Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

AIMS, RISKS AND LIMITS OF MEDICINE

14th of December 2001

SUMMARY

PRESENTATION

Since its establishment (1990), the National Bioethics Committee has devoted its attention to bioethical issues connected on the one hand to the progress of scientific knowledge and the resulting technologies, and on the other to positive news and problems that have arisen in medical practice. In this second field we can find, for example, the Opinion on *Bioethics and Education in the Healthcare System* (7th of October 1991), that on *Information and Consent Related to Medical Acts* (20th of January 1992), and the wide research coordinated by prof. Gaetano Salvatore on *Ethics, the Health System and Resources,* motivated especially by the need to assess medicine's aims and priorities in relation to the rising costs and the possibility of the economy, the presentation of which took place on the 5th of May 1999.

Even before this date, however, the need had arisen for an overall look not only at the aims, but also the risks and limits of medicine. These issues had been addressed, at the international level, with a broad multicentric research, called *The Goals of Medicine,* promoted in the mid-nineties by the Hastings Center, coordinated by Daniel Callahan and based on the analysis of the controversies arisen in all traditional medical fields: saving and prolonging lives, curing illnesses, relieving pain and suffering, the satisfaction of personal choices and the autonomy of patients, the prevention of death.

The final report of *The Goals of Medicine* research was published in 1997 and was accompanied by a book by Callahan titled *False Hopes*, in which three negative characteristics of Western medicine were reported: the idea of dominating nature, having unlimited horizons (including avoiding death) and the tendency to expand, invading and medicalizing every aspect of human life. Almost at the same time Roy Porter, one of the most authoritive historians of medicine, published a comprehensive summary of what he calls *Medical History of Humanity* (Norton, London 1997 and New York 1998), to which he attributed as title a superlative: *The Greatest Benefit to Mankind:* medicine, therefore, as a major benefit offered by progress for the good of humanity. Obviously Callahan, in criticizing false hope, does not ignore the extraordinary accomplishments of medical progress; and Porter, in exalting its benefits, does not ignore its failures and the problems of the medicine of the past and present: but the juxtaposition of the two titles is indicative of wide historical and ethical controversies that have arisen in the last decade.

It is in this context that the NBC has began elaborating the opinion on *Aims, Risks and Limits of Medicine.* The work has been led by an *ad hoc* group*,* coordinated by Prof. Angelo Fiori (with Dr. Elena Mancini as coordinator of the NBC's scientific secretariat) and made up by colleagues Massimo Baldini, Mauro Barni, Isabella Coghi, Francesco D'Agostino, Carlo Flamigni, Eugenio Lecaldano, Vittorio Mathieu, Demetrio Neri, Aldo Pagni, Vittorio Possenti, Giuseppe Savagnone and Bruno Silvestrini. In addition to the contribution of these Committee members, the group has made use of the fruitful collaboration of Dr. Robert Bucci, Prof. Giovanni Federspil and judge Amedeo Santosuosso. The broad range of the topics discussed concerns the concept of illness, the epistemological evolution of medicine, the relationship between "scientific

medicine" and "alternative treatments", the relationship between costs and benefits, the rules of human trials, the relationship between doctor and patient and between medicine and society, financial needs and the decision on the priorities of care. The group has repeatedly reported on its work in NBC's plenary meetings, which focused in particular on the function and meaning of medicine in today's society and the need to re-examine the relationship between doctor and patient, which has often became confrontational and risks, as well as being profoundly altered from a moral point of view, arousing widespread litigation. The doctor-patient relationship has been examined in historical-critical terms, starting from the traditional model based on benefic paternalism, through the doctrine of the patient's autonomy and contractual relationships (physician/client), leading to the creation of relationships of trust based on empathy and on what has been defined by Prof. Flamigni as "the ethics of small virtues". Rather than chronologically distinct phases, these models have proven to be experiences that cross over, and necessarily intertwined in order to ensure the effectiveness of interventions and the autonomous decision of those involved, especially through the ethical training of the operators and provision of appropriate information to patients. Since the doctor-patient relationship is always placed in a social context, the long text of this opinion mentions the issues of fairness in health, which previously had been the object of a separate document *(Bioethical Guidelines for Fairness in Health,* 25th of May *2001).*

This opinion on the *Aims, Risks and Limits of Medicine* was finally unanimously approved at the NBC's plenary meeting of the 14th of December 2001.

The President
Prof. Giovanni Berlinguer

1. Introduction

1. A current reflection on the *goals* of medicine is to be considered essential because of the profound changes in medicine over the past fifty years and the prospects for further developments in the near future.

This is an attempt that has already been made, in recent decades, by many authors who are responsible for an increasingly rich literature on the subject. Bioethical profiles do not constitute only one aspect among many, but one of the essential elements.

If in fact the doctrine and practice of medicine is placed in a central position in the gamut of bioethical studies and the reflection on human conduct in life sciences and in healthcare is one of its main purposes, it is even more important to clarify matters, in the knowledge that the resulting analysis and conclusions are temporary, because of the increasingly accelerated dynamism of the transformation of many aspects of human societies, especially those that promote and use technological progress most. However, these societies also pay a considerable price for it.

The interest of the entire society in medicine, in its existing expressions, is shown first of all by the daily attention paid by the media to announcing new scientific knowledge and new diagnostic and therapeutic proposals; to data, whether encouraging or discouraging, on the spread of certain illnesses; to special cases involving unexpected medical successes or failures, often attributed to professional misconduct and/or inadequate facilities and healthcare organization.

The wealth of literature on biology and medicine is another proof of this interest, because, although it is mostly scientific and technical - and therefore mainly dedicated to the experts – it increasingly involves a plurality of students of non-medical disciplines, to which we owe the development of specific fields such as anthropology, sociology, philosophy of medicine and, above all, bioethics.

This centrality of medicine in today's society, however, has failed to fully clarify the position of the doctor, characterized by an ambiguity that not only has not dissipated over the centuries, but is actually becoming more marked at the end of this century, presenting future scenarios that are more heterogeneous and complex, due mainly to the coexistence of scientific and extra-scientific medicine, which is actually in high demand and practised even in the most economically developed societies. It is without doubt possible, and indeed necessary, to attempt to clarify this, precisely in the way this document intends to do, but the difficulties are relevant not so much in terms of concepts, but in their practical application.

It is certain that it now requires a dialogue between the internal fields of the "corporation" of doctors - condensed into codes of conduct that increasingly seek to take into account the needs of healthy and sick citizens - and the demands made by society not only through laws (which by the way are almost non-existent in relation to the issues we are trying to identify here), but also through an appropriate *collective information,* for now increasingly unsatisfactory because it is distorted and devoid of clarity with regards to the core of the relationship between science and the practicality of the so-called medical "art", on the one hand, and the objectives shared by society, on the other.

From this point of view, the well-known Oviedo Convention on Biomedicine assumes great importance, as it makes it compulsory for the Party States to ensure that the fundamental problems posed by the development of biology and medicine are the subject of an “appropriate public discussion”, particularly in light of the pertinent medical, social, economic, ethical and legal implications (Art. 28).

Since ancient times, humanity has attempted to solve the problem of disease, proposing in a dynamically changing, unbroken sequence solutions that have been mostly accepted by other citizens, although sometimes with limits established by repressive or regulatory laws, primarily aimed at punishing the failures that, from time to time, were considered to be beyond the acceptance of the unavoidability of disease and death. Some examples of the *“need to regulate medical activities by placing limitations on them”* are the sanctions imposed on physicians in ancient Egypt, the severe penalties prescribed by the Hammurabi Code, and he regulation of medical studies in Rome since the time of Caesar who, after giving Roman citizenship to all physicians, who were often Greek immigrants, instituted a course of study (anyone who had followed it was “medicus a republica”) which later evolved into special schools for the teaching of medicine, established by Alexander Severus in a gradual and organic organization of the roles of physicians (chief physician Palatine, popular archiatrists, free doctors, gymnasium doctors, military doctors, etc.).

The history of medicine through the various historical periods - from Babylon to this day - mainly documents ideas on the nature and causes of illnesses and their remedies which, while they have changed radically, especially with the onset of modern medicine, are based on a single thread made up *of autonomous proposals by individuals-physicians or by groups or schools,* in a position of effective supremacy (now defined "paternalism") mitigated by individual refusals or by laws such as those we have mentioned as an example.

The known stages of this long history, which cover at least five of these millennia, should be used as the original parameter for the *purposes of medicine* because *only by referring to them can we understand, in a comparative analysis, the most profound and radical changes within them, capable of inspiring a bioethical reflection.*

If every human activity carried out in the context of social groups - whatever their size - is embodied in a mutual trade of goods and services, which industrial society has multiplied to an extraordinary degree, we can see very clearly the peculiarity of human activity as regards the body and mind of fellow men, which is aimed at ascertaining and treating illnesses. This peculiarity is mostly evident when we consider the surgical aggression to illnesses, which causes physical injuries, often profound and devastating, to the patient.

Only starting from this basic fact, we can read the long history of medicine and its present, in which *the benefits* appear to have reached the highest levels, but *the risks,* often translated into *real personal costs,* are correspondingly high in number, percentage and quality, being higher than in other risky human activities, such as, for example, damage related to means of transport and work related illnesses.

Therefore, the problem of the *relationship risks/benefits* - in individuals and in society as a whole - estimated by *subsequent verification* of the *relationship*

costs/benefits, ends up becoming bioethically crucial when it implies the *limits* of applied and also experimental medicine on man and, in a rightfully ecological vision, even on animals.

Medical practice has been defined by some as a *set of practices aimed at curing diseases and the experience that accumulates around them.* It is a definition which, in its elementary simplicity, can be accepted on condition that the extent of the concepts of "disease" and "healing" are clarified. Among the many similar definitions of medicine we can also mention another one: "the art and science of diagnosis and treating disease, as well as maintaining health". It is in this case a conventional definition, which however does not capture all the richness and plurality of the scope of medicine, its goals and practices.

2. The concept of disease

Human health, according to the known and generally accepted definition of the World Health Organization (WHO) is a condition of perfect physical, mental, social well-being and it does not simply mean the absence of illness.

In fact, medicine is entrusted today, in its daily activities, also to *non-illness:* both with regards to the increasingly extensive area that theory and medical practice reserve to the "primary" prevention of illness, and for the large number of individuals who daily, in fear of being ill (due to various ailments or because alarmed by the hammering information about the spreading of certain diseases) undergo check-ups, in order to prevent the so-called "secondary", often being instead in "good health", indeed a more realistic concept than that of perfect well-being conceived by the WHO.

The concept of illness also lends itself to *extensive formulations,* which broaden the original concept of individual, anatomical and functional alteration to the ill-defined area of sociopathy, namely, the "discomforts" and "disorders" produced by the socio-cultural and environmental context.

As for the concept of *"recovery",* it is intended as implicit - in the sinthetic definition we are using - that medical-surgical practices are *in principle* aimed at treating diseases, but they don’t necessarily reach their goal, because illness can evolve into chronic or worsen and lead to death. In addition, the frequent iatrogenic pathologies, due to the risk of many diagnostic and therapeutic practices, can on their own contribute to impaired healing, worsen the condition, establishing new and autonomous morbid conditions, or even causing death.

The “*treatment*” of illness, in the broad meaning we have just identified, requires the precise and comprehensive *knowledge of each disease* and would also require the full *knowledge of its causes.*

The progress made especially in this century has undoubtedly been relevant, but there are still large gaps and limitations. Only in the last two centuries, but especially in the second half of the twentieth century, so-called scientific medicine (see *infra)* has been able, first progressing slowly, then quickly, to build an organic body of nosologic knowledge and identify with sufficient reliability the primary causes of many diseases – as well as the concurrent causes: predisposition, lifestyle and others - in order to enable the development of effective treatments to

heal them or prevent their worsening, or otherwise help the patient to withstand them.

This historical fact clearly indicates how long the path of medicine has been before achieving knowledge and tools that are able to overcome the barriers of the "mystery" of illness. The efforts made in the course of millennia, with primitive and inadequate means, has allowed successive levels of approach to a “layman’s” conception of the human body, its functions and the diseases that afflict it: but the cost has been profound and there have been recurrent crises of disappointment and reflux towards magical or fanciful ideas, such as for example the notion of "Humors" which, starting from the *Corpus Hippocraticum,* withstood many centuries before being abandoned.

In the primitive phase of the ancient cultures of which we have documented knowledge, such as the Babylonian and Egyptian, the medical work has had connotations of minor religious function, closely intertwined with religious beliefs and magical practices, on the basis of the belief that the majority of diseases has a divine origin and an unpredictable course.

Despite these erroneous beliefs, since then, drugs of plant and animal origin have been empirically identified, and the importance of diet.

With the analysis of Alcmaeon of Croton (late VI, early V Century) and Anassagora of Klazomenai (active in Athens in the mid-fifth century) took body the secular concept according to which nature is an organism that has regularity and legality separate from both the divinity and the intervention of man: the complexity and specificity of the biological organism must be understood according to the specific method of the physician that associates a careful analysis of symptoms to a logical-rational level of interpretation and prediction. The three essential moments of this method were already in the anamnesis, the diagnosis and especially the prognosis, which is essential in guiding therapeutic intervention.

From this phase of authentic change, it could be argued that the branch of *"secular" medicine*, which prevailed in the end, and its progressive separation from the mainstream, which continued in any case, of that medicine that, for convenience, we will continue to call *"magic"* to indicate its fantastic nature about the causes and remedies of disease.

Because of the coexistence of these “two medicines”, for millennia medical activity was inspired, and took place and developed, according to a process which has seen slow progress in the knowledge of some aspects of the body’s normal and pathological anatomy and some of its functions and dysfunctions, but without possessing reliable etiological notions and truly effective therapies, in the contextual continuation of paraphilosophical beliefs and baseless interpretations of the structure and function of the parts that harmoniously make up the human being, and of the causes and nature of various diseases.

Medicine has been based for a long time on etiological notions about the cause of diseases, without any foundation acceptable today, even after definitive proof of the natural origin of diseases and the identification of the causes of many of them.

Only in recent centuries, the concept at the basis of the physician’s activity has been to come to the final realization that *illness is a natural process that affects the human (and animal) body,* leading to the conclusion of the "secular" line

of thought, which in its embryonic state had been outlined around the fifth century BC. These goals, still dynamic and in evolution due to the variety of illnesses and the forms with which they occur in individual patients, *have led the doctor to be aware of having evidence-based information, denied to the layman, and of being able to take avantage of it, even more than in the past, to formulate proposals and adopt choices where their professional autonomy, rather than that of the parients and healthy people, prevails.*

3. The epistemological evolution of medicine

The long evolutionary path that has been outlined can therefore allow the schematic subdivisions of the epigenesis of medicine in later ages, based on different types of *episteme* (knowledge):

- the first long period has had as its episteme *the identification of the causes of illness on mainly metaphysical foundations;*
- the second period, which can be made to start from the 1600s, has had as its episteme the belief to have reached decisive scientific proof based on real scientific research, which started at that time;
- the third period, the present one, is characterized by an episteme focused on *the discovery of the complexity* that was paradoxically promoted by the certainties of technology. It is a discovery that comes from philosophy and physics and has produced an awareness of the fact that "the world", as a whole, is not linear, but irregular, variable, unstable, precarious and uncertain; in short, *complex*.

Unfortunately, this modern concept of *complexity,* which implies *prudence in beliefs and practice, awareness of the limits and risks,* has not been adequately and widely taken on by doctors, and this is by some considered one of the causes of today's crisis of identity in the role of the doctor in society and of the uncertain position of his/her art between the physical and natural sciences.

