a duty that in the field of aesthetic surgery, where it is required that the patient will achieve a real improvement in his overall physical appearance, it is particularly meaningful, with the consequence that the omission of that duty, regardless of the success of the intervention and independently whatever the nature of the obligation of performance of professional services, shall not relieve the doctor of liability, whether in contract, tort, if it does occur - as a result of the intervention - a harmful event" (Cass. civ., No. 9705/1997). The principle is always valid (Cass. civ., No. 14638/2004.) that in any event informed consent is necessary: "In the contract for the provision of intellectual work between the surgeon and the patient, the practitioner, even when the object of his performance is only the means and not of result, has the duty to inform the patient of the nature of the intervention, the scope and extent of its results and the possibilities and probabilities of the results to be obtained".

licitness of the treatment; in these cases the physician should, for deontological and ethical reasons, manifest unwillingness, without however abandoning the patient but suggesting other less invasive possible solutions.

Therefore, it is essential to carry out a balanced evaluation on a case by case basis, as it is often difficult to know the limits of the therapeutic measures, able to help those requesting surgery to overcome their uneasiness.

In this context, the risk of the patient ending up in inexperienced hands or in the workshop of a ‘merchant of operations’ or of being transformed from a “patient” to a mere “customer” is an increasingly present and worrying reality. There is a fine line between licitness and collusion in the field of aesthetic surgery whenever the physician tends to encourage the unrealistic illusions of the individual with insufficiently motivated operations. Consequently, therefore, there is a need for particular rigour and attention in the information given by the doctor even as regards the non-therapeutic nature of the act. The aim of specialists should be to offer their expertise to help solve the patient’s problem, not the selling of a service without their being concerned whether it is the most appropriate.

Furthermore, it is cause for concern that in Italy - according to a survey conducted by the Italian Society of Plastic Reconstructive and Aesthetic Surgery (Sicpre) - those who work in the business of “aesthetic touch-ups” are estimated to be much greater in number than the members of the Society itself, with the possible risk of there being many “improvised” professionals. As with many other medical specialties, this is due to the regulations for practicing the profession, which in our Country is very permissive, as anyone who has a degree in Medicine, is licensed to practice, and registered with the Order of Physicians, can in theory undertake medical activities which require a high level of specialisation. Alongside this theoretical possibility one must contrast the control of the schools of specialisation and professional societies, and correctly informing the users of the general public. For this purpose the NBC recommends that the advertising of surgical intervention and the obtained and obtainable results in this field should take place on accredited websites which are certified by competent public institutions.

2.3. The protection of minors and those incapable of giving consent

International charters generally recommend that in any medical procedure, involving individuals who do not have the capacity to consent, there must be special protection, based on the ethical and legal standards adopted by States.

In the present case of aesthetic surgery, as already mentioned, it is not generally essential medical intervention, let alone life-saving intervention, and therefore in the case of a person who is incapable of giving consent this shortcoming can not in any way be redressed, given the absence of connection between the authorisation of the person exercising power (usually the parents) and an initiative that brings real and direct benefit to the health of the incapacitated person. Acts of this kind come under “highly personal acts,” that can not be taken by someone other than the person directly concerned, to be precise, it is not possible to be substituted by anyone else neither by parents nor by the legal representative.

Should anyone want to take into account that the incapacity to act, or the inability to perform legal acts until the age of 18, is essentially attributable to acts related to the sphere of assets, it is possible to expand the decision-making autonomy of the minor who has reached sufficient capacity to take a conscious decision (the so-called older-minor), regarding tending to his “existential” interests. On the other hand, we must also take into consideration the particular psychological relevance that in adolescence some aesthetic conditions can have, which can be experienced as intolerable and the cause of suffering and uneasiness.

To guarantee the formation and awareness of consent there should, however, be precise circumstances. The authorisation of the parents is primary, as they qualify as a *medium* of the child’s will, being attentive to precise information and sufficiently certain that the motives put forward for surgery are not completely disconnected from the therapeutic context or conditioned by an unreal expectation, or dictated by a non-objective and proportionate perception of the world and the social ideals surrounding the teenager. Other guarantees can be obtained through the provision of specific counselling, with trained personnel giving information commensurate with understanding about the risks and benefits of the intervention.

The concern that forms of distress and anxiety may arise in adolescents regarding the development of their body, the possible distorted perception of their body appearance, leads the NBC to support the choice made by certain legislations, such as the Spanish one, to ban, during certain times, in the context of audio-visual programs forms of advertising that may lead to the rejection of their body image and facilitate social exclusion because of a physical condition determined by weight or aesthetic factors. Also considered highly appropriate by the NBC is the legislative prohibition to carry out breast implants on minors for purely aesthetic reasons, and the establishing of information requirements for patients who wish to undergo such operations or who approach aesthetic surgery too soon at an age when the body has not yet completed its development⁹⁰.

In this context, the issue of aesthetic surgery on minors with Down syndrome gains bioethical significance, normally this syndrome, as well as altering physical appearance, causes mental retardation, usually with a mild to moderate degree of impairment of several cognitive areas. For this disability there is a recurrence - indeed to some extent, even an amplification of - the problem of obtaining valid consent as well as the many limitations already set out above with regard to the minor or incapable adult. It must be considered that the decision to take the path of aesthetic surgery even for therapeutic purposes (improvement of respiratory dynamics, feeding and language), is based not on the will of the minor or incapacitated person with Down syndrome, but only on that of the parents. The NBC believes that surgery that complies with functional type needs must be considered legitimate, as is the case for any intervention carried out on the minor or incapable person that proves necessary for ascertained physical reasons. However, great caution is necessary in implementing these operations, given their complexity and

⁹⁰ On 22 May 2012 the Parliament approved the law establishing national and regional registries of breast implants, information obligations to patients, as well as ban on breast plastic surgery in underage patients (Chamber Act No. 3703-B). Exceptions are cases of malformations or breast diseases, operations guaranteed by the National Health Service. The register of the prosthesis must allow full traceability of materials used and the follow-up of patients. The available data, guaranteed by suitable privacy, will enable monitoring of the patient over time, and may provide useful information to prepare guidelines on the use of safer and more effective. diagnostic techniques.

painfulness, their non-permanent nature (requiring further intervention during growth) and given that certain traits and physical defects can, in turn, diminish with the growth of the child. It is up to the parents with the help of the doctor to ascertain that these surgical operations are performed in the interest of the person with Down syndrome and in keeping with beneficence.

As regard purely aesthetic operations, not involving functionality, the members of the family generally put forward two motivating factors. The first is to cancel or reduce as far as possible the evidence of diversity present on the body, and the second to reduce the social stigma and avoid possible reactions of rejection, especially in those social contexts where the culture of integration is less developed.

There are numerous studies that have shown how it is difficult to achieve any benefit to the person with Down syndrome through these operations and that frequently there is the possibility of causing the opposite effect: the aesthetic somatic change can determine in the minor a sense of alterity to his own image (hindering the process of self-identification) and the perception of being rejected by the social environment and especially by those who should take care of him. Moreover there is the risk of increasing the illusion, for family members, that aesthetic surgery modifies the condition of disability.

The Committee believes that acceptance of disability should not take place through modification of the external body, but through recognition of the person, which is expressed in the relationship and acceptance of his existential condition.

Therefore the NBC sees no ethical reasons to justify those with Down syndrome being treated any differently from the provisions established regarding minors or the incapacitated, as being unable to exercise their own highly personal rights, they can not be subjected to medical treatments that are not necessary for health.

3. Reconstructive surgery

Reconstructive plastic surgery raises bioethical issues only partly comparable with those related to aesthetic surgery and as regards the retrieval of organs it falls within the context of deceased organ donation.

Recent developments in this field of medicine in various Countries open the way for the ‘reconstruction of the human body’. The main obstacle to the expansion of this type of transplant is represented by the anti-rejection therapies, and therefore immunosuppressive therapies. In the near future an effective treatment free or almost free of side effects should be attained (such as, in particular, the onset of tumors) capable of preventing the rejection of tissues that come from another human being, it would open up the technical possibility of reconstructing every part of the body. Currently, in addition to transplants of bone, muscle, vascular segments, skin, teeth, etc., compound tissue transplants⁹¹ are performed consisting of upper and lower limbs, fingers, feet, face, abdominal wall, larynx, and uterus.

In this context, the aesthetic and therapeutic components are closely related, but the latter prevails over the former. The primary aim of reconstructive surgery is the repair of a functional impairment caused by trauma, accident, illness, etc. or the correction of a congenital malformation. These are “non-life-saving transplants,” that make their foundation of legitimacy the protection of physical integrity and health of the patient, in consideration also of the general quality of life (which also includes psycho-social aspects).

Some reconstructive surgeries are recently leaving the sphere of experimentation and pilot studies or attempted cures. Others still have an experimental character as insufficiently tested by experience, resulting in uncertainty about the possible positive or negative effects. The experimental dimension does not just consist in the technical execution of the operation, but also includes consideration of the side effects of the intervention. There is not yet a sufficiently high number of operations and adequate observation time of the follow-up (at least 10-15/20 years) to have reliable data on organ survival rates and on the implications for the patient. Among these there are included the transplants performed on the face, which can be

⁹¹ Transplants are carried out to date in Italy, Spain, France, Austria, Belgium, Poland, United States, Canada, Malaysia. Recently, Australia, Brazil, Argentina, Lebanon, Turkey, New Zealand, China, Japan. The first hand transplant was performed in Italy by Prof. Marco Lanzetta Hospital San Gerardo Hospital in Monza in 2000. This was followed by two others, and a bilateral hand transplant performed in October 2010 by the team of Prof. Massimo Del Bene, the head physician, again at the San Gerardo Hospital in Monza.

small or large in extension (total or partial) and the transplantation of limbs. It is true that these kinds of reconstructive surgeries, in many cases, therefore, can be defined as *experimental treatment transplants*, they take place in situations where the disability suffered by the patient, is no longer physically and / or psychologically sustainable or otherwise curable⁹², and as such this means that the operation represents the only valid and real hope for the health of the patient, understood as the possibility of reacquiring a relational, sentimental and professional life.

The NBC believes that such interventions, although not essential for the survival of the patient, are nevertheless ethically justifiable, albeit subject to an evaluation of the relationship between benefits and risks, also considering the possibility that the anti-rejection drugs and their long-term use (even lifelong) could compromise health or cause the formation of tumors. It must be said that in this context, scientific research has recently made considerable progress, allowing early diagnosis of rejection in order to treat and prevent it⁹³, control side effects if not actually reducing or even eliminating them in certain cases⁹⁴, taking immunosuppressive drugs. In particular, in the case of external organ transplants, the receiver is generally a healthy person - in the physical sense of the term - (as opposed to those who receive an internal organ who live with their condition of illness), so they are better able to support and respond to treatment and side effects.

Nevertheless, health risks currently exist and the choice between them and the possible advantages of transplantation should be entrusted to the patient. The delicacy of the issues involved once again calls for particular attention to consent which assumes that the patient is given full information in order to enable the taking of a decision that is personal, free,

⁹² It should be kept in mind that by using sophisticated techniques of autotransplantation, important results can be obtained: it is possible to transfer to the face portions of skin, subcutaneous tissue and muscle from the abdomen or back and take it from undamaged areas, such as the back, large tissue grafts without the patient having to resort to anti-rejection therapy. Transplantation should be selected only when there are no alternative treatments that are less invasive and risky.

⁹³ As regards, in particular, the hand transplant, the visibility of the organ allows immediate diagnosis (compared with internal organs). In addition, the simultaneous transplantation of a piece of skin positioned at hip level allows anticipation of rejection in order to treat it before it even occurs.

⁹⁴ Currently under experimentation is transplantation, with organ, of bone marrow which, by producing cells not in competition with the original cells, helps to prevent rejection.

and conscious and objectively in the patient's exclusive interest. The consent, with the information to be given, obliges the doctor, even more than is usually the case for indisputably necessary operations, to draw attention to the complexity and delicacy of the surgery and thus highlight the uncertainties of the results and risks associated with the side effects of treatment after surgery, even faced with a performance according to *leges artis*. For this purpose it is essential to provide a specific consultation, involving physicians, psychologists, psychiatrists, physiotherapists. The consultation should take place well in advance of the surgery, have wide margins of time and continue as long as possible even after surgery. The consultation would also involve family members, called on to participate and support the person in the decision. Furthermore, it would also be opportune to draw the attention of the patient even to the consequences that the operation may have in other spheres, especially work (the possible discontinuance or modification of a privileged position for the disabled) and insurance (changing insurance contracts for health due to the risks of drug therapies after surgery). It is also hoped that implementation of appropriate informed consent will also make use of new information technologies, facilitating the collection of information and knowledge through access to sites accredited by competent government institutions as well as national and international registries where the latest studies in this sector are published and where publications generated by scientific studies can be found.

As regards the regulatory aspect, reconstructive transplants generally fall within the context of the regulations governing the removal and transplants of organs and tissues⁹⁵. And in fact, in several European Countries (e.g. In France, Spain and even Italy), multi-tissue transplantation (hand, upper limb, lower limb, foot, face) is considered equivalent to an organ transplant. This is based on consideration of several factors: the exacting surgical commitment, the objective difficulty in finding the donor; the impossibility of preserving the tissue and the objective necessity of using the organ transplantation network for the donation transplantation event; the need to monitor the follow-up of the receiver.

⁹⁵ In our Country the legal regulation is given by Law No. 91/1999 (*Provisions for the removal and transplantation of organs and tissues*).

However, unlike the more usual transplants (kidney, liver, heart, etc.), there are some specific difficulties in the procurement of organs and tissues. The fact that this transplantation is not for life-saving purposes but for therapeutic intervention, in many respects still partly experimental today, may alter the therapeutic alliance with donors. They and their families may be less favourably disposed to a destination that is not decisive for the life of the recipient, even in consideration of the therapeutic nature of the operation and the not always reliable results. Also not to be underestimated is that there may be a lack of willingness to donate part of the face and limbs, both because this alters the appearance of the cadaver, and for the symbolic, identitary and relational significance which they have. Especially in face transplants, the fear may also arise - under discussion on a scientific level - that the recipient could acquire the somatic resemblance and certain forms of expression of the donor. This means in terms of consent that these situations are regarded as “exceptional cases” and call for a selective and personalised request to the families of the donors. And this, notwithstanding that, at present, the law keeps silent on this point: there is no provision for “partial consent/dissent” and donors are multi-organ donors.

It must be added that for this type of transplant there is the difficulty of finding compatible donors since the problem is not only the genetic similarity but also external appearance (donor age, colour, skin texture, size). Just as a further obstacle to cadaveric donation may come from the prohibition present in some legislations, like our own, of designation to individual beneficiaries with whom the donor could be linked by family or emotional ties. This is a precondition for living organ donation. And even though there is here no condition of urgency, the analogy with such a donation seems to offer support to this choice, as well as the principle of beneficence, which does not preclude the provision of privilege to the people who are with us in a special relationship and for whom we have a particular responsibility.

Finally, alongside the scarcity of available organs there is a further problem, related to the selection of recipients. Since resources are scarce, the selection must be made on medical grounds, both privileging the bearers of deep and irretrievable lesions with significant functional deficits (such as an absence of both hands or legs, the impossibility to take food,

trouble breathing, the disfigurement of the face, etc.), as well as by evaluating the patient's ability to bear and endure the potential consequences, not only physical, but even psychological of the operation.

All these difficulties - which have a negative effect on reconstructive surgery - require more public awareness campaigns for the donation of external organs and tissues, as typically takes place in the donation of internal ones.

4. Recommendations

A) With regard to aesthetic surgery

1. Being a strictly non-therapeutical intervention, the NBC reiterates the deontological criteria governing medical practice, sometimes-disregarded in this specific field-in favor of compliance with the request expressed by individuals, and emphasises the unacceptability of disproportionate intervention, as it is overly intrusive or unnecessarily risky and inappropriate in relation to the possible benefits requested by the patient or that become a sort of 'aesthetic persistence' or mere exploitation of the body.

2. Moreover, the NBC believes that the licitness of the intervention should be subject to certain conditions and priorities, set out below:

- the balancing of risks and benefits should be commensurate with the psychological and physical conditions of the patient, with regard also to the perception that the patient has of his own body and the results expected from surgery;

- the functionality of the organs concerned must take priority over the aesthetic result;

- the information given to the patient must be complete, with adequate counselling, including psychological counselling, and clear and comprehensive reference to the psycho-physical complications, the limits of practicability of the surgery and the possibility that the patient's expectations may not be completely met.

3. The NBC believes that there are general limits on the licitness of purely aesthetic operations on minors and people unable to give consent, unless these interventions are not in their sole objective interest in terms of health and psychological balance during adolescence.

The protection of minors should also be guaranteed by banning advertising and television broadcasts which lead to the rejection of self-image.

Those working in this sector should be informed and made aware of the responsibility regarding the risks their messages can transmit.

In particular, the NBC does not consider legitimate aesthetic surgery on children or incapacitated adults with Down syndrome, aimed at the conformity to social canons of 'normality', especially if it is invasive and painful.

4. The NBC believes in promoting appropriate social information and education as to the risks and benefits of aesthetic surgery. It calls for a critical awareness of the importance that the decision to undergo these operations must be both independent and responsible, taking into account the influence that can be exerted by undue external pressures, including today's consumer and media culture allied with the increasingly pervasive business of beauty and fitness.

5. The NBC hopes for greater rigour in the training and professionalism of the aesthetic surgeon, also aimed at achieving an understanding of the psychological and ethical aspects related to this specific medical practice.

In this context there should be promotion of professional *guidelines* that reiterate this specific responsibility.

B) With regard to reconstructive surgery, with particular reference to the most invasive transplants (e.g. limbs and face)

The NBC recommends the following:

1. Although not essential for the survival of the patient and though still - in some respects and in some areas - therapeutically experimental, these interventions are ethically justifiable, subject to a careful evaluation of the risks and benefits, relatable to a general consideration of the improvement of the quality of life of the patient.

2. Appropriate counselling is required in advance of the operation and which lasts in time (extended even to the family), due to the complex issues that involve risks and benefits, accompanied by a constant psychological monitoring of the recipient. The follow-up is essential, not only for the patient, but also to acquire useful data for the development of future medical technologies.

The patient should be informed accurately and comprehensively of the risks for health and the severity of the anti-rejection therapies and the fact that in any case they lead to a dependency on these drugs (with possible negative outcomes) which could even last a lifetime.

3. It is hoped that in the implementation of appropriate informed consent there will be use of new information technologies, promoting the collection of information and knowledge through access to sites accredited by government institutions, as well as national and international registries where the latest studies in this sector are published and where scientific publications generated by the study can be found.

4. Awareness raising campaigns are recommended for the donation of external organs and tissues, as typically takes place for the donation of the internal ones.

In this context, the possibility of an integration of the legislation providing for “partial” consent or dissent to external organ donation is also hoped for.



Presidenza del Consiglio dei Ministri



CONSCIENTIOUS OBJECTION AND BIOETHICS

12th of July 2012



PRESENTATION

The NBC has perceived the need to address in general the issue of conscientious objection in bioethics, as previously called for on several occasions with regard to specific questions, and it has set up a working group coordinated by Prof. Andrea Nicolussi, and composed of the following members, Profs. Salvatore Amato, Luisella Battaglia, Adriano Bompiani, Stefano Canestrari, Roberto Colombo, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Emma Fattorini, Carlo Flamigni, Silvio Garattini, Marianna Gensabella, Assuntina Morresi, Demetrio Neri, Laura Palazzani, Vittorio Possenti, Giancarlo Umami Ronchi and Monica Toraldo di Francia.

The document examines the moral aspects of conscientious objection and focuses on the legal side, to which the objector ultimately turns to when requesting to be allowed not to fulfill legal commands contrary to his conscience.

The new frontiers of bioethics increasingly offer a new challenge to the democratic constitutional and pluralistic State. On the one hand, this is to avoid imposing obligations contrary to conscience and the instrumental use of those who exercise a profession. It is often overlooked that the recognition of rights implies a projection of requirements and therefore the claim to behaviours that may even not be compatible with professional deontology. What emerges is, a larger problem of the protection of professional autonomy both from the viewpoint of freedom of the community of professionals to personally reflect and to determine the specific purposes of the profession exercised, as well as from the viewpoint of the freedom of the professional individual in relation to a possible legal hetero-determination regarding the aims of their work. The exercise of a profession involves not only technical discretion, but also deontology.

Moreover, the consciousness of the individual is not confined to the deontological dimension; it concerns the individual as a person not just a professional. The right to conscientious objection (CO) presents itself, therefore, in the first place as a right of the person which a State that is constitutionalised and sensitive to freedom of conscience can not but legally

safeguard. But it is precisely because it is legally protected that this right should be integrated into the legal system, as is the case with all rights, and also because the power to evade a legal command must be justified and not mortify the principles of legality and legal certainty indispensable to the experience of law. First of all conscientious objection can not be limited to an arbitrary refusal to obey, but - with the exception of individual reasons - it must also have an intersubjective significance which in bioethics can be perceived in reference to inviolable human rights recognised at the basis of constitutionalised right. In this perspective, CO not only protects the freedom of the individual conscience, but it is a democratic institution, because it prevents, in the case of highly controversial matters inherent to fundamental values, a majority of them from “requisitioning” even the problematicity and rejection of doubt. However, the recognition of CO does not imply a kind of power to boycott the law, whose validity must be guaranteed as well as that of the exercise of rights provided for therein. It is in this perspective that legally tenable CO is configured.

For these main reasons, the Opinion, with the favorable vote of all and only one abstention, concludes that “conscientious objection in bioethics is a constitutionally founded right (with reference to inviolable human rights), and constitutes a democratic institution, in that it preserves the problematic nature of the issues related to the protection of fundamental rights without binding them to in an absolute way to the power of the majority, and it must be exercised on a sustainable basis.” Therefore, the legal protection of conscientious objection should neither restrict nor make more difficult the exercise of rights conferred by law or weaken the bonds of solidarity deriving from their common membership of the social body.

These findings give rise to some recommendations: in the protection of conscientious objection, which follows from its being constitutionally founded, it is necessary to take adequate measures to ensure the provision of services, taking care not to discriminate neither objectors nor non-objectors, and therefore the organisation of tasks and recruitment that can balance, on the basis of available data, objectors or non-objectors.

The Opinion also deals with the main points of detail regarding the topic of CO in bioethics, such as the need for consistency controls, the distinction between obligations to act and not to act and the difficult question of the criteria for determining who may claim CO.

The document was drawn up by Profs. Andrea Nicolussi and Antonio Da Re, respectively, with regard to the moral and legal perspective, relying on extensive written contributions submitted by Prof. Demetrio Neri, as well as those by Profs. Salvatore Amato, Stefano Canestrari, Marianna Gensabella, Assuntina Morresi and Laura Palazzani. The Opinion was finally approved in plenary session by those present (Profs. Salvatore Amato, Luisella Battaglia, Adriano Bompiani, Stefano Canestrari, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Marialuisa Di Pietro, Romano Forleo, Silvio Garattini, Marianna Gensabella, Assuntina Morresi, Demetrio Neri, Andrea Nicolussi, Vittorio Possenti, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa) with only one dissenting vote by Prof. Carlo Flamigni.

Profs. Cinzia Caporale, Bruno Dallapiccola, Riccardo Di Segni, Silvio Garattini, and Rodolfo Proietti absent from the plenary session subsequently voted in favor.

The President
Prof. Francesco Paolo Casavola

1. Reasons for the Opinion and consideration of the definition of CO

The NBC has dealt with conscientious objection concerning specific bioethical and biogiuridical issues⁹⁶ in a number of opinions. This opinion aims instead to address the issue from a broader bioethical and biogiuridical point of view considering conscientious objection (CO) as the claim of individuals to be exempted from a legal obligation⁹⁷ because they believe that this obligation is inconsistent with a command coming from their own conscience and that it also infringes an important fundamental right in bioethical and biogiuridical fields.

