

ITALIAN NATIONAL BIOETHICS COMMITTEE

TOBACCO USE

21 March 2003

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INTRODUCTION

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

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

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

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

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

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

Tobacco consumption raises a number of sensitive bioethical issues, as there is a clear *conflict of interest* between one segment of society and society as a whole. Health is at stake, both that of smokers and non-smokers: a precious gift, a basic right enshrined in the Constitution. But the principle of *self-determination* is also at stake; i.e., the limit to be

recognised or defined for the political and social independence of conscious, individual lifestyle decisions, including, and above all, those that are harmful to one's health. As with all bioethical issues, tobacco consumption is therefore, inevitably, a bio-political, bio-legal, and bio-economic issue. In that vein, the *Italian National Bioethics Committee (NBC)* has readily accepted the invitation of the Minister of Health, Girolamo Sirchia, to address this issue.

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

Rome, 9 April 2003

Prof. Francesco D'Agostino
Chairman of the National Bioethics Committee

SUMMARY AND RECOMMENDATIONS

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

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

Smoking

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

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

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

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

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

Dependence

Dependence is a critical element of the problem, both because it makes it very difficult to quit and because involvement of public health institutions varies based on the significance given to this process. It should therefore be analysed in depth, not just in and of itself, but also, and primarily, in relationship with the tendency towards the abuse of drugs in general.

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

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

However, not all drugs lead to dependence. Furthermore, dependence not only varies from one drug to another, but from one person to another. LSD (lysergic acid diethylamide), and probably other hallucinogens, appear to not produce dependence, but there are other factors which make them dangerous nonetheless. While 90% of the adult population drinks an alcoholic beverage on occasion, the percentage that develops a dependence is relatively low. The frequency of dependence rises sharply both for opiates and, apparently, for tobacco. The disclaimer "apparently" is necessary, however, because while it is well known that nicotine creates a high degree of dependence (Benowitz, 1992), there is no precise data on the number of people who smoke occasionally without developing such a dependence. Common experience would suggest that this happens relatively infrequently and, in any event, less often than with alcohol.

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

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

Physical health risks

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

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

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

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

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

An underrated problem

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

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

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

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

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

The first two factors are to some extent shared by alcohol consumption, while the third puts tobacco consumption in a similar category to opiates. It remains to be seen, however, to what degree dependence is linked to the intrinsic properties of nicotine and how much is due to the act of smoking and, above all, to how quickly smoking allows the body to absorb the nicotine. The forms of nicotine used to treat smoking merit further research in that regard. Finally, it is important to point out that dependence involves an “incapacity to maintain an acceptable level of physical and mental well-being without the aid of the drug” (Silvestrini, 2001). This generally accepted definition of dependence implies the morbid aspect of the phenomenon. Both for this reason and the fact that dependence transforms the use of tobacco from free choice to compulsion, as well as for reasons of pure convenience, dependence should be assessed in terms of the overall harm caused by taking the drug. This would then justify including treatment of the addiction as a high priority among the services provided by the public health system. Prevention would certainly be less costly than the consequences generated by the lack of such measures.

Ethical issues and recommendations

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

Smokers

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

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

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

Smoking is currently a legal choice of an individual that cannot be prohibited, except for minors, and which cannot result in a reduction in the healthcare to which every individual has a right, although increased awareness of the damage caused by tobacco consumption places responsibility both on individuals and governments to discourage a phenomenon which presents an obvious health hazard.

Non-smokers

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

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

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

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

Government

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

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

- promoting accurate information on the hazards of tobacco consumption. This campaign must involve both smokers and non-smokers. Through the school system, children can be transformed from victims into active players in a civic battle in the name of growth, solidarity and life. It is also essential to count on the full, committed support of the healthcare system, beginning with physicians;
- limiting the damage caused by tobacco consumption through focused anti-smoking campaigns, while at the same time increasing the effectiveness of measures aimed at limiting the extent of the phenomenon and at protecting people from second-hand smoke. We also recommend taking a close look at dependence and treating it as an illness that needs to be cured. Strict application of the quality standards for cigarettes and tobacco products in general is also needed, with particular emphasis on looking out for attempts to deliberately increase dependence;
- engaging in more research into the unknown or little understood aspects of tobacco consumption. For example, more research is needed on the mechanisms of dependence, not only with regard to individual differences, but also in relation to the methods of nicotine intake. In addition to discouraging young people from harming themselves through drug use and to providing assistance after dependence has set in, in-depth research is required into factors of primary prevention. A greater understanding of these and other critical aspects would help in the fight not only against nicotine addiction, but also against drug addiction in general. Taking this into account, the competent ministries should promote unbiased research subsidised by public funding;

- favouring reconversion in the sector, providing assistance to the various producers and companies in the industry. Wealthy nations, which pay the highest price for tobacco consumption in terms of death and disease, must take responsibility for this problem, which is the same as that of other drugs. This is not just a practical obligation, but an ethical one as well;
- prohibiting all types of marketing of smoking-related products and brands, and to enforce effective sanctions. One ethically reprehensible example of this kind of large-scale marketing which still exists today can be seen in motor sports such as Formula 1 racing. This prohibition should also apply to all forms of indirect advertising, such as the use of tobacco brands and trademarks to market other types of products.

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

Conclusions

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

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

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

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

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

It is a complex problem, with aspects that go beyond ethical, social and medical to encompass the economy and employment. Therefore, along with all the other measures, we need to convert tobacco production into other crops that can provide sufficient income

to everyone concerned, and to study the issue in depth from other points of view, including the therapeutic standpoint.

