Bioethics and Human Genetics: Consensus Formation in Europe

Ludger Honnefelder

Philosophisches Seminar der Universität Bonn, Lehr- und Forschungsbereich II

In a few years the human genome will be decoded completely. Our current knowledge of genetically determined dispositions to diseases will be significantly extended. Genetic tests with a hitherto unknown breadth, simplicity and reliability and based on electronic chips will be available. The development of embryonic stem cells will open the different stages in the development of life to manipulation by humans. And this will lead to an unknown and as yet incalculable broadening of the possibilities for genetic diagnostics and, in particular, gene transfer.

How do we want to handle that broadening of possibilities? Can it be left to the free interplay of forces? Do we need rigid prohibitions? Or is there a third way? How would such a third way need to look in order to safeguard individual freedom while at the same time establishing the necessary limits?

Everyone who has thought about the necessity for setting those limits knows how difficult it is. Where do we start? What are the points of departure on which we all agree and could base a consensus? And if we could find such a consensus, how can the established limits be enforced effectively? What we see here is a fundamental conflict in modern society: the freedom which it provides yields a significant increase in potential knowledge and practice. Yet just this potential causes effects which force us to restrict that freedom.

We already know that the setting of limits cannot be achieved on a national level alone. Because the dynamics that drive the broadening of our potential knowledge and practice in research as well as in the market environment operate at an international level. For the setting of limits to be successful it must transcend borders at least with respect to basic standards, that is: it must occur at a European and international level. This then is the complete picture of the challenge we face: if the dynamics of scientific and technological development are not to be left to themselves and if not everything that can be done is done without societyís intervention, then we need a process of consensus formation which not only respects the pluralism within one society but also yields the sort of partial consensus which proves to be sufficiently dependable across
national borders.

I.

The document which first confronted the European public with the whole weight of this problem and thus with the weight of the publicís problems was the draft of an 'European convention on the application of biology and medicine' to human beings, which was commissioned by the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in 1991.

The development of consensus formation in modern society regarding biomedicine began back in the late 1960s in the United States. It was sparked off by three factors: it was realised that the decision about who should have access to the new but inadequate number of dialysis places would mean that the chance of life would be allocated; it was understood that the emerging field of intensive medicine would be confronted with decisions for which there were virtually no criteria and procedures; and it was noticed that the intensive research into biomedicine which was suddenly taking place entailed the danger of abuse.

The responses made to these challenges are characteristic: the new types of case-by-case decisions were packaged together and handed to an ethics commission to bring transparency to the alternative decisions, and, in addition to the work of this commission, academic institutions were set up, like the Kennedy Institute of Ethics or the Hastings Center, to attempt to clarify the new ethical questions via interdisciplinary studies and forms of curricular teaching, and, last but not least, an attempt was made to identify the accepted ethical principles from which the desired decision-making criteria and rules could be derived. At the same time, the tradition of common law helped: where there are no relevant court rulings, it permits recourse to recognised ethical principles. Back in 1947, on the basis of this tradition, and long before this trend began to emerge, the first document on scientific ethics of this type was produced: the Nuremberg Code on Human Experimentation, which was used in the Nuremberg trials on doctorsí criminal experiments during the Nazi time. This was a listing of ethical principles subsequently used in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the United States to formulate the ethical principles of research in the Belmont Report in addition to the National Research Act of 1974. The fact that the ethical dimension was integrated into the use of the new biomedicine in the United States earlier and more successfully than in Europe, and particularly in Germany, is probably largely due to this strategy.

In Europe, the debate began later, and originated not from the experience
of abuse but from the problem of regulating the new activities. Due to the fact that research and applications were increasingly developing on an international basis, in the 1970s the Council of Europe began to draft resolutions and recommendations designed to achieve a harmonisation of the minimum standards of national legislation. Since the legal tradition in continental Europe does not permit the direct recourse to ethical principles of common law, people turned to the ethical consensus formulated in the constitutions of the various countries and in the codes of human rights. However, it was increasingly felt that whilst these codes, mainly in the form of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950, can form the basic framework, they need to be further evolved to take account of the specific activities of biomedicine, so that a framework of principles and criteria can be formulated from which minimum legal standards can be derived for the various fields. It was decided in 1991 that this should take the form of a framework convention and supplementary protocols, i.e. additional international conventions referring to the various fields of application.

Apart from the attempt by the Council of Europe to initiate the Europe-wide formation of a consensus about minimum legal standards in the area of bioethics, there has been the attempt by UNESCO to achieve a similar world-wide consensus, especially for the area of human genetics, through a General Declaration on the Human Genome and Human Rights. As a declaration it does not have the binding force of a ratified convention under international law; however, as a declaration of intentions by the agreeing member states and that agreement has now been given also at the level of the United Nations it represents an important impulse for world-wide adherence to the necessary minimum standards.