The belief to be able to reach scientific "certainty", although it appears unfounded today due to the *complexity of the phenomena* that scientific research continually reveals, has however had the important role of scientific stimulus, which has gradually led medicine to leaving behind previous stages and reaching in the twentieth century, with incredible speed, the existing targets. These, although characterized by large and persistent gaps, have made the approach to medical diagnosis and treatment radically different, so much so that they led to the creation of that body of doctrine and means that are defined as *scientific medicine,* to distinguish it from the so-called *traditional medicines, or alternative or non-conventional.*

But it could eliminate some of the essential characteristics of medical activity, which are based on the large use, especially in therapy, of empirical methods that often remain such or transform into scientific methods if we arrive at the scientific explanation of their effects. So far, in addition, it has not been possible to eliminate the erroneous beliefs that exist in laymen, but also in many of the doctors, about the state of science and of the art of medicine, which is often overestimated with regards to its level of knowledge and, above all, the power of the medical art.

We must accept this fact, because otherwise we risk of grossly misrepresenting *the aims* of scientific medicine and *the nature of the means* at its disposal and above all *the limits of such resources.* And we also run the risk, with regards to *ethics,* to not draw any boundaries to the work of the doctors, a boundary that must instead be identified as far as possible by the entire society, which uses and supports medicine both economically and by appreciating it and stimulating it, fuelled by the hope of health and a prolonged life.

What is currently designated as *scientific medicine* – in contrast to *non-conventional medicine,* as it is called today in the European community, the so-called Traditional or Alternative Medicine - is essentially based on the *scientific or experimental or Galilean method.* The basic anatomic, histologic and cytologic knowledge, of biochemistry and molecular biology, normal and pathological, allow Scientific Medicine - unfortunately still in a very partial way - to know the real causes of many diseases and the anatomical and functional dysfunctions of organs and systems resulting from them, and to propose diagnostic and therapeutic methods whose practical value is verified by comparing it with other methods, and that are improved, modified or even abandoned, according the results of field trials.

Theoretical medicine, namely, medical biology belonging to the ranks of *natural sciences,* has *started* to become scientific with William Harvey, and it has definitely become a *mature science* when, in 1985, the great physiologist Claude Bernard published in Paris his introduction to the study of experimental medicine. *Clinical medicine,* in turn, has become scientific in the last decades of the 1800s and the early 1900s.

To clarify the scope of the statement according to which medicine is a science, it is first of all necessary to have an idea, albeit unclear, of *what is* "*science*"*, intended in its current meaning.*

Natural science is essentially characterized by an empirical and objective knowledge, knowledge, that is, fundamentally based on phenomena that fall under our senses. In addition, a great deal of epistemological reflections showed that the objectivity of modern science is not equivalent to the certainty of truth, but rather corresponds to the idea of inter subjectivity. In fact science is, by its very nature, universal knowledge, *a knowledge that, in principle, all men must agree upon.* But it intends to be *public knowledge,* so it must be based on observation, on which we can establish a general consensus.

Objectivity and intersubjectivity in science are therefore synonyms: and are essential to building a knowledge that does not depend on a single scientist but is *everyone's heritage,* a concept that is found in the statement by Claude Bernard: "Art is I, science is us".

Science, and medicine as science, is a fundamentally empirical, rational, universal knowledge, attained with a method, a method that is unique and stable over time.

It was Claude Bernard's great merit to have supported and defended the idea that the study of physiological and pathological phenomena in such a complex object as the living organism is no different in its method than an extremely simple object, like a heavy body that is attracted towards the centre of the earth. This is the fundamental concept expressed in his famous passage: "the physicist and the

physiologist, although the first deals with the manifestations of inanimate matter and the second with the phenomena occurring in living matter, share the same purpose, both in fact aim to know the cause of the phenomena studied".

In short, in the last two centuries medicine has been laboriously establishing itself as an *experimental science.* It has increasingly adopted the quantitative language of science, the bare and essential speech, objective observation, calculation, the operationism of the concepts, the systematic control of the theories. In addition, clinical activity has established itself as a scientific activity, as it sunk its roots in the world of experience, because the evidence on which it is founded are inter subjective and because the concepts it uses are empirical concepts. The clinician, finally, adopted the same mental attitude of the scientist: he/she continuously tests his/her diagnosis, explains the phenomena through laws, strives to anticipate and tries to change the course of nature.

A specific nature of *scientific medicine* is also its constant progress, the result of the dynamism of basic biomedical science and the practical experience that now is confronted and continuously updated on a worldwide scale. The beginning of modern medicine in its current form started, as already mentioned, in the 1800s – a period of transition after the “certainties of previous centuries” - in the context of the knowledge of physiology and biochemistry that have been progressively implemented, the birth of the bacteriology and the first concrete progress in pharmacology.

In the Nineteenth Century, a more complex medicine than the purely symptomatologic one that had until then dominated clinical activity, took hold. Two main levels of medicine are configured in this manner: an easier one, practiced by family doctors and based primarily on the experience of the individual doctor, and the other, based instead on the first knowledge of the authentic mechanisms of disease and was practiced by most educated physicians, who kept in constant contact with the acquisitions from the scientific world. From this historical phase, the current, real scientific medicine started, its acquisition of knowledge, means, but above all scientific methodological rules, has reached its highest level in recent decades. The experimental method, which is the foundation of other sciences as well, also guarantees the relentless progress of scientific medicine.

The aims of scientific medicine have also undergone, in the past few years, an expansion that is related to the *increased availability of means* produced mainly by technology, resulting in a broadening of the *boundaries* to include services that have raised serious questions about their intrinsic legitimacy, the opportunity to overcome them and the dangers that can arise in today's and future society, and for medicine itself and the medical profession.

It is common knowledge, and not disputed, that the purpose of medicine is *the diagnosis and treatment of illnesses* but also their *prevention*. However, in this concept, which seems unquestioned, there is already ambiguity and uncertainty because the pact that medicine and doctors have with the collective and the individuals is often shrouded in hope, which is however due even in the most difficult and desperate cases, both for obvious humanitarian reasons and the uncertainty that is part of every medical treatment, the simplest as well as the most complex. Then the *aims of medicine* fragment and become a *wide series of objectives* that can or cannot be realised in relation to the intrinsic nature of the

illness, its stage, the patient's resistance and his/her response to therapy. *In other words, the objective of "recovery" becomes only one of many that medicine can aim for and ensure.*

In these inevitable uncertainties, which are present in many cases, is the germ of possible reactions of disappointment, rejection and conflict because the "contract" between doctor and patient, however explicit and informed, has too many margins of uncertainties not to involve *a high level of potential disappointment in the patients and their negative reaction towards the doctor.*

This is probably the main cause of the lasting and actually increasing recourse to the so-called non conventional medicine or traditional alternative medicine, which not only coexist with scientific medicine, although they are radically different from it in principle and in most of the practice, but seem instead to be flourishing even in the most developed countries.

4. Alternative care practices

Treatment practices that are alternative to scientific medicine, undoubtedly represent a relevant problem in the field of the treatment of illnesses, as their use is widespread also in the most advanced countries and it finds supporters amongst doctors as well, who, in great numbers, suggest them and practice them.

The variety of these empirical methods explains the differences that exist even when defining them. Therefore, the European parliament in its 1997 resolution (A4-0075/97) called them non-conventional medicines, feeling that they have in common "the fact that their validity is not recognised or is only partially recognised; that we can call "alternative" a medical or surgical treatment able to substitute another one and "complementary", a treatment used to integrate another one; that is misleading to talk about an "alternative" or "complementary" medical discipline, as only the precise context in which therapy is used allows us to determine if in that case it is alternative or complementary; that an alternative medical discipline can also be complementary". The name alternative medicine is however considered more valid by the experts, who believe that it is not appropriate to define scientific medicine as "conventional", because this could lead to wrongly thinking that it comes from an agreement between those who practice it and choose its rules. Therefore, defining alternative medicines as "non-conventional" could reduce how different they are to scientific medicine to a simple individual choice, which would stop us from mentioning the known Popper principle of falsifiability, as an element to distinguish between science and pseudo-science. And the requisite of complementarity is also not accepted.

Having therefore chosen the name alternative care practices or alternative medicine, we must remember other denominations like unofficial, non-scientific, heretic, parallel, complementary, sweet, natural medicine. They are an heterogeneous constellation of doctrinal systems and remedies that, for various reasons and in different amounts in each country, are not adequately legitimised by the public institutions in charge of healthcare. Despite this, millions of people, even with a reasonably high level of education, see them favourably and with interest and it cannot be thought that they do so only because they are

disappointed by other solutions or because they are sure of their efficacy. Alternative medicine confronts official medicine, also called scientific, orthodox, western or, more simply, “medicine”, which is a constellation of doctrines and remedies just as heterogeneous, but increasingly based on scientific premises for the treatments suggested, and on strict verifications, carried out with scientific criteria, both of successes and failures. Currently we cannot doubt that the progress of medicine is exclusively due to scientific medicine, whilst alternative medicines is an essentially static field.

The resolution of the European Parliament, which is a non-scientific body, is therefore to be considered mostly an acceptance of the lasting and widespread use of alternative medicines, it blurres its boundaries and it does not condemn their use, in principle.

Similarly, the last version of the Italian Code of Medical Ethics, published in the Autumn of 1998, does not stop doctors from recurring to alternative medicine although with limitations, as in Art. 15 it states that “the power to choose unconventional practices respecting the decorum and dignity of the profession is expressed in the exclusive field of direct and unquestionable professional responsibility, keeping in mind, in any case, that any non-conventional therapy should not subtract the citizens from specific treatments of proven efficacy and requires acquiring a consent”.

Alternative medicines must therefore be considered in this document because they are still part of the medical practice also during the period of the maximum development of scientific medicine, feeding, in this way, the very ancient branch of medicine with “magical” aspirations, both in the conception of the cause of illnesses and their treatment. If we share the alarm of an editorial, a few years ago, in the authoritative *Nature* (30, 787, 1988) – according to which the problem of alternative medicine is the most menacing challenge to western scientific medicine, as it puts into question its foundations – it is evident that the ethical duty of a position that implies, if possible, the solution of the problem posed by Karl Popper, of the *demarcation,* which is the need to identify a clear division between medical science and pseudo-science.

It’s a very complex problem not only because it requires ways to discriminate that are completely reliable – which exist – but also because once the clear distinction between the two fields has been made, the really scientific one and the non-scientific, at the same time the rejection of non-scientific treatment methods is not automatic, on condition that when they are offered to patients, this happens in an atmosphere of absolute clarity and honest information. On the other hand, the called-for and needed “demarcation” must take into account also the mistakes and the not uncommon mystifications and manipulations that are recognised as negative aspects of scientific experimental medicine, which usually places its methods, practice and results outside of science, in the area identified as pseudo-science, which can be just as deceptive, and even more so, than alternative medicines, due to a stronger power of suggestion in an era dominated by science and technology.

Alternative care practices, in their current growing dissemination also in the most underdeveloped countries, therefore represent a phenomenon of primary importance in the analysis of the actual aims of medicine, its limits and risks.

They are mostly inherited from the distant past of pre-scientific medicine or, if recent, they have a genesis and principles similarly autonomous from Galilean official science. They are based, generally, on principles that biomedical science is unable to verify the foundation of, and on practical results, especially in the field of therapy, which sometimes seem positive, or are believed to be such, also because of the suggestive psychological elements that these "therapies" are able to evoke. Or they are positive, in certain illnesses, because they cause physical manipulations (like chiropractics, Chinese acupuncture, electroacupuncture, zonal massage, etc.) not very different in their empirism, from physical treatments that are prescribed by scientific medicine (massage, magnotherapy, laser therapy, hydrotherapy, etc.).

The best known alternative medicines have been used for centuries in the least developed countries. In western countries, however, the medicines of those countries have been disseminated, together with other more recent non-conventional medicines, in these last decades and this in the period in which official biomedical sciences have achieved their best successes. The vast movement of opinion that supports them usually looks at science skeptically, or with suspicion if not even with hostility and often hopes for a return of the imaginary realm of uncontaminated nature.

In the alternative medicines we include various and/or numerous medical practices referred to with different names: natural medicines, heretical medicines, "sweet" medicines, parallel medicines, non-official medicines. They are based on doctrines and practices that have a very different "scientific" status: some of them are essentially empirical practices, like herbal medicine and chiropractics; others have distant roots in rational scientific thought; others link to other esoteric traditions or even magic. We can distinguish *services with organisations and premises* (acupuncture, argillo-therapy, biofeedback, biorhythmology, chiropractics, macrobiotics, electroacupuncture, physiotherapy, hypnosis, hydrotherapy, music therapy, homeopathy, reflexology, autogenous training, vegetarianism, yoga); and *services without organisations and premises* (anthroposophy, auricolotherapy, ayurvedic medicine, chromotherapy, healers, iridology, Hatayoga, zonal foot massage, faith healing).

Alternative care practices are often carried out by people without a degree in medicine, who practice without checks, but also by many doctors who carry them out with continuity, it's not always clear whether out of conviction or because they believe them to be economically advantageous. It is certain, in any case, that a considerable percentage of common medical practice given by qualified doctors is based on alternative methods that are not included in official treaties of medicine and surgery used in degree courses or diplomas. Only some of these methods – for example acupuncture, homeopathy – are currently the object of separate training in some European countries. The CENSIS has calculated that, in Italy, already in 1982-1983, about 40,000 doctors offered non-conventional medicine – 6,000 of which continuously – and that currently about 3.5 million patients recur to it every year. An investigation by the ISTAT in 2001 indicates a much higher number of users, equal to about nine millions. In the USA, Eisenberg and colleagues calculated that, in 1993, the annual expense on alternative medicines was about 13.7 dollars (*Unconventional Medicine in the United States. Prevalence,*

Cand Pattern of Use, “New Engl. J. Med.”, 328, 246, 1993). In the last years the phenomenon has considerably increased, so much so that, according to recent data, four Americans out of ten in 1997 used some kind of non-official medicine, with a 50% increase compared to 1990 and with an overall expense of 27 billion dollars, equal to about 43,000 billion liras, paid personally by the patients. Mac Lennan and Wilson (1996), on the basis of 3004 interviews carried out in the South of Australia, calculated an overall expense of almost 1,000 million Australian dollars each year for “alternative” medicines and therapists (*Prevalence and Cost of Alternative Medicine in Australia,* “Lancet”, 347, 569, 1996).

With regards to the reason for this incredible phenomenon, the common opinion is that one of the main causes – but not the only one, if we consider the general tendency of man to believe in non-scientific ideas, like astrology – is the frequent worsening in the doctor-patient relationship that happens within “scientific” medical practice, of the psychological benefits deriving from the longer time doctors who practice alternative medicines dedicate to the patient, empathy, personalisation of care, ability to raise hope about the results with regards to chronic illnesses, and in general from the fact that “alternative” doctors give maximum attention to the health of the patient more than to his/her illness.

If we try to analyse the relationship between the patients (and in general current public opinion) and scientific medicine, it is inevitable to see the essential difference, in this historical period characterised by increasingly advanced medicine, between medicine and what happens to anyone who offers a service and products (a professional who is not a doctor, artisan, industrial worker, businessman, etc.) with regards to the relationship with his/her “clients”. In most of the relationships, although there is the possibility of fraud or error or inadequacy, today there is an expectation of technical competence which science and technology have accustomed us to.

In the doctor-patient relationship, instead, despite the incessant elaboration of the principles of truthful information to the patient and his/her independence, there is within the patient, more and more often, a diffidence about the efficacy of “official” treatments, joined to a fear of suffering and the risks caused by invasive diagnostic and therapeutic practices (including pharmacological ones) and death. The truth is feared and reassurance is sought as a primary good. “Magical” suggestions that characterise a large part of alternative medicine, also due to the apodicticity of prescriptions, often answer these psychological needs and often because they have a real effect, at least “psychotherapeutic”, in minor pathologies, which would have healed naturally or, if chronic, needed help, even psychological.

These factual realities – the ethical evaluation of which, with regards to doctors and non-doctors who carry them out, is inevitably negative because it uses scientific “truths” that are mostly unfounded or non-verifiable – must however lead to a careful analysis of their apparently paradoxical refusal of scientific and biotechnological medical progress. In some measure, we could compare this situation to some positions of the environmental movement, like for example the diffidence and hostility towards transgenic food.