I. THE ISSUE IN CONTEXT

1. HISTORICAL AND INTRODUCTORY COMMENTS

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

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

It is estimated that every year Italians spend over €8 million on cigarettes alone.

The properties of tobacco are essentially attributable to nicotine, a liquid, oleaginous and volatile alkaloid. Present in the leaves at concentrations of between 1.6% and 9%, this substance acts on the ganglia of the nervous system, which serve as a gateway to a host of central and peripheral functions, both stimulatory and inhibitory, including paralysis. The impact of nicotine varies depending on the dose: at low doses it more often than not leads to stimulation, while high doses result in inhibition, and can even bring on paralysis. Vasoconstriction predominates at arterial bed level, along with increased blood coagulability.

Individual responses to nicotine in part depend on genetic and environmental factors. An individual may at times obtain a sensation of pleasure and peace from a cigarette, and feel stimulated at other times. Beneficial effects have also been recorded in regard to learning abilities and focus. In the extraordinary breadth and variety of its effects, tobacco is similar to alcoholic beverages and cannabinoids, which explains the widespread uptake of these drugs wherever they are easily available. By way of comparison, the effects of opiates, cocaine and amphetamine-like stimulants are, generally speaking, much more circumscribed.

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

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

In addition to nicotine, the tobacco plant also contains low levels of other alkaloids such as lobeline, anabain and nornicotine, whose effects are fairly similar to nicotine.

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

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

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

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

recommendations¹. The first section of the document outlines the principal characteristics of tobacco addiction, while the second offers suggestions on how best to tackle this problem.

¹ Pursuant to Article 1 of its founding act, the National Committee for Bioethics has been assigned the following duties:

- preparing an overview of the programmes, objectives and results attained by research and experimentation in the field of life sciences and human health, where necessary by obtaining all necessary information (...);
- formulating opinions and recommending solutions, where necessary for the purpose of preparing legislative acts, (...) having regard to the protection of fundamental human rights, dignity, and other values as set forth in the Italian Constitution and in international accords that Italy has signed.

2. REASONS FOR SMOKING

Why do people start smoking?

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

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

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

All of these general reasons could equally be applied to other social phenomena: Saturday night street racing, which can often be fatal; fashion and the imitation of charismatic people, which prompts many young people to dress up like and mimic the body language of their models, often in large groups at concerts or night-clubs. This is not to devalue the reasons why people start smoking; on the contrary, precisely because these reasons are so deeply rooted in human nature shows how difficult it is to resist.

Dogmatic opposition to smoking may even perversely reinforce these motivations. This would appear to be true of educational campaigns which, because they only emphasise how dangerous the drug is, can actually increase the appeal of smoking to young people, particularly those for whom smoking is a way of breaking the rules, rebelling against society, standing up for themselves and showing how reckless they are.

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

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

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

fatigue, hunger and thirst, enabling people to exert themselves in ways that otherwise would be impossible.

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

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

3. ADDICTION

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

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

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

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

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

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

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

rather than sedation; increased anxiety rather than sedation; mydriasis rather than miosis; more rapid breathing rather than slow breathing; diarrhoea rather than constipation, and so on.

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

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

Manifestations of addiction are not perceived as long as the drug counterbalances them, although they are present within the body. This is demonstrated by the fact that as drug addiction progresses, the quantity of the drug needed to reproduce the initial effects increases, and tolerance begins to establish itself. In the case of tobacco, this can involve increasing from a few puffs on that first cigarette, which provoke a sensation of stupefaction and dizziness, to 20, 40 or, in extreme cases, 80 cigarettes per day, a quantity that no longer causes any such problems. Describing drug addiction in terms of a homeostatic reaction (a natural defensive process) should by no means undervalue its importance. The body restores its own functional state by reacting to the drug and the changes it induces. In order to preserve its equilibrium these changes must be counterbalanced by an opposite force. What this means is that the body enters an unstable balance that is not the same as physiological balance, because the drug is necessary to maintain equilibrium. The withdrawal symptoms the body suffers if the drug ceases to be available are the exact opposite of the drug’s initial effects. Simply stated, the counteradaptations express themselves with violence. During withdrawal from smoking people become irritable, find it hard to concentrate, suffer from sometimes high levels of bradycardia, and so on. Withdrawal from opiates includes hyperalgesia, increased sensitivity to physical and mental pain, excitement and adrenergic stimulation. Withdrawal from adrenergic psychostimulants leads to dejection, narrowing of the pupil and other similar effects.

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

This is the reason why only drug addicts undergoing withdrawal associate their suffering with the lack of the drug, and have such a clear and insistent need to procure it.

The strength of these effects varies from drug to drug. It reaches a peak with opiates, which act on a mechanism that is indispensable for survival, the alarm signal inherent to physical and mental pain. Psychostimulants, which intervene on mental

processes for which the body allows a certain leeway in either direction, generate intermediate-level affects. There are practically no such effects for hallucinogens, because their point of entry is not subject to any strict control; dreams, for example, allow our mind to wander physiologically, completely detached from reality, without any restrictions whatsoever.

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

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

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

4. HARM

4.1. General features

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4.2 Smoking and reproduction

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

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

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

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

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

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

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

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

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

A number of epidemiological and research studies have shown that cigarette smoke can also negatively impact male fertility by altering the characteristics of seminal fluid. This suggests that certain components of cigarette smoke directly or indirectly interact with

male gametes by modifying their function and vitality. A number of scholars have described the alterations generated by smoke on the amount of ejaculate, as well as on nemasperm concentration, motility and morphology (Evans *et al.*, 1981; Shaarawy and Mahmoud, 1982; Pacifici *et al.*, 1993). Differences between one research project and another may reflect not just the number of subjects taken into consideration, but the type of cigarettes smoked; furthermore, different criteria apply to the classification of smokers according to how many cigarettes they consume on a daily basis.