In this sense, CO is understood according to a more specific meaning than a general attitude of intentional dissent towards the command of authority, which is expressed in the refusal to obey a precept of the legal system considered in conflict with the obligations arising from their moral convictions. In addition, it presents itself as distinct from both the right of resistance, meaning the denial of the validity of law of the State and the legitimacy of state authority, as well as from civil disobedience that tends to be a collective phenomenon with the purpose of highlighting the injustice of a law and induce the legislator to reform it.

The objector does not challenge the validity of the law as such or the legal system as a whole nor even the legitimacy of state authority, but asks to be allowed not to obey the law in order to act a manner consistent with his own moral values. Hence the personal nature of CO, consequence of the contrast between legal command and moral obligation, this element is not

⁹⁶ The following documents directly or indirectly refer to conscientious objection: *Issues related to the collection and treatment of human seminal plasma for diagnostic purposes* (5 May 1991); *Ethics committees* (27 February 1992); *Prenatal diagnosis* (18 July 1992); *End-of-life issues in bioethics* (14 July 1995); *Vaccinations* (22 September 1995); *Identity and status of the human embryo* (22 June 1996); *Opinion on the "Convention for the protection of human rights and biomedicine"* (21 February 1997); *Animal testing and health of living beings* (8 July 1997); *Pregnancy and childbirth from the bioethical standpoint* (17 April 1998); *Advanced treatment statements* (18 December 2003); *Note on emergency contraception* (28 May 2004); *Alternative medicine and the problem of informed consent* (18 March 2005); *Bioethics in dentistry* (24 June 2005); *Assistance to pregnant women and post-partum depression* (16 December 2005); *Differentiated alimentation and interculturalism* (17 March 2006); *Conscious refusal and renunciation of healthcare in the patient-doctor relationship* (24 October 2008); *Alternative methods, ethics committees and conscientious objection to animal testing* (18 December 2009); *Note on the pharmacist's conscientious objection to the sale of emergency contraceptive products* (25 February 2011).

⁹⁷ In what follows in § 6 we will also examine the question of the content of the obligation against which objections can be made, that is, whether it refers to obligations to act or even not to act.

found in what has been defined as structural (or institutional) objection (see Resolution 1763/2010 of the Parliament Assembly of the Council of Europe), and therefore, not dealt with in this opinion.

In synthesis, fundamental and minimal points that characterise CO under consideration are: 1) the refusal to obey a significant law in the bioethical field 2) the fact that this rejection is due to the will not to violate their moral convictions or religious principles 3) the desire to bear witness through their behaviour adherence to a certain vision of the world 4) the request (addressed to the legal system to legitimise disobedience so as not to be subjected to sanctions and therefore the need to anchor CO to constitutional values that make it consistent with the duty of loyalty to the Republic and to uphold the law and the Constitution (Article 54 of the Constitution).

In this perspective, different from the one which places CO within a dualistic perspective of contrast between a formal law (e.g. the law as such) and a just law from which the objector draws the reasons for his objection, CO loses the purely negative connotation of rejection of law and authority from ‘*contra legem*’ it tends to become ‘*secundum legem*’, because it searches and finds, precisely in law, the space to express a personal moral or religious view that is not incommunicable. When CO is envisaged and governed by the law it can be viewed as a possible object of an option legally allocated to those finding themselves in conflict with an obligation imposed by the law and an obligation of their conscience, they prefer to opt for equally legitimate alternative behaviour according to limits and appropriate methods to ensure that the space for individual choice is compatible with the orderly conduct of social life. However, it remains the symbol of a contrast not remedied by single legislative provisions, despite the will to stay within the dictates of the legal system. However, this will, allows differentiation of CO from civil disobedience, which has a distinct nature of generalised revolt. However, the distinction is less clear in the option (or clause) of conscience that intends to preserve the principles of “good faith” of the individual professional in specific and particular situations, as for example emphasised in Art. 22 of the Code of Medical Deontology. With respect to this, the CO recognised by law has a more general and abstract nature, as it follows a statement made by the subject who intends to abstain in the future from certain services without his

actually waiting to be in the particular situation of conflict of conscience. Moreover, as the NBC has already noted in its Opinion on *Vaccinations* (22 September 1995) it is not conscientious objection which invalidates an obligation of conscience, but a different scientific evaluation compared to the one at the basis of a legal precept, such as supporting the idea of the uselessness of vaccination.

The question of conscientious objection, especially when claimed by a professional, on whom the law imposes duties that may conflict with obligations deriving from his conscience for the protection of fundamental rights, is proposed to an increasing extent because of the problematicity and the sensitivity of the bioethical and biogiuridical issues which involve fundamental human rights in a new and often controversial way. As CO can be invoked in many areas of social life, it is especially in healthcare that there is the greatest frequency of issues that seek recognition or at least debate about it and its implications. At the same time, the spread of requests for self-determination encourages conflict between various freedoms of conscience to the extent that the implementation of the autonomy of one requires the collaboration of others, especially those who exercise a professional activity distinguished by specific aims. Hence the difficult balance between the protection of individual liberty, addressed to someone for expertise and experience capable of providing a specific professional activity, and the protection of the freedom of those who provide such activities and decide to follow their conscience even when not fulfilling the requests that have been put forward; hence also the need to protect the autonomy of the community of professionals to form and maintain their professional status, not only when the technical appropriateness of the required professional act is at stake⁹⁸ but also when what is called into question is the purpose, in the axiological sense, of the actual professional activity⁹⁹. But the need to secure a clear zone of respect of individual

⁹⁸ We tend to talk about scientific objection although the distinction is not always perspicuous. One can think of several borderline cases. For example, the objector to the removal of an organ from a person believed dead according to existing criteria of assessment could legally found the objection on the basis of his ethical opposition to the removal itself, or because of his scientific opposition to those assessment criteria.

⁹⁹ In bioethical literature, at opposite poles of the debate are, on the one hand, the so-called 'incompatibilists', that is, those who believe that the CO of the doctor is incompatible with his profes-

conscience emerges even according to the pluralist principle that characterises contemporary democracies, as well as the principle of laicity understood as non-interference of the State in respect of individual morality. Indeed there are those who attribute conscientious objection to “the technical nature of the pluralistic society” emphasising also that “the lack of shared values can not be replaced by ‘the ethics of many’ “imposed by legislative instrument, therefore by means of the most typical of majoritarian procedures”. The question of conscientious objection, in other words, challenges the same liberal conception, which encourages the idea of self-determination, calling on this concept to remain faithful to the primacy of the individual related to the State organisation that can be threatened even from the claim to total implementation of the will of the majority.

Moreover, there is no denying the serious problematicity of conscientious objection itself imputed, not always wrongly, that can be misused as an instrument of sabotage in the hands of highly organised minorities or abused by opportunistic individuals. In addition, CO takes on public importance to the extent that they are presented as a possible cause for socially relevant justification, not purely internal, of the failure to comply with of a command, and entails the intersubjective communicability of the consciential reasons that oppose the fulfillment of the command. In short, CO even raises the issue of internal and external limits and the methods for exercising it compatible with the duty of loyalty to the social community.

2. The moral perspective

To fully understand the meaning of conscientious objection, it is important to first reflect on the value and meaning of the conscience, which in fact objects to and, opposes an order or a law in force in the name of a

sion (the doctor must never claim CO) as a) his professional duty requires him to operate in the service of patients, b) the patient has the right to be treated by the doctor, c) CO produces inefficiency and inequity in medical care (cf. J. Savulescu, *Conscientious Objection in Medicine*, in “British Medical Journal”, 2006, 332, pp. 294-297) and on the other, so-called ‘compatibilists’, ie those who believe that the doctor can and should always claim CO, as a) he can / should precede his moral values-professional values in relation to what is requested by the patient, b) the medical profession is not mere execution of the patient’s request, c) the doctor can not act against his moral and professional conscience (see M.R. Wicclair, *Is Conscientious Objection Incompatible with a Physician’s Professional Obligation?*, in “Theoretical Medicine and Bioethics”, 2008, 29, p.171 ff.).

moral or religious reference regarded as superior and binding in the strict sense. The etymology of the word (*cum-scientia*) can in this way help to capture some important aspects. First of all conscience has to do with knowing, knowledge (*scientia*), the moment of knowing, even before that of personal awareness, well exemplified by terms such as “to be conscious of” or “be aware of” qualifies the experience of consciousness, even when this is exerted, as in the case of CO, in a strictly moral sense. The element of knowledge is therefore linked to the purely moral dimension. This link appears to be fundamental: the appeal to an ethical request of additional rigour is not based on mere subjective experience or on some extemporaneous opinion. The moral judgment on the virtue or otherwise of the act and the subsequent activation of the volitional component of the subject which then leads to the choice stand on knowledge, which among other things should be recognisable and communicable (something like a *cum-scientia*). The originary and constitutive relational and interpersonal nature of the conscience shows how this is not interpretable in terms of closure and self-reference. When this kind of self-sufficiency¹⁰⁰ is given, the meaning of CO is inevitably affected and often declined in purely subjectivist terms, if not, in extreme cases, of depreciation or even rejection of the bond of belonging to the legally regulated community. This aspect, however, does not challenge the primacy of the moral and subjective point of view in relation to impositions of the community, when they seek justification only through the claim to substitute the actual individual in defining his interests and values; although it should be pointed out that, this is not strictly normativity with respect to which the question of conscientious objection arises, and which however concerns commands justified by a public interest or the need for protection of persons other than the actual objector.

More generally, a simplistic and distorting interpretation of CO would inevitably regard those who intentionally want to evade the general observance of the principle of legality and, at the same time, expect that

¹⁰⁰ Niklas Luhmann writes to this regard: “The conscience is no longer *syn-eidesis*, *con-scientia*, con-science, common knowledge, it is no longer, in absolute, any knowledge, but a kind of erudition of the originality of the self which we can only take note of with surprised tolerance and respect it, but which can not be tested with regard to content” (*Freedom of conscience and consciousness*, in Id., *The differentiation of law*, Il Mulino, Bologna, 1990, p. 267). It follows that “everyone has the right to his conscience. The content of consciousness, therefore, can not be related to super-positive law and bound to it” (*Ivi*, p. 268).

their choice, while morally justified, would be for no reason attributable to the ruling of the law, in which case these would be forms of civil disobedience or resistance to power which, as we mentioned, are not covered here.

Equally distorting are the applications of an opportunistic type which debase the very meaning of CO. As will be seen, the challenge lies in being able to combine the respect for personal freedom, especially when this makes an appeal to intimate and deep convictions, perceived as inevitable, with respect for the rights of others and the bonds of solidarity deriving from their commonly appertaining to the social body. In this sense, the refusal to obey a particular rule, for reasons of conscience, contextually implies basic adhesion to the legal system as a whole, and in particular to those principles and values, established constitutionally which readily seem to be a possible *trait d'union* between personal innermost convictions of a moral nature, and positive legal norms: in other words, the CO as it is understood in this document manifests a conflict between different possible interpretations of constitutional values.

From the above it emerges that CO is qualified in the properly moral sense. It refers us to a further perspective, compared to the strictly legal one, in which it highlighted the limitations and rigidity. Recalling the fruitfulness of such a moral perspective does not exclude possible legal formalisation. Indeed, the complexity of the many issues relating to CO stems from the fact that this was originally a moral phenomenon, which however, needs to come under consideration by the law. The protection of an area of effective communication between moral and juridical elements, although presumably often problematic and difficult, is a prerequisite for the proper recognition of CO, and this area of communication finds clear exemplification in the reference values and principles of the Constitution.

3. Conscientious objection and constitutionalised right

As regards the juridical context the contemporary issue of conscientious objection marks and intercepts a thorough revision of the very concept of right compared to the one commonly widespread in the juridical culture formed in nineteenth-century continental Europe and predominant until

before the second half of the twentieth century¹⁰¹. Formally, this evolution has occurred in what could be defined as Constitutions after Auschwitz (as in Italy and Germany), which in the late twentieth century redirect law by recognising the human person as being the center of the legal system and therefore the purpose of it. This overrides a conception of law as a mere result of the power to enforce laws: it is no longer considered as a simple product of the power of ruling, but finds its justification precisely in some fundamental values recognised in Constitutions (see, for example, Art. 2 and 3 of the Italian Constitution)¹⁰². In this sense right, without losing its autonomy with respect to other points of view (moral, religious, economic, technical, etc.), divests the claim of self-referentiality and embraces the principle of inclusion and debate on fundamental values according to reason as temperament of a legality understood in a rigid and abstract manner without limits¹⁰³.

Moreover, a right that is secularised can not accept fundamentalism of any kind, but must be open to the balance between values that are in genuine collision (conflicting in actual fact and not only apparently) without falling into the paradox of surrogating the reference to the absolute with the absoluteness of the point of view of the majority.

Hence the idea that the Constitution implicates an opening, within certain limits, to conscientious objection as a result of the balance between the value at the basis of the foundation of the legal command object of CO on the one hand, and the principles of freedom of conscience, pluralism and secularism on the other. Even the German Constitution goes so far as to expressly provide for CO to military service which is an extreme hypothesis, as it inheres functionally to a duty to defend the homeland,

¹⁰¹ In some respects the accreditation of conscientious objection brings continental law closer to the sensitivity of Common law Countries, where, within a context of plurality of religions, the recognition of conscientious objection was favored by the refractoriness toward the legalistic monopoly that constituted however the model of the Countries of the European continent.

¹⁰² The establishment of the judgment of the Constitutional Court - the so-called judge laws - proves that legal rules can no longer be conceived exclusively as the product of the will of the majority, who instead is not invested with absolute power but encounters the limits of the constitutionality of laws.

¹⁰³ In other words constitutionalised right, aware of the problematicity of certain issues, endeavours to reconcile the principle of legality and protection of the conscience of those who refuse to fulfill a command which is considered contrary to a fundamental constitutional value (in the words of Antigone, "with rules not of an hour ago, nor of a day ago... [but] of mysteriously eternal life").

which for example our Constitution qualifies as a “sacred duty of the citizen” expressly providing for the obligation of military service (Art. 52 of the Constitution)¹⁰⁴. Therefore, if a legislative provision was considered necessary for CO to military service, considerably less problematic is CO in areas, such as health care in which we can not speak purely and simply of the derogating nature of CO to a constitutional principle¹⁰⁵. Whenever it comes to issues that are inherent to supreme constitutional values such as human life (see Constitutional Court No. 27/1975 and No.35/1987), the CO invoked in defense of a particular interpretation of these values can not be said to be bluntly derogatory and its constitutionality is founded *a fortiori* compared to cases where it is relevant in the military context¹⁰⁶. In these controversial areas CO takes on the function of democratic institute preventing that parliamentary majorities or other organs of the State deny in an authoritarian manner the problematicity concerning the boundaries of the protection of inviolable rights. Coherently therefore Law No.194/78 on voluntary interruption of pregnancy and Law No.40/2004 on medically assisted procreation, in providing for forms of intervention on prenatal human life, have safeguarded the possibility of CO by the subjects professionally involved.

And then on the basis of the recognised need for the protection of animals Law No.413/1993 has also introduced CO to animal testing, in addition to the context of the protection of human life.

¹⁰⁴ In Italy it is precisely on deciding on conscientious objection that the Constitutional Court (164/1985) has accepted a distinction between the sacred duty of defense (mandatory) and the obligation of military service (derogable by law). In any case, the recognition of the constitutional compatibility of the legal discipline that Italy has admitted CO to military service, resolving a doubt that the German Constitution clarifies directly, implies a very extensive act of opening to CO in general.

¹⁰⁵ Full legal recognition of CO to military service, which took place also in Italy following the spread of the culture of “non-violence”, was very significant for the accreditation of CO generally, since the Constitution already states that Italy repudiates war as an instrument of aggression to the freedom of other peoples and as a means of resolving international disputes (Article 11): CO has in fact given the opportunity of reassessment of the same sacred duty of defending the fatherland, distinguishing it from the military service whose obligation laid down by Art. 52, was considered susceptible to fulfillment by ‘objectors even by way of alternative activities.

¹⁰⁶ Otherwise, one should accept the thesis which devalues freedom of conscience degrading it to a purely individualistic phenomenon in respect of which the principle of legality would always prevail. According to this perspective, CO would always have a derogatory nature, regardless of the context of values in which it is invoked, precisely due to the general consideration of the irrelevance of the individual’s inner convictions in relation to the cogency of the law.

4. Laws in highly controversial areas of constitutional importance and CO for the safeguard not only of freedom of conscience, but also tension to fundamental values

This comparison also shows that the debate on CO can not be reduced to the simple claim of freedom of conscience. The valuation of the freedom of conscience and religion as a founding value of a pluralistic legal system remains undisputed, but the same need for balance between the constitutional values which underlie the right to CO prevent configuring it as an absolute right and at the same time lead to a differentiated consideration of the reasons of conscience that can be invoked in support of the objection itself. A differentiation seems necessary due to the different constitutional weight of the reason put forward in support of CO.

In addition, a differentiation is also necessary as regards the question of the possible need for the legal regulation of CO and its methods of being exercised, depending on the reasons of conscience invoked by the objector and their corresponding or not to fundamental constitutional values. Moreover, only in this way, is it possible to avert the danger of indiscriminate CO not regulated by law, just as, on the other hand, the iniquity of constitutionally founded CO, deferred however exclusively to the will of the same majority that imposed the legal order against which CO may be invoked¹⁰⁷. In this way the legal system would recoil on itself in an authoritarian sense, reducing CO to a concession of the majority even when the objector makes claim to a reason presented as an extension of the protection of a primary constitutional value. In other words, it would deny its democratic nature in a constant tension to fundamental values, by depriving itself precisely in the experience of that critical request invoked with regard to the very constitutionality of that right¹⁰⁸. In addition, CO in this way marks a further distancing from the idea of “the ethical State” as a pretext to impose *ex lege* only one moral point of view. This democratic connotation of

¹⁰⁷ Of course, even when CO is deemed constitutionally founded, it always needs to be legally regulated so that it does not become indiscriminate CO, otherwise, a judicial evaluation (in the hypothesis even of the Constitutional Court) that knows how to accept their request, notwithstanding the possible legislative inertia, without however allowing it indiscriminately.

¹⁰⁸ Another cause of exoneration from liability for breach of obligations is, as is well known, is the constitutionally recognised right to strike.

constitutional legal systems is a conquest of civilisation, to be regained continuously and laboriously and it is not easy to preserve, because every majority can succumb to the temptation to overcome those same limitations that may justify the democratic formation of the majority. This characteristic of the contemporary pluralistic and democratic State is also confirmed by the provision of CO in numerous international texts ratified by Italy (Art. 18, para. 1, Universal Declaration of Human Rights; Art. 9, co. 1, European Convention for the Protection of Human Rights and Fundamental Freedoms, art. 18, para. 1, International Covenant on Civil and Political Rights, Art. 10, co. 1, the Charter of Fundamental Rights of the European Union)¹⁰⁹ In this perspective CO should not be regarded as a threat by a majority conscious of the democratic foundation of its very existence and eager not to close authoritatively the discourse on the understanding and scope of the protection of fundamental values. Moreover, many of the bioethical issues move in very problematic contexts (*hard cases or casus perplexi*) or gray areas in which the need for right to establish certainty in one way or another should not be paid at the dear price of imposing *ex lege* the negation of the same problematic issue. Therefore, at least in the more serious cases of “tragic” contraposition between (constraint of) legality and conscience, it is the constitution itself (culture, constitutionalistic ethos) that aspire to avert it, in the sense that constitutionalised right accepts a space for criticism of the decisions of the majority.

5. Communicable and coherent CO with the autonomous formation of professional ethos (a principle of legal non hetero-determination of professions)

If in the final analysis the right to CO can be configured constitutionally as a fundamental right of the person (Articles 2, 3, 10, 19, 21 of the Constitution), nevertheless a purely subjectivist conception is not admissible, that is, a conception that excludes consideration of the contents of the objection and therefore eventually leads to the a comparison between

¹⁰⁹ The European Parliament resolution of 7 February 1983 states that the right to freedom of thought, conscience and religion must be counted among the fundamental rights. For internal legislation, cf., Art. 1, Law No. 230/1998 (New provisions on conscientious objection).

the values reiterated by the objector and the values protected by the law, against which the objection is directed. A subjectivist approach may be valid only when the conflict exclusively relates to the rights or interests of the subject himself; here one remains within the perspective of the individual, whose conscience is undoubtedly inviolable¹¹⁰. If, however, the recognition of juridical significance is also called for, then an objective exteriorisation is needed, which takes into consideration the rights and interests of all the parties involved in various ways and that makes it possible to evaluate the balance between colliding values. Regardless of the most adequate reconstruction of CO, in any case, the freedom of conscience alone is not sufficient to establish CO *secundum legem* but it must be integrated by the value recalled by the objector so as to be able to conduct the balance between the same freedom of conscience and the value which was invoked by the objector,, on the one hand, and the value protected by law, on the other.

When the law acts on the protection of a fundamental good such as life or health (the main assumptions for CO in bioethics and bio-law), the value recalled by the medical objector represents a different interpretation of the value protected by the Constitution; and the tendency of legislation to provide for in such cases the legitimacy of CO testifies, on the one hand, the fact - mentioned previously - that constitutionalised right accepts a space for criticism of the decisions of the majority; and, on the other, that the recognition of CO constitutes an application of a general principle, so that, outside of these cases directly provided for, there is still at stake a constitutional value of equal status, the right to CO would be the result not of a mere analogical extension of these rules, but directly of the general principle they express.

¹¹⁰ In these cases, however, rather than recourse to CO one might suppose the constitutional illegitimacy of the norm that claims to replace the subject in the evaluation of his own individual interest when the consequences are borne by the same subject, and the decision does not involve the active collaboration of others, but rather abstention. The responsibility of the individual towards himself is a pre-eminent value over the impositions of the community on him. For example, if a norm imposed a Jehovah's Witness, to protect his health, to undergo a blood transfusion which he would refuse according to the precepts of his religion, the reason for the refusal becomes irrelevant for the State, as in the sphere of the individual the will of the individual prevails. Equally irrelevant for the State is the reason why others, although not motivated by religious reasons, refuse, any other type of treatment, even through advance directives.

On the other hand, CO assumes a distinctive importance when it is invoked by a person in the exercise of a professional activity, as shown by the fact that in general it is duly provided for in the deontological codes of professional Orders. Very clear in this respect is the deontological Code Italian doctors (2006) in which the general assumed principle is that “the practice of medicine is based on the freedom and independence of the profession which are the inalienable right of the doctor” (Article 4)¹¹¹ and in accordance with Art. 22 “the doctor to whom performances are required which are in conflict with his conscience or his clinical conviction may refuse his services, unless this behavior is not of immediate and serious harm to the health of the patient and he must provide the citizen with every useful information and clarification”. Furthermore, in the oath of the deontological Code it states that the doctor is committed to respecting the legal rules only if they “are not inconsistent with the aims of my profession¹¹²”.

In addition to the purely individualistic dimension of CO, there is a professional dimension in which the conscience (*cum-scientia*) is formed within a professional *ethos* that is defined according to the purposes characterising each profession. The possibility of conscientious objection keeps alive the sense of professional identity preventing heterodetermination - by law or by external imposition - of the professional regulations of the category of professionals in consideration¹¹³. This does not mean that doctors who are not conscientious objectors do not identify with professional *ethos* or that objectors are necessarily more coherent with it, only that the possibility of CO foreseen for all doctors, provides an additional margin of appreciation and therefore the safeguard of a professional *ethos* that, although not necessarily crystallised nor monolithic, does not have to coincide with legal heterodetermination.