A more in depth comparison between the journey that characterises the progressive dissemination, against the general tendency, of “sweet” alternative medicine – which in effect goes through the same journey of the ancient magical

and arcane medicine – and that of official scientific medicine, allows in fact to identify, in the two fields, a similar relationship with public opinion, even though they offer very different "products".

The search for "clients" in fact, in both cases, uses the usual advertising methods that, even for scientific medicine, are changeable in time and often consist in "authoritative" propositions coming from current scientific ideas and also by commercial pressures.

We must recognise that scientific medicine also largely uses, to obtain the consent to practices, public and private information that give improper and insufficient guarantees of scientific treatment, at times for impudent superficiality, more often because of needs linked to the individual case and to the limits of medicine and to that of the doctor.

Therefore we can find points of contact not with regards to the foundations – which are radically different in scientific and alternative medicine – but with regards to the psychological aspects of the doctor-patient relationship, which in both fields can use suggestive methods.

And it's on these issues, on these areas, that we must apply bioethical analysis, *which consists primarily in identifying the real possibilities, and therefore the limits of scientific medicine in healthcare and in the autonomy of the patient towards care. In order to give a truly informed consent, it's important in fact that the patient takes into account that also the "certified" treatments of scientific medicine are inevitably imperfect and often deceptive. With regards instead to non-conventional medicine, acceptable only in marginal and substantially harmless situations, it is essential for the information to clarify the basis of the proposed care, also and especially when it is unknown (like in the majority of cases).*

The problem of iatrogenic pathology – due to drugs and surgery – for its exponential growth, requires also a bioethical reflection, which some authors started a while ago, especially with regards to the hypermedicalisation of society. This is a problem that is part of the growing preoccupations for the reality of the neo-industrial world, in which the habit of consuming the products of technology have caused needs that are believed to be difficult to give up, also because they are promoted by a web of interests that involves a vast number of people.

5. The aims of medicine

Even in the lasting, but essentially non-decisive differences of doctrinal opinion on the ideas of health, illness, ailment and infirmity, we can recognise that the undisputed universal matrix of medicine is the common human nature, which implies illness and physical and moral pain also in relation to the fear of the future and death. In comparison to the past, scientific knowledge and the exchange of medical knowledge and practices is a heritage common to all. The patient's well-being is considered everywhere the doctor's primary obligation, and a similarly inescapable obligation for all of society, which must work to make equally accessible to everyone adequate healthcare. The recognition of the patient's right to *autonomy* and, most of all, *information,* which must come before the eventual *consent* to treatments suggested by the doctor, is increasingly agreed upon – and

it aims to be universal in all cultures -, and the doctor actually has the duty and right to make suggestions on the basis of current knowledge and the specific needs of the patient. They are all universal and fundamental values which, at least in pinciple, give medicine its current identity and are compatible also with national and regional traditions.

Despite this, the search for a complete agreement on the aims of medicine and, even more, on the specific meanings of these aims, causes confrontations that cannot be easily reconciled, especially with regards to the most innovative and cutting-edge aspects of current medical interventions.

The recent Report by the Hastings Center – called *"The Goals of Medicine: Setting New Priorities"* (cf. in "Notizie di Politeia", n. 45, 1997) – asks, amongst other things, if it is justified to suggest that medicine has aims with a universal validity, namely, aims that must be common to all cultures and others that are the distinctive sign of the various cultures they belong to.

Asking therefore if the aims of medicine are *intrinsic models of medicine itself or social constructions*, the Report by the Hastings Center says that, with regards to the nature of medicine and its aims, there are two notions that, although in contrast, have integrated each other for a long time.

According to *the first notion*, medicine has intrinsic aims susceptible of being "discovered". *The second notion* accepts that the aims we believe we "discover" are generally social constructions linked to time and history.

The supporters of the first notion say that the proper aims of medicine represent the typical answer of medical practice to the universal human experience of illness, inspired by the need to heal, help, assist and cure, which started with the dyadic doctor-patient relationship, on which medicine maintains and strengthens its vitality.

Therefore, although recognising the duty to be more transparent regarding both the intrinsic limits of medicine and the cultural conditioning that it receives from the outside, it is still necessary to identify its aims and purposes for its intrinsic vocation to promote and defend human health and the protection of the patient.

The second notion, according to which the aims of medicine are a social construction, comes instead from the realisation that, with the changing of times and cultures, the nature of medicine and its aims also change. The ways to interpret illness, infirmity and various ailments, as well as the answer to these experiences is complex and dynamic, characterised by many clinical practices without a substantial and stable basis. Knowledge and practices follow the times and societies in which medicine operates and therefore they are at the service of all the objectives that society believes to be important, being bound by the same restrictions that affect other social institutions.

In the conflict between these two visions of medicine emerges the problem of establishing if medicine has the task of defining *on its own* its history and traditions, its values and direction, or *whether it must leave this task to society*. The Hastings Center believes that a valid answer to this alternative is, instead of a conflict, *a continuous dialogue with society*, during which each of the two interlocutors look for their legitimate field of action, their rights and duties. We take for granted, however, that *the starting point of medicine should be found in its*

history and traditions. On the other hand doctors, healthcare personnel and patients are part of society, so that it is foreseeable that *it will never be possible to clearly divide the institutions of medicine and other social institutions.*

In this perspective of dialogue, we need to take into consideration primarily the restrictions and points of view that, with regards to medicine, *put bioethics and medical ethics in a position of priority*.

One of the most current and relevant aspects of the identification of the *aims of medicine*, destined to become more prominent in the future, is the constant changing of structural, organisational and economic needs caused by the almost incessant medical progress, which implies also a constant monitoring and evolutive planning.

It is not therefore only the means – but undoubtedly those too – *but the aims of medicine that must be re-examined ex novo, although partially, also to verify their compatibility with society's human and economic resources.*

In this re-examination, we must avoid considering the goals achieved as stable objectives, a step towards definite further successes. It would be an unfounded optimistic view, based on the *erroneous idea that the defeat of illness is near and final*. Even many infectious diseases, believed to be eradicated, are coming back also in the countries that are better equipped to fight them, and their dissemination and seriousness in many areas of the world continues, both in relation to intrinsic environmental conditions and the limited availability of economic resources that, on the other hand, are insufficient even in the richest countries.

There is no doubt that the prevalent focus, in these last few years, concentrates especially on the *tools* and *means* of medicine and healthcare, rather than their *aims*. Therefore the analysis of the management and organisational aspects, of the cost and problem of funding, the issue of privatisation, political and bureaucratic innovations, and other undoubtedly interesting ones, have prevailed. *Bioethical analysis*, which has progressed in an incessant and considerable way, concentrated mostly on individual problems, the most current ones, which more urgently require evaluations and decisions. But the central issue of the current aims of medicine, which we will try and identify here, has remained a little hidden, probably because of the complexity that connote it.

In listing *the main and traditional aims* that define medicine, the report by the Hastings Center, which it seems appropriate to refer to, wonders whether medicine must always be necessarily "against ageing and death" and therefore to what extent it should go to prolong human life, especially if it's ending. It also wonders if really, and absolutely, the traditional aim of promoting and maintaining health is valid, if the term "health" could have different meanings in the different stages of life and if truly illness and infirmity should ever be accepted and if it is reasonable, through the current means of *predictive medicine* based on genetic testing, to know much in advance the probability of having to face certain illnesses during the course of our life. The list of questions extends to ask if medicine must also deal with (in order to help resolve them with its means) the "anxieties of daily life", existential, psychological and spiritual problems, which people necessarily encounter in their life also in relation to social violence, environmental risks and other aspects of life, including also various types of pain and suffering, physical

and psychological and therefore if also euthanasia and assisted suicide are part of the realm of medicine or not.

Therefore, a central issue is the problem of the *boundaries of medicine*. We can say that generally they could be indicatively left to the doctors, assigning however to society the responsibility of giving doctors all the tasks they cannot carry out for the benefit of each citizen. But in this eventual, flexible vision, we must ask ourselves if medicine is able to answer issues of this magnitude and if these eventual temptations – which are in some way already happening – do not lead to a hypermedicalisation of *society,* with all of its damaging effects.

Amongst the collateral effects of medicine – which certainly cannot be included in the *aims* but are linked to them and therefore to the *functions of medicine* that answer the peculiar needs of society – we must mention *its relationship with economy*, not only from the point of view of the *resources* that it takes from society primarily for healthcare reasons, but also for *what it produces*, feeding the industry and commerce of the products necessary to medical activity, and therefore the profits, the consequent investments and the occupational effects.

Medicine and healthcare become in this way significant forces in political life, both nationally and internationally, the impact of which in society has reached such levels that it requires a reflection with a particularly wide scope to allow both an up-to-date global evaluation, and specific propositions and not only generic mentions, although due, of respecting deontological and legal regulations, these, in addition, almost non-existent in Italy with regards to the basis and fundamental rules of medical activity.

The problem that must be tackled and resolved first is therefore the *broadening of the areas of competence and activity of medicine*.

With regards to scientific medicine, it seems evident, at least theoretically, that all the problems emerging from social life – in their various modern expressions, when we anticipate negative psychophysical effects, real or potential, for the individuals and the collective – inevitably imply their biomedical study, and an analysis of the applicative consequences, when possible. These problems belong to the vast area commonly called public medicine, which involves primarily, but not exclusively, state and state-controlled public institutions and premises.

Hygiene is traditionally, and in its successive evolution, the branch of medicine that in its current expressions (social and epidemiological medicine, community medicine, occupational medicine and industrial and agricultural hygiene, etc.), tries to monitor the “hygienic” conditions of air, water, soil, food, factories and nearby inhabited areas, identifying the most disparate risk factors of illness or even discomfort, from bacterial and viral ones, to chemical and physical ones (today including atomic and electromagnetic radiations), to psychophysical stress factors.

The indications of *Primary Prevention* that come from them represent one of the most important frontiers aimed at constantly monitoring the evolution of the risks connected to technological evolution. It is futile to add that in this area the links medicine has with vast parts of today’s knowledge – chemistry, physics and, obviously, biology – are very close and of essential importance.

The identification of the risk factors of illness can be carried out with *a prior* evaluation, generally based on considerations on the scientific possibility of the pathogenic role of a certain factor and eventually on the basis of animal trials. A typical example is that of the feared pathogenic action of electromagnetic radiations – increasingly widespread – with regards to which there is now a vast literature, which however does not present conclusive opinions.

The risk factors of illness are also looked for, and non always truly identified, mostly *afterwards*, after noticing manifestations of an illness that has already happened to man, and of which we research the etiological agents for the ultimate aim of preventing their dissemination and action. This is the most specifically clinical area in which, in truth, is right to put also *secondary prevention* as it is an activity aimed at quickly finding *the existence or not of already present pathologies in their initial phase*, that is, more susceptible to therapeutic and hygienic treatments – by removing the risk, if possible – and apt to guaranteeing success.

From these elementary considerations it is evident that *the broad background on which medicine links with a very wide part of individual and collective human activity.* It is an area that has reached its current size starting from the industrial revolution (also in ancient medicine, however, great importance was always given to elementary and individual hygienic precepts) having as significant precedent, with regards to occupational risks, the work by Bernardino Ramazzini, *De Morbis Artificum Diatriba* (1700).

A relevant part of the problems that modern bioethics deals with belongs, essentially, to this area. In fact bio-engineering techniques used to grow transgenic plants and animals, as well as being a general ecological problem (relative to the quality of life, food resources, survival of animal species, bio-diversity, etc.), present *risks of possible hygienic relevance, which must be the concern of scientific medicine, hypothesising the nature of each risk and accepting its level and the eventuality that it has already happened.*

In the public medicine sector we must mention, as a particular aspect of the aims and functions of medicine, *all the medico-legal activities carried out by doctors,* which are financed by the “social state” (services for disability retirement, disabled citizens, accidents, occupational illnesses, work-related causes) to which we have to add those belonging to the field of private insurance for civil liability, disability and expenses due to illness. Their economic effect, which is very important, links with the problem of the distribution of resources and therefore the general needs of medicine, in healthcare research and activity. These medico-legal activities have also developed organically, and progressively, starting from the end of the 19th century and disseminated especially in the second half of the 20th century. All the public welfare services that imply medico-legal tests and assessments are without doubt carried out by doctors. They extend to the medico-legal aspects of military healthcare, disabled citizens, handicaps and in-service accidents and therefore to a relevant part of the vast area of private insurance.

In these sectors we cannot anticipate individual bioethical problems as such. But if we reflect instead on the *bioethical problem of the allocation of resources* that has been present in healthcare for some time, it seems instead evident that *the global balancing of the distribution, namely, the choice of investment and refusal, can involve a global re-examination of medical activities* that implies not

only possibilities of radical reforms but also a reconsideration of its medico-legal function, its rules and practice, which have suffered many distortions in these last decades.

After what we have said, it is however appropriate to remember that the traditional field of medicine that is believed to coincide, in public opinion and for the doctors themselves, with the *primary aims of medicine,* is that of *diagnosis, therapy* and *prognosis.*

In the research of the phenomena that connote medico-scientific practice in the current historical phase, and from which we have to start *assessing their aims/risks/costs/benefits*, we can attempt to identify them remembering the bioethical objectives that our analysis proposes and recalling in summary also notions that we have in part already expressed.

The following can be considered such characteristics:

- Exponential increase, in quality and number, of the services through an incessant creation of diagnostic and therapeutic means, both pharmacological and in terms of tools;
- Invasive means, even pharmacological, and the connected risks of complications and side effects;
- Constant mix of scientific premises controlled through trials and *effectively empirical* applications in individual cases, in the incessant dynamism of diagnostic and therapeutic propositions;
- Difficulties in applying to healthcare, public and private, the general organisational model typical of the industrial/post-industrial society to reduce an activity of services defined by a “case by case”, essentially amateurish approach;
- Progressive extension of the notion of “therapy” to treatments that involve a *medical act*, the “therapeutic” justification of which is to be found in the “desires” and the psychological discomforts that can follow when they are not satisfied (plastic surgery, assisted insemination), or in refusing extreme suffering (euthanasia, assisted suicide);
- Progressive growth in the number of individuals who, for the increase in life expectancy, better social conditions, the efficacy of medicine in prolonging life in patients affected by serious chronic illnesses and also for the dismantling of mental hospitals as psychiatric institutions, require *permanent care* (medical, nursing, voluntary) in facilities or even at home. All these phenomena, impressive for their dimensions and complexity, explain the continuous crisis of the medical profession and more in general, of public and private healthcare. It explains the growing conflict beween healthy and ill citizens and doctors, which ends almost always in penal or civil courts and represents one of the biggest problems medicine faces at the moment and in the near future.

6. The risks of the cost/benefit evaluation

The risks of scientific medicine (essentially “commissive”, unlike those mainly “omissive” of non-conventional medicine) must be now taken as a point of reference for a correct evaluation of the *costs/benefits relationship*, which has a

central role in identifying the *limits* that it's appropriate to set to the expansion of medicine, namely, its *aims*.

To the risks, which translate in *human costs (and implicitly also economic) due to complications, side or secondary or unwanted effects, iatrogenic illnesses*, is dedicated a vast amount of scientific literature, which tackles it directly and indirectly on occasion of the public presentation (in journals, books, conferences) of new therapeutic propositions or experimental and applicative experiences. There is no treaty of internal medicine or surgery, or pathology of any branch of specialist medicine that, in discussing a certain illness, does not follow the traditional paragraphs of definition, etiology and pathogenesis, symptomathology, also that of the clinical varieties and the course with the relative, possible *spontaneous complications*, in themselves independent from medical intervention. These are "complications" that in many cases can lead to chronic illness with various degrees of disability or even death.

These complications can be mistaken, clinically, for those that can be more appropriately defined as *iatrogenic complications*. Commonly we qualify a *iatrogenic illness* one which, due to the doctor's diagnostic or therapeutic treatment, has the characteristic of neo-illness in comparison to that already occurring and required treatment. It is a distinction that can remain on condition that we consider it a particular category of the general class of "iatrogenic complications".