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

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

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

Cigarette smoke contains a high concentration of oxidising agents which are capable of altering the quality of semen. All of these effects may be correlated to the dosage and duration of smoking involved. As these oxidising substances are highly reactive mutagens, it follows that heavy smokers run an increased risk of DNA damage. Bibliographic evidence shows that smokers suffer a significant rise in oxidative damage to nemasperm DNA compared with non-smokers. This increase is proportional to the concentration of oxidising substances present in cigarette smoke (Fraga *et al.*, 1996). Because spermatozoa are unable to repair this damage, the oxidising agents that accumulate during the final spermiogenesis phases may increase the likelihood of passing mutations on to the zygote.

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

One in four women of fertile age is a smoker (ISTAT, 2000). Of these, 62% of women stop smoking during pregnancy, 30% cut down on their daily cigarette intake, and 7.4% continue smoking as before. These figures indicate a certain degree of awareness that smoking is harmful. Italy's 2001-2003 National Health Plan set a target of reducing to zero the number of expectant mothers who smoke.

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

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

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

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

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

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

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

5. DETOXIFICATION AND RECOVERY

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

The main methods that have proven to be effective are:

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

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

Intervention by physicians and nurses.

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

A second review analysed the effect of recommendations and other interventions by nursing staff, compared with no intervention or other treatment (Rice and Stead, 2001). Undertaken predominantly in hospital outpatient facilities, such action proved to be effective, and influenced patient behaviour outside the hospital environment as well. In such cases, more intense, frequent and longer-lasting interventions were no more effective than less intensive forms of intervention.

Counselling.

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

minimal interventions (sessions lasting fewer than 10 minutes, self-help material and standard assistance).

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

“Aversion” therapies.

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

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

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

Self-help material and telephone counselling.

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

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

Alternative therapies.

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

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

Pharmacological therapy.

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

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

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

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

6. LEGAL ASPECTS UNDER COMMUNITY LAW AND ITALIAN LAW

Community Law

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

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

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

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

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

⁴ See Article 152, par. 1, sub-section 1.

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

⁶ See Article 152, par. 4, sub-section 1c).

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

⁸ *Official Journal of the European Communities* (“OJ”) no. L22 of 25 January 2003.

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

Before returning to the contents of the Recommendation, it is important to note that it gives a comprehensive unity and consistency to other non-binding anti-smoking measures adopted by the Council in recent years, even before the European Community was endowed with specific competence in the field of public health protection. These acts include: the Resolution of 7 July 1986 of the Council and the representatives of the Member States meeting within the Council regarding the first European action plan to improve the health and quality of life of its citizens by reducing the number of cases of cancer, giving priority to anti-smoking measures⁹; the Resolution of 18 July 1989 of the Council and ministers of health of the Member State, meeting within the Council, on banning smoking in places open to the public, providing guidelines for the Member States to protect non-smokers from environmental tobacco smoke;¹⁰ the Council Resolution of 26 November 1996 on reducing smoking in the European Community, recognising the need to develop an effective strategy against tobacco consumption;¹¹ the Council Conclusions of 18 November 1999 on combating tobacco consumption, underscoring the need to develop a comprehensive strategy to protect minors in particular;¹² and the Council Resolution of 29 June 2000 on action on health determinants. The latter resolution, in particular, took note of the results of the debates held at the European Conference on Health Determinants in the European Union, held at Evora on 15 and 16 March 2000, which placed particular emphasis, *inter alia*, on the role of tobacco in this context and which recommended a series of practical and targeted steps to address the challenges in this sector.¹³

Although prevention of smoking and anti-smoking measures are priorities for the health policies *strictu sensu* of the European Community and the Member States, the tobacco industry’s advertising, distribution and promotional strategies nevertheless foster tobacco consumption, and help to increase the already high level of mortality and morbidity associated with tobacco products. To address these issues, which cannot be dealt with by legal means on the basis of Article 152 alone in view of the previously mentioned limits to this provision, the Community has adopted other anti-smoking measures in the context of the internal market and the removal of barriers to ensure the proper operation of the market. These include a series of binding measures based on other provisions contained in the Treaty of Rome such as Article 47 on the right of establishment, Article 55 on the free provision of services, Article 95 on the approximation of the laws of the Member States, and Article 133 on the common commercial policy. Separate mention should be made of Articles 36 and 37 under which numerous acts have been adopted since the 1970s with the basic aim of supporting community tobacco production and the market, in line with the protectionist goals of the Common Agricultural Policy.¹⁴

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

¹⁰ *OJ* no. C189 of 26 July 1989.

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

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

¹³ *OJ* no. C218 of 31 July 2000.