¹¹¹ The professional autonomy of the doctor is recognised in the case law of the Constitutional Court: cf. Constitutional Court 282/2002, 338/2003, 151/2009.

¹¹² Moreover, Article 4 (Professional standards of conduct) of the Oviedo Convention provides that “Any intervention in the health field, including research, must be carried out in accordance with the rules and professional obligations, as well as in compliance with the rules of conduct applicable in this case”.

¹¹³ In the medical field the question of professional purposes may also be conditioned by legislation aimed at defining the concept of health in a different way from how it is understood by the same health professionals.

A recent example of possible legal interference was recorded during the introduction of the rules governing the crime of illegal immigration, when the idea of mandatory reporting of the illegal immigrant by doctors and by social workers was debated. In both cases, the professional Orders reacted – albeit received differently - in the belief that the acts imposed on them (the reporting of illegal immigrants) seriously called into question the basic reasons for their very profession¹¹⁴, as well as being prejudicial to constitutional values. So any possible law obliging the doctor to administer a blood transfusion despite the refusal of the patient of age and fully aware (e.g. Jehovah's Witness) would impose a heteronomous idea of the profession as the implementation of mandatory services even for the recipient, rather than of services offered to people who are free. CO in this case would allow the doctor to comply with, as interpreted in accordance with his conscience, the principle of respect for the human beings in health care (Art. 32, para. 2 of the Constitution) to which the same deontological code seems to be inspired. Another example of heteronomy might be read in some strict interpretations of the law, more common in the past, according to which it is forbidden for doctors to give terminally ill patients in severe pain extreme doses of sedatives so as to relieve pain but which could hasten the death of the patient who accepts the risk; such an interpretation of the law would compress and ignore the duty to accompany the patient even in the last stages of life and to alleviate suffering, a duty which the doctor may perceive deontologically but also personally as cogent¹¹⁵.

The formation of professional ethos seems to join personal self-reflection, of which conscientious objection is a direct expression and a wider dimension that involves the entire professional community, necessary

¹¹⁴ The National Council of social workers on 08.07.2009 recommended its regional councils “not to initiate disciplinary proceedings against social workers enrolled in the profession Order who were criminally prosecuted for not having complied with the obligation to report of crime of illegal immigration, in their capacity as public officials or operators of the public service”. The objector, in other words, is considered to be defending the integrity of the profession as the Order intended in its real experience: the illegal immigrant who turns to the social worker to get help, maybe even help to know his legal position, distorts the sense of the profession by bending to the requirements of public order and repression that do not seem to belong to its specific the welfare functions.

¹¹⁵ The assumption, however, from the point of view of CO, is problematic because it concerns a possible obligation not to act but in the text it is referred to as an example of legal interference in the statute of the medical profession and which would be better to put to the professionals themselves and to their common thoughts.

for both the protection of members as well as to generate an evaluative synthesis between the various points of view of those who exercise the same profession. Instead the idea that a professional choice implies automatic acceptance of the duties imposed *ex lege* - possibly even against the deontological code - is fruit of an authoritarian conception of the law that does not allow for the autonomy of professional bodies in the definition of their purpose and consequently of their identity, and reduces the profession merely to depersonalised technique and purely methodical expertise, insensitive to the issue of purpose. Radicalising this approach, for example, if the law imposed on doctors to make themselves available to carry out death penalty sentences, not even in these cases would conscientious objection be allowed.

6. Legally sustainable CO in bioethics: coherency checks, the principle of legality and CO related to the obligation not to act

The issue is particularly problematic given the obvious need to respect the principles of legality and legal certainty (Article 54 of the Constitution), as well as rights by law¹¹⁶ In a Country such as Italy the question of respect for legality can not be underestimated and CO must be configured in such a way so as to avoid any confusion on the matter. The challenge for the legal recognition of CO consists precisely in avoiding undermining the principle of legality and to make the legitimacy of objection, especially when inherent to fundamental constitutional values, coexist with the protection of those individuals entitled to the legally foreseen rights¹¹⁷.

¹¹⁶ For example, CO can not be a means to disregard the right to terminate a pregnancy in the cases provided by Law No. 194/1978, or more generally, the right to obtain the administration of pharmaceuticals appropriately prescribed.

¹¹⁷ In a similar line of thinking, the Constitutional Court recognised the constitutionality of CO in judgments No. 467/1991 and 43/1997. As regards the constitutionally required character of conscientious objection there is a significant position taken in the majority report of the Justice Committees of the House Health and Hygiene (rapporteurs: Hons. Mr. G. Del Pennino and Berlinguer, who considering the possible concerns about the erosive effect of possible mass conscientious objection state: It did not appear permissible to prohibit recourse to conscientious objection in a matter involving such delicate matters of principle and in which the imposition by law of a given behaviour, would indeed, constitute a constitutional violation”: cf. G. Galli, V. Italia, F. Realmonte, M. Spina and C.E. Traverso, *L'interruzione volontaria della gravidanza* Milan 1978, p. 398.

Firstly, it is important to deal with the concern that CO can be abused and therefore the means of exercising it must be regulated in order to reduce this risk which, however, can not be completely eliminated. It is worth recalling in fact an inherent limit to the law, the impossibility of full and final determination of the inner will of individuals (through the so-called trial of intentions), which must always be kept in mind when it comes to the legal protection of expressions of will of individuals, so this limit may not become a pretext for stifling the freedom of conscience of those who invoke it. The question arises to a certain extent in terms of the functional legal safeguards to rule out CO that is reasonably (rightly) dubious.

In this respect, the need for so-called proof of coherence is normally highlighted and is deductible *a posteriori* i.e. after the person has invoked CO in general, and this proof regards the possible incompatibility of subsequent acts to conscientious objection (e.g. Art.9 of Law No.194/1978 provides that conscientious objection “is revoked immediately if the person who claims it takes part in procedures or interventions for the termination of pregnancy provided for in this law, excluding the cases referred to in the previous paragraph”, This refers to cases in which” given the special circumstances their personal intervention is indispensable to save the life of the women in imminent danger”).

Secondly, the need to make CO compatible with the principle of legality provides the point of view with respect to which this document can consistently address the issue of the content of the legal obligation for which CO is invoked. Indeed, reference is usually made to CO relating to *an obligation to act*, which implies abstention by the objector, but there are also those who propose the admissibility of CO related to *an obligation not to act*, which implies commissive behaviour by the objector and therefore the creation of the fact possibly prohibited by law. While abstention allows others to substitute the objector and do what he is not willing to do, active behaviour *contra legem* leaves no room for a substitution that safeguards the application of the law. It follows that if one wants to perceive CO as compatible with the principle of legality, CO related to obligations not to act should be ruled out precisely because infringement of the obligation coincides with the ultimate violation of the legal precept without the possibility of organising a substitutive service that allows for the safeguarding of the principle of legality.

7. The difficult question of the criteria for determining who may claim CO

A delicate question concerns the subjective demarcation of conscientious objection on the basis of participation, of variable directness, in a specific act or activity. On this point there is a more rigid position that requires the direct causal collaboration of the person who is entitled to CO and a more open position that allows it even in cases of merely auxiliary participation. But the fact remains that morally and legally the criterion of causality is not always accurate, as when reference is made to purely naturalistic causality, because causality is always affected by the subjective criterion of attribution of responsibility (intent, negligence), so that intentional facilitation can often be more severe in terms of ascription of responsibility, of unintentional direct causation.

Moreover, with reference to the field of health, the issue becomes complicated in so far as the surgical treatments can be replaced by new treatments made possible by recent developments in pharmacology and therefore the axis of the question shifts, because there is a regression in the action of the doctor from the material act consisting in surgical treatment to prescription of the drug or, in the case of the pharmacist, to its administration. The issue is not restricted in importance to voluntary interruption of pregnancy, with regard to which, the NBC has already had the opportunity to express itself in reference to the CO of doctors and pharmacists regarding abortive drugs or whose potential for abortivity is not excluded¹¹⁸. The question also arises in other situations: consider, for example, the prescription and administration of lethal drugs, certainly illegal in Italy, but permitted in other countries.

In general, the restrictive interpretation of the legitimacy of CO as an exception to be specifically provide for, must be examined in the same way as the principle of equality, to determine if the exception is justified in relation to individuals not included by law; the exception might in fact produce unreasonable discrimination of others (objectors nevertheless, but

¹¹⁸ Cf. *Note on emergency contraception* (28 May 2004); *Note on the pharmacist's conscientious objection to the sale of emergency contraceptive products* (25 February 2011).

not *secundum legem*) that could be found in conditions similar to those of the persons specifically provided for by law (objectors *secundum legem*), thereby configuring a privilege for the latter.

In any case the delicacy of the issue, together with the scarce possibility of identifying an abstract and universally applicable legal rule that does not excessively widen the number of objectors or reduce it in a discriminatory manner, may recommend the intervention of the Orders or, more generally, of professional associations to specifically define the persons entitled to CO and the situations in which it can be claimed. This suggestion is included in the recent opinion of the Spanish Bioethics Committee¹¹⁹.

On the other hand the problem of the demarcation of the right to CO must be understood in the light of the principle that it is not an instrument of “sabotage” of legitimate legal disciplines, and therefore when CO is permitted there must be organisation of a service that nevertheless allows the exercise of legally recognised rights despite the non-participation of the objector¹²⁰. It could be summarised as neither sabotage of the law by the CO nor sabotage of CO by the law.

The aspect of the protection of rights is particularly relevant in cases of CO that have not been legally foreseen. In such cases, due to the lack of legal regulation of the manner of exercise, there can be an imbalance to the detriment of the individuals entitled to those rights (e.g. the right to obtain a drug by presenting the medical prescription), the decision of the objector would in fact hinder the exercise of those rights. Inevitably the matter is then put to the judicial authorities, the objector runs all the risk of how his behaviour will be assessed, taking into account that the judge can not fail

¹¹⁹ Comité de Bioética de España, *Opinión del Comité de Bioética de España sobre la objeción de conciencia en sanidad*, p. 15, found on the website:

<http://www.comitedebioetica.es/documentacion/docs/es/La%20objecion%20de%20conciencia%20en%20sanidad.pdf>.

¹²⁰ In the Opinion of the NBC on the objection of pharmacists, conscientious objection is accompanied by the provision, voted by an overwhelming majority, under which in any event the provision of the service must be ensured. A different degree of protection of CO can be hypothesised depending on the directly causal or facilitating participation of the objector to the fact. For example, in American literature with regard to the objection of pharmacists it was argued that it would not be allowed when in practice the pharmacy service is located in an isolated area where the drug could not be promptly bought in a neighboring pharmacy. Cf. E. Fenton – L. Lomasky, *Dispensing with Liberty: Conscientious Refusal and the “Morning-After Pill”*, in “Journal of Medicine and Philosophy”, 2005, p. 589.

to take into account the consequences. This implies that a control law for CO in general terms or for specific cases would be extremely worthwhile and that this should be accompanied by an indication suitable measures to ensure that the service is not in fact undermined, for example, with a prediction of the figures responsible for its implementation and the penalties for non-compliance, i.e. the conditions to avoid the conflicts of conscience that could be harmful for the proper conduct of social life¹²¹.

Ultimately CO must be compatible with the system of legal order and it is this element that mitigates also the concerns of those who rightly fear a trivialisation of it. Heroic CO is not and can not be legally recognised CO: in cases of resistance or civil disobedience, the person must bear the full legal consequences of his behaviour. The legal system which has imposed a certain duty or legal obligation in the biojuridical context does not intend to contradict itself by accepting CO, it is simply not willing to close the space for discussion on fundamental values and lose its inclusive and pluralistic nature. Therefore as long as the legal system has the strength to accept CO, it manages to maintain a certain balance; when on the other hand CO is not recognised or objectors are discriminated, legality once again takes on the character of Creon (authoritarian) - *sola auctoritas facit legem* - and CO is forced to assume once again the tragic features of the sacrifice of Antigone. The challenge of the democratic state is to maintain the tension to its fundamental values while respecting the principle of legality.

Conclusions and recommendations

The NBC considers that:

a) Conscientious objection in bioethics is constitutionally founded (with reference to inviolable human rights) and must be exercised in a sustainable way; it is an individual's right and a democratic institution necessary to keep alive the sense of problematicity concerning the limits of the protection of inviolable rights; when CO is inherent to a professional activity, it contributes to preventing an authoritarian definition *ex lege* of the purpose of the same professional activity;

¹²¹ Cf. the NBC Opinion Note on the pharmacist's conscientious objection to the sale of emergency contraceptive products of the 25th of February 2011, p.11.

b) The protection of CO, for its own sustainability in the legal system, must not restrict or make more difficult the exercise of rights conferred by law or weaken the bonds of solidarity deriving from common membership of the social body.

On this basis it puts forward the following recommendations:

1. In recognising the protection of CO in the cases considered in bioethics, the law must provide appropriate measures to ensure the delivery of services, by possibly identifying a person responsible for the same services.

2. CO in bioethics must be regulated in such a way that there is no discrimination of objectors or non-objectors and therefore no burdening of either, on an exclusive basis, with services that are particularly heavy or deskilled.

3. For this purpose, we recommend the setting up of an organisation of tasks and recruitment in the fields of bioethics in which CO is applied, which may include forms of personnel mobility and differentiated recruitment so as to balance, on the basis of available data, the number of objectors and non-objectors. Checks usually *a posteriori* should also ensure that the objector does not carry out activities that are incompatible with the one to which objections were raised.

PERSONAL REMARKS

A personal remark by Prof. Carlo Flamigni

Supported by the Catholic Church, pro-life movements have, for years, been calling for the practice of conscientious objection to voluntary abortion to be recognised as an institution of constitutional status together with its recognition as an “inviolable human right.” The National Bioethics Committee has now promptly satisfied this request approving by majority vote an articulate document that aims to achieve two objectives made explicit in the final page, dedicated to “Conclusions and recommendations”:

1. *“Conscientious objection in bioethics is constitutionally founded (with reference to inviolable human rights) and must be exercised in a sustainable way; it is an individual’s right and a democratic institution necessary to keep alive the sense of problematicity concerning the limits of the protection of inviolable rights”.*

2. *“CO in bioethics must be regulated in such a way that there is no discrimination of objectors or non-objectors and therefore no burdening of either, on an exclusive basis, with services that are particularly heavy or deskilled”.*

To put it more simply (the language of the Opinions of the NBC is not always easy to decipher) conscientious objection to voluntary abortion (and in the future, who knows, even related to euthanasia) is something so noble and virtuous that the objector must be guaranteed the right to refrain from carrying out the (public) service requested by law *without any burden*, ignoring the fundamental rights and freedoms of citizens entitled to receive that service. In fact, the law one asks not to obey, would only be the result of an occasional formation of a parliamentary majority (so it may lack an appreciable ethical significance) whereas, the right to conscientious objection to that same law would be legally tenable because it would find foundation in human rights (in this case not respected by law) and it would be useful to keep alive the sense of respect for inviolable rights. Reaffirming the right to conscientious objection in bioethics, the document recognises that the services provided by the law in this area must be duly implemented. This is, in synthesis, the message contained in the proposal of the majority of the NBC.

Before going into the Opinion approved by the majority of the NBC, I would like to illustrate some of the positive aspects. The first, that is certainly acceptable in my view, is that, even implicitly, the majority of the NBC recognises the existence of a “right to abortion”, since it acknowledges that the provisions of Law No.194/78 should not be obstructed, having become an unwaivable accomplishment. In fact, in the “Conclusions and Recommendations” (the only part -according to widespread opinion – which is read by journalists) the Opinion states that *“protection of CO, for its own sustainability in the legal system, must not restrict or make more*

difficult the exercise of rights conferred by law.” In plain terms, the service of abortion provided by Law No.194 must be guaranteed and is not questioned. After having reiterated that all possible forms of discrimination should be avoided, both for objectors as well as for non-objectors, the document acknowledges the need to achieve “*an organisation of tasks and recruitment in the fields of bioethics in which CO is applied, which may include forms of personnel mobility and differentiated recruitment so as to balance, on the basis of available data, the number of objectors and non-objectors. Checks usually a posteriori should also ensure that the objector does not carry out activities that are incompatible with the one to which objections were raised*”.

This step includes a new feature that seems to me of great importance; not only the organisation of the tasks in services but also the “*organisation of recruitment*” can (and perhaps should) take account of the situation that might arise following the spread of conscientious objection, providing for example forms of recruitment in the services reserved for non-objectors. That the majority of the NBC (always characterised by a high density of Catholics) recognises this point is certainly a considerably important step, which is combined with the other great novelty of stating that “*ultimately conscientious objection must be compatible with the legal system*”, in doing so the majority of the NBC confers albeit minimal “ethical certification” to the law, as it recognises very clearly the duty to deliver the services provided for in relation to medically assisted abortion.

What has been highlighted is a result that is anything but negligible, and it is perhaps for this reason that some lay members have subscribed to the majority Opinion. In fact, in “political” terms this conclusion is acceptable, but since the National Committee is not a substitute for Parliament in which the required mediation for legislative acts takes place, rather, it should be a centre for cultural elaboration that clarifies and identifies different ethical solutions so that citizens and the political forces can then decide what is more appropriate to accept for the common good, therefore the solution given seems totally inadequate and unacceptable both from the cultural and ethical point of view. Despite not having been always present, I must express my dissent from the majority Opinion and I will now try to articulate some of the reasons which have led me to withhold assent of the document.

The first reason is of a very general nature and regards the choice of technical language unsuitable for comprehension by citizens not accustomed to the jargon of bioethics. In actual fact what is needed is more straightforward style, written in a simple and pragmatic form, intended to present both the real data as well as the problems that may arise, clarifying also the reasons for which conscientious objection can “*be invoked in many areas of social life, however, it is especially in healthcare that there is the greatest frequency of issues that seek...debate about it and its implications*”.

We all would have expected an answer to these questions from a National Bioethics Committee; personally I considered right an objective assessment of the difficulties which can be encountered by laws of the State faced with a strikingly high percentage of objectors, so much so as to give rise to hope in some of them regarding a declaredly inapplicable rule, the legislator must go back and acknowledge his mistake.

What is the overall credibility of conscientious objection in Italy, at least as regards the voluntary interruption of pregnancy? No sensible person can believe that 90% of gynecologists who refuse to perform terminations of pregnancy in some of our regions has really listened to his conscience and not instead to other, certainly more vulgar appeals. Unable to separate the wheat from the chaff, taking into account the consequences of these objections (often involving entire health facilities, to the point of configuring a real conspiracy against State law) it is only natural to wonder why, as the lesser of two evils, public health units and hospital directorates have not wanted at least to use the remedies that the same Law No.194/78 establishes first and foremost staff mobility. These are important issues that deserved further detail and which were not even considered. In this way, the document endorses the assumption that conscientious objection is always and solely requested on the basis of sincere moral scruples. According to logic and common sense this should indicate to all that the rapid growth in the number of objectors could be (and in many cases is) the consequence of opportunistic choices which have nothing to do with morality. I am personally convinced that greater attention to empirical data would have revealed a very different reality from that suggested in the document.

The second reason for my dissent is more specific and arises from the decision of the Opinion of the majority not to present in any way the problematicity of conscientious objection on a theoretic level. For example,

we have neglected the position of those who argue that conscientious objection should find a way to be made credible through obligations - the more burdensome the more troublesome the inconvenience caused by the non-delivery of the service – which serve to certify real and profound opposition: Garino¹²² writes that this provision of treatment, in some way unfavourable to the objector, is essential to reaffirm the overall validity of the original precept and confirm its sacrificial value, as proof, of the refusal to carry out the task expected and provided for by regulation.

Even less consideration is given to the diversity of problems that arise in different historical situations. In fact, “historically”, conscientious objection was to military service, it was practiced by the young conscript whose distinct moral principles induced his objection against violence and war, however he could not choose not to do military service as it was an obligation imposed by law on citizens. After suspension of forced conscription, the problem of conscientious objection to military service disappeared.

Radically different is the condition of a young man approaching higher education and who instead, can choose the profession to undertake: barring other specific barriers, he may decide to study law, engineering, economics, social communication or medicine, and therefore to accept the obligations deriving from these professions. Similarly, those who choose to enter the magistrature, or to become a journalist, must consequently accept all the tasks related to their chosen post, without any possibility of appealing to “conscientious objection” regarding services that he is in disagreement with, the same must also apply for other professions, including health care. The matter is central because one has to wonder why this structural inequality between different activities should be allowed: some elective professions (the choice to be a judge or pursue a military career) *do not* provide for conscientious objection with regard to the duties required by institutional responsibilities, as opposed to others (the choice to be a gynecologist or the scrub nurse in gynecology). A “perturbed conscience”, disturbed by the possibility of having to perform unacceptable acts, should prompt youths who have to choose their lifetime profession to

¹²² Term *Obiezione di coscienza*, in the Appendix to *Novissimo Digesto Italiano*, Utet, Turin 1984, pp. 338-364.

reflect further before choosing a job that will surely involve certain moral problems which will cause them serious difficulties: to be a gynecologist means being committed first and foremost to protection of a woman's health, to terminate an unwanted pregnancy means the same thing, protection of a woman's health. anyone who does not think that way is advised to carefully re-read Law No.194/78.

Not only has the majority opinion failed to take into account the problems and difficulties that are hidden in the institution of conscientious objection, but it has not even considered the different theoretical positions and alternatives to those included in the document. For example, there is no mention of the fact that strong reservations to conscientious objection have been put forward by authoritative Catholic jurists such as Capograssi and Piola¹²³, whose claims have been completely ignored. Even as a partial remedy to this limitation, I will briefly outline the position of a constitutionalist at the University of Modena and Reggio Emilia, Gladio Gemma, who argues that objection can become the expression of a right to ideological intolerance, because frequently the objector sees the non-objector as an immoral person, so that the objection is translated into an instrument of negation of the principle of laicity because it allows the holders of a public office to put their personal convictions before the full respect of their institutional duties, i.e. those deriving from their position¹²⁴. Conscientious objection therefore damages democratic principles because it can nullify legislation of public interest. Gemma denies the existence of a logical link between the recognition of the rights of conscience and the foreshadowing of the Institution of Conscientious Objection in positive law, an irrational Institution as it is a combination of incompatible elements. This is a legally codified right to civil disobedience. In this sense, the proposal of conscientious objection *secundum legem* involves a judicially irrational

¹²³ G. Capograssi, "Obbedienza e coscienza", in *Opere*, vol. V, Milan 1959, pp. 198-208; A. Piola, "Obiezione al servizio militare e diritto italiano dopo il Concilio", in Id., *Stato e Chiesa dopo il Concilio*, Milan 1968, pp. 201-233.

¹²⁴ I take freely from some of his works: G. Gemma, *Brevi note critiche contro l'obiezione di coscienza*, Botta (ed), *L'obiezione di coscienza tra tutela della libertà e disgregazione dello Stato democratico*, Milan 1991, pp. 319-338; and *Obiezione di coscienza ed osservanza dei doveri*, Mattarelli (ed), Doveri, Franco Angeli, Milan, pp. 55-74.

right, based on a combination of juridically irreconcilable elements, since conscientious objection *secundum legem* is configured as a right guaranteed by the State not to comply with provisions of the law issued by the State itself. It is quite obvious that this “right” would be granted to particular groups of individuals who, due to their personal convictions, disagree with the rules approved by a legitimate and democratic Parliament, and which - in this case - are confirmed by a popular referendum. It is difficult to understand how a right to not comply with juridically configured obligations can actually take substance, that is, can a legally codified right to disobedience be upheld.