The phenomenon of iatrogenic pathologies, in exponential growth, is a central problem in the further expansion of medico-surgical treatments because it's one of the causes – although not the only one – of the conflicts between doctors and patients, which lead to penal and civil lawsuits for medical malpractice and, consequently, scare the doctors (causing the distorted phenomenon of the so-called defensive medicine), induce insurance companies to progressively restrict the area of guaranteed cover to doctors and healthcare facilities.

The common expressions of *complications, side or secondary or unwanted effects, iatrogenic illnesses* require some explanations and clarifications.

The so-called *side effects,* also euphemistically called *"unwanted" effects* or *adverse reactions* – which are generally listed in the information leaflet in the packaging of any authorised medicine – sometimes linked to *absolute or relative overdose* or to the existence of *unknown or overlooked contraindications* or to *interactions with other medicines*, are generally considered less important and therefore more and almost implicitly tolerable. They also belong to the large class of "iatrogenic complications" and it is appropriate to stress this for the need of a more rational global classification. In addition they can be in some cases highly harmful, temporarily or forever, and even lead to death.

Amongst these *side effects* it is not usual to include, actually wrongly, those linked to any kind of surgical intervention. In this field, are generally called "complications" the anomalies in the post-surgery course, compared to the most common ones. However a more careful reflection leads us to put together *the "normal" consequences of the surgery,* even the most modest and local one, in the sphere of the unpleasant but tolerable "side effects". So post-surgery pain, the existence of the surgical wound that has to heal, the unpleasant effects, although temporary, of the aenesthetic. There is in fact no conceptual difference between

these *implicit* side effects and those caused by many medicines: like for example intestinal disorders after taking antibiotics orally. The complications that the illness itself can cause often contribute to the iatrogenic pathology in its various aspects.

It follows the conclusion that *the current variety of medical and surgical treatments, because potentially burdened by many risks of collateral, temporary or permanent or even mortal damage, completely independent or contributing to the illness that required treatment, represents a condition that has to be known by the patients (and by their relatives) and be explicitly included in the therapeutic alliance.*

The qualitative and quantitative range of these harmful phenomena cannot be underestimated by the doctors – who tend to continue on the road of hypermedicalisation, in which they often stray – or by the patients and their relatives, who more and more often require medical treatments, feeding a *negative cycle* which uses the same mechanisms that rule consumeristic society. The offer of medicine – often in excess compared to what the needs are – can be linked to a growing demand by the public for health checks and the treatment of ailments and illnesses. This is a situation that cannot be compared to that of the first part of the 20th Century when the patients, and their relatives, were often reluctant to go to hospital and medical treatments were mostly carried out at home and in surgeries.

In the wider perspective, we can place the critical reflections of Ivan Illich, who elaborated interesting concepts of *clinical iatrogenesis*, *social iatrogenesis* and *cultural iatrogenesis* (cf. *Medical Nemesis – the Expropriation of Health,* Cuernavaca, 1976; *Limits to Medicine*, London, 1988). He calls *clinical iatrogenesis* “not only the damage that doctors inflict with the intent of curing or of exploiting the patient, but also those other torts that result from the doctor’s attempt to protect himself against the possi bility of a suit for malpractice”: it is the anticipation of the concept of defensive medicine. Second level iatrogenesis has been called *social medicine*, for which “medical practice promotes uneasiness reinforcing a morbid society that pushes people to become consumers of curative, preventive, occupational, environmental, etc. medicine”.

Second level iatrogenesis manifests itself in various “*symptoms of social supermedicalisation*”, which constitute what Illich calls “expropriation of health”. It is finally called *cultural iatrogenesis* that of the third level in which healthcare professions “have, on health, an even more profound cultural negative effect because they destroy the potential ability of the individual to personally and individually face his human weakness, vulnerability and uniqueness. *The patient who is controlled by contemporary medicine is only an example of humanity who is controlled by its harmful techniques*”.

7. Human trials

In the vast area of the *risks and human cost* of medicine, and of the damage that follows them, a particular and central place is given to *trials*, which are a process that is intrinsically linked to the development of medicine and surgery.

It is usual to limit the meaning of the noun to *trials regulated by law*, which involve primarily new drugs and only marginally new technological products. This

is an activity that has a wide scope and involves healthcare facilities in most of the developed world and is supported by the industry, which has to provide scientific documentation, standard and deriving from human and animal trials, according to the norms of good clinical practice that are currently the object of European directive n. 20/2001, which shows both how effective and how tolerable (in truth often relative) the product and the technique are.

In reality the concept of *trials* must be extended to a large part of medical practice in its historical and current aspects, and in its effects on each *individual* patient.

We must distinguish, in fact, between *human trials for a specific purpose or in the strict sense,* and *trials with a non-specific purpose*: a much more common situation and with not clearly defined boundaries, which is the consequence of the applicative dynamism of new diagnostic and therapeutic propositions released incessantly into the profession. This second category *in effect assumes the essential, although informal character of human trials, which are carried out during the process of dissemination of a new drug or method between doctors and the consequent learning and perfectioning of it, by each doctor or team*. It is a process that often ends with the definitive adoption of a drug or a certain diagnostic or therapeutic technique, but just as often with abandoning them because of the excessive inconveniences or their proven inefficacy.

In the last few years international bodies have appealed with increasing strength to the ethical duty to control human trials. Numerous documents have been produced, on some of which the National Bioethics Committee has given its contribution of comments and proposals.

The most important documents on human trials regulated on the basis of international declarations, European Community and national regulations are essentially the following.

The Helsinki I declaration –approved at the 18th World Medical Assembly in 1964 and then issued in 1975, 1983, 1989, 1996 and 2000 during the 52nd assembly of the Association – is the fundamental document on human trials for a specific purpose and it represents the most known and important legitimisation, at the international level, of biomedical research practices that have the objective to “improve diagnostic, therapeutic and preventive interventions and to understand the causes and development of illness”. The 2000 edition fixes 32 fundamental principles for all medical research.

This form of human trial for a specific purpose aims at specific objectives of scientific research, mostly of an applicative and not “pure” nature, to ascertain if drugs for therapeutic or diagnostic purposes, already registered or to be registered, are effective and tolerable,; or also to verify comparatively the value of new technical procedures of various kind. This experimentation is also called “therapeutic” as, although it has the purpose of acquiring new knowledge, it has a diagnostic and therapeutic potential in favour of the patient. We can instead call “non-therapeutic” those human trial that have the essential aim of verifying certain scientific hypotheses without any direct benefit for the healthy volunteer who accepts to participate.

The general methodology of this de facto experimentation – that is, carried out according to scientific rules that are generally standardised – is mostly based

on the so-called *randomised clinical trials* (RCTs). These “trials” have a precise connotation, as they are a transversal study that employs one or more control groups in contrast to the group that has the treatment, and which one of the two branches of study on the subjects used for the trial has it, is chosen *at random*. The control group is given a *placebo* or the usual standard therapy. Often being assigned to one and the type of treatment are not known to the patient but only to the doctor (*single-blind*), whilst at other times they are not even known to the doctor (*double-blind*). These tricks have the purpose of avoiding that in the evaluation of the results there are interferences due to the researcher’s prejudices who, in this way, can also study the purely psychological, suggestive effects exercised by the treatment on the control patient. The Health Ministry adopted, with the decree of the 15th of July 1997, the Guideline for Good Clinical Practice for carrying out clinical trials on medicines (European Union, 1996), which presents a rigorous approach aimed at avoiding harm and abuse to the patients who undergo the trials, often burdened with the risk of direct or indirect iatrogenic damage (due to the lack of treatment to patients who are given a *placebo*).

Also at the European Union level, the 4th of April 2001, the European Parliament and Council adopted directive n. 2001/20, regarding the reconciliation of the legal instructions, regulations and administrative decisions of the member states of the Union relative to the application of the norms of good clinical practice in carrying out the clinical trial of drugs for human consumption. This directive came into force on the 1st of May 2001 and it will have to be included in the member state regulations before the 1st of May 2003.

Amongst the new things introduced by the European Community, it is possible to recall, in extreme synthesis, the methods to give and withdraw informed consent, in particular in the case of minors and incapacitated subjects, the right of all the subjects involved in the trial to talk to a person independent from the researcher to gain additional information on the progress of the trial itself (c.d. *point of reference*), the measures on the protection of privacy and exchange of information between member states, the simplification of the procedure to authorise the start of the trial and the measures intended to reinforce the role of ethics committees especially when the clinical studies are taking place. We cannot say the same, however, with regards to the agreeing to the studies, within which the committees are called to have less important roles than anticipated, for example, in the Italian legislation on the clinical trials of drugs (on this point, see the NBC document *Guidelines for Ethics Committees in Italy* of the 13th of July 2001).

In addition, the directive sanctions the legal importance of the regulations of good clinical practice, formally attributing to them binding efficacy. Particularly significant, from this point of view, is the anticipated “dissemination in all the European Community” of GCP regulations, in the sense that the directive gives the Community the necessary competence to adopt and review in time, in order to take into account scientific progress, the abovementioned principles of good clinical practice adopted in Helsinki. It is an important development, which will allow the formulation of GCP regulations applicable in the European Community by bodies that are politically or institutionally legitimised (and not only technically),

able to formalise in legal regulations also the trends deriving from good clinical practice.

Within the European Council, the international organisation created in 1948 to protect fundamental rights and freedoms, which today includes 43 European States, is in advanced phase of elaboration the Protocol on Biomedical Research additional to the Oviedo Convention on Biomedicine recalled above, which will become binding for the member states once the ratification procedures anticipated in national legislations have been completed.

This protocol finalises the object and the aim of the research, some general principles, the role of the ethics committees, the information to subjects who participate to the research in order to obtain an informed consent, privacy, security and supervision, and some special cases like emergency clinical conditions and the freedom of individuals, research on pregnant or breastfeeding women. The fundamental cornerstones of the protocol are the primary protection of the dignity and identity of the human being in order to guarantee for everybody, without discriminations, respect for his/her integrity and other fundamental rights and freedoms regarding any research that implies interventions on a human being. The interest and well-being of the person who participates to the research must prevail on the interest of society and science. Biomedical research must be followed voluntarily and subjected to the rules of the protocol and other regulations that ensure the protection of the human being; when it requires interventions, it is justified only if there is no alternative of comparable efficacy; *it must not involve disproportionate risks in comparison to its potential benefits;* finally *it must be scientifically justified according to criteria of scientific quality, and carried out according to the profession's rules and standards, under the supervision of a qualified expert*. These principles are essentially the same as those more analytically taken into consideration in the last edition of the Helsinki Declaration by the World Health Organisation, of which we highlight certain points, like the consideration of the impact on the environment and the welfare of the animals used in research (Art. 12); the monitoring role of the ethics committee and the need for its definite independence from the researcher, the sponsor and other possible forms of undue influence (Art. 14); the permanence of the responsibility of the researcher with regards to the consequences of the research, regardless of the obtained informed consent (Art. 16); the fact that the doctors, after having carefully assessed the risks to the patient, also from the point of view of manageability, must stop the trial if the risks are more than the potential benefits (Art.17). Other fundamental principles are the higher relevance of the objectives in comparison to the risks, especially in the case of healthy volunteers (Art. 18) and the reasonable probability that the populations in which the research is carried out can benefit from the results of the research (Art. 19). With regards to the subjects who are mentally incapacitated and under age, the selection of the subjects who participate to the research must be particularly rigorous, not only obtaining the agreement of the legal representative (and also that of the minor if he/she has a sufficient level of maturity) but also guaranteeing that these are necessary investigations to promote health in the population of reference and that they cannot be carried out on mentally incapacitated subjects (Art. 23-26).

Of equally relevant interest from an ethical perspective are *"the trials for non-specific purpose" of a diagnostic and therapeutic nature* to the ethical aspects of which scientific literature has dedicated marginal attention.

These types of trial on man – substantial and informal, regulated apparently by the principle of informed consent and by the doctor's responsibility – always happen when a new diagnostic and therapeutic method is introduced and, in effect, it represents the essence of the dynamic historical process that characterises medical and surgical treatments.

In this context it is necessary to include also extreme "experimental" therapeutic attempts – when there are no alternatives, or when the usual methods are completely ineffective – which are usually included in the category of experimentation as such. This point of view can be found in the whole history of medical progress, which occurred at a high human cost, not only in the past, and not even a far away past, when the doctor did not have effective and sufficiently safe means, but also in the current era.

A few examples can clarify the statement better. In the extraordinary journey made by cardiovascular surgery, the possibility of operating on an open chest, with a non-beating heart as the blood is carried around the body by extra-corporeal circulation for the duration of the surgery, was first envisioned, then carried out on lab animals, then carried out on patients who needed cardiac and surgical treatment. *Learning new techniques, the decision to apply them to man, the study of the results and their inconveniences, the correction of the methods as difficulties appear, all happened through a pioneering activity, for its "experimental" nature applied directly on man, carried out on the individual patients who accepted the vagueness of the results that inevitably accompanies the first outcomes.* It is clear that these attempts are not part of the typology of experimental *trials*, generally carried out to study the effectiveness of drugs. In fact these are directly therapeutic decisions, although they are preceded by studies on animals and by preparing adequate tools.

The cost of these pioneering phases notoriously present a high level of complications and mortality that, however, to go back to the example, gave cardiovascular surgeons the possibility of perfecting their techniques to the point of reaching a satisfactory standardisation. "Experimental" has to be considered, from this point of view, not only the very early phase of the various other cutting-edge surgical applications, but also the generalised learning of the techniques by the surgeons, for each of whom generally are necessary more or less long periods of apprenticeship, with the relative and inevitable cost for those patients who, without a full understanding of their role, gave their consent to the new type of treatment.

What has been said has only the aim of highlighting that *in effect a great part of medical progress inevitably goes through experimental phases on man even if they are not explicitly recognised as such*. The patients and their families maybe are in some measure aware of it: despite that, it seems surprising how they try, often at any cost and especially in the most serious cases, to undergo the newest and for this reason more uncertain therapies. Such is the fear of illness and death, and such the strength of hope, and the faith in medical progress, that any suggestion that seems to offer a glimmer of hope to improve health and especially save or prolong life, is welcomed often without hesitation. In this way we can

explain the “journeys of hope” and, especially in the oncological field, giving in to the most disparate propositions of *alternative therapy*, often completely unfounded from a scientific point of view. Unfortunately, doctors and non-doctors, irresponsible or greedy, take advantage of this. But this trusting availability of the patients and their families also benefits the better doctors who, without brave agreements, full of hope, could never concretely carry out their suggestions, often temporary, and improve the way they occur through the *in vivo* experience.

Also the variety of boundary, or further, treatments of official medicine, namely, in the area of the various alternative medicines, answers to the same psychological mechanism and ends up in effect having “experimental” characteristics. In these sectors the possible harmfulness is mostly due to the patient’s more or less prolonged privation of consolidated official therapies. It is evident that *in this field the consent is even less informed* than that given to the cutting-edge experiences of official medicine, whilst instead it is important to promote the patient’s awareness of the risks for his/her health.

Concluding this complex and difficult issue, we must realise that in medical progress, both when the nature of illness was still unknown and medicine was unable to provide truly effective care, as well as in the current phase of great development of scientific medicine, *empirism has prevailed and still prevails,* as medicine implies a case by case assessment and essentially experimental aspects, although currently under the guidance of rules of thumb, to which we attribute – not always with reason – definite scientific value.

8. The issue of the doctor-patient relationship

The role of the doctor in society has to be considered to always have been ambiguous, and this not only has not dissipated in the course of the centuries but it’s getting worse at the end of this century, envisaging maybe even more difficult future situations. This clarification will not be easy and it cannot be final. It is certain, however, that a dialogue is now necessary between the internal trends of the doctors guild – summarized in deontological codes that increasingly try and take into account the needs of health and sick citizens – and the requests expressed by society, not only through laws (which are almost non-existent relatively to the issue that we try and identify) but also through appropriate collective information, still unsatisfactory because deformed and devoid of clarity about the central issue of the relationship between science and medical procedures, on the one hand, and aims shared by society, on the other.