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

The first of these measures was Council Directive 89/552 of 3 October 1989 on the coordination of the laws, regulations and administrative provisions of the Member States as regards television broadcasts (the so-called “Television without Frontiers” directive), banning any form of television advertising of tobacco products and establishing that television programmes shall not be sponsored by natural or legal persons whose main activity is producing or selling tobacco products.¹⁵ More recently, the European Parliament and Council adopted Directive 98/43 of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States on the advertising and sponsorship of tobacco products,¹⁶ and Directive 2001/37 of 5 June 2001, on the manufacture, presentation and sale of tobacco products.¹⁷ The first directive was struck down by the Court of Justice judgement of 5 October 2000¹⁸ and, in its place, in May 2001 the Commission made a proposal for a directive on the advertising and sponsorship of tobacco products which is currently at the approval stage in the Council.¹⁹ This is a proposal to prohibit tobacco advertising in print media, radio broadcasting and information society services (i.e. Internet), and to ban sponsorship, on the part of the tobacco industry, of radio programmes or events taking place in - or with participants from - more than two Member States, or which have in any case cross-border effects. Directive 2001/37, on the other hand, is limited to making the legal framework created by other Community directives more consistent and harmonious, taking account of trade flows between the Community and third countries.²⁰

The need to adopt measures to reduce the demand for tobacco products, in the context of a global anti-smoking policy, was reiterated by the Council in the Recommendation of 2 December 2002 concerning, in particular, the advertising, marketing or promotion practices used by the tobacco industry to promote tobacco consumption among consumers and non-consumers and, in particular, among children and adolescents. Such practices and strategies include, for example, the use of tobacco brand names on non-tobacco products or services (brand-stretching) or clothes (merchandising), the use of promotional items (such as ordinary objects like ashtrays, lighters, umbrellas and other similar objects) and of tobacco samples, the communication of sales promotions (such as discounts, free gifts, bonuses or an opportunity to participate in a promotional contest or game), the use of billboards, posters and other indoor or outdoor advertising techniques (such as advertising on tobacco vending machines), the use of tobacco advertising in cinemas, as well as any other forms of advertising, sponsorship or practices directly or indirectly intended to promote tobacco products. The Council recommendation begins by noting that in cases where only certain forms of direct tobacco advertising are prohibited, the tobacco industry tends to shift its advertising

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

¹⁶ OJ no. L213 of 30 July 1998.

¹⁷ OJ no. L194 of 18 July 2001.

¹⁸ See Case C-376/98, in *European Court Reports 2000* p. I 08419.

¹⁹ OJ no. C270 of 25 September 2001.

²⁰ The acts that were repealed and recast in Directive 2001/37 were Council Directive 89/622 of 13 December 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of certain types of tobacco for oral use (OJ no. L359 of 8 December 1989), amended several times, and Council Directive 90/239 of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes (in OJ no. L137 of 30 May 1990). It should be noted that the Court of Justice has also ruled on the validity and interpretation of Directive 2001/37: see the judgement of 10 December 2002, case C-491/01, in *European Court Reports 2002* p. 1-11453.

expenditure to other marketing, sponsorship and promotion strategies, using creative and indirect ways to promote tobacco products, especially with young people.²¹

To counter such practices, which limit the effect of partial bans on tobacco advertising, the Council recommends that Member States, in accordance with national legislation and practices: adopt appropriate legislative or administrative measures to prohibit tobacco sales to children and adolescents²² as well as certain forms of tobacco advertising and promotion;²³ require manufacturers, importers and wholesale traders in tobacco and in products and services bearing the same trademark as tobacco products to provide Member States with information concerning their expenditure on advertising, marketing, sponsorship and promotion campaigns not prohibited under national or Community law;²⁴ guarantee protection from exposure to environmental tobacco smoke in indoor workplaces, enclosed public places, and public transport;²⁵ develop strategies and measures to reduce the prevalence of smoking, such as strengthening overall health education, particularly in schools, and general programmes to discourage the initial use of tobacco products and to overcome tobacco addiction²⁶; make use of young people's contributions to health-related policies and actions, especially in the field of information, and encourage specific activities which are initiated, planned, implemented and evaluated by young people; implement appropriate price measures on tobacco products so as to discourage consumption; implement all necessary and appropriate procedures to verify compliance with the measures set out in the recommendation; and inform the Commission every two years following the adoption of the Community act, of action taken in response to the recommendation.

Lastly, the Council recommendation takes due note of the efforts being made at international level, in the context of the World Health Organisation (WHO), in drawing up and adopting a framework convention on tobacco control.²⁷ The preparatory work for this convention began in 1999 and that the draft agreement, approved in March 2003, established that signatory states should introduce legislation into their own national systems to prohibit, essentially, tobacco advertising and the sale of cigarettes to minors, as well as to promote higher taxes on smoking, to strengthen action against smuggling, and to emphasise the concept of producer responsibility. The text was due for signature in mid-2003, but its entry into force depends on a large number (at least 40) of ratifying countries.²⁸ Aware of the importance of ensuring that its recommendation be consistent with the proposed contents of the framework convention, the Council invited the Commission to monitor and assess the developments and the actions undertaken in the Member States and at Community level; to report on the implementation of the proposed

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

²² For a purely indicative list of the main types, see point 1 of the recommendation.

²³ See point 2 of the recommendation.

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

²⁵ According to the recommendation, priority should be given, *inter alia*, to educational establishments, health care facilities, and places providing services to children.

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

²⁷ See also the Council Conclusions of 5 June 2001 on the WHO Framework Convention on Tobacco Control (OJ no. C174 of 19 June 2001).

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

measures, on the basis of the information provided by the Member States, not later than one year after receipt of Member States' information submitted in accordance with the recommendation; as well as to examine the effectiveness of the measures set out in the recommendation and consider the need for further action, particularly if internal market disparities appear in the areas covered by the recommendation.