According to Gemma this proposal may give rise to a number of developments, all with logical and legal inconsistencies:

1. There is a risk of recognition of the indiscriminate prevalence of individual conscience over any legal precept colliding with it. In this case, any duty of citizens would find an absolute limit in their own conscience. Given that the possible objections of human conscience to obligations established by law are virtually endless, and as it is not practically possible to identify cases where the request to disobey the law is made in the name of self-interest and not personal conscience, no rule would have the guarantee of being observed and laws would no longer have their actual meaning of indicating patterns of obligatory behaviour, but rather only the value of advice, which one can but is not compelled to abide by. This could be the start of an individualistic anarchy which might be also capable of supplanting the democratic order system.

2. The other possible implication could be to provide recognition that is not indiscriminate but delimited to individual conscience with regard to the precepts of legislation that contrast with the said conscience, This could take place, for example, when one wants to protect certain human rights, incurring other inconsistencies of a legal and institutional nature.

To allow the refusal of services, necessary for public interest purposes, may therefore result in the nullification of legislation guidelines of public interest. It would lead to such a paradoxical situation, of a state mandated by citizens which indicates binding behaviour and at the same time allows minorities, more or less limited in number, to refuse to provide certain services, and by so doing, oppose the will of the people and in total contrast with the logic of democracy. In this case, the will of

the majority, that requested the legalisation of abortion, would be overruled by a majority of objecting doctors, a clear defeat of logic as well as democracy.

For a more detailed presentation of this argument I asked Gemma to sum up his position, which he has kindly consented to do putting it in writing:

“Two theories can be sustained regarding conscientious objection, to use the language of jurists (especially lawyers): a principal and a subordinate one (in the case of non-acceptance of the first). The first is constituted by radical contestation of conscientious objection and its recognition on a legislative or jurisprudential level. The subordinate theory is represented by the delimitation of the legal scope of conscientious objection. (*This second theory is of a mediatory nature and I do not consider it essential to include in this text*).

As regards the radical contestation of the figure in question, a number of reasons can be put forward.

A) The configuration of a right to disobedience (of rules considered to be immoral by the objectors) seems incongruous. Laws, understood in an objective sense, as a set of rules with the function of (contributing to) guaranteeing the co-existence of individuals, therefore the availability of goods and resources useful for their existence (*in primis*, public safety, a minimum of social solidarity, etc.). This can be ideally conceived as a result of a social contract (which historically of course never took place), under which the members of a political community undertake, regardless of their philosophical, political, and moral convictions, etc., to comply with rules that are established for the common good. Are these juridical rules sacred and inviolable as divine precepts? Absolutely not, this is obvious. However, faced with the ethical-political contestation of juridical rules, there are two rational and legitimate solutions.

Within the framework of a legal system, accepted, on the whole, even by the objectors, the faculty must be given to the latter to propose the repeal or revision of the rules considered to be unacceptable based on the ideas (also) of moral of those contesting them. Consequently, the faculty to propose and act for the success of the proposal - a legislative amendment, without any breach of existing laws. In contrast to this is the second solution: the right to rebellion. The existence of a right to rebellion may be

accepted, but only on an ethical-political level when confronted with a legal system that is rejected for its values. For example, the rebellion even with arms of the anti-fascists against the fascist regime was morally licit (indeed commendable). But the thesis is sustainable only on the ethical-political level. Besides, nobody has ever thought of criticising the fascist regime for having legally denied, the right of anti-fascists to take up arms against fascism!

The legal recognition of conscientious objection has this inconsistency: it corresponds to the legalisation of a claim to not comply with laws, which can find, if at all, only ethical and political justification, and therefore extra judicially.

B) The foregoing on the duty to comply with rules of law, save for revolutionary refusal, is reinforced by the observation that in democracies there are constitutions which acknowledge moral issues far more than authoritarian regimes do and prefigure the instruments of protection. Even our own constitution has adopted many ethical principles, inherent to the human person - think of dignity, freedom, solidarity, etc. - and confirmation of this is found if we read the speeches of the members of the Constituent Assembly, *in primis* those of the Catholic deputies, who were among the most active in the drafting of our fundamental Charter. Certainly, the Constitution, in its words and even more so in its evolution, acknowledges and protects shared moral values and leaves the door open to different ethical orientations and consequent legislative guidelines. Nevertheless, it can be said that, in general, the rules of law introduced under the force of constitutions such as ours, have either a minimum of ethical lawfulness (although, of course, questionable according to specific moral convictions) or else they can be eliminated through guarantee mechanisms (making conscientious objection superfluous).

C) Conscientious objection is configured as a right to liberty, a moment of self-determination of the individual, however a mixture of very different legal forms operate with this configuration. For instance, personal freedom is one thing, which mainly concerns an area, a range of action, of the holder of the right, while a claim that operates within the context of functions or services is quite different. To give an example, the freedom to accept or reject treatment is one thing, very different is the claim of the doctor not to treat those who have the right to be treated, similarly the right

to go to court to obtain a (favorable) judgement, quite the reverse is the claim of the judge not to pass judgment and refuse to issue sentence. The right to non-compliance with obligations due to conflicts of conscience do not derive at all from the recognition of rights of conscience, such as religious freedom.

D) Conscience, that is, the good on which the right to conscientious objection is based, is a very wide and undefined matter that is not suitable for circumscribing a legal claim. Conscience has many possible manifestations: a religious fundamentalist might feel the duty not to treat or not to assist an unbeliever; an anarchist might consider the payment of taxes, etc. contrary to his conscience. The conscience of an individual can result in many different moral and political imperatives in conflict with public or professional duties, and if one wants to acknowledge a right to non-compliance with laws in the name of conscience this opens an abyss in democratic order system (for authoritarian or totalitarian systems, by definition, the problem does not exist).

E) Finally, it is an oddity that the State recognises the right to non-compliance with its own laws because they are considered immoral. That fact that the parliamentary majority may not be a moral authority, and that laws may be criticised (as well as subject to proposals for modification) for even ethical reasons is out of the question. However to go from this to the acknowledgment of a revulsion to state laws and the protection of this repugnance is a far cry. Moral rejection and the criminalisation of a juridical rule may be tolerated if not transformed into unlawful conduct, however, that they should be legal consecrated does not seem very rational”.

I will attempt to draw some simple conclusions from these considerations. In the case of the law on voluntary interruption of pregnancy a number of values are at stake that concern the respect and protection of the existence of fundamental freedoms of citizens: in principle, the approved rule could be detrimental to these values. Since they are enshrined in the Constitution, it is clear that their violation - and even an indirect insult regarding them - would make the rule constitutionally illicit. If this were demonstrated, the hypothesis to resolve the problem by allowing conscientious objection would be inadequate at the very least, equally inadequate would be the decision to grant freedom of speech to a very small number of citizens to resolve the

apparent lack of legitimacy of a non-democratic government which has made the prohibition of freedom of speech its guiding principle. The correct answer would of course be to resort to legitimate instruments, always present in a civilised Country, specifically created to defend the legality in similar cases. If on the contrary a law concerning protected values such as existence and freedom is recognised as constitutionally legitimate, then it must be considered functional to the defense of the values in question. Naturally, this does not mean that this is an objective and incontestable function, but much more simply that the laws approved by Parliament and the people concerning values and freedoms constitute, by implication of the system, protection of the rights in question. It would then be an incomprehensible contradiction that the same system which legitimately deemed that a given rule should protect existence and freedom allows conscientious objection with regard to its decision.

To these wise considerations Gladio Gemma adds a final personal one. The claim to object according to conscience can not rely upon irrationality and the fantasies of the applicant or of a (more or less organised) group of them, but rather it must have clear scientific credibility, within the limits of sound common sense. This means that those entitled to define and clarify what is true and what is false according to current scientific knowledge must be established - and it is on this point that the majority of the NBC should have given a precise opinion. To avoid misunderstandings I will give an actual example: any reasonable person who knows about science is aware of the latest data on the mechanisms of action of progestins used for emergency contraception and that the only direct experiences conducted with human embryos and human endometrial tissue certify that, in this case, there is no mechanism of inhibition of implantation. This means that until there is evidence to the contrary (which is not even feasible at the moment) anyone requesting to be excused from prescribing these progestins for the supposedly embryocidal effect (the possibility of it having an abortive action was ruled out long ago) is acting only in *mala fide* (in these cases ignorance or incompetence can not be accepted as justification).

I have expanded to present different theoretical perspectives from those adopted by the majority Opinion both to show that the problem of conscientious objection should have been dealt with in a different way from

how it was set out, and also to point out that the primary task of the Committee should have been to inform correctly and objectively about the various positions on the subject, presenting even those contrary to the ones favoured by the majority. A possible proposal could perhaps be put forward only after an objective presentation of the various positions, leaving the task of a legislative choice to other bodies. Instead nothing of the kind: the majority of the NBC simply ignores and disregards positions that differ from its own, elevating itself to a normative source for “Italian morality”, as if it had the chrism and the ability to grasp and explain authentic “Italian values” - with almost a claim to “infallibility” derived perhaps from the fact that a committee with 90% Catholic members can not fail. As I have already stated on other occasions the position taken by the majority of the NBC is mystifying and is far from interpreting the task that should be carried out by a National Committee in a secular, democratic and pluralistic State.

The third and final reason for my dissent from the majority Opinion regards the justification of the argument that conscientious objection should be seen as an exception clause *secundum legem* that, in some ways, would strengthen the legal system. According to Gemma’s thesis, this proposal should be seen as incongruent at the very least; let us now see, in more detail, if it is possible to clarify the reasons that make it unacceptable.

In order to grasp the heart of the proposal of the majority Opinion one should consider the definition of “conscientious objection” which has been selected: *“the claim of individuals to be exempted from a legal obligation because they believe that this obligation is inconsistent with a command coming from their own conscience and that it also infringes an important fundamental right in bioethical and biojuridical fields”*.

Therefore there are two conditions, according to the majority of the NBC, which are the basis of conscientious objection:

1) *the “subjective” perception of a strong and deep contrast between a legal duty resulting from the obligation to obey the law and a moral obligation to follow the dictates of one’s own conscience; and*

2) *the “objective” discovery that the legal obligation is detrimental to a fundamental human right.*

The key point of this definition is that the “subjective” aspect is not in itself sufficient to justify conscientious objection, because otherwise it could undermine the rule of law which is binding on compliance with legal

obligations. If the subjective perception of a moral contrast were enough, one should also accept conscientious objection of all liberals the payment of taxes, or that of all lovers of hazard to the speed limits, and so on: in short, it would be the end of the social function of law. On the contrary what establishes the institute of conscientious objection in bioethics is that the moral obligation perceived by the conscience closely links to the protection of some fundamental human right that is neglected in this case: that is why conscientious objection does not would have anything to do with individual protest, it would be “communicated”, and it should be clearly distinguished from civil disobedience or “scientific objection”¹²⁵.

The referral to human rights is the key, according to the majority of NBC, which would provide a firm legal basis to conscientious objection. Indeed, *“the refusal to obey a particular rule, for reasons of conscience, contextually implies basic adhesion to the legal system as a whole, and in particular to those principles and values, established constitutionally which readily seem to be a possible trait d’union between personal innermost convictions of a moral nature, and positive legal norms”*. This overall loyalty to the legal system as a whole, is, moreover, in turn morally supported by the fact that the Italian Constitution of 1948 has abandoned the nineteenth-century conception *“law as a mere result of the power to enforce laws: it is no longer considered as a simple product of the power of ruling, but finds its justification precisely in some fundamental values recognised in Constitutions”* which are precisely human rights. Thanks to this change the law *“divests the claim of self-referentiality and embraces the principle of inclusion and debate on fundamental values according to reasonableness, temperament of legality understood, according to Creon, in a rigid and abstract manner without any limits”*.

Under this happy situation in which State power (*imperium*) is constitutionally subject to human rights, we can establish that “trait d’union” or the relationship between the “intimate personal connections”

¹²⁵ As noted in the Opinion of the majority, it would be “a simplistic and at the same time distorted” interpretation to see conscientious objection as the claim “of those who intentionally want to evade general compliance with the principle of legality and, at the same time, expect that their choice, albeit morally justified, is not for any reason attributable to the statutes of law, in which case we would be faced with civil disobedience or resistance to power which, as mentioned, are not dealt with here”.

and “positive legal norms “that, according to the Opinion of the majority, not only provide a firm legal basis to conscientious objection, but would also assign to it *“the function of democratic institute preventing that parliamentary majorities or other organs of the State deny in an authoritarian manner the problematicity concerning the boundaries of the protection of inviolable rights”*”.

Since the spheres regarding human life are those in which some “fundamental human rights”, seem threatened, this explains why conscientious objection today concerns the most controversial issues in bioethics such as abortion, protection of the embryo and euthanasia. This also explains why for the majority of the NBC the institute of conscientious objection applies not only for the individual citizen but also for the whole category or class of health care workers: *“the idea that a professional choice implies automatic acceptance of the duties imposed ex lege - possibly even against the deontological code - is fruit of an authoritarian conception of the law that does not allow for the autonomy of professional bodies in the definition of their purpose and consequently of their identity, and reduces the profession merely to depersonalised technique and purely methodical expertise, insensitive to the issue of purpose”*. Health care providers, in fact, would be directly involved as a class in the protection of “human rights” regarding human life, the fundamental reason for which conscientious objection is limited to this elective profession and not to others (judges, journalists, military professionals, etc.).

Lastly, this close connection between conscientious objection of health workers and “inviolable human rights” also explains the different position of conscientious objection to animal testing. The majority Opinion acknowledges that, *“on the basis of the recognised need for the protection of animals Law No.413/1993 has also introduced conscientious objection to animal testing, in addition to the context of the protection of human life”*. It is therefore clear that in the case of animal testing conscientious objection is allowed under the specific law approved by Parliament *“on the basis of the recognised need for the protection of animals”* and not as a consequence of the recognition of one of their “inviolable rights”, which instead would be the basis of conscientious objection in the field of human medicine. Not surprisingly, the majority opinion promptly specifies that a *“differentiation seems necessary... in*

relation to the different constitutional weight of the reason put forward in support of conscientious objection”, a differentiation which “is necessary also as regards the question of the possible need for the legal regulation of conscientious objection and its methods of being exercised, depending on the reasons of conscience invoked by the objector and their corresponding or not to fundamental constitutional values. Moreover, only in this way, is it possible to avert the danger of conscientious objection ... deferred exclusively to the will of the same majority that imposed the legal order against which conscientious objection may be invoked”.

Here we come to the crux of the matter that aims to demonstrate that if conscientious objection were recognised as “*a concession of the majority even when the objector makes claim to a reason presented as an extension of the protection of a primary constitutional value*”, this solution would demonstrate a recoiling of the legal system on itself, in an authoritarian sense. The legal system, “*in other words, would deny its democratic nature in a constant tension to fundamental values, by depriving itself precisely in the experience of that critical request invoked with regard to the very constitutionality of that right*”. Indeed “*conscientious objection should not be regarded as a threat*” the principle of legality and the laws passed by the majority, but it should be looked upon favorably by the same majority as the democratic institution that allows “*not to close in an authoritative way the discourse on the understanding and scope of the protection of fundamental values*” or the chime that announces those values and rights.

That’s why according to the majority of the NBC “*in the final analysis the right to conscientious objection can be configured constitutionally as a fundamental right of the individual*” and as such should be encouraged and protected by the same State which at the same time, issues a law that imposes opposite duties. This would also win “*the challenge for the legal recognition of conscientious objection (which) consists precisely in avoiding undermining the principle of legality and to bring together the legitimacy of objection, especially when inherent to fundamental constitutional values, with the protection of those who are legally entitled to the rights provided*”. The final conclusion is that “*the legal system which has imposed a certain duty or legal obligation in the biojuridical context does not intend to contradict itself by accepting*

conscientious objection, it is simply not willing to close the space for discussion on fundamental values and lose its inclusive and pluralistic nature. Therefore as long as the legal system has the strength to accept conscientious objection it manages to maintain a certain balance; when on the other hand conscientious objection is not recognised or objectors are discriminated, legality once again takes on the character of Creon (authoritarian) - sola auctoritas facit legem - and conscientious objection is forced to assume once again the tragic features of the sacrifice of Antigone. The challenge of the democratic state is to maintain the tension to its fundamental values while respecting the principle of legality”.

The words reported clarify that the position adopted by the Opinion of the majority is divided into three different theories:

A. Conscientious objection should be considered “*as compatible with the principle of legality*” as acceptance of its legitimacy does not undermine or contradict the duty to respect laws;

B. Conscientious objection in the health sector is not merely a “*concession of the majority*” to a group of citizens that requests exemption from obeying a law (as is the case with animal testing), but it should be configured “*constitutionally as a fundamental human right*”;

C. Conscientious objection takes on “*the function of democratic institute preventing that parliamentary majorities or other organs of the State deny in an authoritarian manner the problematicity concerning the boundaries of the protection of inviolable rights*” demonstrating in a tangible manner that, “*it is not willing to close the space for discussion on fundamental values*”.

As can be seen the three theses are different and each of them put forward increasing claims. Thesis (A) is opposed to the general criticism of conscientious objection portrayed as a real contradiction within the legal system: as observed by Gladio Gemma, accepting objection means legalising the right to disobey a binding rule introduced for a good purpose and that is socially beneficial.

Gemma’s position could be challenged, or could find a precise limit despite its being valid in general, seeing as in certain circumstances it may be more appropriate to grant conscientious objection in order to prevent social problems that are more serious than the ones which the legal obligation actually aims to impede: at times it may be worthwhile

to defer and overcome the obstacle with an ad hoc concession that decides in favor of all the positions expressed. In this sense, one could introduce an “exemption clause” to prevent or mitigate vibrant social conflicts.

Thesis (B) is opposed to this solution stating that conscientious objection is a genuine *individual right*, which has an immediate practical consequence: the exercise of conscientious objection can not require any “heroic” commitment and it can not entail extra service duties or other additional burdens of any kind. If conscientious objection were a concession of the majority accepted to avoid worse problems, one could also consider additional workloads or penalties (to be determined separately depending on the circumstances), but if this is a right it can not involve burdens of any kind. This also explains why the majority Opinion has no difficulty in acknowledging “*that conscientious objection can be abused*” and therefore “*the means of exercising it must be regulated in order to reduce this risk which, however, can not be completely eliminated*”. Precisely because it is a right of the individual, this right must be protected even if it gives rise to improper use, so one must also willingly accept to tolerate a large number of “objectors for personal convenience” This would also explain why in this case the risk of misuse should be tolerated, while in other areas (such as the possibility of conception), even a slight risk is unacceptable and must be strictly excluded.

However, the (B) thesis is in turn sustainable only on the basis of thesis (C), which provides the theoretical justification and is the “Archimedean point” of the whole proposal of the Opinion of the majority, which stands or falls with it. Not only is conscientious objection compatible with legality but it becomes an important value, a “*democratic institution*” because it keeps it open “*space for discussion on fundamental values*” that would otherwise be established in an authoritarian manner from state power.

Underlying thesis (C) is the idea regarding the change brought about by the Republican Constitution thanks to which the law would have abandoned “*the claim of self-referentiality and self-sufficiency accepting the principle of inclusion and debate on fundamental values according to reason as temperament of a legality construed in Creon’s manner, that is to say in a rigid and abstract manner without limits*”. This means that the

legal system provides for two levels which are at the basis of the distinction between “*the law of Creon*” consistent with the respect due to the law as the fruit of state power (Creon: *sola auctoritas facit legem*), and “*constitutional law*” consistent with the respect due to the legal system on the whole which acknowledges its submissiveness to the greater values expressed in the human rights recognised by the Constitution. It is thanks to this distinction that the majority Opinion succeeds in upholding thesis (A), namely, that conscientious objection is compatible with the principle of legality. On the one hand, the law must be complied with as the expression of *Imperium* (Creon) that deserves due respect as part of the system of legal order deriving from the (legitimate and democratic) majority of citizens, but on the other hand, conscientious objection is legitimate when the law (of Creon) is not respectful of fundamental human rights recognised in the Constitution that is the basis of the same legal system.

In addition, this distinction legitimises conscientious objection as a fundamental right of the individual (thesis (B)) that would be guaranteed by the Constitution as (constitutional) law foresees that state power (the law of Creon) is respectful of human rights. Therefore, in the absence of the latter condition (i.e. when rights are violated), (constitutional) law provides a legal basis for the right to conscientious objection.

Lastly, thanks to the distinction between the two levels of the legal system (Creon’s legal system and the constitutional legal system), conscientious objection becomes a democratic and positive institution (thesis (C)), because it prevents parliamentary majorities to deny “*in an authoritarian manner the problematicity concerning the boundaries of the protection of inviolable rights*” permitting to keep open the “*space for discussion on fundamental values*”. It becomes quite clear why the majority Opinion intends to “*avoid undermining the principle of legality*” and at the same time attempts “*to make the legitimacy of objection, especially when inherent to fundamental constitutional values, coexist with the protection of those individuals entitled to the legally foreseen rights*”. Hence the “compatibilist” solution according to which both the right to conscientious objection of the health care worker and the right of women to utilise services provided for by Law No. 194/78 must be ensured.

At first glance, the solution may seem “Solomonic” because it allocates to each applicant a little of what is requested, but more careful reflection reveals that the price to be paid is unacceptable, because it involves theoretical incongruities that are combined with a certain “cultural provincialism” that precludes gaining adequate insight into the situation.

The first of these inconsistencies is generated by the fact that the Opinion of the majority starts by taking for granted that Law No. 194/78 is the result of the mere (authoritarian) power of Creon generated by the parliamentary majority that approved it and, if anything, by the popular referendum that confirmed it, but it is essentially a (morally) unjust law that is contrary to “human rights”. It almost seems to assume that such a law has been approved by a despotic power (Creon) proffered only to find a tragic remedy to the spread of illegal abortion generated by the sexual intemperance of women, even at the expense of the “human right” to life in the prenatal stage. After 34 years of Law No. 194/78 the widespread mentality is so accustomed to the legality of abortion to convince the majority of the NBC to acknowledge that at this time it is not possible to call into question the provision of services for medically assisted abortion, but it intends to affirm that the discussion on fundamental values must at least remain open, especially as regards the “right to life” of the embryo jeopardised by other practices introduced in recent years. It is thanks to this constant criticism of the permissive abortion legislation of Creon that perhaps a further enlargement of the attacks on prenatal life may be prevented as occurs with RU486 and the like, with similar expedients.

It is to say the least astonishing to see how a National Committee identifies the legal and constitutional basis of the right to conscientious objection to abortion on the basis of the implicit and predictable premise that Law No. 194/78 is a law of Creon against the “human right” to life in the pre-natal stage, so conscientious objection to abortion would become the democratic institute which, in a society accustomed to the licitness of abortion, keeps open the debate on fundamental rights and testifies in favor of that “right”.

This judgment is so hard and surprising to cast doubt on the actual objectivity of the Committee and are grounds to point out once again how

the overwhelming influence of Catholic culture conditions its judgment. This assessment of Law No.194/78 is so unjust and offensive that it alone justifies my clear dissent from the majority Opinion, why on earth as a citizen of a democratic and secular State should the idea cross my mind that Law No.194/78 is the result of the mere (authoritarian) power of Creon affirmed in violation of a “human right”.

Not only the sense of respect for the democratic State and the laws enacted by it, but also other theoretical considerations lead me to structure this issue in a completely different way from the one underlying the Opinion of the majority. To succeed in overcoming this “cultural myopia” which usually characterises the NBC’s perspective, all too careful to remain within the margins of its ideological matrix to look beyond our borders, it must be acknowledged that the protection of prenatal life is not one of the “human rights”. In this regard it is sufficient to recall that in 1948 the UN Assembly did not include among the human rights neither the specific subparagraph proposed by Chile on the protection of prenatal life (*“Unborn children and incurables, mentally defectives and lunatics, shall have the right to life”*) nor the alternate text backed by Lebanon that included this condition: *“Every one has the right to life and bodily integrity from the moment of conception, regardless of physical or mental condition, to liberty and security of person”*¹²⁶.