From this point of view, the European Community directive on the application of the regulations of good clinical practice in the clinical trials of drugs, mentioned above, gives to all the subjects involved in the trials the right to call on a person independent from the researcher to gain additional information on the progress of the trial itself (c.d. *point of reference*).

Amongst the central themes in the debate on the difficult *problem of the doctor/patient relationship* is that of the so-called *medical paternalism* and the related problem of the *patient’s autonomy*, the most difficult to resolve in the

current phase, and that will maybe be such also in the future, because of the intricate complexity of healthcare in the last fifty years.

It is useful, for convenience of discussion, to use a schematic division into three evolutive phases of the doctor/patient relationship that has been used in 1985 by Mark Siegler, of the Center for Clinical Ethics in Chicago (cf. *The Progression of Medicine. From physician Paternalism to Patient autonomy to Bureaucratic Parsimony,* "Arch. Intern. Med.", 145, 713, 1985). The author, already at that time, summarising known notions, highlighted the fact that in the United States, after the end of *the first period*, which lasted millennia, called *the Age of Paternalism*, came *the second period* called *the Age of Autonomy*, which lasted a short time because it was quickly replaced by the *third period,* designated by Siegler as *the Age of Bureaucracy*, also called *the Age of Parsimony*). This categorisation, certainly useful from a conceptual point of view, must not however be interpreted rigidly, almost as if it actually represents the orderly succession of geological eras, but rather as a list of the most general trends, which in reality overlap, influence each other, with continuous conservative or evolutive oscillations.

In Italy the succession of these periods is posticipated of a few years, because, although the antipaternalistic doctrine of autonomy still has some hold, we are in effect in the age of bureaucracy, or age of parsimony, characterised by a restriction of economic resources. We call *paternalism* (a term that T. L. Beauchamp, in *Medical Ethics: the Moral Responsibility of Physicians*, 1984, attributes to Kant and Stuart Mill both in its general meaning and in the meaning applied to medical treatments) the "interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interest or values of the person being coerced" (Dworkin G., *Paternalism,* Belmont, 1971; *Theory and Practice of Autonomy,* Cambridge, 1988). In the *Encyclopaedia of Bioethics* (1995) edited by W.T. Reich, Bruce Miller believes that "paternalism" in medical treatments consists in treating a patient against his/her will, on the basis of the principle that the doctor is professionally obliged to provide care in the interest of the patient, because he/she knows better than the patient what is best for him/her ("doctor knows best").

Actually, the thesis according to which paternalism comes from ancient medicine is not accurate, because *the reading of Hippocratic texts, and other references, amongst which a well-know passage by Plato in the Laws (IX), lead us to believe that ancient medical deontology did not actually prescribe an authoritarian relationship of the doctor towards his/her patients, but on the contrary a relationship based on dialogue, persuasion and the continuous explanation of the development of the illness from the patient to the doctor, to allow him/her to make the necessary changes to the treatment.*

Antipaternalism (which the last edition of the *Encyclopedia of Bioethics* believes to be in decline) is today one of the main cornerstones of the *doctrine of the patient's autonomy*, elaborated after the second world war and it implies a negative judgement that seems generally shared although it is clearly vague, elaborated for convenience of dialectic opposition. However, we recognise that this principle also allows exceptions because of the crucial crux of the paternalism/autonomy issue, namely, in cases of extreme emergency, with

undoubted risk for the life of the patient, paternalism is "justified" in ignoring, at least in part, the patient's wishes. For this reason, some authors, to overcome the obstacles that practice puts between the rigid theoretical ideas of autonomy, coined the expressions of *weak paternalism* in contrast to *strong paternalism* (Ten C.L., *Paternalism and Morality,* "Ratio", 13, 60, 1971; Feinberg J. *Legal Paternalism,* "Can. J. Phil.", 1, 106, 1971; Dworkin) leaving us also uncertain with regards to the objective criteria to distinguish the first from the second. "Weak paternalism" would be a "concession" in exception to the rigid criteria of autonomy, as we admit that for an individual who is mentally unable to make a decision, who refuses a useful and necessary treatment, is possible to obtain a "vicarious consent" to protect his/her interest. These are situations common in clinical practice, especially in the case of minors and adults with reduced mental capabilities, for whom it is evident the need of a "paternal/brotherly" relationship with the patient and for whom the term "paternalism" ends up being partially improper because it is not appropriate to describe the almost infinite range of individual situations that characterise the dynamic dyadic doctor/patient relationship.

The excessive schematisation that characterises the bipolar contrast paternalism/autonomy-antipaternalism is weakened in the identification of four models for the doctor-patient relationship suggested by Emanuel and Emanuel in 1992 (cf. *Four Models of the Physician-patient Relationship,* "Jama" 267, 2221, 1992). The first model, the most traditional one, is the *paternalistic model* sometimes called "*parental" or "priestly"* in which the doctor-patient relationship tends to ensure that the patient receives the care that better guarantees his/her health and well-being. It is the doctor who assesses the patient's condition and establishes the diagnostic and therapeutic means most appropriate to this objective, giving him/her selected information that encourages him/her to give his/her consent to any intervention that the doctor believes to be best for him/her: to the point of informing him/her authoritatively of the decisions made and therefore proceed with the treatment. This model presumes that the doctor has objective criteria to establish the best choice, that the patient accepts the suggestion (even though he/she does not like it), and finally that in the relationship between autonomy and well-being, choice and health, the patient's autonomy is placed second. In this way the doctor's obligation is at its highest level, as he/she assumes on him/herself all the responsibility, including that of acquiring other doctors' opinions when his/her competence is not sufficient.

The other three models – *informative or scientific, interpretative, deliberative* – are part of the doctrine of autonomy (cf. *infra*).

The so-called "paternalistic" phase – which in the second half of the twentieth century was accused of being authoritative and self-referent – has lasted thousands of years during which the link between doctor and patient has been essentially dyadic and a few strangers, except from the family, could be part of this personal, magical realm of the treatments. It was a model of medicine based, more than today, on trust in the technical capabilities of the doctor and on his/her morals, sustained by the attribution of magical powers to the doctor, and it was characterised by the patient's dependence and the control exercised by the doctor.

The results of medicine during this long period have been notoriously very modest because of the essential lack of truly scientific knowledge, except for the data coming from observing the most obvious symptoms on the illnesses.

The old healthcare system, in its simplicity and "poverty", also had some important positive aspects. It was, first of all, *low cost*. If it could not provide a real *cure*, it gave symptomatic *care* and a lot of value to information (intended as *prognosis*), which was a mystery known only to the expert doctor who would give it to the patient in measured "doses". At the same time it was *a medicine that, not very suitable to treating the physical manifestation of the illness, dedicated itself to the psychological aspect* and was based on the teaching of principles of hygiene and preventive medicine according to the limited knowledge of that era. In this system, the doctor was the source of information, psychological support and symptomatic care.

We can ask ourselves today, almost in disbelief, how this medicine so poor in notions and tools could dominate the minds and bodies of our ancestors for such a long time. But the explanations can be found not only in the fact that there were no alternatives in pre-scientific medicine, but also in the constant research, by the patient, of a "fatherly-brotherly" relationship, *still* a constant feeling in large part of the population, because of the psychological component linked to suffering and the need to be reassured also in the most severe cases. It is definitely this the main reason that pushes millions of patients in the most developed countries to use practices of non-scientific alternative care and to prefer them to the practices of scientific medicine.

The doctrine of the autonomy of the patient and the contractual model relate to the concept of autonomy in moral philosophy and in bioethics, which recognises the human capacity of self-determination and the principle that each person's autonomy must be respected. The problem is formulating a precise concept of self-determination and establishing how and how much the autonomy of the individual must be respected. In clinical bioethics (or, if we prefer, in medical ethics) the individual patient's right to autonomy can be in conflict with the professional obligation of the doctor to benefit his/her patient.

The doctrine of autonomy in effect contrasts the *contractual model* of medicine (according to which the patient decides) to the *paternalistic model*. It is possible that it came mostly because of the increase of iatrogenic negative consequences, direct of indirect, to diagnostic or therapeutic treatments. From these situations, and in the civil tribunal in the USA where in 1957 a trial for compensation due to medical liability took place (*Salgo V. Leland Stanford, Jr. University Board of Trustees*), came *the doctrine of the informed consent* strictly linked to that of *autonomy*, because it requires for the patient to know not only the treatments he/she will undergo but also the possible negative effects, in order to give him/her the individual possibility of accepting or refusing the treatment also if it puts his/her health and life at risk. The Court's decision was followed by a further decision by the Kansas Supreme Court (*Natanson V Kline, 1960)*. The scientific knowledge developed in the course of a few centuries, but grown exponentially in the period following the second world war, could not but become, as far as possible, heritage to be shared by doctors and healthy and sick citizens, in an essentially liberal society in which there is free circulation of ideas and new

knowledge, supported by powerful media, available to all. *And it was not possible that the increased risk of the means of medicine and surgery, and of the harm which would follow the implementation of the risk, would not recall attention on the rights of the patients and their family.*

The elaboration of *principles in defense of the patients* was therefore inevitable when faced with medical propositions of increasingly wide range, more invasive in the body and mind, not inspired, like in the past, to confused and arbitrary knowledge – and as such actually impossible to correctly transfer because of the lack of reliable basis – but to credible scientific knowledge. This new need, in addition, can be linked also to the progressive and rapid disappearance of analphabetism, to the widespread availability of mass media (TV more than print) and of the growing awareness of our own rights, due to a social and political evolution.

The second of the four models of the doctor/patient relationship designed by Emanuel is *the informative model,* sometimes called also *scientific model or "engineering" or "consumer model"*. In this model, which typically corresponds to the doctrine of autonomy, the objective of the doctor-patient interaction is for the doctor to give the patient all the indispensable information, *leaving him/her free to choose the treatment that the doctor will carry out*. Information concerns the possible nature of the illness, the diagnostic and therapeutic means necessary to identify it and treat it, the nature and the probability of the risks and benefits, and any eventual uncertainty in medical knowledge. In this model there is a clear distinction between facts and values: the patient's values of reference are known and clear to him/her but he/she does not have the facts instead. It is the doctor's duty to illustrate them whilst it is the patient's task to assess, on the basis of his/her criteria, and make the final choice. There's no place, in this model, for the doctor's values, or for his/her judgments on the patient's choice. In other words, the doctor is a technician who gives the patient the necessary elements to decide and exercise control on the actions of the professional. In this way the patient's autonomy has a clear and decisive prevalence. The third model by the two Emanuel is *the interpretative model* that mediates the *unrealistic extremism* of the informative model. The objective is to identify the patient's values of reference and what he/she really wants, and help him/her to choose the treatments that are in line with those values. In this model also the information is basic *but the doctor helps the patient to analyse, articulate and interpret his/her values and which means can better realise them*. To do this the doctor cooperates with the patient, who often is unaware of his own values and aims, to identify them and also place them in order of priority. Only then the doctor decides which diagnostic and therapeutic treatments better realise the objective but he/she does not force them on the patient, who remains in the end the arbitral of each decision. The doctor, in this model, acts as a counsellor who helps the patient to know and choose. The professional's obligation to diligence, in this model, therefore implies a challenging process of involvement in which the patient's autonomy is sufficiently respected.

The fourth model of the Emanuel's is *the deliberative model*. In this model the patient's values are not necessarily considered as preconceived and fixed, but are considered open to development and revision through discussion. The objective of the doctor-patient interaction is that of helping the patient to identify the values that

are more closely connected with a level of health that can realistically be achieved in a certain clinical situation. Therefore the doctor must start with the information of the health conditions and from this basis help the patient to identify the type of values involved in the possible diagnostic and therapeutic options. This happens through a discussion that disregards any possible implication of non-medical problems and in any case is not compulsory. *In this model the doctor is seen like a teacher or a brother who involves the patient in an effective dialogue, in a balancing of the pro e cons of what can be better for him/her in that situation.*

The recent report of the Hastings Center on *The Goals of Medicine: New Priorities*, which expresses ideas we can largely agree upon, effectively summarises the principles that are the foundation of autonomy, although it also appears lacking in the study of their compatibility with the needs of medical practice. The report states that the increasingly determined and explicit recognition of the respect due to people, which implies the right to self-determination – namely, the patient's autonomy – in medicine and in healthcare, sanctioned in a large number of international declarations, is an important progress in contemporary medicine. It also states that if the central focus of medicine has always been *the health* of the individual, more recently *it has been put forward the idea that the aim of medicine, maybe instead its most important aim, can be that of autonomy in its broader meaning*: the self-determination of the choice of *how to live*. However if the ultimate objective of health is that of allowing an individual life, freely choosing between all the possibilities without the impediments inherent to illness and infirmity and therefore if health aids *the possibility of freedom*, it would be wrong to see in freedom an aim of medicine. *Health*, states the report, *is a necessary but not sufficient condition of autonomy, and medicine cannot avoid this limitation. In fact to the promotion of freedom cooperate many other institutions, like for example school, therefore medicine clearly cannot achieve it alone, even though at times it can offer important contributions to the improvement of autonomy.* The field of medicine is the well-being of the body and mind, says the report by the Hastings Center, *not the overall welfare of the person*. To achieving that, medicine can only give important contributions and, even when it does it, exclusively for some aspects of life.

If we really think about this, the so-called age of autonomy is defined for having *again* (that is, like at other times in the past) questioned *the doctor's limits*, which link with the broader problem of the *limits of medicine*.

In the so-called *age of autonomy*, says Siegler, the objective of the *cure* focuses on the outcome rather than the *"taking care"* and the *prevention* of illness. *The financial costs* linked to the rapid scientific and technological evolution that has led to the doctrine of autonomy, have not been considered, for the last few decades, a relevant factor and in any case certainly not a factor to consider of primary importance in comparison to others and in particular *the patient's autonomy, his/her needs and his/her desires*.

During this period, which has already been followed by what is by now to be believed to be the "age" of parsimony, the dyadic relationship between doctor and patient has started to dilute and slacken, especially in hospitals, because of the plurality of the services given by many doctors to one patient (fragmentation and pluralisation of the relationship), in a kind of assembly line with a strong

technological element, made necessary by the complexity of the organisation of healthcare. The balance of power, *at least theoretically*, has slowly and progressively moved from the doctor to the patient, especially because of the doctrine of informed consent and the potential threat of lawsuits against doctors for liability of having violated the consent rule.

In the U.S. the doctrine of autonomy in its extreme form has been considered of libertarian and consumerist character and has long been subject to critical review by prominent bioethicists (Clements and Sider, 1983; Callahan, 1984; Thomasma, 1984; Veatch, 1995). Their argument was the opposite, namely that the maintenance and restoration of health is considered to be a priority of healthcare authorities. This is, after all, the crucial transition that marks the difference between the rigid concept of autonomy and the time-honoured rules of medical ethics.

In a broader examination of this difficult issue, the Hastings Center Report cited attempts to mediate, stating that as it is an error to make autonomy a fundamental goal of medicine, it is similarly a mistake to make the overall welfare of society the primary purpose of medicine: the first would be excessively individualistic, and the second too community-oriented. It is not within the powers of medicine to determine the overall good of society. To play a general role in promoting social welfare, beyond the more limited goal of providing for the health of citizens, medicine should be able to pass judgements of more general character and to determine when its capabilities can be used to support the goals of society or when they should be subordinated to them. But it is not able to do so, and if it could tolerate being used for such a purpose, this would jeopardise its integrity and the achievement of its goals. A society that made use of medicine to remove the unfit, to serve partisan political purposes, to make it the handmaiden of political authority or even just the executor of the will of the people would soon lose its central role and its integrity.

In fact, the moral principle of patient autonomy conflicts with the duties of the doctor only in extreme circumstances, which may justify the positing of two opposing theories: one that always gives precedence to the duty to provide treatment and save lives and health, and the other where the overriding principle is instead free and independent decision, whatever the consequences, including the worsening of the disease or death.