Italian law

Turning to the Italian situation, it should first be noted that the general regulation of tobacco smoking dates back to Law 548 of 11 November 1975, which placed a total ban on smoking on public transport and in certain public places,²⁹ with the aim of protecting citizens' health.³⁰

In practice, smoking was prohibited in certain places from the mid-1950s under measures applying to certain categories of enterprises where particular kinds of manufacturing were carried out or which involved specific dangers.³¹ It was precisely the need to extend and generalise the protection of workers from the dangers related to or caused by smoking, including passive smoking, that inspired subsequent legislation. In addition to Presidential Decree 303 of 19 March 1956 containing general regulations on workplace hygiene, there was also Legislative Decree 277 of 15 August 1991 transposing a series of Community directives into Italian law dealing with the protection of workers from risks deriving from exposure to chemical, physical and biological agents at work,³² as well as Legislative Decree 626 of 19 September 1994 implementing another series of directives aimed at improving health and safety conditions in the workplace.³³ The 1994 decree requires employers to limit workers' exposure to carcinogenic agents, including by means of no-smoking notices and by adopting appropriate measures to protect non-smoking employees in places where workers spend their break times.³⁴

The overall legislative framework described above has been further developed by the courts, with a general trend towards an evolutive interpretation of the provisions (Zeno-Zenchovic, 2002). In fact, following a number of rulings by administrative judges, who gave a broad interpretation to the provisions of Law 584/1975, the directive of the

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

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

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

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

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

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

Prime Minister of 14 December 1995 was adopted, prohibiting smoking in certain government or public service facilities. This directive established that government departments shall implement the ban on smoking contained in the above-mentioned law, exercising their administrative, regulatory and disciplinary powers as well as their policy-making, supervisory and control powers over companies and institutions they control and over licensed or contracted private companies. The directive also established criteria for the identifying premises where the ban should apply and established that the government departments referred to in the measure could, in any case, extend the ban to other areas not specifically mentioned in Law 584/1975 on the basis of their autonomous regulatory and disciplinary powers.

Finally, it should be noted that in addition to the legislation covering tobacco advertising and warning messages on packages, which was also adopted to implement Community directives,³⁵ the recent Law 3 of 16 January 2003 contains provisions regulating government departments.³⁶ Article 51 of this law, entitled "Protection of non-smokers' health" prohibits smoking in enclosed places with the exception of private areas not open to users or the general public and specifically marked smoking areas. These areas must be equipped with a ventilation system for air exchange whose technical specifications are to be defined in an administrative regulation to be adopted, acting on a proposal of the Minister of Health, no later than 180 days following the publication of the law in question (i.e. no later than June 2003). Furthermore, the law requires bars and restaurants to provide non-smokers with one or more zones with a surface area greater than that of smoking areas.³⁷ It is important to note that in order to give industry associations the time to provide appropriate information and create awareness of the problem, the above-mentioned provisions will enter into force a year after the law is passed (i.e. no later than June 2004). The law also provides for the definition of new procedures for ascertaining infringements of current smoking restrictions and confirms the provisions governing smoking bans on government premises.

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

³⁶ *Gazzetta Ufficiale* no. 15 of 20 January 2003, S.O., no. 5.

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

II. Guidelines and Proposals

1. Information

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

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

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

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

The liberal concept of an adult capable of choosing how to behave after weighing up the costs and benefits is itself an ethical postulate that, while much debated in theory, is fundamental in practice. Its validity presupposes the ability to understand and choose, which we acquire gradually in the first two decades of life. This in turn prompts the adoption of strict legislation prohibiting conduct aimed at fostering tobacco use in minors. While ethically correct, such protection of minors is often ineffective and, in any case, must be accompanied by education based more on suggestion and influence than rules. It is worrying that smokers more or less consciously pass on their dependence to the people they love (especially spouses) rather than those to whom they are indifferent. As a result, verbal warnings not to smoke from parents who smoke are regarded by children as false, even if given in good faith. In dealing with this general problem (unlike smoking overall, which is in decline, it is actually getting worse), social psychology should focus on the more specific parental duty to protect children from dependence on tobacco.

2. INFORMATION FOR EDUCATION AND PREVENTION

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

Positive signs of such a change are scarce on the ground, given the increased violence registered in all age groups, with recurrent tragedies even within the home. Adults, who should be dealing with these developments and searching for solutions, are themselves a direct cause. Both parents are absent from the home because of the economic structure of global society, which forces mothers to work outside the home to make ends meet. As a result, parents have been substituted by television, which has become the main educator, friend, role model and point of reference for children, who have been left irretrievably alone. "Latch-key" kids eat fast-food meals alone and shut themselves indoors in front of the television. Television, however, does not aim to educate children and make them into mature, happy adults. The sole aim of television is to attract viewers and beat the competition to maintain and possibly increase advertising rates. The result is a programming on all channels - shown in the afternoon and early evening slots that attract the highest number of child viewers - which features stories hyped beyond belief in the quest for the most gruesome and disturbing aspects of terrible events often involving other children and teenagers both as victims and perpetrators, are.

It is widely argued that journalists have one duty: to seek and report facts. Yet we forget that child viewers are not mature enough to exercise critical judgement. They are simply subjected to the negative aspects of horrible events without parents to help and guide them. They are literally left alone to process behaviour that seems entirely normal through the distorting lens of television, which can artificially magnify or shrink events and images as it pleases.

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

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

Thorough knowledge of the scope and nature of the problem is essential if we are to respond correctly. This requires collecting and analysing all available data, and identifying trends and origins in order to decide strategy. A preliminary, objective overview of the current situation, developed by gathering and cataloguing all available data, is needed to prepare the ground for specific or general surveys and research.