If we look beyond the Italian Province we must acknowledge that after the UN Conferences in Cairo (1994) and Beijing (1995) there is a strong tendency to include among human rights also “*sexual rights*” and “*reproductive rights*”. Their affirmation is not yet certain, but at the very least the NBC should have given an account of the ongoing debate, rather than subjecting it to preemptive censorship without even a mention.

If there is no “human right” for the protection of prenatal life, then the alleged legal and constitutional basis to the right to conscientious objection in bioethics disappears and along with it the entire proposal

¹²⁶ Cf. M.A. Glendon, *Towards a New World. Eleanor Roosevelt and the Universal Declaration of Human Rights*, Macerata 2008, p. 430. Even the Vatican diplomat scholar Ettore Balestrero acknowledges that human rights do not provide for the protection of prenatal life. See E. Balestrero *Il diritto alla vita prenatale nell'ordinamento internazionale. L'apporto della Santa Sede*, Edizioni Studio Domenicano, Bologna 1997, p. 88.

put forward by the majority Opinion fails. In addition, it opens a new perspective: we can see that - beyond the historical problems about its genesis - Law No.194/78 was not the simple result of the mere authoritative power of Creon (exercised by a tyrannical majority”), but it turns out to be the tangible means by which in the late ‘70s that very “human right”, that is the right to health of women was protected - almost advocating the notion of “reproductive health” which is the basis of “sexual rights” and “reproductive rights”. Far from being in contrast with the non-existent “right to life in the prenatal stage”, Law No. 194/78 was a forerunner in the specific protection the human rights of women: first of all, the right to health, understood in accordance with principles and limits accepted by modern states. For this reason the slogan “A good doctor does not object” launched in a recent campaign promoted by “the objectors to easy objection” seems particularly pertinent. Indeed, it is difficult to justify health care workers that exercise conscientious objection to interventions aimed at protecting the reproductive health of women¹²⁷.

At a time in history when are increasing measures to protect reproductive health one would expect a National Committee of a modern, secular and pluralist State, to be ready to value practices that increase people’s freedom and to be critical of cultural survivals and other prejudices that are invoked in order to offer resistance to human rights protection, including the right to health. In contrast, the majority Opinion continues to repropose the Catholic thesis that abortion would violate an alleged but non-existent “human right” to life in the prenatal stage, a premise which is certainly not valid, but still useful to promote conscientious objection to a genuine right of the individual, with the ultimate aim to keep open the discussion on fundamental values and inviolable rights that would be trampled on by Law No. 194/78. This view tends to overturn the picture of the situation, presenting the voluntary interruption of pregnancy as a highly immoral practice, entrusted to

¹²⁷ It is up to the health professions to understand that the first duty is the service to women’s health, including reproductive health: just as reluctance and delays in the administration of analgesics must be overcome, the same applies as regards the reproductive sphere. This is however a broader discussion to be explored separately.

people with no sense of ethics; this stance tends to overturn the picture of the situation, by presenting voluntary interruption of pregnancy as a highly immoral practice, entrusted to people with no sense of ethics, in this squalid picture the enlightened behaviour of conscientious objectors stands out as a noble exception, the new champions of the protection of human rights. Instead I personally feel able to declare, with a certain pride, that even with all the limitations due to historical events, Law No.194 was passed to protect the “human right” to health (including, but not limited to, reproductive health): it ensues that Law No.194 does not violate human rights, and conscientious objection to abortion is not a right of the individual. It is crucial to reaffirm this perspective both because it allows to look favourably on the new proposals of reproductive medicine (which may require changes to Law No.194 in order to increase the freedom of women) and also because awareness that law 194 is in line with human rights is liberating for everyone. It is even for this reason that I dissent from the majority Opinion that settles on the same line of criminalisation and guiltiness that has always characterised the Catholic world.

However, there is at least one other serious inconsistency in the majority Opinion that deserves to be reported. Let us try to assume, of course absurdly, that the opinion is shared and that we are all in agreement in recognising that conscientious objection in bioethics is not a protest against Law No.194/78, but only a complex clause *secundum legem* able to strengthen the legitimacy of legal system as a whole as it would constitute “*a democratic institution necessary to keep alive the sense of... protection of inviolable rights*” (rights that would naturally be violated by the provisions of the law in question).

If this were so, then we would be faced with at least two problems. First, we should ask ourselves whether a State which clearly violates human rights so cynically may be structured in such a way as to be also even willing to recognise conscientious objection in bioethics. The second question that we should ask ourselves (and here I refer to some of the considerations made above) concerns the behaviour of the NBC: is it morally acceptable for a Committee like ours to find that a certain lawful practice is clearly contrary to human rights and merely propose as a solution the right to conscientious objection, as a useful institute (?) to keep open the discussion on fundamental

values, explicitly stating willingness to “*avoid undermining the principle of legality*” that allows the delivery of abortion services? This statement, however, is equivalent to an “ethical certification” of Law No.194/78, albeit modest, but nevertheless unmistakable. So, in what way would this law be a clear violation of human rights? Moreover, if a law was actually in clear contradiction with human rights, would it be correct to avoid criticism and denunciation of it? Faced with an inhumane practice, would it be sufficient merely to request the right to conscientious objection for certain workers? If the majority of the National Committee truly believes that Law No.194/78 involves a blatant violation of human rights, then one can not understand its willingness to “*avoid undermining the principle of legality*” and its only seeking to “*to make the legitimacy of objection... coexist with the protection of those individuals entitled to the legally foreseen rights*”. It seems to me that this solution reveals an unacceptable moral incongruence, which is another reason for my dissent to the majority Opinion.

The final conclusion is that if one abandons - as I believe necessary - the idea that conscientious objection is regarded as the banner raised in defense of human rights and in particular the “right to life” in the prenatal stage against a law enacted by a power of Creon, then conscientious objection in the health sector is no longer a “fundamental right”, but may be permitted provided that the objector is required to accept an appropriate burden (carrying out a supplementary service that integrates the missing due service or adopting the criterion of mobility of staff may not be adequate compensations) that prove the solely and purely moral motivations underlying the request. To continue to defend the current situation which merely exonerates from service anyone who requests it means to defend the privilege of too many “objectors for convenience”, that is, to continue to power widespread immorality.

A personal remark by Prof. Assuntina Morresi

The opinion “Conscientious objection and bioethics” addresses the issue of conscientious objection (hereafter CO) from a general point of view, without reference to specific situations provided for by Italian law: the contents of the document have a general validity and relate to any case in which CO can be invoked.

The validity of the considerations developed is however verifiable precisely in what is the most well known model in our Country, namely CO as provided for by Law No.194/78 on the voluntary interruption of pregnancy (hereafter vip).

This personal remark aims to integrate the document approved (even by me) with considerations and data on CO as intended and implemented by Law No.194/78, to support and confirm the conclusions and recommendations made in the opinion.

The data on the implementation of Law No.194/78 are public and accessible thanks to the reports that the Ministry of Health presents annually to Parliament. Data collection involves the ISTAT, the regions, the National Institute of Health and the Ministry itself, in the manner described in the text of the reports, also available on the website of the Ministry of Health.

From examination of the data available to date, it is clear there is no correlation between the number of conscientious objectors and waiting times for women who access vip, but the means of access to vip depends on the organisation of each particular region.

As shown below in an example, on the basis of the available data we see that in some regions with the increase of conscientious objectors there is a decrease in the waiting time for women, and vice versa, in other regions with the decrease in the number of objectors there is an increase in waiting time, contrary to what one might imagine.

In other words, it is not the number of objectors in itself which determines access to vip, but the way in which healthcare facilities organise themselves regarding the implementation of Law No. 194/78.

Even today, in fact, it is possible for the regional healthcare organisation to implement both forms of staff mobility¹²⁸ as well as forms of differentiated recruitment methods, as suggested in point 3 of the conclusion of the NBC Opinion.

¹²⁸ Law No. 194/78, Art. 9 “Hospitals and authorised nursing homes are required in any case to ensure the accomplishment of the procedures provided for in Article 7 and carrying out of operations for interruption of pregnancy requested according to the procedures prescribed in Articles 5, 7 and 8. **The region monitors and ensures implementation through staff mobility**”. (The bold is mine).

Recruitment limited to fixed term contracts (also referred to as “attendance fee”): possible “ad hoc” state competitions for permanent positions, not intended for objectors (without even considering the question of compatibility with the regulations on non-discrimination of workers) would still not be decisive for healthcare organisation.

It is unthinkable that a person who is employed on a permanent contract as a non-objector should be denied the opportunity, thereafter, to change his mind and become a conscientious objector. Indeed as already occurs, some doctors who at the beginning of their careers state that they are not objectors later on become conscientious objectors and vice versa. Possible forms of permanent recruitment reserved for non objectors, - even if allowed by legislation - could not therefore guarantee the provision of services, as it could not oblige a doctor or a healthcare worker, taken on as a declared non-objector to remain so forever.

But on the other hand also some of the organisations that question the implementation of CO in Law No.194 confirm that the problem is primarily organisational, in a recent press conference on the situation in Lazio in fact, the LAIGA (Free Italian Association of Gynecologists for the application of Law No.194/78) stated inter alia: “*With recourse to external contracted practitioners and doctors on attendance fee objection falls to 84%, still more serious by 80, 2% as reported by the Minister of Health, who in his report does not consider the fact that some of those not objecting in actual fact do not perform voluntary interruption of pregnancy*”¹²⁹.

In other words, the current legislation allows differentiated recruitment, specific to non-objectors, some of these, however, for unknown reasons, do not carry out vip, this fact is certainly not due to the percentage of conscientious objectors (and it would be interesting to go into the reasons for this).

The recommendations of the opinion of the NBC are, therefore, consistent with what is currently the case in Italy under Law No. 194/78

¹²⁹ <http://www.associazionelucacoscioni.it/rassegnastampa/aborto-consulta-decide-su-legge-194-nel-lazio-oltre-il-90-medici-obiettore>.

which, if applied correctly, permits both the right to CO and at the same time access to vip for whoever should request it in accordance with the same law.

Conscientious objection and application of Law No.194 - example (see table below)

Key to the table:

Ar: abortion rate: number of abortions per 1000 women of childbearing age, between 15-49 years.

n. ab: number of abortions in absolute value, useful to assess the numerosity of interventions.

object.: objectors, specified as a percentage among gynecologists.

w. tm. % <14 days.: waiting time, defined as time that elapses from the issue of certification and the operation. In this case, it indicates the percentage of women who wait less than 14 days. including 7 days for reflection as provided for by Article 5. It is an indicator of the efficiency of law enforcement.

w. tm. 22 to 28: the percentage of women who wait between 22 and 28 days from the issue of the certificate and the operation, including the 7 days reflection period as provided for by Article 5

Urg: indicates the percentage of abortions in which the physician has issued a certificate of urgency, for which the operation is performed as soon as possible (without the seven days reflection period).

The first line relates to national data. We see that from 2006 to 2009 the number of abortions decreased both as a rate and in numerosity. Objectors increased from 69.2 to 70.7%. The percentage of women who wait less than two weeks (let's say "little") from the issuing of the certificate and the operation increased, from 56.7% to 59.3%, which means that the "service" improved. At the same time, the percentage of women waiting for 22 to 28 days diminishes (from 12.4% to 11.1%) (let's say "a lot").

So in three years in Italy objectors have increased and waiting times have decreased, therefore improved.

The table then shows the same data, region by region, and we find that the circumstances are extremely diverse.

For example, in Lazio, objectors in three years increased from 77.7 to 80.2% and waiting time decreased (an increase from 47.8% to 54% in the women who wait “little”, and a fall from 17.2% to 13.3% in those who wait “a lot”). A similar pattern occurs in Piedmont, for example.

In Lombardia, however, objectors have decreased and waiting times have increased, therefore worsened (a decrease in the women who wait “little”). In Umbria, the situation is as in Lombardia, but more marked in the figures: objectors fall from 70.2% to 63.3% and women who wait “little” decreased from 51% to 40.0%, and those who wait “a lot” increased from 13.3% to 19.0%.

In Emilia Romagna something different again happens: objectors decreased along with waiting times, which therefore improved.

From these examples we see that there is no correlation between the number of objectors and implementation of the law.

In short: the means of implementing the law depends substantially on regional organisation, the overall result of various contributions, which of course, vary from region to region (and probably even within the same region).

I would also like to draw attention to the urgency data: the regions in which more certificates are issued urgently are always Emilia Romagna and Toscana.

For a proper interpretation, the data should be contextualised, and examined together with even complex considerations regarding healthcare organisation, as demonstrated by this simple example: if this data - that Toscana and Emilia Romagna have always been the regions with the highest number of abortions as an emergency measure - were considered per se, one could infer that the women in these regions are not properly informed, and that the network of counselling is by no means efficient, the so-called “active offer” is not very effective, since a very large number of women are too late to make the request for abortion compared with the national average, and therefore many of them must resort to the urgency procedure.

However, only by contextualising can one interpret this fact as a political and healthcare orientation of the two regions, in their implementing the law they evidently tend to bypass the one week reflection period.

| REGION | 2009 | | | | | 2006 | | | | | |
|----------------|------------|---------------|-------------|----------------------|-------------|------------|---------------|-------------|-------------------|-----------------|------------|
| | AR. | N.AB. | Object. | W.T.M. %< 14 d | URC | AR. | N. AB. | Object. | W.T.M. %< 14 d | W.T.M. 22-28 | URC |
| ITALY | 8.5 | 118579 | 70.7 | 59.3 | 11.1 | 9.2 | 131018 | 69.2 | 56.7 | 12.4 | 9.4 |
| NORTHERN ITALY | 8.7 | 53958 | 65.2 | 55.3 | 12.3 | 8.6 | 59829 | 65.2 | 53.2 | 13.3 | 9.3 |
| Piemonte | 9.7 | 9485 | 63.8 | 60.1 | 10.8 | 8.6 | 11030 | 62.9 | 51.1 | 13.7 | 7.3 |
| Valle d'Aosta | 7.6 | 217 | 18.2 | 66.2 | 7.9 | 5.5 | 274 | 16.7 | 40.5 | 7.8 | 4.4 |
| Lombardia | 8.8 | 19646 | 66.9 | 56.0 | 11.5 | 7.6 | 22248 | 68.6 | 58.6 | 11.3 | 6.2 |
| Bolzano | 4.8 | 571 | 81.3 | 62.4 | 9.7 | 8.4 | 564 | 74.1 | 44.7 | 15.2 | 4.8 |
| Trento | 9.0 | 1078 | 55.9 | 48.8 | 17.3 | 8.1 | 1358 | 64.0 | 62.7 | 11.1 | 6.9 |
| Veneto | 6.0 | 6840 | 78.0 | 38.7 | 22.0 | 8.8 | 7090 | 79.1 | 34.0 | 23.4 | 7.8 |
| Friuli V.G. | 7.8 | 2075 | 60.4 | 55.8 | 12.6 | 7.1 | 2107 | 59.8 | 54.4 | 11.0 | 7.5 |
| Liguria | 9.6 | 3219 | 57.3 | 49.3 | 13.6 | 3.5 | 3700 | 56.3 | 51.1 | 14.1 | 4.4 |
| Emilia Romagna | 11.1 | 10872 | 52.4 | 62.0 | 8.3 | 12.4 | 11458 | 53.5 | 56.8 | 11.1 | 20.7 |
| CENTRAL ITALY | 9.4 | 25487 | 69.5 | 56.1 | 12.5 | 12.3 | 28888 | 71.0 | 55.2 | 13.4 | 12.9 |
| Toscana | 9.5 | 7819 | 62.2 | 59.0 | 11.1 | 19.3 | 8879 | 55.9 | 63.3 | 9.3 | 22.8 |
| Umbria | 9.5 | 1920 | 63.3 | 40.0 | 19.0 | 2.3 | 2178 | 70.2 | 51.0 | 13.3 | 2.2 |
| Marche | 6.9 | 2458 | 62.0 | 71.1 | 7.5 | 8.6 | 2581 | 78.4 | 73.9 | 5.6 | 8.1 |
| Lazio | 9.9 | 13290 | 80.2 | 54.0 | 13.3 | 10.3 | 15250 | 77.7 | 47.8 | 17.2 | 9.4 |
| SOUTHERN ITALY | 8.3 | 28839 | 80.4 | 70.7 | 6.8 | 8.7 | 30716 | 71.5 | 63.6 | 9.9 | 7.6 |
| Abruzzo | 8.1 | 2518 | 78.5 | 56.8 | 11.3 | 4.7 | 2709 | 45.5 | 71.9 | 4.9 | 5.0 |
| Molise | 9.0 | 666 | 82.8 | 76.1 | 9.0 | 4.8 | 620 | 82.8 | NR | NR | 5.0 |
| Campania | 8.3 | 12183 | 83.9 | 67.1 | 6.4 | 11.1 | 12049 | 83.0 | 62.1 | 10.3 | 7.4 |
| Puglia | 9.7 | 9682 | 79.4 | 77.3 | 5.1 | 9.7 | 11333 | 79.9 | 60.9 | 11.5 | 10.2 |
| Basilicata | 5.0 | 700 | 85.2 | 82.6 | 3.6 | 6.6 | 701 | 44.0 | 78.0 | 3.5 | 8.1 |
| Calabria | 6.3 | 3090 | 73.3 | 65.5 | 10.1 | 2.2 | 3304 | 73.5 | 64.9 | 10.0 | 2.3 |
| INSULAR ITALY | 6.3 | 10295 | 74.1 | 59.8 | 11.8 | 4.9 | 11585 | 76.3 | 66.0 | 8.9 | 4.8 |
| Sicilia | 6.5 | 7979 | 81.7 | 55.2 | 13.7 | 3.6 | 9303 | 84.2 | 62.0 | 10.5 | 3.7 |
| Sardegna | 5.7 | 2316 | 54.3 | 75.7 | 5.3 | 9.4 | 2282 | 57.3 | 77.8 | 4.1 | 8.0 |
| ITALY | 8.5 | 118579 | 70.7 | 59.3 | 11.1 | 9.2 | 131018 | 69.2 | 56.7 | 12.4 | 9.4 |

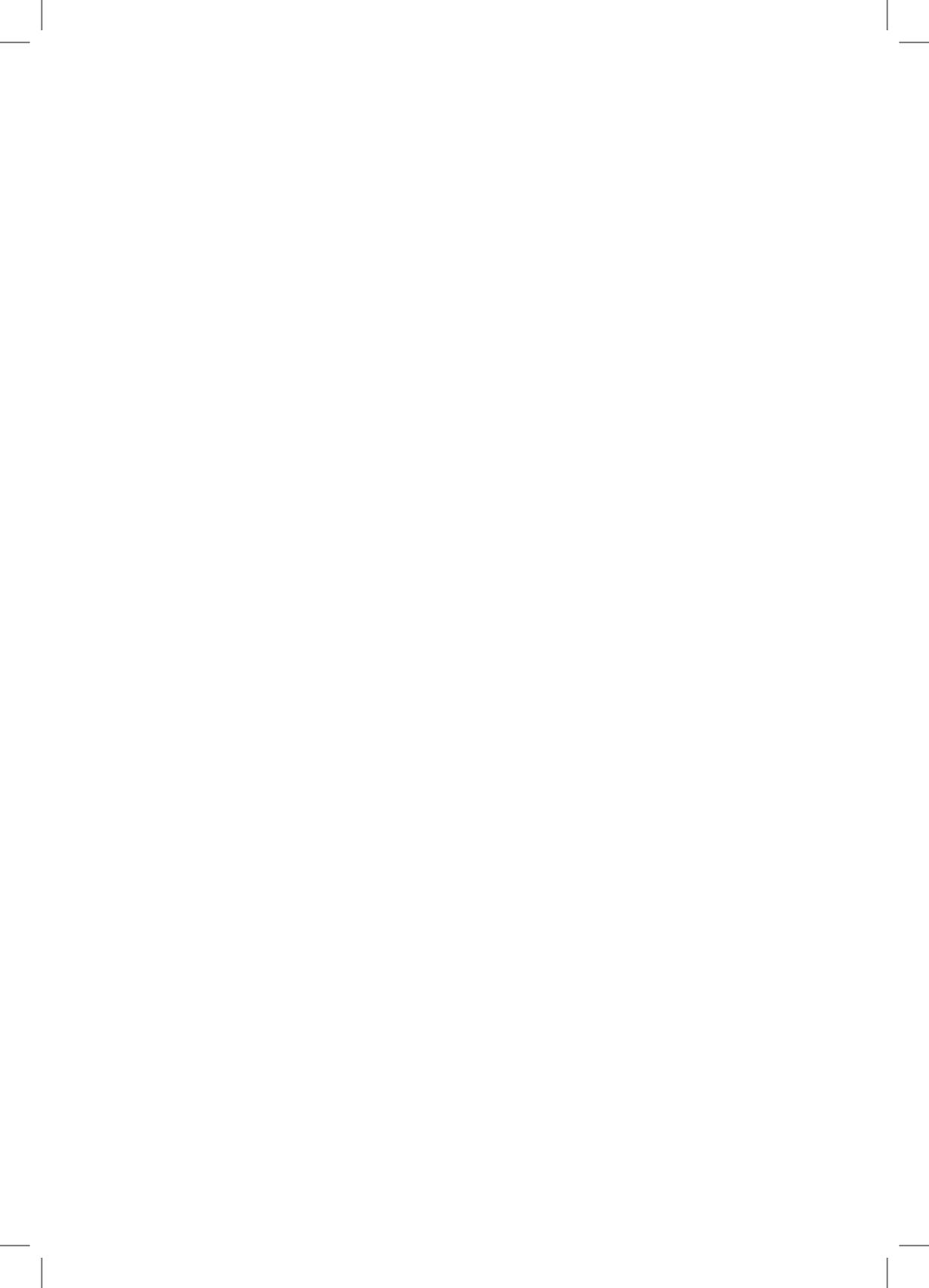


Presidenza del Consiglio dei Ministri



**ON THE NATIONAL HEALTH SERVICE'S
COMMUNICATION TO PATIENTS
OF HEALTHCARE COSTS**

28th of September 2012



PRESENTATION

In reply to a question raised by the Health Minister Prof. Balduzzi, the NBC dealt with and debated the issue of the communication to patients by the National Health Service of the average costs of healthcare services.

In the premise the text introduces the context of the problem, including it in the broad issue of the distribution of healthcare resources (at macro and micro-allocation levels) and analyses the main arguments in favour of and against the mandatory communication of costs to the patient.

Most of the NBC members considered the mandatory communication not ethically justified and imposed on the patient, granting it only in the case of authorisation given by the latter at the moment of being discharged from hospital or after receiving treatment.

On the other hand, some members of the NBC declared themselves in favour of the mandatory communication of costs, managed with due attention, as an instrument of transparency in a liberal democratic society.

Despite this divergence, the NBC was unanimous on the modalities of the communication (for some possible, for others mandatory), above all with the recommendation to avoid patients being made to feel guilty and discriminated against and to respect the need for privacy of personal details on their state of health. The communication of costs – the Committee goes on to recommend – must not be considered the only instrument for the citizens' awareness of healthcare costs, but must be included in the context of an overall social education to increase awareness of the close connection between individual health and social health, stimulating consciousness/knowledge and the assuming of responsibility by citizens with respect to the prevention of pathologies and risky behaviour and the curb on and proportionality of the demands made on the healthcare system. Once again the Committee hopes that citizens/patients are guaranteed, in the respect of the wish of whoever wants to know, the access to both general and more detailed information with regard to the costs sustained by the NHS for treatment received or to be given.