However, the extreme positions of the doctrine of autonomy are often at odds, at least in Italy, with other norms that doctors have to follow in many situations, in particular that which is called the position of guarantee, which comes into play when the patient is reliant on their care, though not when they are at home and deliberately refuse any assistance, a situation which can only justify coercive intervention in the case of mental incapacity.

The so-called "era of autonomy" was already in decline in the U.S. in 1985 with the arrival of the so-called “era” of thrift, into which it is clear that Italy has fallen today, owing to the progressive squeeze between the overall economic costs of medicine and the limited availability of resources, which is producing a substantial reduction of the freedom of decision of both patient and doctor. It should be noted, however, as mentioned earlier, that this distinction between different "eras" in terms of the interpretation of the ethics of the doctor-patient

relationship must be considered an explanatory model which cannot in itself be applied to the historic situation or to the everyday practice of medicine.

Notwithstanding, it may nevertheless be noted that in Italy this new phase began a few years ago, and that now it shares a space with the principle of autonomy, which still holds the lion's share of space in magazines and at conferences, where rhetoric wedded to principles that are not applicable in medical practice often holds sway, though these principles are unfortunately applied with growing severity in the courts, the scene of a number of declarations of principle returning to haunt the doctors who made them. In the everyday reality of medicine today, the era of thrift is now taking over uncontested, with restrictions on expenditure and an acceptable cost/benefit analysis ruling the day and demanding a purely bureaucratic analysis of risks and benefits.

The quality of care, already difficult to define on its own account, is increasingly becoming a target ever more closely related to the cost of treatment, which is much easier to identify and quantify. In this new era, the dyadic ratio between doctor and patient will be further weakened in terms of healthcare facilities – those which deal with the most important diseases – because the doctor is ever more burdened with responsibility for multiple interests which include the members of staff at the institution in question, hospitals, politicians, and in the United States – and probably soon also in Italy too - insurance companies. The doctor who is asked to take responsibility for cost-saving measures and at the same time to assume the role of manager sees their duties multiplied through the existence of multiple polycentric relationships.

The legislative trend is often led by the needs of the balance sheet for healthcare resources, and outlines for the hospital doctor a role which ever more obviously bears the hallmarks and limitations of the era of parsimony. The race to meet the scheduled hospitalisation periods from the perspective of demands for economy in health spending leads to situations of stress for the doctor, increases the probability of diagnostic and therapeutic error, and also reduces the time available for extensive personal contact, with patients entrusted to junior doctors and paramedics, thereby exacerbating the situation criticised in the past and increasing ever more the distance from the ideal relationship between physician and patient enshrined in proclamations on the rights of the latter that are read out in the doctrinal texts and judgements of the courts.

In the two previous phases, the good of the patient was considered to be the predominant issue for the doctor. In the so-called "era" of paternalism, the primary interest was the patient's health as identified by the physician under his or her own responsibility. In the following "era" of autonomy, this was counterbalanced by a primary emphasis on the freedom of the patient and his or her right to self-determination. In the age of parsimony, the good of the patient is placed on scales that include on the other side very different types of good, such as the needs of the hospital, those of the people who work there (including, of course, physicians), and the needs of society as a whole. The decision-making process is therefore no longer only in the hands of the physician or the patient himself.

In terms of medical decisions, medical paternalism and patient autonomy end up being replaced by the efficiency and convenience of institutions and society, based largely on assessments of costs, an issue which has become increasingly

central. In contrast to the two earlier periods, the choices of both doctors and patients will become increasingly subjected to the wishes and decisions of politicians and bureaucrats, to the different multinational drugs companies, to healthcare instruments and materials, and also to the budgetary needs of insurance companies, which, should they come to refuse or dramatically restrict coverage for medical liability, would in fact lead many doctors to abandon their careers, as has already happened on a number of occasions in the United States.

In the new era of parsimony, the doctor-patient relationship risks being worse than both the much-criticised era of paternalism and the more recent age of autonomy. If a patient wishes to extend their hospital stay for any reasonable personal motive, including the understandable fear of not finding adequate support at home during convalescence, to give the most common and simplest example, the strict rules of the DRG* force them to give up their wish to make their own autonomous decision and accept the fact of their being sent home. And if the patient wants to take advantage of facilities that the hospital does not possess owing to its size and lack of availability, they must give up and hope to being accepted in other institutions, which are often far from where they live and thus from their families.

Changes in knowledge cannot therefore change the substance of a relationship which is often made unequal and asymmetrical by the objective condition of the patient’s dependence on the doctor, due to the illness and to the subjective state in which the patient exists. It should be added that in a period like the present, in which the instrument of litigation is employed to ensure maximum protection of patients' rights, it is objectively difficult to rebalance a situation which is by nature unbalanced. Criminal and civil trials are unable to do so and may even produce a more widespread medicalisation which has a negative effect on medical procedures.

It must also be recognised that an asymmetrical relationship is a reality common to all human relationships in which individuals or groups "specialise" in certain activities which become necessary for others or else are imposed upon them, whether it be the military, politicians, traders, engineers, lawyers, teachers, etc, and even the host of hyper-specialised "professions" that we can now find in a society the life and development of which is based on a almost inextricable network of interdependencies. In this dense network of relationships the principle of autonomy, which we will discuss shortly, often becomes a virtual one, despite the fact that space, which should be maximised, remains for decisions and personal actions.

Medicine is certainly no different from other "specialisations", especially those typical of the intellectual professions, which, despite each having its own characteristics, could also, broadly speaking, often be accused of "paternalistic" attitudes, even though what is imposed on the "customer" is not achieved by means that are directly coercive. It is also understandable, given the unique nature of the objectives of medical activity and its links to health and life - primary goods that are constitutionally protected in Italy, but subject the risk of iatrogenic damage - that particular attention is paid to the healthcare profession and that it, unlike other professions, is now questioned in a very specific manner, resulting in crises and conflicts of increasing intensity and severity.

On a doctrinal level it is therefore difficult to detect a real difference between the deontological ethical principles and precepts of the era of Hippocrates and those that make up current deontological codes, principles that have always inspired the praxis the majority of honest (in the broadest sense of the term, including competence and diligence) doctors, based on beneficence-in-trust, which sees health as a relational value which is the "objective of both patient and physician, who "situate themselves in a relationship of mutual trust in which they pursue the greatest interest, that of health". On a practical level, too, the imbalance between doctor and patient cannot be eliminated, but the physician is certainly expected to make an effort to minimise this asymmetry, in accordance with a commitment that forms part of his art on a technical level, even before a moral one.

In addition to health, there are other values and fundamental human rights, and it is probably this that creates the main tension between the so-called "paternalistic" and "contractual" approaches to medicine. This is the basis of the demand to recognise patient autonomy, which gives rise to the principle of informed consent and the right to refuse treatment. To enable this principle, the doctor has the duty to inform the patient about risks associated with the therapy and its costs, even in personal terms and in relation to other values. However, health, while not an absolute value, is the value that forms the purpose of medicine, and it is therefore the primary task of the doctor, unlike other individual values such as autonomy and well-being. The protection of patient autonomy does not therefore consist in negotiating health as a common model of the doctor-patient relationship, but in agreeing choices on the means, the relationship between costs and benefits and on the assessment of the risks that the patient is willing to run. The patient may not accept this approach and may choose to find another doctor, but the doctor is not required to go against his clinical judgement and consent to the wishes of the patient, should they not arrive at a shared therapeutic decision.

To dub an entire era that lasted for millennia, like the much-criticised era of "paternalism", with its negative connotations, would at very least imply that the ethical doctrines formed during that long period had theorised unreasonably authoritarian conduct on the part of the doctor, but this does not correspond to what the history of medical ethics has handed down to us. Another issue, of course, is the negative judgement that might be made on the conduct of individual authoritarian doctors, based on an erroneous concept of their own role and its limits, which in some circumstances leads to abuse. If, in fact, medical paternalism is taken to mean the arrogance of those doctors who exercise, often unconsciously, a power of suggestion and moral coercion that leads them to substitute in an apodictic way the will of the patient, taking advantage of the latter’s ignorance and their own knowledge, this is a problem and probably will always remain so in the future: he who possesses certain, specific skills finds himself in a privileged position which allows for abuse, whether conscious or unconscious. "Paternalism" does not, therefore, designate an era, but only individual professional behaviours which are unfortunately still common, often associated with personality traits and characterised by arrogance and a deficient ability to communicate diagnoses, treatment and prognoses with an attitude of

respect and humanity. This attitude is not even "paternal" in the true sense of the term, and becomes paternalistic in a negative sense, that of the imposition of truths and of conduct at a time when the applicant is in a state of need, and therefore of inferiority.

To define the long history of medical care, even if it was given in the face of a lack of medical knowledge, with the dismissive label of "paternalism" is a superficial attitude that is disrespectful of the very long line of doctors who have gone before us over the millennia and who have shown so much merit in difficult situations which were marked by a relatively slow growth in scientific knowledge, which in fact began to take off in the seventeenth century. If the worst type of paternalism, both ancient and recent, must be rejected and fought against, it is on the other hand important to recognise that from the previous millennium we should recall that spirit and practice that rests on a brotherly, and also maternal and paternal solidarity with patients and with the relatives who suffer with them.

9. The relationship between medicine and society

The need to define the relationships between society and medicine is now essential, especially in developed societies, where the demands that society makes on healthcare services risk becoming at times unjust, as well of course as unaffordable.

With this in mind, it is vital to ask the question: which health do we intend to achieve? It is clear, of course, that in the answer to this question lies the "purpose and limits" of medicine which this document aims to identify and which may constitute the realistic "social contract" that can be drawn up between medicine and society.

The question arises in relation to the growing demands that society makes on medicine. In developed countries, encouraged by the sometimes utopian ideas formulated by the WHO – based on the definition of health as a "state of complete physical, psychological and social well-being" or on goals such as "Health for All by the Year 2000" – there has been a reduction of the space allowed to medical intervention, to the point where it is considered as a reference not only to achieve health but also goals (youth, beauty, happiness) which should be kept separate from health, just as needs must be considered differently from even legitimate desires. The needs and desires of advanced society is the subject that we should like to examine in this chapter.

The origin of the transfiguration of medicine in the common view held in developed societies clearly is not to be found only in the culture that the work of the WHO has helped to spread. Another major root of the problem may be identified in the mercantile distortion of the concept of health, which is not alien to the progressive medicalization of needs and desires in our society.

The growing prestige which medicine enjoys, not undeservedly, has actually led, as well as to the undoubted cultural benefits represented by the increased value attached to human life, to the temptation to consider medical services as the only resources for the improvement of individual and collective health. The fascination exerted by information driven in this direction has

in fact produced the widespread belief that the natural human desire for wealth and happiness can be satisfied above all by medicine, and that this objective can be achieved only through the purchase of a service that provides goods (drugs) and medical services. One of the most important factors behind this view of medicine on the part of society is so-called technological thought, the technological formulation that is the basis of current thinking on medicine, fuelled by the power of commercial interests as the "myth of technology".

This boost, through the action of a series of conditioned impulses, sometimes explicit but more often implicit or subliminal, can affect choices in terms of the distribution of economic resources and changes in public opinion, as well as effectively preventing the population from recognising their real needs, and therefore choosing in accordance with their real interests. People tend to recognize the white coat as the mark of status of a true "plenipotentiary" in the search for total well-being. On the other hand, neither scientific corporations nor companies that produce medical goods refuse the attribution of so rewarding a role to their activities. It is enough to consider certain routes of medicalisation for which representatives of the medical profession believe themselves to be responsible. To give one example among the many (WHO data), 6% of U.S. children classified as hyperactive are undergoing psychopharmacological treatment. On the other hand, if the menopause and old age become, instead of physiological life situations, pathological conditions to be treated, if the stress of work no longer requires a certain amount of physiological rest, but often pharmacological treatment, and if the information provided by the statistics that are common to every scientific society may give the impression that every Italian citizen is affected by two or three serious diseases, all of these scenarios cannot but have a profound impact on the scope of the tasks that are assigned to medicine, often on the basis of its own proposals.

This expansion of tasks brings with it the risk of failure even in comparison to traditional primary objectives. In fact, overburdening with the most diverse services, in addition to leading to an ever greater consumption of resources which is less and less tenable even in the most affluent societies, is continually and exponentially creating a crisis in the health system as a whole and in particular in those areas which fall within its undoubted jurisdiction and which require specific treatments and specific organisations.

This typically occurs in those situations where the cause of illness is attributable directly or indirectly to social factors, as in the case of drug addiction, of which the most authentic causes are to be found in social deprivation. The medical treatment of alcoholism or drug abuse, for example, produces generally poor results when it is not accompanied by integrated social policies. The comparison between socioeconomic factors and health, and the measuring of correlations between improvements in health and social policy initiatives can provide useful lessons for the taking of such essential decisions. The excessive, and therefore unrealistic, demands made on medicine carry with them the risk of reducing the moral and political commitment as regards the objectives to be achieved by medicine for the benefit of society as a whole. Those goals that have been recognized as a priority for decades, such as prevention and health education, involve therefore authentic and homogeneous epidemiological analysis,

sufficient information not contaminated by triumphalism or personal, corporate/industrial and commercial interests, and, finally, the rational political decisions necessary to avoid waste and ensure that the organisation that today forms the basis for truly effective curative and preventative medical treatments, and not merely "discretionary" ones.

10. The economic crisis of healthcare systems and the criteria for priorities

There is no doubt that the persistent and often increasing economic crisis of health systems has multiple, complex causes, among which the increase in the number of performances provided per head and the increase in the cost of materials and personnel feature prominently, but the insufficient attention paid to the central problem of priorities in healthcare is also relevant, and this of course also assumes a decisive importance in bioethical terms.

If in fact a reduction in costs involves a reduction in health services, it is essential to use ethical criteria which are essentially different from the archaic principle of privilege, which eventually leads to the unacceptable singling out of the patient who is in a socially weak position.

Before reflecting on the criteria, it is essential to identify the principles that are to be governed by such criteria.

A primary principle, in terms of health, is the extent to which good health is deserved. To state that health is a value that is deserved - that is, an asset that allows the enjoyment of all others, and therefore of paramount importance - guides all subsequent approaches taken. The principle of deservedness indicates that the "production", or defense, of health represents a value independent of the financial profitability of "production". This means that health - if it really is a question of such - must be pursued beyond purely economic considerations (operating deficits, the breaking of caps on spending, the need to balance budgets, etc.). The "production" of this may also not be governed by the laws of the market alone, but it must be ensured regardless of the presence and/or extent of any profits. Moreover, according to a precise constitutional wording that remains nevertheless a reflection of a fundamental human right, the value of the deservedness of health must be guaranteed to all, which in an entirely free market system is generally not the case.

It is in the nature of the value of health that the application of economic concepts such as supply and demand, price and value, or market and consumption is extremely difficult. The range of professional services that comes with the increasing pace of medicine in turn creates an increased demand, as often happens in a consumer society: this, after all, is the mechanism that produces hypermedicalisation.

It may therefore occur that the health offer does not match up to a real need, but that it is - as we have seen - the result of a view mediated by other interests (business, professional, etc.). Attempts made in other countries to identify priority criteria have all sought to separate the sphere of needs from that of wishes. To distinguish between needs and wishes is not easy, and according to

some currents of thought is not even legitimate, but it is necessary, at least as far as planning fair, effective and efficient health systems is concerned.

The Swedish experiment in developing a model for rationing health spending showcases the primacy of ethics, which acts as a guarantee for the criteria established later as regards priorities in healthcare. On the other hand, the experiment carried out in the U.S. state of Oregon was from the very beginning based on a set of semi-automatic and even algebraic criteria through the application as a utilitarian matrix of so-called "felicific calculus" (founded on the sole ethical criterion of the quality of life and moderated with certain adjustments, but still overwhelmingly based on this sole criterion). In the Swedish experiment, too, the criterion of the efficacy of treatment in relation to improvements in the quality of life is present, but it is not the only ethical parameter taken into consideration, and - despite being one of the basic criteria of the ethical platform – stands in a lower hierarchical position than others. The ethical principles adopted in Sweden are that of human dignity (the most important, and under which every human being has equal dignity and rights, regardless of their characteristics and their role in society), and those of the need for human solidarity and of the relationship between costs and benefits. The benefits are measured in improvement in health and in quality of life. This is an aspect of the Oregon programme too, though balanced by the presence of other prominent and ethical references.