Changes in the communication sector are so rapid that the actions needed to pursue this aim can quickly prove inadequate or obsolete unless constantly updated. This requires an analysis of emerging trends in this sector in order to foresee problems as early as possible. On this basis, the planning of appropriate measures can then be continually and swiftly adapted.

The fight against tobacco use has to begin with these general premises on communication with young people and children so that data collection can be focused on the growing problem of smoking in this category.

The second phase is the critical elaboration of the information gathered. This is a highly specialised task requiring an ability to identify and isolate the most significant messages in the midst of the enormous flow of data. These have to be analysed, interpreted and developed to establish their scope and social impact, and to forecast future developments. This must then be placed in context with other sectors (even very different ones), from the economy to the arts, in order to trace an overall picture.

Parents, teachers and other persons in contact with young people are inundated with partial or contradictory messages. This forces them to find their own forms of communication after evaluating the vast range of media aimed at the children and young people in their care: an individual effort whose outcome is increasingly inadequate to what is required, given the continual expansion and diversification of the world of communication.

In order for this individual effort to be scaled down to ensure an acceptable relationship between effort and result, a consulting service should be planned. This could be general or specific to certain needs, and made available to groups concerned with positive communication for children. This would be particularly useful to help government departments intervene in this sector.

In the third phase, the results of this activity would be translated into the language of institutions (in order to facilitate necessary intervention) as well as that of the communications industry to guide it, as far as possible, towards respect for childhood and young people. The aim, one which will hopefully attract ever greater consensus, is to promote healthy and balanced child development.

Continuing to apply this approach to tobacco use, it is by no mean difficult to identify actions which should be adopted. The problem should be dealt with on the basis of a collection of data that covers all aspects of young people's lives (which are closely intertwined), including smoking.

3. CHILDREN: FROM VICTIMS TO PROTAGONISTS

The United Nations' Food and Agriculture Organisation (FAO) recently launched an educational initiative entitled "Feeding Minds, Fighting Hunger" geared towards children and young people. The initiative promotes a vision of a world where everyone can grow to become healthy, active and responsible members of society. The programme aims to demonstrate how education and information on world hunger, food security and nutrition constitute key factors for change.

The aim is to give life to a symbolic international classroom where students examine and discuss the same problems, in the hope of preparing them for active participation in the creation of a world free from hunger. Under the project, teachers all over the world will have contemporaneous access to the same teaching materials at three levels of education. The materials will be produced by an international group of experts from the project and translated into different languages. They will deal with hunger, malnutrition and measures needed to help young people develop their understanding of the world's interdependence, as well as their own capacity to contribute effectively to world change, whatever their age. The objective of education, therefore, is to form generations of young people capable of becoming responsible world citizens who are united in a universal effort of solidarity and aware that there is no problem in the world, including world hunger, which cannot be solved provided that we commit ourselves to solving it.

The teaching method produced during the development of this FAO initiative could be adopted as a model to facilitate the successful prevention of, and fight against, tobacco use. On this basis, improving the quality of life (which is also the framework of our initiative) is considered a realistic and sustainable goal if founded on a vast, widespread effort of education and information which begins with children, young people and their families.

To this end, it seems appropriate to produce educational programmes which can be discussed at special awareness meetings, following the principles which inspired the FAO initiative. The implementation of such programmes could be then monitored.

Above all, these programmes will develop practical activities, on-site learning and play activities at different levels which involve families as much as possible. Teachers could follow up discussions with drawings and written pieces that provide a focus for meetings, exhibitions and other activities. These can involve scholastic, regional, national and international institutions, as well as citizens themselves, with the full participation of students' families, and foster awareness of the issues involved.

There is nothing like drawing and healthy competition to encourage children to do their best. A big concluding event is the best way to leave everyone with a lasting memory, confirming that, in the middle a crowd that shares our hope, we are not alone.

4. RESEARCH

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

Basic research

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

This concept is summed up in a famous expression:

“And yet it moves”

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

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

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

Moreover, resources are not unlimited, which means that they need to be diverted from other uses relating to needs that are usually more pressing than knowledge in and for itself.

To divert resources to basic research, scientists not only have to compete with others to convince those holding the purse strings of the merits of their project, but also to take on a moral obligation towards those providing the resources and towards society in general. This means that basic research is subject to strong ethical constraints which, without distorting it, create a commitment to operate for the good of society by multiplying, and returning to that society, the resources it has received. Galileo described research as the light and benefit of reason, while Daniel Bovet speaks of the thirst for knowledge and the need to put it at the service of mankind (Bignami, 1993).

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

influence the research but to direct it where it is most needed, in the knowledge that the investment made is not just wise but will also be profitable in the longer term.

Applied research

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

A great deal of knowledge is already available on nicotine addiction and smoking, even more, perhaps, than that still to be acquired. This knowledge concerns, for example, the health and social aspects of the phenomenon; many of its primary and secondary causes; and its social, economic and employment implications, which cannot be neglected. The technology and other instruments, including financial ones, needed to translate this knowledge into practical applications are also available.

A smoke-free society: this is the primary objective. It is, however, an objective that does not seem to be within reach in the medium term. In the meantime, applied research is seeking to reduce the harm caused by smoking by adopting a strategy already applied successfully in the fight against other forms of addiction (Marlatt, 1996). A report (2001) by the distinguished Institute of Medicine, available for consultation at www.iom.edu, assigns a key role to the development of potential reduced-exposure products (PREPs), which as their name suggests can potentially reduce the harmfulness of smoking, and to treatments that can help smokers recover from their dependence. The industry also needs to be converted by nudging it towards different processes or uses of tobacco than those currently adopted.