The document, edited by the Vice Presidents Profs. Lorenzo d'Avack and Laura Palazzani and written with the contribution of all the NBC members in the plenary session of the 28th of September 2012, was

unanimously approved by the following: Profs. Amato, Battaglia, Bompiani, Canestrari, Caporale, D'Agostino, Da Re, d'Avack, Di Segni, Flamigni, Forleo, Garattini, Guidoni, Palazzani, Proietti, Toraldo di Francia, Umani Ronchi, Zuffa. Absent in the plenary session the following later expressed their approval: Profs. Dallapiccola, Di Pietro, Gensabella, Morresi, Possenti and Scaraffia.

The President
Prof. Francesco Paolo Casavola

1. Premise

There is a more and more visible gap between the increase in healthcare costs and the decrease in the available healthcare resources.

The increase in healthcare costs is due to various factors: the development of medicine enables the population to live longer, but at the same time this makes the percentage of citizens with chronic and disabling illness increase and, therefore, with serious healthcare problems; the trend to no longer accept illness as an inescapable fate but to experience it as an event to be faced in all ways possible; technological progress, in the diagnostic and therapeutic fields, with the offer of new costly intervention possibilities in favour of the ill and, last but not least, the inefficiencies, the useless interventions, the waste and corruption that have had repercussions on the capacity of the NHS to satisfy the growing demand, optimising the use of the existing resources.

The decrease in the available resources has been caused by the economic crisis and by a need to curb even healthcare costs by means of the planning and rationalisation of healthcare policies, an abolition/reduction of waste and an optimisation of the use of the available resources.

The gap between the increase in costs and reduction of available resources makes the choices which have always been faced in healthcare increasingly more difficult in the relationship between state/healthcare, facility/doctor-healthcare, operator/patient. In healthcare policy, the question of macro-allocation (choice of how much to invest in health and in its various sectors) and micro-allocation (choice between alternative treatment for a patient or selection of patients for the same treatment) constitutes an important and consolidated chapter of bioethical reflection.

In Italy the problem arises with specific reference to a public health system that recognises each citizen the right to health protection, healthcare and medical assistance (Art. 32 Const.). With the collection of resources by means of the proportional income contribution, the state is guarantor of equal access to healthcare resources, at least for basic needs.

Until today the healthcare costs sustained by the State for treatment and assistance were not made known to citizens. The Lombardy Region, with select committee resolution No. IX/2733 of the 6th of December 2011, bearing “Decisions concerning the management of the Regional Socio-

Healthcare Service for the year 2012” foresaw that citizens be informed of the costs, as the 1st of March 2012, by this meaning the reimbursements made to the healthcare facilities, that the Regional Healthcare Service sustains for hospitalisation and consultancies enjoyed by the citizens¹³⁰.

This initiative by the Lombardy Region focussed the attention on a number of problems that require both an ethical and juridical reflection, insofar as they relate the question of the value of health and the economic costs to guarantee it, in the context of the relationship between individual and social wellbeing.

The Health Minister, Prof. Renato Balduzzi, asked the National Bioethics Committee “to consider whether the introduction of such obligation of transparency might not have prejudicial effects on the actions that the National Health Service must bring about to correspond to the duty of improving the patient’s wellbeing, above all when suffering from serious illnesses and whether the just economic reasons are not in this case unbalanced with respect to those of humanity and solidarity”¹³¹.

Different standpoints arise with regard to this, on the basis of the arguments that are compared.

2. The different reasonings

Among the reasons justifying the direct communication of the costs of healthcare treatment and public assistance to the patient, the following can be considered:

1. The need to show the costs of healthcare in the notifications to the patient related to hospital admittance and specialist treatment, according to the criteria mentioned above, enables the citizen to know how much the community in which he or she lives contributes with taxes, the modalities of the use of public resources by the State and the regions and the extent of personal contribution with regard to the services received.

2. The patient’s knowledge of the costs fosters an awareness process of the close connection between individual and social health and the

¹³⁰ See attachment No. 2.

¹³¹ See attachment No. 1.

assuming of responsibility in the use of healthcare resources, with possible positive consequences in terms of the rationalisation of expenses and reduction of waste.

3. The transparency in public healthcare costs financed by the National Health Service in the different regions can allow the citizen to compare and judge the efficiency of the structures involved, relating them also to private costs.

4. The availability of economic data becomes an opportunity for public debate with the participation of the media and social networks, resulting in greater transparency and better control of expenses.

Among the reasons against the compulsory and direct communication of the costs of healthcare services to the patient, the following can be considered:

1. In the Italian Health Service the protection of health forms part of a solidarity concept of the division of the expenses among those with the most and least benefits. Healthcare and medical assistance for basic needs are due actions towards every citizen regardless of the costs sustained.

2. The communication of information on costs to the patient expresses an economic 'calculating' logic in healthcare that can encourage choices (collective and individual) that introduce the reference (at times even as priority) to costs into the risks/benefits balance, risking making the premises of the justification of the non giving of care/medical assistance considered inefficacious insofar as too expensive compared with the poor therapeutic relevance. Such logic impoverishes the medical principle of beneficence, the very sense of medicine as 'taking care' of the ill person and mortifies the social concern towards those who are in need.

3. The communication of the costs to chronic patients, subject to repeated hospital stays, can increase their distress. Hospital admittance itself usually creates a state of identity disorientation and greater psychological fragility (especially in more serious cases or those with an uncertain diagnosis), which create the need for an empathetic welcome and not one of making them feel guilty, even indirectly.

4. Awareness of the costs can have serious outcomes on patients who can be led to decrease the ethical perception of the dignity of their own life, considering their life condition as not worthy of being lived and perceiving their existence as a burdensome and 'costly' (in terms of individual

suffering and economic family and social costs) biological process. In this sense the information of the costs could urge the patient to refuse further treatment, or contribute to this.

3. The considerations of the NBC

Before the hypothesis that the Lombardy Region should keep the resolution in question, and other regions opt for an analogous communication of information, the analysis of the arguments in favour and against the communication of the costs of the medical record to the patient, the Committee replies to the question with the following observations:

1. The majority of the Committee¹³² considers that:

a) the mandatory communication to the patient of the costs of medical treatment received is not ethically justified, in consideration that the protection of health is a citizen's fundamental right and a duty by state and society.

It is important that the state and regions formulate homogenous measures and strategies aimed at rationalising the use of healthcare resources, but the curbing of expenses in the administration of public healthcare funds must not lapse into forms of bureaucracy or business- making of healthcare, lacking in respect for the dignity of the patient as a person;

b) the communication of costs, to the extent that it is considered relevant, must take place when requested by the patient, at the moment of being discharged from hospital or during treatment or should the patient be incapable, by his or her legal representative at the time of discharge or medical treatment;

c) the non mandatory communication of costs to the patient must not, however, mean absence of knowledge. On the contrary, should they wish so, it is important that all citizens be able to have general and individual information on healthcare expenses.

In most local health units (ASLs) the doctors of the area periodically receive the list of the services carried out with the expenses variance for

¹³² Bompiani, Canestrari, D'Agostino, Da Re, d'Avack, Di Segni, Flamigni, Forleo, Guidoni, Palazzani, Proietti, Toraldo di Francia, Umani Ronchi, Zuffa. Absent in the plenary session the following later expressed their approval: Profs. Dallapiccola, Di Pietro, Possenti and Scaraffia.

each with respect to the average. In the hospitals the doctors and managers receive adequate information on the DRGs (Diagnosis Related Groups) that correspond to their interventions. It is therefore appropriate to also allow citizens/patients to access information of both a general and specific nature with regard to the costs sustained by the NHS or regional body for the services to be allocated or received. It is to be hoped, for the very reason that the objectives are those of transparency and the assuming of responsibility, that the possibility of knowing the average costs regards all the services and does not concern only a part of these, in particular the ones whose costs to the citizen are below those reimbursed by the region, and not those on the contrary that are above. More generally, a website could be foreseen, at regional and national level, which all taxpayers can access in order to check the macro and micro allocation of the resources and, above all, to compare the healthcare costs. This could curb costs, avoid a lot of waste and produce a qualitative improvement in the healthcare organisation.

2. Some members of the NBC¹³³ share the opportunity for citizens to also access information of a general nature and on unitary costs, and consider however that the mandatory communication kept separate from the medical record, if managed with due attention out of sensitivity for the individual, is not only bioethically legitimate, but constitutes an important instrument in the growth of a liberal democracy. A liberal democracy manages its service transparently, informing citizens who must never be considered paternalistically, in this case only as patients to be taken care of (sensitive, incompetent, fragile). The citizen is and must remain, despite his or her illness, an active and responsible part in the running of public affairs, capable of exercising a control on the services given insofar as part of the community, which transparency contributes to strengthen.

3. The Committee is unanimous in considering that the communication of costs (prior consent for some; mandatory for others):

a) be given with an ad hoc document and not in the medical record, an obligatory document at least in the case of admittance to hospital and reserved for keeping clinical records related to the genesis of the illness;

¹³³ Amato, Battaglia, Caporale, Garattini, Neri.

b) be given with suitable criteria and modalities to avoid a sense of guilt and the mortification of the patient, with fitting reassurance on the care of the illness and any need for assistance due;

c) must in any case be founded on the recognition of equality and non-discrimination of sick persons; a differentiation in treatment by reason of the patient's age, his or her capacity to understand, state of health (more or less serious pathologies) is not to be considered ethically legitimate and – lastly – the costs themselves (more or less onerous pathologies): it would be like clearly expressing and stressing – more or less indirectly – the seriousness of their condition, of which they may not be aware;

d) respect the need for the confidential nature of the personal data related to the patient's state of health and of any activity concerning the latter;

e) must not be considered the only instrument to foster citizens' awareness of healthcare costs, but must be included in the context of an overall social education to increase awareness of the close connection between individual health and social health, stimulating awareness/knowledge and the assuming of responsibility on the part of the citizen with respect to the prevention of pathologies and risky behaviour and the curb on and proportionality of the demands made on the healthcare system.

The Committee furthermore hopes that:

f) citizens/patients are guaranteed, in the respect of the wish of whoever wants to know, the access to both general and more detailed information with regard to the costs sustained by the NHS for services received or to be given.

g) the transparency on economic costs pursues the objective of making not only patients/citizens responsible but above all the health service administration and the doctors, for the purpose of leading them to more rational choices in the use of resources, considering the appropriateness of treatment and the compatibility with the funds available.

The evaluation of treatment and its compatibility with the resources available is above all left to the doctors, considering both the clinical and organisational appropriateness of the chosen diagnostic therapeutic course,

where the patient can only propose or refuse. The evaluation of the appropriateness of the interventions, together with quality, and the definition of the levels of essential assistance are central arguments in the activity of the NHS and the Ministry of Health, besides being professional constraints and internationally recognised rules of conduct¹³⁴.

¹³⁴ Oviedo Convention, Art. 4.

ATTACHMENT: Letter of request of Minister Balduzzi to the National Bioethics Committee

Dear President,

the Lombardy Region, with select committee resolution No. IX/2633 of the 6th of December 2001 bearing “Decisions concerning the management of the Regional Socio-Healthcare services for the year 2012” defined and approved healthcare and socio-healthcare planning guidelines, the system framework, plans and regional development programs for the year 2012, identifying as basic requirements, the integration between healthcare authorities and innovation in technical-healthcare and administrative processes. Measures able to improve access to services, the appropriateness/effectiveness of surgeries and the continuity of treatment, as well as organizational and managerial solutions in order to integrate the activities of the healthcare authorities, have been indicated as key priorities.

The Lombardy Region stressed the central role of local healthcare authorities in protecting the citizens’ health, in particular as regards to healthcare and socio-healthcare needs; even through differentiated means of access to care procedures.

Specifically, from the 1st of March 2012, it has been made mandatory (see attachment 1, “planning guidelines”) for physicians and hospitals to indicate in the medical records related to hospital admittances and consultancies, the costs of healthcare services, including any extra costs the patient is charged with. Both the above, to be indicated in the letters of release from the hospital and in all communications to the patient. This procedure is carried out in order to make the citizen aware of how the community in which he or she lives finances, through taxes, health services he or she receives and the extent of his or her personal contribution.

The Committee is required to express an Opinion on the compatibility of the provisions of the above-mentioned resolution of the Lombardy Region with the principles of our legal order, in that, from March 1st 2012, it bears “an obligation for both public and private authorities whether they are admittance or consultancy units to communicate to the citizen, the cost of the health service divided between the cost sustained by the Region and if necessary that of the citizen”.

In particular, it is required to consider whether the introduction of such obligation of transparency, regarding the cost of the services sustained by the Region, could have prejudicial effects on the actions that the National Health Service must bring about to correspond to the duty of improving the patient's wellbeing, above all when suffering from serious illness and whether the just economic reasons are not in this case unbalanced with respect to those of humanity and solidarity.

Best regards.

Renato Balduzzi



Presidenza del Consiglio dei Ministri



**FOOD ANIMAL PRODUCTION
AND ANIMAL WELFARE**

28th of September 2012



PRESENTATION

The National Bioethics Committee has on several occasions paid attention to the ethical issue of the protection of animal welfare in the different contexts of life and the utilisation of animals by man. The maturation of an articulated ethical position *for animals*, that is not merely related to the *treatment of animals by humans*, is reflected in the variety and complexity of the *ad hoc* Opinions directed at specific and differentiated analysis of the bioethical profiles related to inherent subjects such as the veterinary profession, animal testing, alternative methods to animal testing and conscientious objection, ritual slaughter, the use of animals in activities related to health and human well-being ('assisted therapies and activities with animals') and practices designed to change the appearance and morphology of companion animals for aesthetic purposes.

In a European framework of growing awareness to animal welfare, now regarded as an issue of public ethics, this document addresses one of the best known, customary and oldest forms of animal use, that is, for the production of meat and in general of products of animal origin intended for man. The topic - entrusted to a working group coordinated by Profs. Luisella Battaglia and Cinzia Caporale, together with Profs. Salvatore Amato, Francesco D'Agostino, Riccardo Di Segni, Carlo Flamigni, Marianna Gensabella, Assunta Morresi, Giancarlo Umani Ronchi and Grazia Zuffa - deserves renewed attention as currently it is characterised by an accentuation of the tendency to extend forms of industrial production, which significantly reduce the *quality of life* of animals.

When we define something as "good to eat", it is argued that, we should not refer only to what satisfies the palate and respects gastronomic or dietary criteria, but also to whatever expresses our value options, and meets certain ethical requirements of integrity and transparency of the whole productive chain as well as attention to the parameters of animal welfare, as fully described in scientific literature and for the most part provided for by the norms of the European Union.

The position of the NBC, in this perspective, is directed at supporting biocultural ethics which overcomes a conception of animals exclusively as a means for the satisfaction of human needs and interests and which

recognises animals as sentient beings worthy of protection. Biocultural ethics aims to expand the traditional scope of interest of ethics to encompass in moral considerations “every aspect of the relationship between living species”.

The Opinion concludes that, while taking into account the centrality of man and the legitimate interest in the price of products of animal origin, especially in times of economic crisis, it is necessary to achieve a comprehensive assessment which examines the problem in the light of a broader and forward-looking concept of *benefit for society as a whole*, including the world of production, respecting human health, animal welfare and environmental sustainability. Several specific recommendations arise from these conclusions: 1) promotion of a culture of enterprise and supply chain with a considerable enhancement of human responsibility towards animal welfare; 2) adoption of a specific labelling system applied to productive and zootechnical activities based on quality standards of excellence with respect to animal welfare and along the whole supply chain; 3) tangible respect of the consumer’s right to know, even through the promotion and implementation of information and awareness campaigns on behalf of the supervisory authorities; 4) timely activation of the creation of a European Network of Reference Centres for animal protection and welfare in order to favor the establishment of more sustainable forms of animal farming and production throughout all the Union; 5) promotion of scientific research in the field of animal welfare, particularly for productive livestock, and development of an *animal-based* assessment system; 6) maximising the crucial role of the veterinarian in the assessment of the living conditions of animals and identification of parameters of their well-being; 7) activation of professional training for personnel involved in the care and management of animals.

The document was drawn up by the coordinators of the working group, Profs. Luisella Battaglia and Cinzia Caporale, with the precious collaboration of Prof. Salvatore Amato and some external experts who sent their written contributions or participated in a seminar: Prof. Barbara de Mori (Researcher in Moral Philosophy, University of Padova), Dr. Agostino Macrí (Head for the food sector of the National Consumers’ Union), Prof. Franco Manti (Professor in Social Ethics, University of Genoa), Dr. Romano Marabelli (Head of Department of veterinary public health, food safety and

the governing bodies for the protection of health, Ministry of Health), Prof. Fabio Pammolli (Professor of Economics and Management and Director of I.M.T. Advanced Studies Lucca), Prof. Michele Panzera (Professor of Veterinary Ethology and Animal Welfare, University of Messina), Dr. Paolo Scrocchi (Director General of the Italian Breeders' Association). A special mention is due to Dr. Pasqualino Santori, President of the Veterinary Bioethics Committee and already a Member of the NBC, who was an integral part of the working group and contributed to the drafting of the document.

The Opinion was unanimously approved in the plenary session on the 28th of September 2012 (Profs. Salvatore Amato, Luisella Battaglia, Adriano Bompiani, Stefano Canestrari, Cinzia Caporale, Francesco D'Agostino, Antonio Da Re, Lorenzo d'Avack, Riccardo Di Segni, Carlo Flamigni, Romano Forleo, Silvio Garattini, Laura Guidoni, Laura Palazzani, Rodolfo Proietti, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa). Profs. Bruno Dallapiccola, Emma Fattorini, Marianna Gensabella, Aldo Isidori, Claudia Mancina, Assunta Morresi and Demetrio Neri, absent from the session have subsequently expressed their adherence.

The President
Prof. Francesco Paolo Casavola

1. Food choices and animal welfare, bioethical profiles

There is perhaps no other human behaviour more charged with symbolism than eating: as a sacred act, a time for socialisation, cultural expression as well as imagination, emotion and memory. To speak of nutrition is, in some way, to speak of man's inner life, his history, his social and ethical identity and religiosity. Every food choice reveals who we are, manifests our inclinations, our preferences, but at the same time, in terms of public ethics, contributes to the consolidation of certain production policies to which, consciously or unconsciously, as consumers we implicitly assent¹³⁵.

In recent decades, especially in Europe, there has been a growing awareness of animal welfare, now regarded as an issue of public ethics, and the 'animal issue', i.e. the problem of a proper treatment of non-humans, has become a strongly felt problem. Hence a series of questions arise on how to reconcile the ethical standards referred to in this Document with the mistreatment of animals and consequent suffering, especially in the food supply chain. In essence, the question is whether we can continue to consider animal suffering as a necessary evil in our lives or whether we must *inevitably* choose between human welfare and animal welfare. These questions are of great importance especially for bioethics, which is called upon to reflect, by way of its interdisciplinary vocation, on the possibility of developing a pattern of eating that is *ethically sustainable* in respect of the interests of all the subjects and parties involved, capable of reconciling the preferences and habits of conscious and responsible consumers with the needs of production as well as those of animal life.

¹³⁵ The consumption of products of animal origin in human nutrition varies depending on availability and price (possibly influenced by support policies and incentives) and local cultures and traditions. Making quantitative estimates is rather problematic. Factors of complexity are, for example, the evaluation of the actual contents of substances of animal origin in finished products and the calculation relating to imported goods, which is difficult to implement. In addition, different sectors and different States use different methods to measure the phenomenon. According to the latest data from the *Food and Agriculture Organization of the United Nations* (FAO), the consumption of animal products is steadily growing, especially in developing countries or wherever local production has been developed. It is estimated that in the world around 230 million tonnes of meat are produced annually (FAO, 2008), with potential problems of scarcity for the new demand coming from countries such as China and India. In the EU, the annual value of livestock farming activities is approximately 149 billion euro.

Without necessarily seeking to call into question eating meat and products of animal origin, one wonders whether it is possible to intervene on the *way* in which it is carried out, by improving animal welfare conditions in a manner compatible with the interests - including the economic ones - of the consumer. In this respect it should be noted that there is a steady increase in the number of commercial experiences in which market justification is compatible with the development of animal husbandry systems that protect the living conditions of animals and respect the ecosystem.

When we define something as *good to eat*¹³⁶ we must therefore refer not only to what satisfies the palate and respects gastronomic or dietary criteria, but also to what is the expression of our value options, and corresponds to our idea of *good living*, together with what complies with specific ethical standards of correctness and transparency of the whole supply chain as well as paying attention to the parameters of the 'quality of animal life' (parameters fully described in scientific literature for several decades and for the most part adopted by 'the European Union'¹³⁷).

In order to speak about 'the quality of animal life' it is necessary first of all to gain the perspective of the quality of the human-animal relationship, intended as a willingness to assume the responsibility of a commitment to the quality of animal life at the same time fully preserving the quality of human life. Often, not considering the quality of animal life means in fact to neglect important aspects of the same quality of life of individuals and society as a whole.

¹³⁶ "Good to Eat: "Riddles of Food and Culture"- originally titled "The Sacred Cow and the Abominable Pig"(1998, published in Italy in 2006 by Einaudi) - is a famous book by American anthropologist Marvin Harris. The author's approach has a more limited scope than the present Document; it relates to the interpretation of the diverse eating habits of peoples and in particular their food taboos, which is seen as *rational optimisation of natural resources*. What is considered *good to eat*, according to the studies by Harris, is so because it is not harmful to health, it is widely available and because it is so effective. Convenience acknowledged by populations - the author argues - is only subsequently transformed into a precept of an ideological or religious nature, or social norm perceived as being inviolable.

The concept of *good to eat*, however, has very ancient roots, with vast and profound meanings. In Genesis (2.9), for example, God gives to man the fruits of the earth described as every tree that is pleasing to the eye and, of course, *good to eat* (among these is the tree of life and the tree of the knowledge of good and evil).

¹³⁷ Consider, for example, that in recent years the European Union has dedicated to animal welfare, on average, almost 70 million euro per year in direct subsidies to livestock farmers and supporting training activities and information for workers and the general public.

Claims that modern industrial farming systems are by no means adequate for the basic needs of animals, can no longer be dismissed as a mere ‘anthropomorphic’ perspective to the issue of animal welfare. These conclusions are in fact based on the consolidated research of ethologists, physiologists, agronomists and veterinarians, scientists and professionals certainly not suspected of mere zoophile sentimentalism, that have been joined to bioethicists in their supporting the need for change. This line, however, has long been welcomed by the new legislative guidelines.

The now extensive scientific literature on this issue also sees a gradual shift of focus from the physiological parameters of well-being - detectable by quantitative measurement - to the qualitative aspects of the needs of animals, through an evaluation of *preferences* and the *ability to feel*. Between the seventies and the nineties, there was a progressive shift from a negative definition of well-being as “absence of disease” to that of the “satisfaction of needs” before finally reaching the so-called “*feelings approach*” which refers to the *perceptual* states and feelings of animals¹³⁸.

The same spread of ethics committees dedicated to the protection of animals has placed as a central issue the identification of operational requirements which take into account the capacity of *sentience* and ability to meet the physiological and ethological needs of individual species, initiating reflection on the theme of well-being in an interdisciplinary perspective and examining the ethical implications stemming from it. This enrichment of the concept of well-being also includes the contributions made by the new orientations that have emerged from the international debate on the subject of animal bioethics: on the one hand, the guidelines which enhance the *care approach*, and therefore the special responsibility that humans must perceive towards the sentient beings over which they exert power and make use of to achieve their aims, and on the other hand those who follow the neo-Aristotelian approach of *capabilities* and believe that this idea may be applied also to the animal world, viewing this extension as a new frontier of the principle of justice.

¹³⁸ The term *feelings* refers to the cerebral states of the animals induced by environmental stimuli and cognitive processes.