In Sweden, when this scheme is applied to health services two separate priority schemes are used: the macroallocative, or political-administrative, one, and the microallocative, or clinical, one.

In Holland, too, an attempt has been made to ration the use of resources, guided by the principle of the identification of ethical criteria to define priorities. The Dutch model identifies four filter criteria to arrive at a definition of essential treatment: clinical need, clinical effectiveness, efficiency and collective responsibility.

Firstly, then, the basic package may include only those services that are necessary from a clinical perspective. Having defined health as the capacity to have normal biological and relationship functions, the need for healthcare is connected to limitations on these functions.

Secondly, only effective care can be included in the basic package. The Dutch doctors questioned have estimated that only 20-40% of the healthcare financed by the social security system has been proved effective. The application of this criterion can therefore significantly reduce the care provided and its cost, limiting these interventions to those of proven evidence-based usefulness.

The third filter is represented by efficiency, which can be measured by the cost-benefit approach, and the fourth filter criteria is that of collective responsibility. According to this criterion, the package of basic healthcare – which cannot be entrusted to individual responsibility – or, in other words, the services related to health needs which are in the collective interest come to include those services that have the characteristics of pure public values, and the consumption of which can produce significant external effects that benefit the whole community, such as collective prevention, environmental hygiene controls and targeted research.

In its reflections on the priority choices, the Dutch Commission recommends that particular attention should be paid to the protection of the weakest, most vulnerable and helpless patients, as well as those who are less responsible or less informed, mentally or physically handicapped, psychiatric patients and the elderly, especially given the disadvantages that may result from a system of managed competition such as that promoted by the reforms that are under way in the Netherlands.

From the analysis of these international experiments we may gain, on one hand, an awareness of the weight resting on the ethical assessments used in the definition of the criteria for the rationing of resources. The attempt to distinguish, and to place on a lower level, those interventions that might be included within the framework of the "medicine of wishes", in comparison with those that aim to restore health to a state preceding a pathological event. All of the difficulties inherent in operations of this kind are quite clear, namely that the system is designed to select the most important services in order to determine their financial eligibility. In this respect it is hard to argue with those who, like the philosopher Engelhardt Jr., posit that it is impossible to reconcile the containment of costs, quality of care, equity of access to services and freedom of choice. But if the goal is not perfection, but the perfection of the system of delivery, then we can certainly identify the following criteria which are useful for the attainment of the goal of healthcare that meets as far as possible the needs of society without succumbing to the costs involved:

- The suitability of the technical means used, firstly, and their most appropriate use;
- the valuing of human resources, both in terms of refresher training for operators and exploiting the potential of groups, by encouraging the voluntary sector but also through the organization of solidarity, potentially a huge resource, but too often dissipated in many kinds of separate action;
- the enrichment of the operational goals of health services, not only for the production of diagnostic and therapeutic services, but also as a vehicle for a genuine culture of health, so that the "production" of health is achieved through the implementation of appropriate behaviour on the part of the population;
- the implementation of social policies that address the determinants of illnesses related to marginalization, loneliness and poverty.

Prevention, understood in its broadest sense, which is implemented on all three of its levels of intervention (etiology, pathogenesis, and rehabilitation), may represent an important solution to the problems that will afflict medicine in the future and its relationship with society.

There is no doubt that primary and secondary prevention, as well as reducing costs related to the onset of many diseases or the severity of others at a variety of ages, also permits longer survival and increases the number of the elderly, and thus geriatric care costs. On the other hand, the positive side of prevention still remains, because it is an indisputable fact that it avoids so-called intangible costs (suffering) and provides health benefits which constitute a primary asset.

As the future of developed societies in which a growing percentage of elderly people is now inevitable, all political, cultural and social initiatives which serve to work towards the recovery of the role of older in the community deserve to be

made an undisputed priority. This is a commitment that may also produce benefits reflected in the field of health, by reducing psychosomatic pressures related to loneliness and the marginalization of the elderly, while the importance of preventative measures aimed at rehabilitation, including procedures to reduce disability in old age and levels of dependence.

It is also important to underline the role that prevention may play, via the medium of health education, in the identification of real healthcare needs and the implantation in the population of "healthgenic" behaviours with a resulting decline in demand and rationalization of resource management. In this regard, it should be noted that health education programmes based on the involvement of the population and on voluntary participation achieve better results than those based on the principle of taxation (or even solely on the establishment of norms), or those based on one-way, top-down measures. In such cases involving participatory schemes, it is possible to observe an interesting ethical evolution of the principles informing health education programmes, with parallel improvements in the outcomes of these programmes.

11. Limits and risks of scientific medicine

The "pact" between medicine and society is likely to be jeopardized by the provision to citizens of insufficient information regarding the risks and limits of scientific medicine. Society could agree to question the "legitimacy" of its own requests, which are ever more extensive and demanding, and thus reduce demand through the sharing of the rationing of resources and priorities, but only on condition that people are adequately informed about the real character of medicine, namely its imperfections and the intrinsic element of risk. At present this information is lacking, and in its place are often unreasonable expectations.

In the United States, as well as in Great Britain, the existence of data on medical errors is leading to an evolving debate that will lead to a stricter assessment of the professional standards of healthcare workers through real periodic suitability tests. If the constant updating of health workers' skills represents a cornerstone of the fundamental conditions for the new pact between society and medicine, however, the same must be said – and to an even greater extent, if it is possible - to the level of knowledge at the source of the service. Even the most up-to-date of doctors, in fact, cannot altogether avoid the error and still less the failure inherent in a risk-oriented profession, if the instruments of updating (in the first case, clinical experimentation and scientific literature) do not take into account what is truly useful to the patient, what is not, and what is frankly harmful. In this regard, however, the expected progress was unfortunately not recorded, despite the principles of evidence-based medicine having been recognised for some time. This is a problem that affects society as a whole, and the public also suffers the consequences of the constant disinformation which occurs as a result of the often uncritical emphasis on the benefits of a medicine and insufficient focus on its risks, side effects, uncertainties, worthlessness or possible harmfulness.

Among the many examples which might be cited, we shall limit ourselves to noting the overall consumption of drugs and the side effects related to these. There are several thousand drugs currently on the market, and for all of these marketing is preceded by appropriate experiments. The number and character of damaging and sometimes severe side effects, however, despite being mentioned in the leaflets that have to be accompany the medicine, cannot in themselves be understood by patients, either because of the terminology used or because it is inconceivable that the doctor might be able to explain in detail the nature of these and the level of risk. It might be added that there are also significant differences between EU member states and serious inconsistencies in the rules that govern the activities and policies regarding the regulation and marketing of drugs. In this context, the appearance of serious effects caused by a drug – which, according to recent estimates in the United States, occurs in some two million cases a year, with over a hundred thousand deaths, namely the fifth most common cause of death – is not accepted by the injured party or by their relatives, who are essentially unaware of the specific risks and thus are inevitably inclined to blame the doctors.

This problem is also important from an economic standpoint. A recent study estimated the annual cost of the improper use of drugs in the United States as more than US$76 billion, and there is evidence that in Italy and in France 20% of drug costs relates to products the effectiveness of which is unproven. Recent research into the economics of pharmaceuticals has also indicated that the costs associated with the inappropriate or excessive use of medication may be even higher than the initial cost of the purchase of these drugs.

These costs include additional costs related to the increase in hospitalizations, protracted stays in hospital, outpatient visits, diagnostic procedures and treatments due to additional problems that arise as a result of therapy with prescription drugs. If we also include in these calculations indirect costs resulting from loss of productivity, overall costs in the U.S. would amount to a figure of between US$138 and 182 billion, thus situating mortality and morbidity related to the use of medication among the heaviest consumers of healthcare resources.

In Italy poisonings and toxic effects of drugs (DRG 449-451) resulted in 1994 in more than 20,000 hospitalizations, and about 28,000 in 1995. This data, however, understates the problem for at least two reasons: firstly, because it relates only to adverse drug reactions already coded as the principal diagnosis, and secondly, because they relate only to adverse reactions and not also to inappropriate doses and incongruous therapeutic choices.

More problems are raised by vaccines, in relation to which there have been demands from many different groups for the lifting of their mandatory status, or at least a for better understanding of the epidemiology of the adverse effects they may cause. In an editorial, the director of the British Medical Journal (Smith 1999) summed up the essential information that must be provided to the public: that death is inevitable, and that most serious diseases cannot be cured; that antibiotics are no use in the treatment of flu; that artificial implants sometimes break, and that hospitals are dangerous places; that every drug also has side effects; that the majority of medical interventions provides only marginal benefits

and many have no effect at all; that screening also produces false positives and false negatives; and that there are better ways to spend money than using it to acquire medical technology.

Rewriting the rules of the relationship between society and medicine in order to establish a new pact for the coming years, requires on the part of medicine a significant requirement for sincerity, which is no doubt difficult primarily for technical reasons, but neither can the psychological reasons be ignored. However, such an effort must necessarily be made, and the media should contribute to this too, abandoning any temptation towards hype or easy accusations, which are among the main obstacles that inhibit the sincerity of doctors.

12. Justice at an intercontinental level: the problems of developing Countries

The ethical criteria that should guide the creation of models for the rationing of resources in economically-developed countries take on a different and even greater dimension when it is a question of the inequities that plague healthcare delivery in poor countries.

Indeed, while in developed economies there are ethical issues involved with the distribution of health services in the case of resources which are not unlimited but potentially sufficient to fulfill the basic needs of the entire population, in less developed countries the economic problems are still so serious that they are likely to lead to ethical wranglings about the causes of this great disparity between resources and living conditions and possible interventions that might be taken to remedy this level of need. A few examples and figures illustrate the size of the economic problem and the diversity required in terms of the ethical approach needed. In developed countries, life expectancy at birth is 77 years compared to 56 in low-income countries (excluding China and India). The infant mortality rate, meanwhile, is 6 per thousand live births in developed countries, while in poor countries it is 88 per thousand. In developed countries, per capita health expenditure is on average $2,400, as opposed to $18 in poor countries. But the most shocking figure of all is related to Gross Domestic Product (GDP). Despite the fact that 93% of the diseases that afflict the world are concentrated in low-income countries, home to 84% of world population, only 10% of global GDP is spent on health in these countries. The remaining 90% is spent in rich countries. This inversion between needs and spending (the data comes from the World Bank) has, quite significantly, been dubbed the " inverse care law". It should be noted that the situation is even more dramatic for women, who have in poor countries been the victims of real discrimination in terms of healthcare, nutrition and access to scarce health resources.

It seems clear that at the origin of this imbalance is the principle of "inverse rationing", which tends to favour the production of health services not in accordance with need, as it is viewed from the healthcare spectrum of developed countries, but because of market demand. It follows that industries engaged in the production of healthcare services should, for example, privilege the production of the elements required for the treatment of chronic diseases and of the elderly as opposed to the production, on an equally large scale, of drugs for tropical

diseases. The problem also affects research. In fact, the investment required for the development of an anti-malarial drug seems unlikely to generate profits comparable to those obtained by discovering an anti-hypertensive or anorectic drug of proven safety. Doctors are also are becoming more common in rich countries (2.5 doctors per thousand inhabitants), where there is less need of them, while in poor countries, where training and salary costs are very high, the percentage is 0.4 doctors per thousand inhabitants.

In this dramatic global dimension, the principle of justice presupposes firstly the abandoning of geographical criteria as the limit within which the expansion of the implementation of justice policies for the allocation of health resources is implemented. Ethical principles of reference are, in fact, in no way related to the territorial dimension. What is at stake, then, is equal access to healthcare on the basis of equal need (without regard to personal factors such as age, social role, etc.). This is a cardinal principle of healthcare services in many developed countries, and that same moral responsibility that leads us to ensure that this principle exists within our national borders cannot be limited in any way by the definition of a geographical border. What we see before our eyes is the result of a lack of practical measures to redistribute resources and a lack of direct and transnational political intervention: the unstoppable phenomenon of mass migration from poor countries may increase to a level as to upset the future of the rich countries. At the same time, globalization not only implies economic opportunities, but also obligations and risks. It is not too far-fetched to imagine a reality in which the movement of masses of dispossessed leads to the spread of new diseases currently eradicated in the North-Western corner of the world, made more ominous still by the irrational use of antibiotics, another consumerist distortion typical of rich countries, where there is now an increasing number of resistant microbial strains.

It is not the fear of being "invaded" by poverty which should spur us into action, of course. To the ethical considerations already mentioned one should add, by way of conclusion, one further point on the argument that it is impossible to remedy such a gulf of inequality, an argument which is indefensible on the basis of the facts. It has in fact been shown that the first significant results (even if only the reduction of infant mortality simply through the distribution of packaged salts and water as an immediate remedy for the dehydration caused by diarrhoea) are easily achievable and in no way Utopian. To achieve the goal of a reduction in mortality it is often enough to provide basic healthcare, better education for the mothers who look after the children, the learning of sanitary measures, and better nutrition. From this point of view, no intervention is as important as prevention in terms of its ability to achieve significant successes in an extremely short timescale, and for this reason it takes on an unquestionable ethical value and practical effectiveness.

SYNTHESIS AND RECOMMENDATIONS

1. This paper has, as the title suggests, attempted to identify not so much the many bioethical issues that medicine presents - which are mentioned in the

details of the proposal and are also the subject of other documents from the National Committee for Bioethics (such as Bioethics and the training of health personnel (September 7, 1991), Information and consent to medical actions (June 20, 1992), Ethics, health and resources (July 17, 1998) - but rather the central bioethical node which constitutes the aims of medicine.

This issue involves the identification of the character, of the individual and collective costs and the extent of social consensus granted to medicine by the community, a consensus which adapts to information about the problems that medicine encounters in the course of its evolution. There can be little doubt that this is the crucial issue that hangs over the near future, and even more so the distant future.

In fact, the daily choices which lie ahead for individual patients, and which they have the opportunity – and in some cases even the ethical duty – to accept, and the choices that are required of the whole of society, both today and tomorrow, in terms of the sacrifice of more and more important resources and of the human costs linked to the iatrogenic damage produced by different causes related to medical or surgical treatment, represent a complex and extremely difficult issue in which all citizens must be involved.

A first aspect of the subject is certainly represented, as already mentioned, by the definition of the goals that medicine should pursue, and in particular by the contrast between a universalist concept of these goals and one that emphasises the differences that characterize different cultures even as regards healthcare and the curing of diseases.

This conflict between different concepts of medicine leads to the clear emergence of the further question, namely whether medicine can define its own goals based on its history, ethics, and scientific development - and thus in a sense from its own internal nature - or whether it should be accepted that the goals should be determined from the outside, leaving this task to society as a whole.

The National Bioethics Committee recommends, instead of confrontation, the search for a continuous dialogue between society and medicine in order that medicine becomes aware of the social role it plays, which is to become increasingly important, and that citizens, especially the sick, are informed and aware of the possibilities, and also the risks, that are inherent to development of this role. The evolution of medicine does not concern only the means but also, and indeed primarily, its goals, which must undergo a continual process of definition and redefinition in terms of the assets and human values involved. It should be stressed in any case that this evolution cannot change the ethical vocation of medicine to provide healthcare and to alleviate suffering, as otherwise there is a risk of this knowledge becoming no more than a set of techniques of solely instrumental value.

2. There is no doubt that medicine possesses special characteristics that distinguish it from all other human activities.