PREPs.

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

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

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

Another important aspect of the problem concerns the evaluation of the effectiveness and toxicity of the new PREPs. This should be done through trials conducted before such products are put on the market, rather than after the event, using the tragic figures produced by epidemiological studies, as has been the case thus far. With the knowledge currently available, it is possible to carry out studies *in vitro* (on single cells or organs) or *in vivo* (on laboratory animals or volunteers), using validated biomarkers that can reliably predict the chronic damage caused by smoking (Shields, 2002b). One question that still remains to be clarified is which authority should be responsible for authorising the marketing and sale of PREPs. Many commentators consider this to be a task for the bodies with responsibility for regulating medicinal products, following the classic procedure of pre-clinical and clinical trials. The U.S. Supreme Court recently denied the Food and Drug Administration this authority (FDA, 2000), thereby creating a regulatory vacuum that is holding back the development of effective PREPs.

Smoking cessation

The spread of smoking is linked not just to the mental effects of nicotine, which make smoking pleasurable and desirable, but also to the strong dependence that it creates in smokers (Benowitz, 1992). Many instruments are available to treat this condition. The most common are nicotine-based substances used in nicotine replacement therapy (NRT), which is administered through chewing gum, patches, nasal sprays or inhalers (Kotlyar and Hatsukami, 2002). This treatment eliminates exposure to the other toxic substances present in tobacco smoke, especially combustion products, and in this respect has some similarities with the controlled administration of drugs such as methadone (Dole, 1981). The available data also suggest that it is more effective than placebos in helping smokers to quit (Silagy *et al.*, 2001). However, many questions remain to be answered, especially as regards the importance of dosage levels and the forms and means of administration. With respect to this last question, dependence seems to be linked not just to the intrinsic characteristics of nicotine and other drugs, but also to their speed of absorption. Opium addiction increased enormously when users turned from taking the drug orally to smoking and then injecting it, in the form of morphine. These forms had the effect of increasing the speed of absorption of the active ingredients. A similar phenomenon emerged with cocaine, the smoking of which led to the development of crack. The effectiveness of the nicotine formulations and means of administration used in dependence-reduction methods needs to be evaluated in the light of this knowledge. Bupropion, an anti-depressant that reduces nicotine withdrawal symptoms and the compulsive need to smoke (Nichols, 1999; Jorenby, 2002) opens the way to a different approach to smoking cessation.

Converting the industry

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

intermediates in the synthesis of compounds that could have a number of different applications. Working closely with the world of basic research, the applied research community needs to address these problems, which are also posed by other drugs.

The shadow of pseudoscience

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

The tobacco companies have funded epidemiological studies and publications that cast doubt on the true danger of passive smoking (Barnes and Bero, 1998). In 1988, a group of multinationals set up the Center for Indoor Air Research, without troubling themselves over the inherent conflict of interest (Barnes and Bero, 1996).

These and other situations explain the abysmal reputation that has been earned not just by the tobacco industry but also, naturally, by the studies and researchers revolving around them. Many distinguished public institutions have decided not to accept funding from tobacco companies and many funding bodies reject applications from researchers receiving support from the industry (Cohen *et al.*, 1999; Cohen 2001). Richard Smith, the editor of the *British Medical Journal*, recently resigned his medical journalism chair at the University of Nottingham after the University accepted funding from British American Tobacco (Ferriman, 2001). Some argue that scientific journals should not even publish articles funded by the tobacco industry (King and Yarney, 2000), a policy adopted by the two official journals of the American Thoracic Society (Roberts and Smith, 1996).

To understand why individuals or organisations adopt such positions, we need to bear in mind the power accruing to the multinationals through their profits. These profits amount to billions of dollars, about a thousand times greater than the funding available for public research. Between 1954 and 1966 more than 300 public institutions and nearly 1100 researchers in the US obtained funding from tobacco companies. In 1994 alone, 375 scientific articles on research promoted and supported by the industry were published (Roberts and Smith, 1996). Even without going so far as to alter or conceal findings that from their point of view are negative – which would be offensive to science, even more than to the industry – all the industry needs to do to deflect research is to nudge it towards futile or innocuous objectives.

This problem arises each time science is contaminated by economic, political or ideological interests: in such cases, it is transformed into pseudoscience.

To avoid these risks, it is not enough for biomedical research to be conducted only by public institutions, as some authors suggest (Bolinder, 1997). The greater, primary need is to tirelessly advance the ethical debate on science, undue influence, freedom and the responsibilities of science to society.

GLOSSARY

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

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

Drugs are part of the broader category of pharmaceuticals.

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

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

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

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

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

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

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

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

Withdrawal syndrome or crisis: psychological and physical disturbances caused when a drug for which dependency has developed is discontinued abruptly.

Withdrawal symptoms tend to be the opposite of those caused by the drug: for example, hyperalgesia (extreme sensitivity to pain) as opposed to analgesia, excitement as opposed to sedation, miosis as opposed to mydriasis (contraction and dilation respectively of the pupil) and so on.

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

Tolerance: progressive resistance to the effects of a drug, usually after the repeated use of the substance.

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

Drug addiction or dependency: the compulsive and conscious need, which generally arises after repeated exposures, to take a drug not just to reproduce its initial effects but also to avoid the unpleasant effects caused by its absence and maintain an acceptable state of physical or psychological well-being. Drug dependency may involve one or more drugs. Not all drugs give rise to dependency.