Along this line - with a growing emphasis on the interplay between economics, development, society and ethical criteria - fits the position of the *Food and Agriculture Organisation of the United Nations* (FAO), which, in addition to identifying the protection of animal welfare as a principle valid not only for the ethics of advanced societies but also for the development strategies of the poorest countries, it supports the need to provide cultural education programmes in support of economic growth and, at the same time, the protection of animals and the environment. This means, of course, making regulatory updates¹³⁹ and soliciting proposals for action which facilitate the efficient provision of livestock activities, taking into account the diseconomies related to environmental and sanitation problems, but above all it means reaching a global assessment that examines the problem in the light of a broader and far-sighted concept of *benefit to society as a whole*, with respect of human health, animal welfare and environmental sustainability.

¹³⁹ References to national and EU regulations: in Italy the protection of animals, including fish, reptiles and amphibians, bred or kept for the production of foodstuffs, wool, skins or fur or for other farming purposes is regulated by Legislative Decree No. 146/2001 implementing Directive 98/58/EC and specific rules for rearing calves pigs and laying hens. Directive 882/2004/EC on the assessment of the wellbeing of animals in production provides, among the obligations of the Member States, national control programs for animal welfare and the Decision No. 778/2006, applicable from 1 January 2008, establishes uniform rules for the control of animal welfare extended to all species of livestock. The “National Plan for Animal Welfare” (PNBA), issued by the Ministry of Health in 2008 stems from the need to comply with Community provisions unifying the method of implementation and scheduling of controls. It is important to note that Article 13 of the Treaty on the functioning of the Union recognises the status of *sentient beings* to animals and establishes that account should be taken of the needs relating to animal welfare. In 2006, the Community Action Plan on the Protection and Welfare of Animals 2006-2011, adopted by the Commission, for the first time faced together the different elements of relevant EU policy. The “Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on EU strategy for the period 2012-2015” offers new lines of action that take advantage of progress in science and technology in order to reconcile in the implementation of existing legal provisions, animal welfare and economic realities. Indicators of the quality of the product based on the evaluation of the conditions of animal welfare have also been introduced in two recent EU measures (Directive 2007/43/EC EC Regulation No. 1009/2009) and were the subject in 2012 of the recommendations of the experts of the European Food Safety Authority (EFSA). All these aspects have been summed up in “Communication from the Commission to the European Parliament to the Council and the European Economic and Social Committee of 19.01.2012 on the strategy and the European Union for the Protection and Welfare of Animals 2012-2015”. Lastly it is worth mentioning the “Council Conclusions on the protection and welfare of animals” (3176th Agriculture and Fisheries Council Meeting, June 18, 2012), which essentially converges with the Commission in stressing the need for a holistic approach, it encourages a high level of protection at national level and promotes greater transparency to support informed choices from consumers.

In fact, nutrition may now become a sort of litmus test that demonstrates customs, lifestyles, moral choices, memberships, mutual recognition, and the relationship with one's body, other species and the Earth as well as awareness of unprecedented responsibility.

2. Scientific perspectives on animal welfare

In 1965, the scientific community reached a first definition of 'welfare' understood as a general term that encompasses both physical and behavioural well-being of the animal, as measured by indicators of physiological, behavioural and reproductive systems, and on the basis of longevity. The Brambell report¹⁴⁰ establishes certain parameters commonly used from then on in order to ensure an acceptable level of well-being for farm animals. It is to the latter that, according to the majority of experts, there should be ensured, as far as possible, the following five 'fundamental freedoms', of which the fourth and fifth are the most difficult to define unambiguously: 1) freedom from hunger, thirst and malnutrition; 2) freedom from environmental discomfort; 3) freedom from pain, injury and disease; 4) freedom from *fear* and *stress*; 5) freedom to express species-specific behavioural characteristics.

The definition of well-being was later updated in 1992 by the *Farm Animal Welfare Council*¹⁴¹ in Great Britain on the basis of new knowledge concerning animal life acquired in the meantime in scientific literature. In this way a process of interdisciplinary research initiates aimed at identifying methods to manage animals kept for farming, which is not limited to ensuring minimum standards of well-being but also intends to significantly improve their living conditions¹⁴². It is precisely in relation to this aim

¹⁴⁰ The Report of the Technical Committee to Enquire into the Welfare of Animals kept under Intensive Livestock Husbandry Systems (HMSO London, 1965) is one of the first official scientific documents on animal welfare. It was commissioned by an *ad hoc* committee set up by the British government following the uproar caused a year earlier by the publication of the book "Animal Machines" by Ruth Harrison, regarding the welfare of intensively reared animals. The *ad hoc* committee was led by Professor Roger Brambell, DVM.

¹⁴¹ Advisory Committee of the British government on these matters until 2011, originally formed as a result of the Brambell Report.

¹⁴² The *Animal Welfare Science* is concerned with the evaluation and assessment of animal welfare and is a rapidly expanding subject. In Europe it is taught in all faculties of veterinary science.

always dutifully supported and substantiated by scientific evidence, that the concept of 'quality of life' is introduced in reference to the animal world, with a significant change in perspective from the traditional view. Animal welfare concerns now a number of factors that have to do with the quality of the surrounding environment, with all the relationships that an animal maintains with it and with the same quality of life, in the specific situation in which it finds itself. Any attempt to assess welfare, according to several authors, should consider the available scientific evidence relating to the *feelings* of animals, derivable from their structure and their functions (*capacity*) and their behaviour ('the *feelings* approach'). So, according to this acceptance, to ensure its welfare, it is essential for the animal to enjoy, in addition to the physical health necessary to guarantee the functioning of the fundamental properties of the living being, also the opportunity to reasonably put into practice the behavioural responses that allow its integration in the surrounding environment.

Over the last few years, research has understood that animal behaviours imply the presence of complex physiological mechanisms of adjustment, integration and control. Social behaviour, in particular, reveals adaptive modules that can be understood only if one accepts complex features in the processes of brain functioning. According to recent studies, for example, *privation* becomes *suffering*¹⁴³ when an animal is prevented - by physical restrictions or lack of adequate stimuli - from manifesting in addition to strict 'physiological needs', even what might be termed the *cognitive representation* of the same needs. It can be said that, when considering animal welfare, the question of 'behavioural needs' should not be overlooked and indeed it is of fundamental importance.

It is also on the basis of this kind of research, that numerous sides have ascertained that current techniques of industrial farming deprive animals of the opportunity to meet the essential needs to put into practice certain behaviours defined as *maintenance*¹⁴⁴, which, similar to

¹⁴³ Moreover, without the animal being able to giving a 'cultural' meaning to such hardship and suffering.

¹⁴⁴ Among these, there is for example freedom of movement inside an appropriate space suited to the characteristics of the species. The impact on welfare is also particularly marked in overcrowded conditions, since the animals are not only prevented from complying with social spaces and hierarchical distances, and even without the necessary space for pressure sores, for

the concept of homeostasis, are of primary importance for the proper functioning of the neurosensory systems of the animal and its well-being.

All the scientific knowledge gained so far in the extensive field of animal welfare applied to livestock production, while considering the open scientific discussion on the various elements, has made it possible to define a set of values and reference quality parameters that have been judged as sufficiently reliable to be gradually adopted at EU and national regulatory levels¹⁴⁵. More knowledge is expected both as regards the assessment of environmental factors that influence welfare, as well as on the assessment of the reactions of animal to these factors.

Of particular interest are the new lines of research that seem to show more effective methods of assessment of animal welfare based on the detection of parameters directly estimated on the same animals (presence of trauma, injury, disease, poor physical condition, etc.), compared with the current methods used that are restricted to measuring environmental parameters or those related to methods of management (temperature, space in square meters, quality of feed, etc.).

According to European institutions¹⁴⁶, the two approaches should be considered complementary and not alternative, with the advantage that a direct assessment - carried out by the so-called *animal-based* indicators mentioned above - shifting the focus from environmental risk factors to the exposed individual animal, this would give the possibility to determine its true state of well-being rather than only presuming it theoretically on the basis of the fact of compliance to the limits and environmental constraints imposed by regulatory standards.

getting up and in some cases, even for a standing position. However, one should bear in mind, as shown by scientific literature, that domesticated animals - which obviously include the vast majority of farm animals - seem to show less suffering in the same conditions of confinement than wild animals.

¹⁴⁵ Point 7, Annex Art. 2, paragraph 1, letter b) of Legislative Decree No. 146/2001 pursuant to Directive 98/58/EC on the protection of animals kept for farming.

¹⁴⁶ See "Communication from the Commission to the European Parliament to the Council and the European Economic and Social Committee of 19.01.2012 on the strategy and the European Union for the Protection and Welfare of Animals 2012-2015" and "Council Conclusions on the protection and welfare of animals"(3176th Agriculture and Fisheries Council Meeting, June 18, 2012).

3. Biocultural ethics

If modern zootechnics has broken the traditional *contract* between humans and animals, *biocultural ethics* - the field of bioethics that deals with the moral problems concerning the management of relations by man towards other non-human beings - intends to take this implicit contract seriously and to renew it, having been in force for millennia. 'Bioculture' is meant as, that set of institutions, social practices and organised activities (such as animal husbandry) in which man uses animals in order to achieve his goals, using them systematically for his own benefit¹⁴⁷. These activities are characterised by two aspects: the domination by man and the reduction of animals to a means.

The need for an ethical approach in this area arises from this recognition of man's power, which needs to be regulated and involves specific responsibilities. One of the fundamental aspects of biocultural ethics is of course the link between power and responsibility. The fact that we exercise power over other non-human beings does not mean that we have a free hand to do whatever we wish or whatever is worthwhile, in fact, this exercise of power involves responsibility for their welfare; if we breed animals to use the products derived from them or their bodies, our responsibility towards them does not decrease, but rather, it is increased. The recognition that these animals render us 'services', that we use them and therefore *live on them* and *upon them*, should make us feel responsible for their welfare, and ensure 'adequate' treatment for the services they render. We are faced with a central issue for our society, since it concerns not just zoophiles, but also consumers of animal products and their keepers, in other words, any person who has a *direct* or *indirect* relationship with them through utilisation.

Therefore, biocultural ethics involves some very important consequences: a) the transition from a *purely* economic perspective to *also* a moral perspective. In this context, animals are not merely *resources* to be exploited, *goods* to be administered rationally, but they appear as sentient beings with their own interests and needs, worthy of protection; b) a change in the human role, marked by the transition from the culture of *exploitation* to that of *care*.

¹⁴⁷ For the origin of the concept of 'Biocultural ethics' cf. "Respect for Nature" by Paul W. Taylor, Princeton University Press (1986).

As mentioned in the previous paragraph, it is through the achievements of science and technology that we have become aware of a power which makes us *de facto* foster the fate of the Earth and the species that inhabit it. It can be deduced that, a practice, cannot be accepted simply because it is *productive*, nor can our legitimate interests as a species justify *any action at any cost*. Therefore, faced with certain practices, we should question ourselves about the kind of sacrifices we impose on animals, which fundamental interests we deny them and whether it is truly *necessary* to sacrifice their welfare.

In particular, one wonders if certain technical changes in the supply chain cannot produce significant improvements without causing considerable renunciation or sacrifice for man, that is, whether the codified system of biosecurity in the supply chain cannot create incremental conditions in welfare such as to justify contained increases in costs for consumers in the short term. In addition, one must calculate how animal welfare affects the economic sustainability of the livestock sector especially in relation to small-scale farmers¹⁴⁸ and also assess whether shortening the supply chain may not compensate for any increases in the costs of farming when determining the final price.

Livestock rearing has now become a standard industrial process aimed at the growth of production: a given quantity of calories, protein and carbohydrates fed to livestock or poultry corresponds to a certain number of kilos of meat, liters of milk, and number of eggs. To the higher production attained there corresponds of course a significant reduction in the end price of the product, which, it should not be forgotten, is in man's legitimate interest, especially in times of economic crisis such as we are experiencing.

Industrial production has, however, imposed in the name of cost reduction, the logic of monoculture that equates efficiency with the standardisation of procedures, equipment, feed, and breeding techniques. Monoculture implies simplification and separation: one animal (or a single

¹⁴⁸ The evaluation the EU as regards animal welfare concludes that welfare regulations have to date imposed additional costs estimated at about 2% of their total value. The increase is, however, attributable to the livestock sectors and experimentation as a whole and should be calculated specifically for separate sectors and take into account all factors (*Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the European Union Strategy for the Protection and Welfare of Animals 2012-2015* - Brussels, 19.1.2012).

plant) for the largest amount (or for the greatest extension) possible. Natural ecosystems, on the contrary, are based on complexity and on integration. In an ideal ecological system, each animal completes the biological cycle and food cycle of the other and the waste produced by one is eaten by the other. Clearly, it is not a case of putting animals together and leaving them free to wander in the fields, but rather to use all technical and scientific knowledge to recreate, through breeding, a natural balance that will optimise production and reduce the social costs incurred. We must therefore reflect on the fact that, there is an ‘invisible’ price to an egg or a portion of meat, which we do not pay at the supermarket checkout, but that affects the level of taxation that the consumer is asked to bear as a taxpayer. It is important that consumers know that in the composition of this ‘invisible’ price there is animal suffering also included, notwithstanding one’s personal convictions on the bioethical issue itself. Therefore, there is nothing nostalgic or primitive in reclaiming systems of production that are ecologically balanced, precisely the opposite: there is a need to develop levels of professionalism adapted to the scientific and technical knowledge at our service in order to obtain tangible, solid and stable long-term benefits also and especially for the citizen-consumer-taxpayer. If we are not scandalised by producing more expensive but safer cars, we cannot reject the idea of food production that, well within the logic of the market, takes into account also moral sustainability and environmental quality.

Consider also that the attribution of value to a particular product is a complex and multifactorial process: it encompasses a cognitive evaluation by the consumer which may be absolute or comparative (*this product is cheaper than the other one*). The perceived value and the mental representation of product characteristics significantly influence purchasing behaviour which is in turn also in relation to profound moral and personal convictions, in this case the attitude people have towards animals.

Biocultural ethics prescribes that livestock farming be carried out in such a way to ensure an *appropriate* quality of life to animals, which presupposes above all, as described in the preceding paragraph, a scientific knowledge of their physiological and behavioural needs. In this way it is possible to adopt methods of breeding which, while taking advantage of the productive capacities of animals without neglecting even economic factors, do not compromise the fundamental conditions of

welfare. These findings confirm the need to carry out an articulated cost / benefit analysis and, above all, to decide which biocultural model to choose each time, seeking an acceptable balance between our legitimate usefulness and animal welfare, perhaps creating parallel markets.

This instance is fully incorporated in the document of the National Bioethics Committee “Bioethics and veterinary science. Animal well-being and human health” (2001), according to which respect for the ethological and physiological characteristics of animals must be of a binding nature in the choices that are made regarding them, and in particular the choices concerning therapy, breeding, their keeping and management. In view of the quality of life of animals - largely in line with Community guidelines - industrial-scale animal husbandry must be discouraged in favor of ethologically and ecologically sustainable animal farming, and promoting ‘ethical supply chains’ from production to consumption through systems of labelling that characterise productive and livestock activities on the basis of quality standards at all levels of the supply chain as a guarantee for the consumer.

Transformation of the relationship with animal alterity has also led to the emergence of a new type of veterinarian that needs to be instructed in the field of applied behavioural sciences in order to be able to recognise the parameters of well-being and define the sensors for the monitoring of *stress*. Similarly, however, veterinarians, as all healthcare workers should have training in bioethics in order to assess the moral importance of the interests of animals and protect them, even by initiating a public debate regarding the choices and guidelines that should direct our conduct towards other species.

Another essential element to consider is the environment. In biocultural ethics in fact a model of ‘environmental integration’ is being pursued, the expression refers to the deliberate attempt to adapt human endeavours to the natural environment, so as to preserve as far as possible ecological integrity.

Factory farming has gradually resulted in: a concentration of production facilities in areas considered to be particularly suitable; an increase in the size of the farms, with a concentration of animals unimaginable until recently, the development of landless animal husbandry, resulting in a loosening of the traditional link between the livestock sector

and agronomy. Salient features of intensive farming are therefore the maximum density of animals on the occupied area, the extensive use of mechanisation and low labour utilisation. Industrial livestock production has grown in response to consumer requests for lower prices and safety guarantees in products of animal origin and as a result of the need by food manufacturers and retailers to have standardised products at affordable prices for the entire population and even competitiveness on the international market. It is evident that the cost of production falls considerably by concentrating animals in confined spaces but, in the face of this, we irreparably alter the characteristic cycle of the agricultural farm that links reared animals, the cultivation of the land and crop production, within a system which had reached its equilibrium. For these reasons, for example, animal manure which, for millennia, has been considered essential to ensure the fertility of the land has now become only one of the major sources of pollution.

The key to genuinely human ethics is therefore in striking the balance between rights and duties: within the perspective of the ontological superiority of man, the fundamental need of animals to develop their natural potential in a suitable environment coincides with man's duty, to limit the demands on animals as sentient beings and towards the entire biotic community. By doing so, the purpose is to highlight the convergence of the *interests* of humanity and the interests of the ecosystem: the *health* of humans, animals and the Earth are inseparable and interdependent.

3.1. Biocultural ethics in the context of corporate social responsibility

Biocultural ethics has raised the issue of the conflict of interests between humans and animals, proposing to establish priority criteria between fundamental and secondary interests, with the purpose of subtracting billions of animals from a life of pain. For these reasons, its role could prove crucial within companies utilising bioculture, such as, breeding farms, particularly with regard to corporate social responsibility, according to which businesses are not only geared to obtaining the maximum profit but they are also committed to reinvesting in socially relevant policies and practices.

If the fundamental purpose of the economy founded on quantitative expansion is to stimulate production, consumption and corporate profits, up to now this has led to a strong emphasis within livestock farms on the commercialisation and manipulation of animals, relegating them to biological machines fed with industrial feedstuffs.

In the livestock sector, corporate social responsibility can mean more investment to improve the general condition of the company, including an improvement in the lives of animals, to the benefit of all stakeholders - that is, all those who are influential or (co) interested in the choices of the company. In this perspective, even animals could be considered as “stakeholders”, virtually and by assonance, notwithstanding their atypicality: given that these *subjects* whose condition and quality of life are affected (or rather determined) by company choices however together, they are influential on the choices of the company, on its production and productivity, and on its actual public image and reputation. Substantially biocultural ethics asks us to understand the needs of animals inside livestock farms and to attend to them and at the same time to respond to human stakeholders who request products and food that comply with the concept of human health and well-being and economic sustainability.

Since there is a connection between the level of animal welfare and human welfare, the *multi-fiduciary stakeholder theory* involves building a relationship of trust relating to the quality of the product, transparency and fairness in the relations between the constitutors of supply chains, the approaches to minimise the imbalance of power in the longer and more complex supply chains and ethically significant investments. The integration with biocultural ethics makes the quality of life of animals also vital for the building of fiduciary relations inside and outside the company binding the company to its stakeholders and vice versa.

Stakeholders (in the true sense, namely humans) can serve as *spokespersons* for animals, both as in those internal stakeholders (people working in the companies) as well as those external stakeholders (institutions and persons engaged in positions of control, local bodies, ethics committees, social and health districts, consumers etc.). In particular, this role must be played by a crucial and strategic figure within the biocultural approach: the veterinarian who, as mentioned, due to his professionalism must personally act as guarantor of the ‘atypical

stakeholders' (animals), interpreting their needs and their ethological requirements and explicitly specify them in order to concretely improve their living conditions on livestock farms.

Even the scientific community has, in this sense, an important task: that of developing increasingly efficient instruments of assessment of animal welfare, to investigate possible solutions and remedies to onerous conditions for animals, to study improvements to procedures, means of production and distribution that make supply chains more efficient, and directly or indirectly more suited to the attainment of animal welfare.

Since corporate social responsibility usually requires the formulation of business codes of ethics, those of companies operating in the biocultural sector must make provision in their articulation of explicit elements to protect animal welfare, ensuring as far as possible that they live and are nourished while under farming conditions, in a manner which is characteristic of their species, as well as ensuring the adequacy of the facilities housing animals.

Equally, social and environmental balances must contain items linked to the expenses related to safeguarding the environment and improvement of the living conditions of animals as well as the level of customer satisfaction, the level of adherence to the quality tests that companies intend to participate in, the use of resources for social purposes, perceived reputation, assessment of the degree of conformity to a voluntary code, and the degree of conformity between the code of ethics and social balance etc.

For companies and for the whole supply chain, in addition to economic and financial performance (balance sheet and capital ratios) and competitive performance (customer satisfaction and indices of effectiveness and efficiency), it will be fundamental to assess *social performance*, given by social and environmental balances and sustainability with respect to animal welfare.

An additional key factor for the biocultural supply chain is the professional training of the personnel involved in the management and care of animals, which should be continuous and specifically orientated: the adoption of criteria for the selection, training and formation of competent staff is recognised and normed in European programs, rightly seeing it as a fundamental objective in order to speak of total quality management.

Recommendations

The National Bioethics Committee has on several occasions paid attention to the ethical issue of the protection of animal welfare in the different contexts of life and the utilisation of animals by man. The maturation of an articulated ethical position *for animals*, that is not merely related to the *treatment of animals by humans*, is reflected in the variety and complexity of the *ad hoc* Opinions¹⁴⁹ directed at the differentiated and specific analysis of various contexts and their related bioethical issues.

This document addresses one of the best known, customary and oldest forms of animal use, that is, for the production of meat and in general products of animal origin intended for man. The topic deserves renewed attention as currently it is characterised by an accentuation of the tendency to extend forms of industrial production, which significantly reduce the *quality of life* of productive livestock as described in scientific literature.

Within the bioethical ethical perspective and corporate social responsibility, in the light of the values and principles outlined in the document, the National Bioethics Committee makes the following recommendations:

1. The promotion of a culture of enterprise and supply chain with a significant enhancement of social responsibility, understood as a commitment to comply with the relative provisions without derogations of the European Directives and to reinvest in socially relevant policies and practices such as improving livestock farming conditions and conduction of animals, and the environmental sustainability of production processes. In order to pursue these objectives, it is suggested firstly to adopt a system of labelling related to a parallel system of productive and livestock activities based on quality standards of excellence. The regulation of the labelling system should make these products easily and

¹⁴⁹ *Bioethics and veterinary science, animal well-being and human health*, 30 November 2001; *Ritual slaughtering and animal suffering*, 19 September 2003; *Bioethical problems concerning the use of animals in activities linked to human health and well-being*, 21 October 2005; *Caudectomy and Conchectomy*, 5 May 2006; *Alternative methods, ethics committees and conscientious objection to animal testing*, 18 December 2009;

unequivocally identifiable by consumers, by way of comprehensible information which does not overlap or duplicate compared to data related to other products for example those of the organic market, even in order to stimulate the development of productive and livestock activities sustainable both ethically and environmentally. Particular attention should be placed on ensuring equivalence between livestock farming conditions and the conditions of treatment of the animals throughout the entire supply chain.

2. Specific and active respect of the consumer's right to know, through the promotion and implementation of information and raising awareness campaigns on behalf of the supervisory authorities. *Knowledge* is the decisive step for the assumption of an ethical responsibility towards animals by consumers: without precluding the centrality of interests regarding human food, or even those of purely an economic nature, an educated consumer is somehow morally co-responsible for the ethical sustainability of the production process, together with those operating directly in the supply chain.

3. Implementation of European Union recommendations, timely activation of public policies that promote the creation of a European Network of Reference Centres for the protection and welfare of animals, as well as harmonization of Community requirements in order to favor the affirmation of more sustainable forms of breeding and livestock production throughout the European Union, in the shortest time possible.

4. Promotion of scientific research in the field of animal welfare, particularly for productive livestock, and development of an *animal-based* assessment system¹⁵⁰.