To remain within the field of bioethical analysis, it may first be noted that its primary goal, based on the defense of a primary value, namely health, which endows whoever practices medicine with an extraordinary power which derives not only from their ability to determine in many circumstances the difference between

life and death, between disability and the fullness functions, between suffering and well-being, but also from the position of psychological weakness and subjection in which the patient is located.

As well as being scientific and professional, it is also an activity that requires highly specialized theoretical and practical expertise which is achieved through long and demanding studies and apprenticeships, and which is therefore reserved for the few. Consequently, the practitioner tends to become closed off in their own field, to use a language which is not easily comprehensible to others and sometimes, unfortunately, to defend specific interests which may not coincide with those of the patient and of the community. Similar situations may also occur in other activities in the field of medicine such as, for example, the production, distribution and control of drugs, information for the public, teaching and scientific research.

To these factual considerations we might also add an observation of an epistemological nature. Disease is a fluid and complex phenomenon which often does not conform to pre-defined templates and which lends itself, therefore, to subjective measures, because of the individual character of the patient and the specific characteristics with which the disease manifests itself. It is also necessary to take into account the fact that the same therapeutic result can be achieved by different procedures, sometimes radically so. It is not easy, therefore, to separate what is certain from what is uncertain and to validate procedures by relating them to a fixed standard, and so the individual therapist must determine these procedures on a case-by-case basis, using the shared but generic formula of acting in accordance with "science and awareness".

To sum up, it should be noted that the current scientific status of medicine is, in contrast to in the past, marked by a focus on an epistemology based on the so-called "discovery of complexity," a complexity which is paradoxically the result of the very certainties that the development of technology and its application to medicine have made possible. This discovery is in its origins a philosophical and physical one which has led to an awareness of the fact that "the world", as a whole, is not linear, but irregular, variable, unstable, precarious and uncertain, or, in a word, complex.

In this context, the NBC highlights the importance of promoting a greater awareness of the complexity of the phenomena which medicine describes and of the inescapable dose of empiricism that characterizes a science in constant evolution, with a view to avoiding miraculous expectations which may become the occasion for outright fraud, or on the other hand uncritical anti-scientific positions that lead to a general mistrust of medicine.

3. What has been stated so far underlines the role played by medicine in contemporary society, which implies, for doctors, as well as a responsibility inherent to their specific professional knowledge and skills, the duty to be involved in a process of constant self-reflection on one’s own principles and methods, which translates into a self-regulation that must be implemented in public in order to constantly renew the request for informed social consent. Citizens’ healthcare needs, in fact, and therefore the explicit demands, or implicit expectations, that they have of medicine are ever higher.

These considerations perhaps allow us to explain, albeit only partially, the shift in the balance in favour of the patient which has occurred in recent years in the doctor-patient relationship, whereby the latter has been accorded the maximum importance compatible with the different situations that take place in everyday life. This cultural movement, which in Italy has also been accepted by the Court of Cassation*, emphasizes the priority placed on the autonomy of patients. However, as occurs relatively frequently, principles that are in themselves valid are often taken to extremes in ways that are incompatible with realities that are undeniable.

Recent doctrinal positions have taken note of this, and postulate a pragmatic distancing from theories that are often difficult to reconcile with the operational reality of medical services. The critical discussion concerns in particular the value of evidence-based medicine and of the autonomy of the patient, contrasted with the technical and professional duty and the inescapable responsibility of choice which affect the doctor.

On reflection it may be seen that the responsibility involved in case-by-case selection reconnects us with a traditional form of medicine, which emphasises the importance of a realistic and responsible choice of what is proper and reasonable for the patient, instead of simply the application of standard theoretical models. From this perspective, the current requirement for "evidence" is not rejected, but what is rejected is the pretension of using it as a universal rule in any situation and for any patient, as well as its claim to guide the doctor’s choice mainly on the basis of statistical knowledge, marginalising his personal know-how and professional experience. It is therefore considered the doctor’s duty to overcome "false evidence" that does not equate to certainties but to degrees of probability which are often contradicted by many "counterindications" that exist in each patient’s personal situation. This concept, defined as the "medicine of choice", considers medicine as a "science" that explains the disease, or as a metascience which explains the actions taken in consequence.

In the current phase of reflection and rebalancing of the doctor-patient relationship, attention must be paid to the medicine of choice, which is characterized essentially by the recognition of the plurality of knowledge and the doctor’s freedom to choose, with skill, prudence, and practical intelligence, the most appropriate and cost-effective option not in terms of conventional models of sickness and the sick, but of patients in their real medical and human situations.

The medicine of choice is, therefore, a medicine of responsibility. More specifically, as regards the doctor-patient relationship this should result in an explicit distinction between the recognition of the ethical value of patient autonomy and an awareness of the specific circumstances in which the doctor operates.

From this point of view, the imbalance between doctor and patient can never be entirely eliminated in practical terms, even though it is certainly the doctor’s duty to reduce this asymmetry as much as possible. Even in the conceptual evolution of ethical codes, medical ethics is still marked by an adherence to principles that have always inspired the praxis of the majority of honest doctors, which is fundamentally based on beneficence in trust, which views health as a relational value that is the "aim of both parties, the patient and the physician", who aim to operate within a relationship of mutual trust in which the

greater interest, that of health, is pursued, creating the necessary balance between patient autonomy and the doctor's responsibility and thus setting the scene for the so-called therapeutic alliance. From this perspective, the autonomy of the patient must be protected, above all through a mutual awareness of the nature of the relationship established with the doctor, particularly as regards the intrinsic objective of the relationship, namely health. Should the pursuit of health be in conflict with other values or interests of the patient and it becomes necessary to make a choice about which there is no agreement with the doctor, the patient may refuse treatment and end the therapeutic relationship. It is not, however, possible to require the doctor to act in a way contrary to what (s)he believes, based on her/his knowledge and clinical experience, the best interests of the patient.

4. This undeniable responsibility which has been described, may, and unfortunately often is, questioned in its criminal and civil law aspects. It is up to society as a whole, adequately informed, objective and critical, to assume a significant part of the responsibility for making choices and to establish a wide variety of support mechanisms, in accordance with global projects to which medicine must adapt with respect and humility to as great a degree as possible. This planning must consider other relevant plans which are closely interrelated but also liable to be placed in an order of priority.

There is no doubt that the primary objective, which should be favoured by being granted a position of high priority, is the short and long-term daily care of those patients for whom advanced methods of diagnosis and treatment enable the disease either to be cured completely, or at least to attempt to provide a partial solution to suffering and need by making them bearable. The tendency, which is from a human point of view quite comprehensible, to devote more attention to that medicine, particularly surgery, which comes under a field that might be called "groundbreaking", often leads to the neglect of the often pressing daily needs of the majority of patients for whom adequate medical services relate mainly to the efficiency of health organization as it is articulated and interconnected throughout the country and made available equally to all social classes.

On a global scale, this principle of equity supposes for countries with advanced economies the serious moral problem of their blameworthy lack of concern for, and even their indirect exploitation of vast areas of the less developed world, as has been illustrated in Chapter 12.

It follows, in short, that it is only reasonable to place as much emphasis as possible on making the best possible use of the resources already available to medicine, to the point where it might be concluded that, given the constraints of the available resources, the investment of these in the pursuit of the primary goals of medicine should be viewed as an inalienable right.

The global aims of medical care must therefore be constantly brought to the attention of the community as a primary ethical issue. In relation to this point, the National Bioethics Committee reiterates its position in support of health policies based on the principles of solidarity and equity, as recently expressed in the paper on equity (Bioethical guidelines for equity in healthcare, May 25, 2001).

5. What has been stated so far does not conflict with the development of knowledge, pharmacology, techniques and tools for diagnosis and treatment.

The fight against disease requires a constant commitment to research in which many countries invest both public and private resources. Modern scientific medicine can no longer afford to operate, as in the distant past, by means of unreasonable and reckless attempts that have certainly caused many victims, and may still go on doing so via iatrogenic diseases and their effects.

Trials are therefore required, and the practical application on humans of methods previously tested on animals is a mandatory step. It is indeed the verification of the effectiveness, but also of the failures and unfortunate damage caused, which allows the validity of new scientific knowledge and the method used to achieve it to be directly demonstrated, especially in terms of its practical utility within the context of a favourable ratio between costs and benefits.

From this point of view the information provided to the patient with a view to their being able to give free and informed consent is particularly important, seeing as the risks of new methods are not always adequately represented to patients who, in the hope of healing or even their own salvation, agree to become subject to what is in fact an experiment, in the truest sense.

Experimentation is, in fact, part of the very empirical nature of medicine, and a large proportion of medical praxis is invested in it, whether from a historical perspective or in terms of the current state of knowledge. In this sense, it is appropriate to clarify that, in addition to direct human experimentation on humans with a specific purpose described as such, there is also a de facto experimentation which, given its non-specific character, is more far-reaching, and its boundaries are not easily definable.

This is the consequence of the dynamic application of innovative diagnostic and therapeutic proposals that are being continually introduced in the medical profession. In addition to highlighting the principles of good clinical practice, as expressed in numerous national and international documents – the last and most important of which is unquestionably Directive No. 20/2001, the subject of thorough analysis by the National Bioethics Committee (see for example the Opinion on the Protocol of the Bioethics Committee of the Council of Europe on Biomedical Research 19th of November, 1999) – the need to inform the public that medical progress inevitably passes through phases of human experimentation must be emphasised. This is necessary for a conscious acceptance of risk and, more generally of empiricism, as understood as an opening-up to what is not yet known, which forms an essential part of medical progress.

6. With this in mind, the identification of ethically acceptable boundaries for medical services and their development is a bioethical issue, especially given the fact that the distinction between a "medical act" and "therapeutic treatment" in the strict sense has become increasingly blurred, as is evident, for example, in the spread of cosmetic surgery. It should not be forgotten, however, that such services also involve the risk of complications, sometimes even serious ones, which will affect the patient directly, but also have an indirect impact on the physician. The problem of establishing a correct relationship between purpose, benefits and risks therefore remains, even in such cases, an important dimension of bioethics.

In this context, discussion of the alleged decline of Hippocratic medicine in the wake of the advent of modern medicine is a sterile one if a broad ethical perspective is not employed and if the discussion does not form part of the broader debate on the “limits to growth” which, while not new, has seen its importance greatly increased in the second half of the twentieth century. This debate emerged into the open in the early 1970s in a logical conjunction with the birth of bioethics, with which it shares the goal of defending humanity. The subject still retains all of its relevance today.

The enumeration of the values to be respected, many of which are contained in Hippocratic texts and specifically in the Hippocratic Oath, allows us to identify principles which are still covered in the codes of medical ethics around the world, even if the concepts involved have been deepened, detailed and extended in accordance with the developments of scientific medicine.

The Hippocratic commitment to "prescribe the most appropriate care to the sick as my knowledge permits me to do" is even today a purpose of medicine which in the present-day context is enhanced by a key criterion which is however not always easy to apply: namely to "use scientific evidence" (as described in Article 5 of the Italian Code of Medical Ethics) and provide prescriptions and treatments that "should be inspired and updated with tested scientific advances bearing in mind the most appropriate use of resources, always in pursuit of the benefit of the patient" (Article 12).

The doctor, in fact, "is obliged to have an appropriate understanding of the nature and the effects of drugs, their indications, contraindications, interactions and unpredictable individual reactions, and of the use of diagnostic and therapeutic methods, and (s)he must adapt, in the interests of the patient, her/his decisions to accredited scientific data and methodologically well-founded evidence". Article 12 also states that "the adoption and dissemination of diagnostic tools and therapies which are scientifically unproven or not supported by adequate testing and clinical and scientific documentation, as well as secret therapies, is prohibited. In no case should the physician accede to requests from the patient which are in conflict with the principles of science and conscience in order to comply with the patient’s wishes and so remove her/him from the tested and effective treatments available".

In contrast, the so-called alternative medicines are on the borderline between science and non-science, on the other side as compared to scientific medicine. However, in view of their distribution and the fact that therapies and drugs derived from them are also prescribed by professional physicians, the National Bioethics Committee proposes to the public, and therefore also to legislators, a timely reflection on the choice of policy as regards the acceptance of such practices on the basis of respect for freedom of treatment, despite the attendant risks of mystification and deception and their direct and objective verification through in-depth analysis followed by additional experimental testing, which will, depending on the results obtained, lead to the publishing of detailed official information by accredited organisations. In this process it must be bioethical analysis that takes on the task of critical reflection on the boundaries between scientific medicine and other medical practices, as well as on the real possibilities and limits of scientific medicine itself.

7. The failures of medicine and the damage caused are to the public often the most notable aspect of medical praxis, and they generate collective reactions which are expressed and amplified by the media, as well as consequences of a legal nature and to individuals.

This is an issue that needs to be addressed through the adoption of solutions which, while they must involve preventative measures, as is loudly requested by insurance companies and viewed as improvements in the efficiency of healthcare provision, to some extent also involve compensation, in case of negligence, or at least indemnities in the case of damage without provable negligence.

These solutions, the design and implementation of which requires specific expertise, bring into the foreground once again the informing of public opinion. The determining and implementation of all the objectives that we have highlighted up to this point implies the in-depth involvement of society as a whole, and thus makes it necessary to provide information to all citizens about the nature, possibilities, limitations and risks of medicine as a science and in practice.

This awareness can be properly achieved only through the provision of transparent information which is sufficient to overcome the obstacles caused by the fear of disturbing public opinion with unpleasant or disappointing news that engenders fear. Only in a context of true transparency is it possible to come to regulatory solutions with a view to providing a legal framework for managing the inevitable cases where the practice of medicine causes harm.

The NBC intends in future to explore in greater depth the bioethical problem of responsibility for healthcare, which has reached serious levels of social relevance.

8. In conclusion, it is possible to state that most of the complex issues examined in the previous pages are believed to be contained within the central ethical issue of the guarantees that the health system as a whole, public and private, must provide to citizens. The rigorous monopoly granted to healthcare professionals
and the high proportion of national income allocated annually to the operation of the health system, in themselves imply the citizen’s right to use a drug with a high degree of reliability and efficiency. It follows therefore that the professional quality of doctors and of the various types of medical qualification now issued by university authorities, as well as the quality of healthcare facilities, are to be considered part and parcel of the presupposed ethical essentials in line with entirely justified expectations, with a view to reducing the risk of failure and iatrogenic damage and of conflicts.

These objectives are at present achieved only to an incomplete and often unsatisfactory degree, and not only in Italy.

This dissatisfaction leads us to trace its causes back to the uneven and often inadequate standards of university and postgraduate training. The preparation of healthcare professionals, to be selected according to the strictest of criteria, is often lacking, and it is possible for students who do not meet the high standards required by the complex nature of medicine today to obtain the qualifications necessary for professional registration and practice. This engenders the practice,

which may not be shared, of "correcting" errors in the selection and training processes of healthcare professionals after the event – or even after this in the case of harm to patients – through the inappropriate instrument of criminal and civil actions, which should only be used in exceptional cases and not as a matter of routine, as is the case today.

It should also be noted that the reform of university and postgraduate education in recent decades has failed to ensure that the number and quality of healthcare professionals is adequate for the needs of modern medicine. The results of these attempts do not appear to be sufficient, and therefore it is clear that there is a need, both ethical and practical, to deal with the issue of training once again, and with the utmost rigour, as the interests of society as a whole must have precedence over the interest of candidates for work as healthcare professionals. The aim must be to regulate the exclusive exercise of a profession dedicated to the protection of a primary value, such as that of health, only to those who demonstrate proven competence (both in the early stages of their activities and subsequently, given the need for constant updating).

The National Bioethics Committee has devoted to this question a specific document (Bioethics and training in the health system*, 7 September 1991), and more recently a memorandum of understanding with the Ministry of Health specifically on the bioethical training of healthcare personnel.

In this document, the NBC reaffirmed the fundamental importance in the present day of training for healthcare personnel, emphasising in particular the need for such training to be ethical and deontological in nature as well as science and technology-based, in order to cope with the complexity of disease, but above all with a view to taking into account in the treatment of the patient her/his human and personal, as well as clinical, dimension.