Many other substances give rise to dependency, but do not cause the compulsive and conscious desire that is typical of drugs. The term drug addiction/dependency therefore serves to distinguish drug addiction from other forms of dependency.

Toxicomania: compulsive desire or need to take a drug to reproduce its effects or avoid the unpleasant effects caused by its absence.

Those affected by the condition are called drug addicts. The term drug addict is used for those cases where the compulsion to take the drug is caused by a state of dependency on that drug, as defined above.

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

APPENDIX

SMOKING AND ALCOHOL: A PSYCHODYNAMIC POINT OF VIEW

Among young people, smoking reflects a desire to be somebody, to gather their courage, to overcome inhibitions, to meet a challenge. For women, among whom smoking is on the increase, the habit is often a part of the feminist struggle.

Use of alcohol (which comes later) also reflects fears of inadequacy, of not measuring up to the adult world. So, better to lose control, to disappear, as one does when drunk. Every drunken spree is a potential suicide, a removal or a maniacal outburst in which one loses control of thought and words, followed by feelings of guilt, self-condemnation and denigration, depression. As with other drugs, however, this self-criticism is short-lived and the return to loss of control is swift.

Why is direct psychological assistance during the addiction phase of smoking, as well as alcoholism, generally unsuccessful?

It is not even much help in either case to label these addictions as characteristic of the “lower classes” or tell users that smoking interferes with sexual potency.

The problem is that the cause that induces the need to seek relief lies upstream in both cases, long before the time addiction takes hold. It involves a need to suck – which also signifies contact, bond, security – so natural to the earliest stages of life. In their suckling, nursing infants establish continuity with the mother through her breast, her nipple, which enjoys omnipotence over him or her. If this need for continuity, which underpins attachment and our initial relationships and the formation of self, is not satisfied, then some people continue to experience this lack and have no peace until this urgent oral need is satisfied. If we “remove” their cigarette or bottle, it is as if we are removing the infant’s connection with the mother. In their desperation, these people turn to food and gain weight. This is one of the reasons women do not want to quit smoking.

In treating obese persons, it has often been noted that in the early part of their lives something was missing in their attachments and bonding, which in their case is often recalled by their parents as especially tenacious, dependent and unbreakable. A close examination of the case histories of smokers, drug addicts or alcoholics reveals similar problems. We notice that something was lacking in their early life, triggering an unquenchable need for oral gratification. Taking our study further, we notice that the obsessive goal of their smoking or other forms of oral gratification is the link that could have been found in the bond - abruptly severed with separation at birth - with the mother’s breast, through the welcoming contact that accompanies nursing and the associated smells (Heraclitus attributed great importance to the sense of smell, which he argued was close to the centre of understanding and the characteristic sense of interiority), contact supplemented by the care that provides all forms of sensorial gratification – together with odours and tactile (especially oral) sensations – that are part of the initial care we receive and represent a human right that every individual has when he or she first enters this world. This right is sometimes expressed in the unconscious fantasies of young smokers, for whom smoking signifies, among other things, a challenge, a desire to “face” the person who once tyrannised them and exact a sort of indemnity for the harm caused by the violation of the right to oral gratification that was the smoker’s due in infancy.

What can we do if the pathological origins of smoking lie in infancy? We must turn to primary prevention, which consists in seeking to understand the individual origins of the disturbance underlying the excessive use of smoking.

The definition of dependence given by the World Health Organisation is entirely physiological in nature, since it underscores the essential mechanism of “counterattack” or attenuation that underlies the preservation of life, even in its most elementary forms. Dependence is thus an expression of homeostasis, i.e. the preservation of life in all of its forms, however basic: it does not matter what life.

For those of us today who study the human mind (not necessarily just psychoanalysts: a geneticist, Creek, has recently written a book on the location of consciousness), the issue of dependence is essential not only in physiological terms but above all in psychological terms. Dependence is associated with great human suffering, which ranges from the use of drugs, alcohol or tobacco to the use of fetishes, incest or other sorts of bond that arose at the time of total dependence, and by this we mean not before the time we entered this world (physiological birth) but before the process of individuation came with weaning (psychological birth).

The great burden of this unresolved dependence, so great as to interfere with autonomous growth, cannot be fully addressed here. For now, we note that it does not lead to independence but rather dependence on reality that permits the construction of a more realistic and less magic self. This unresolved “dependence” is one of the most important factors underlying tobacco use.

Having said this, it is clear that in order to validate the underlying assumption of the psychodynamic point of view outlined here, we must undertake systematic research (including long-term studies) to ascertain whether children who as infants were not allowed to nurse “on demand”, especially with breast feeding, really do turn to tobacco or alcohol abuse in adolescence or, unfortunately, even earlier. While awaiting reliable data, it is advisable to act on the basis of empirical findings gleaned from the extensive clinical experience encountered by many, i.e. that frustrated oral urges in infancy may lie at the basis of smoking, alcohol use and often drug use. We should favour “on demand” breast feeding, aware that this need is entirely personal to each child. Breast feeding (bearing in mind that no two children have the same needs, even in infancy), which for generations was part of the care of each child, free of the prejudices that surround it in unconscious justification, must be the preferred manner of feeding new-born children. To this end, we make this possible for all children, preventing useless interference.

Applying these simple approaches to breast feeding and infancy, we will soon note that even in the case of smoking, primary prevention – which meets the needs of appetite and the original dependence – provides a sound medical basis for preventing risks, bad habits and the disorders that these can produce.

CLINICAL GUIDELINES FOR PROMOTING SMOKING CESSATION

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