5. Maximising the crucial role of the veterinarian in assessing the living conditions of animals and in recognising the parameters of their well-being. In this regard, it stresses the need to activate bioethical training specifically for veterinary staff aimed at highlighting the moral significance of the interests of animals and work effectively to protect them.

¹⁵⁰ See paragraph 2 and footnote 10.

6. Similarly, due attention should be paid to the training of the personnel involved in the care and management of animals. The adoption of criteria for selection, acquisition of specific skills and the training of personnel are in fact conditions also recognised at Community level as necessary measures to ensure total quality management.

Presidenza del Consiglio dei Ministri



**CLINICAL TRIALS IN ADULT OR MINOR PATIENTS
WHO ARE UNABLE TO GIVE INFORMED CON-
SENT IN EMERGENCY SITUATIONS**

28th of September 2012



PRESENTATION

The document deals with the ethical problems of randomised clinical trials on ill or injured patients, adults or minors, who are unable to give their timely informed consent. These are specific situations for which treatment exists but which is not very effective and not able to improve the prognosis. To take away the possibility of clinical trials from these subjects would mean on the one hand to reduce the hope that they might benefit from it and that their illness might be treated, and on the other to stop the therapies available from being improved for patients in the future too.

In the light of the analysis of the international and Italian regulations, the NBC considers a number of solutions emerging in this practice (reference to the members of the family and carers, Opinion of the ethical committee, appeal to the state of necessity), showing their limitations.

In stressing the absolute need to safeguard the subject's rights, safety and wellbeing, the Committee justifies the licitness of clinical trials in emergency situations, should the patient be unable to give his/her valid informed consent and in the absence of a legal representative, in specific conditions: the approval of a protocol – based on strong experimental evidence – by a national ethics committee set up *ad hoc*, independent, made up of doctors and nurses working in the specific sector, jurists, forensic scientists, patient rights representatives and bioethicists; the ascertainment of any possible desire to the contrary previously expressed by the patient; the request for consent deferred by the patient or his/her legal representative; the publication of the results of the trials to avoid unnecessary duplications.

The document was elaborated by a working group coordinated by Profs. Lorenzo d'Avack, Silvio Garattini, Rodolfo Proietti, who also drafted the text. Profs. Adriano Bompiani and Laura Palazzani gave their written contributions. The text was discussed in the working group in which profs. Amato, Morresi, Nicolussi took part.

The text also availed of the contribution of experts who discussed the subject during the hearing: Dr. Carlo Petrini, responsible for the Unità di Bioetica of the Italian National Institute of Health (24 June 2011) and Dr.

Carlo Tomino, Director of the Research and Clinical Trials Office of the Agenzia Italiana del Farmaco (AIFA) (27 January 2012). The pressing need for the document came from a request by Prof. Antonio G. Spagnolo, Director of the Bioethics Institute of the Università Cattolica del S. Cuore (with letter of 26 April 2011), who – in outlining the emergence of the issue in the practice of ethical committees – contributed to the formulation of the text.

In the plenary session the 28th of September 2012 the document was unanimously approved by those present: profs. Salvatore Amato, Luisella Battaglia, Adriano Bompiani, Stefano Canestrari, Cinzia Caporale, Antonio Da Re, Francesco D’Agostino, Lorenzo d’Avack, Riccardo Di Segni, Carlo Flamigni, Romano Forleo, Silvio Garattini, Laura Guidoni, Laura Palazzani, Rodolfo Proietti, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Maria Grazia Zuffa.

Profs. Bruno Dallapiccola, Maria Luisa Di Pietro, Marianna Gensabella, Assunta Morresi, Demetrio Neri were not present at the vote on the document but their approval was given at a later date.

The President
Prof. Francesco Paolo Casavola

1. Premise

The randomised clinical trial (RCT: *randomised clinical trial*) is today the most reliable methodology by which to establish the efficacy of therapeutic interventions constituted by drugs, medical devices, surgery, etc.

Any participation at all in an RCT requires the consent of the patient who must be suitably informed: (a) of the uncertainty of the expected benefits and the possible toxic effects; (b) the fact that the trial is the only scientifically and ethically correct way to treat patients in situations of clinical uncertainty and to resolve this very uncertainty.

There is nonetheless a category of patients or injured, adults or minors, who are not able to give their timely informed consent for various reasons and this raises a serious problem when the efficacy and safety of the therapy is highly conditioned by the rapidity of the intervention itself. Scientific data shows the increased risk of death in the case of delay associated with the need to get the patient's consent. For example, patients with acute traumatic brain injuries, heart attacks, bad ischemic attacks or cardiac arrest. All these situations require prompt action. It is also true that existing treatment can be carried out on these patients, but in many cases this can prove inadequate and not able to improve the prognosis; it is also just as true that if new treatment is proposed, which is potentially more effective and of greater benefit to the patient, these therapeutic protocols need a randomised clinical trial that demonstrates their real efficacy.

As said above, the problem arises above all when the effect of the drug or the procedure is 'time dependent'. In this sense, numerous other examples could be given of situations in which prompt action must be taken:

- tranexamic acid in the control of *post-traumatic haemorrhage* (CRASH-2 trial). Maximum effect for start of therapy within 1 hour. Administration time limit: within 3 hours of the trauma. The delay of 1 hour in the start of treatment reduces the benefit by 63% to 49%;

- induced hypothermia during cardio respiratory intensive care. Start of therapy within few minutes of beginning of *cardiac arrest*;

- pharmacological therapies (hypertonic solutions; drugs that reduce cerebral metabolism) or surgical therapies (decompressive craniectomy) in patients with *acute traumatic brain injury* or *massive cerebral haemorrhage*

with high risk of evolution into ‘cerebral death’ or ‘vegetative state’. Start of therapy in shortest time possible (minutes/hours). Corticosteroids in *traumatic brain injury* (CRASH Trial) (within 6 hours);

- thrombolytic therapy in *strokes* (within 3 hours);
- pharmacological therapy in *myocardial heart attack* (best results with fibrinolytic treatment within 1 hour);
- corticosteroid therapy *bone marrow trauma* (within 6 hours).

Less urgent and, therefore, more easily having the possibility of obtaining informed consent by a legal representative are the cases in which the intervention time is not so immediate, like for example:

- mechanical ventilation in patients with acute lung injuries or *Acute Respiratory Distress Syndrome* (within 36 hours);
- corticosteroid therapy in patients with *Persistent Acute Respiratory Distress Syndrome* (within 48 hours).

To deprive these subjects of the possibility of clinical experimentation would mean on the one hand to reduce the hope that they might benefit from it and that their illness might be treated and, on the other, to stop the available therapies from being improved for patients in the future too. It is thus a question of finding the ethically justified conditions for which trials, even temporarily, may be set up or pursued without harming the rights of the patient.

2. The legislative limitations today

In Italy the problem arises from the impossibility – in practice – to carry out clinical trials in patients that are unable to give informed consent, so much so that it amounts to legal incapacity or actual incapacity, in emergency situations when the ‘therapeutic window’ is minutes/hours.

Ministerial Decree 15/7/1997 Arts. 4.8.1. ff. (*Implementation of the European Union guidelines for good clinical practice for the execution and clinical trials of medicines*) foresaw that a subject incapable of giving his/her informed consent could be involved in a trial only if such consent had been expressed by his/her legal representative, together with the fact that, if it were a non-therapeutic trial (with absence of any direct clinical benefit for the subject), further conditions should be foreseen among which the fact that the foreseeable risks and the negative impact on the wellbeing of the subject were mild.

Nonetheless, as already foreseen in the *Declaration of Helsinki* (1984, present version 2008), even these guidelines granted a significant exception to the need for the legal representative's informed consent. In fact, Art. 29 foresaw 'emergency situations' and situations in which it was not possible to obtain the person's prior consent, nor was a legal representative present. In such circumstances, it was considered possible to enrol the person in the presence of three concurrent requisites: 1) the patient's enrolment must take place according to the measures described in the protocol and the protocol must set out the specific reasons explicitly justifying the involvement of research subjects who find themselves in conditions such as to render them incapable of giving informed consent; 2) such protocol must have received the documented favourable Opinion of the Ethics Committee; 3) the subject, or his/her legal representative must be informed as soon as possible and his/her consent must be asked for.

The same normative content was then adopted by Art. 3.7.8. of M.D. 18.3.1998 (*Reference guidelines for the establishment and functioning of Ethics Committees*).

These provisions have now been replaced by the regulations introduced by Leg. Decree No. 2011/2003, which enforces Directive 2001/20/EC. These regulations are far more restrictive considering that in the case of trials in incapable subjects, no exception with regard to the need for the legal representative's informed consent is foreseen. It follows that it will be possible to disregard the informed consent of the legal representative only in the hypothesis of evident treatment in a 'state of necessity' according to the general exempting contained in Art. 54 of the penal code.

In Italy the legal representative or care support administrator are appointed by the judge. This procedure takes time, while most of the clinical studies aimed at emergency situations assess the effects of the therapies given in the immediacy of the critical situation.

It must be remembered that the *Oviedo Convention* (1997) – ratified by Italy, even though the ratification instrument has not been lodged – foresees a guarantee system to safeguard the incapable similar to the one established by Directive 2001/20/EC. The general principle (Art. 6) is stressed that the trial is licit on an incapable adult only on condition that there is the authorisation from an 'authority or person or body provided by

for law'. In emergency situations, without informed consent, it grants the possibility to proceed immediately to any medical intervention indispensable for the benefit of the health of the person concerned (Art. 8).

This possibility is nonetheless limited to non-experimental interventions, but which already have a proven direct benefit on the patient. The Convention also refers to 'the patient's previously expressed wishes' (Art. 9): this reference can be interpreted as the patient's openness to leave prior declarations with respect to his/her willingness to possible clinical trials in specific conditions of successive incapacity.

Eight years later, the *Additional Protocol to the Convention on human rights and biomedicine involving biomedical research on human beings* (2005) explicitly deals with clinical trials in emergency situations (Art. 19, research on persons in emergency clinical situations), inviting the various national legislations to define the additional conditions for safeguard. The Protocol sets out a number of specific conditions: the ascertainment that the research cannot be carried out on patients not in a state to give consent who are not in a condition of urgency; the protocol shall be approved specifically by a competent body; any relevant previously expressed objections of the person known to the researcher shall be respected; if the expected results of the research do not have the potential to produce 'direct benefits' for the patient, the research must have the aim of contributing to the improvement of scientific knowledge and entail minimal risk to the patient. Any consent or authorisation to continued participation shall be requested as soon as reasonably possible.

At present the *Proposal for a Regulation of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC* (2012) is being debated at Community level and deals with the question of Art. 32 (clinical trials in emergency situations), introducing innovative elements with respect to the directive. The proposal for Regulation takes up once again and reformulates a number of conditions already present in the Protocol: the absence of previously expressed objections by the patient to trials known to the researchers; the direct connection between research and the pathology of the patient on whom the trial is carried out; the presence in the trial of a foreseeable risk and minimal burden; the need to obtain – where possible – the consent of the patient or his/her legal representative.

3. Solutions for informed consent in incapable patients in emergency situations

Faced with these limits, one solution can be to wait for the results of rationalised clinical trials conducted in other countries. This is a solution that raises concern of a scientific nature, insofar as it would involve a delay in the application of new treatment compromising its efficacy, and of a moral nature insofar as use would ultimately be made passively of results of trials carried out by others, without actively contributing to the advancement of knowledge. Not only, but an intelligent use of the results obtained by others nevertheless implies a presence in the field of research.

The problem thus arises of finding a solution that bears in mind the need to safeguard and harmonise important constitutional rights such as the fostering of scientific research (Arts. 9 and 33) and the protection of health (Art. 32). In Italian hospitals a number of ethics committees have formulated operational proposals that have already come into effect, but which maintain a strictly ethical value as they are not in conformity with the juridical norms in force. For example, it is accepted that in the case of children, consent can be expressed by the parents, while for demented adults or adults in a state of coma, the opinion of the legal representative must be sought¹⁵¹.

Other solutions with regard to the identification of figures that may carry out the function of legal representation in the case of clinical trials on incapable subjects can be found in other legislations in and outside Europe.

1) A first practice is the one referring to members of the family or, should there be none, to the caregivers of the patient who are willing to be informed and to collaborate for the purposes of carrying out the trial. They are asked to undersign a form of ‘recognition’ of the clinical situation and of non-opposition to the clinical trial.

¹⁵¹ From the data available at the AIFA (Clinical Trials in Italy, 10th National Report 2011, pp. 191-198) it can be concluded that starting from 2006 over 3000 clinical research protocols were carried out on drugs of which 218 concern studies on subjects who were not able to express informed consent. Over 65% regards trials promoted by profit bodies and the rest by non-profit organisations. About 85% of the clinical trials have as objective the ascertainment of efficacy and safety. 114 trials are considered phase 3 trials; 22.7% concern trials in the neurological field.

Should these not be available, the enrolment of the patient takes place according to the provisions in the protocol and approved by the competent ethics committee.

In cases of temporary incapacity, at the moment of regaining his/her decision-making ability, the subject shall be asked for his/her informed consent for the continuation of the trial and the use of the data already collected. It is furthermore foreseen in these cases that should the incapacity not be temporary the consent must be obtained by the appointed legal representative according to the modalities established by the law.

2) Another type of practice on the other hand takes advantage of the full responsibility of the ethics committee authorising the clinical trial, as the sole decision-making body, barring a request at a later date for the consent to be obtained from the patient for the use of the data gathered from the trial carried out when he or she was incapable of giving consent. In this way the family's consent is foregone from the very start and the ethics committee takes upon itself the title of authority or body foreseen by the national legislation.

3) A final option can be referred to the 'state of necessity', claimed by the doctor or the medical team and recognised by the ethics committee, extending a circumstance to the case in point of clinical trials that is usually used for a consolidated medical intervention able to give a real possibility of saving oneself or others from the danger of serious harm to the person.

This option is included in the need to distinguish within the context of 'research', the type preordained for a huge case record, studied in the smallest detail, expressed in protocols approved by ad hoc ethics committees, from the type of research classified as therapeutic 'trial' (or sometimes mere 'attempt') and which is translated in the use of an intervention or product that seems suitable for use in the case being examined and therefore 'justified' use in the doctor's own responsibility.

4. The NBC's position

a) The NBC considers it necessary to stress the absolute need to safeguard the subject's rights, safety and wellbeing. It retains that in emergency situations, should the patient be unable to expressly give his/her informed consent, then the consent to undergo a clinical trial be

usually given by a legal representative or should this be lacking by other subjects, established by the law, able to carry out such function in a sufficiently timely manner, according to the criteria already adopted in other circumstances involving the health of the subjects¹⁵².

Nevertheless, should they not be present and should their involvement not be possible in time to respond to the need for intervention (circumstances to be documented), the NBC considers it necessary to entrust the doctor or the medical team with the decision to resort to medical treatment which is still in an experimental phase, scrupulously keeping to the conditions, measures and techniques set down in the protocol previously approved by the ad hoc national Ethics Committee (EC) and made up of doctors and nurses working in the specific sector, jurists, forensic scientists, patient rights representatives and bioethicists. The EC must be independent from research bodies.

It must be ascertained – as far as possible - that the patient taking part in the trial has not expressed the desire to not be the subject of experimentation. This is difficult to establish in an emergency, but in some possible situations like for example in the case of a heart attack patient whose doctor already knows his/her wishes or in the case of declarations made before treatment, considered valid for the purposes of consent or dissent to therapeutic/experimental treatment.

Lastly, the criteria of ‘differed consent’ must be applied in the case in which the therapy must continue, given either by the patient, who has regained the capacity to express informed consent, or by his/her legal representative in the case of continued incapacity.

b) With regard to the Protocol the NBC makes the following recommendations:

The EC must apply the usual rules applying to clinical trials. The experimental project must have controls with ‘*gold standard*’ features: it must be a superiority trial with respect to the best that is already available with an evaluation of efficacy carried out randomly on important therapeutic parameters (mortality, morbidity) and a sample adequate for the tested hypothesis. The trials must be randomised so as to guarantee equal treatment.

¹⁵² For example Law 91/1999, Art. 23 (removal of organs); Art. 403 c.c. (care support administrator, appointed to give informed consent to treatment).

The protocols must be made available to the medical community for opportune knowledge and debate. And independently of a positive or negative result, the trials must be published by way of information and to avoid unnecessary duplications. The EC must be periodically informed of the progress of the trial.

The EC should in any case establish a set of additional rules as listed below:

- The new therapy must be directed at conditions characterised by high mortality and disability (acute brain injuries, cardiac arrest, heart attack, ischemic attacks, etc.) and at high risk, with the need for immediate emergency intervention, given that the ‘therapeutic window’ is very short.

- The new proposed therapy must be backed up by important elements establishing a strong likelihood of success. The elements must be based on biological plausibility, pre-clinical studies including animal experimentation models, trials aimed at demonstrating the safety of the proposed therapy to guarantee an adequate risks-benefits ratio. Research must have been carried out on the definition of the dosage to be given and the pharmacokinetic and pharmacodynamic profile as well as, wherever opportune, tolerability trials carried out on healthy individuals (phases 1 and 2). In particular, if possible, the proof must already have been obtained in a healthy volunteer that the new treatment has the foreseen pharmacodynamic effect.

The risks associated with clinical trials must be reasonable in relation to the clinical condition and, in the case of a drug already used for other types of therapy, take the risks-benefits ratio into consideration too.

Conclusions

The NBC:

- a) stresses the absolute need to safeguard the rights, safety and wellbeing of the patient;

- b) considers it urgent, on the part of the legislator, to enact a modification of Art. 5 del Leg. Decree No. 211/2003 allowing clinical trials on incapable adults (legal or actual incapacity) to expressly give their informed consent to clinical trials in emergency situations;

- c) considers it necessary, on the part of the Ministry of Health, to proceed with the drafting of a regulation making it possible to realise

rationalised clinical trials in emergency conditions, when it is necessary to validate prompt new experimental treatment in patients not able to give informed consent;

d) considers that in the case of incapable adults or minors the consent to clinical trials can be given by the legal representative or in their absence by other subjects identified by the legislator, according to criteria already adopted in other circumstances involving the health of the subjects;

e) considers that it is necessary, whenever possible, to bear in mind the patient's previously expressed wishes in a formal and controllable way (in an electronic health file for example), in favour of or contrary to any possible trial and furthermore retains that the criterion of 'deferred consent' given by the patient is necessary should he/she regain the capacity to express informed consent, or by the legal representative should the incapacity persist;

f) in the case in which it is nevertheless possible to obtain the above mentioned subjects' consent in time or to verify prior wishes, the NBC considers it necessary to entrust the doctor or the medical team with the decision to include patients in clinical trials of new treatment, scrupulously keeping to the conditions, measures and techniques described in the protocol approved by the Ethics Committee set up *ad hoc*;

g) considers that the *ad hoc* Ethics Committee must be independent of the research bodies and made up of doctors and nurses expert in the sector, jurists, forensic scientists, patient rights representatives and bioethicists;

h) considers that the protocols must be made available to the medical community for opportune knowledge and debate and that, independently of whether the results are positive or negative, the trial results must be published by way of information and to avoid unnecessary duplications.



NBC OPINIONS AND RESPONSES

2010

- Neuroscience and human experimentation: bioethical problems
- The identification of the human body: bioethical aspects of biometrics
- The improper use of placebo
- Bioethics and education in schools
- The living conditions of women in the third and fourth age: bioethical aspects of social health care
- Prison, suicide and autolesionism
- Criteria for the ascertainment of death
- Secrecy in drug regulatory system procedures
- Kidney donation from a living donor to a stranger (so-called samaritan donation)
- Ethics, sport and doping
- Minor's sexual differentiation disorders: bioethical aspects

2009

- Alternative methods, ethics committees and conscientious objection to animal testing
- Chimeras and hybrids, with specific attention to cytoplasmic hybrids
- Bioethical problems in clinical trials with non-inferiority design

2008

- Pharmacological trials on women
- Conscious refusal and renunciation of healthcare in the patient-doctor relationship
- Premature infants. Bioethical notes

2007

- The destiny of embryos resulting from medically assisted procreation (MAP) and not complying with the conditions for implantation

2006

- Nanosciences and nanotechnologies
- Biobanks and research on human biological material
- Conflict of interest in biomedical research and clinical practice
- Caudectomy and conchectomy
- Ethics, health and new information technologies
- From pharmacogenetics to pharmacogenomics
- Bioethics and rehabilitation
- Differentiated alimentation and interculturalism
- Bioethics and the rights of the elderly

2005

- Assistance to pregnant women and post-partum depression
- Adoption for the birth of criopreserved and residual embryos obtained by medically assisted procreation MAP
- Bioethical problems concerning the use of animals in activities linked to human health and well-being
- Nourishment and hydration of patients in persistent vegetative state
- Bioethical remarks on the so-called “ootides”
- Bioethics in dentistry
- Opinion on “the cellular therapy of Huntington’s disease through the implantation of foetal neurons”
- Alternative medicine and the problem of informed consent

2004

- Precautionary principle: bioethical philosophical and legal aspects
- The use for research purposes of cell lines h1 and h9 deriving from human embryos
- Note on emergency contraception

2003

- Advanced treatment statements
- Ritual slaughtering and animal suffering
- Tobacco use
- Researches using human embryos and stem cells

2002

- Opinion of NBC on the draft protocol on human genetics

2001

- Aims, risks and limits of medicine
- Ethical and juridical considerations on the use of biotechnologies
- Bioethics and veterinary science, animal well-being and human health
- Guidelines for Ethics Committees in Italy
- Violent acts, media and children
- Bioethical guidelines for equal access to healthcare
- Pain therapy: bioethical guidelines

2000

- Psychiatry and mental health: bioethical guidelines
- Therapeutic use of stem cells
- Protection of human embryo and foetus. Opinion of the NBC on the preliminary draft protocol of the Bioethics Committee of the Council of Europe
- NBC statement on the patentability of human embryonic cells

1999

- NBC opinion on the European protocol on biomedical research
- Bioethical guidelines for genetic testing
- NBC opinion on the proposal for a moratorium on human xenotransplantation clinical trials
- Statement on the children's right to a non-polluted environment
- NBC opinion on the Council of Europe White Paper on the treatment of mentally-ill patients

1998

- The bioethical issue of non voluntary sterilization
- Circumcision: bioethics outline
- Youth suicide as a bioethical problem

- Ethics, health care system and resources
- Pregnancy and childbirth from the bioethical standpoint
- Bioethical issues in a multiethnic society

1997

- The bioethical problem of the kidney transplant from a non-blood related living donor
- Cloning
- Childhood and the environment
- Animal testing and health of living beings
- Ethics Committees in Italy: recent issues
- NBC opinions on the “Convention for the protection of human rights and biomedicine” Council of Europe and on the “Preliminary draft of the universal declaration on the human genome and human rights” UNESCO

1996

- Identity and status of the human embryo
- The anencephalic infant and organ donation

1995

- Coming to life
- Ethical aspects of electroconvulsive therapy
- Vaccinations
- Bioethics and the environment
- End-of-life issues in bioethics
- Medically assisted fertilization - Documents by the National Bioethics Committee

1994

- Medically assisted procreation techniques. Synthesis and conclusions
- Human genome project
- Bioethics with childhood
- Organ transplants in childhood

1993

- Report on the patentability of living organisms

1992

- Drug experimentation
- Prenatal diagnosis
- Information and consent related to medical acts
- Ethics committees

1991

- Organ donation for transplantation purposes
- Bioethics and education in the health care system
- Document on the safety of biotechnology
- Issues related to the collection and treatment of human seminal plasma for diagnostic purposes
- Opinion on the resolution proposal concerning assistance to terminally ill patients
- Gene therapy
- Definition and detection of human death



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