The first draft of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine ó known also by shorter titles, an earlier one: Bioethics Convention and a later one: Convention on Human Rights and Biomedicine ó which the Council of Europe had called for, was tabled in 1994. After an intensive debate and critique by the Parliamentary Assembly of the Council of Europe and in the member states, especially in Germany but also in Austria and to a lesser degree in France, the draft was revised and the final version accepted by the Committee of Ministers in September 1996. In April 1997 it became available for signature and ratification by the member states. Since then, about two thirds of the 40 member states of the Council of Europe ó among them France ó have signed and partly ratified the convention. In Germany and Austria this step is still outstanding because the public debate is continuing. Since November 1997 a protocol prohibiting the cloning of human beings has found similar acceptance. In February this year, the Committee of Ministers passed the first draft of a
protocol about organ transplantation for public discussion. In due course this protocol will be followed by a protocol about medical research. Preparatory work is also being carried out for protocols on human genetics and embryo protection.

II.

What then are the main principles of the basic document: the Convention on Human Rights and Biomedicine? What is the core of the legal and moral consensus which it sets out? What distinguishes it from the American approach as encountered in the Belmont Report is the fact, that the European approach is not a collection of individual principles which may be regarded as shared maxims. Rather, it starts out from the notion of human rights, which it links to a complex of principles which may be called the teleology of medical practice. The notion of human rights serves two important functions: under the title 'inviolability of human dignity', it puts at the top the respect for persons (autonomy), the first principle of the Belmont Report. But it takes into consideration that the human being, because of its capacity to be a moral subject, must always be regarded as an end in itself which is united with a psycho-physical nature. For the basic (human) rights protect not only self-determination and unhindered development of one’s personality, both of which are directly entailed by being a moral subject; they also protect as inviolable the basic natural conditions without which such a subject cannot exist. This is most evident in the basic right to the integrity of one’s body and life, which entails the right to life, that is: a prohibition to kill, which protects all human beings. As is well known, there are reasons to hold that the combination of these basic rights entails a further one: the right to health care.

That approach from the notion of human dignity and the right to self-determination, it entails, is most evident in Article 5 of the convention; it ties all medical interventions to the informed consent of the patient. This turns into international law a trend which began around the middle of this century, most particularly with the Nuremberg Code on Human Experimentation; that trend has had an increasing influence on medical ethics and law and signals the end of a medical practice which one may call paternalistic.

However, it must be noted that the convention had previously, in Article 4, tied the principle of informed consent to the principle of binding all medical intervention to the relevant 'professional standards and obligations', i.e. to what we might call the professional consensus of the medical practitioners as expressed in national and international guidelines. At the core of this consensus is not only the commitment to use all therapeutic means only lege artis, but also to do so for one goal alone: to heal or alleviate the
illness of the patient who has come for help, that is for the goals of diagnosis, therapy and prevention of diseases. There are several references to this in the convention; it talks of health purposes in Article 18, of preventive, diagnostic or therapeutic purposes in Article 19, of the benefit of health in Articles 8 and 17, of the therapeutic benefit in Article 19, and of the potential of life-saving in Article 20.

This highlights two things: that the convention draws on two moral and legal sources, and that it combines two complexes of moral and legal principles in a significant way. Both sources on which the consensus expressed in the convention draws are sources of experience. It has been the experience of abuse, even the abuse of medical research and practice, which has made the notion of human rights plausible and accepted world-wide and beyond cultural differences; it is the experience of need and aid which links doctor and patient, i.e. that ethics of care which has yielded professional standards that transcend borders.

Each of those complexes of moral and legal principles – the notion of human rights with its central principle of self-determination and the ethics of care – is clearly a necessary, though not sufficient condition for the moral and legal norms needed for contemporary biomedicine. Only a combination of the two allows medicine to avoid extremes, that is: to avoid the paternalism of the traditional doctor-patient-relationship as well as the degeneration into a mere service industry.

III.

No doubt it would be interesting to investigate the link between the two complexes of moral and legal principles by going through the individual chapters of the convention. The first chapter contains the general rules, states the protection of human dignity and rights in Article 1, and postulates the priority of the individual over the interests of society and of science (Article 2) as well as the guarantee of equal access to health care for everyone (Article 3). The second chapter goes beyond the already mentioned binding of all medical intervention to Informed Consent (Article 5) and deals with the protection of persons who cannot give their consent (Article 6), suffer from psychiatric disorders (Article 7) or have to be treated in an emergency situation (Article 8), as well as living wills (Article 9). The third chapter is dedicated to the issue of the protection of privacy and contains the relevant regulations (Article 10). The fifth chapter deals with scientific research and criteria for its safety (Article 16), especially to protect people who cannot give their consent (Article 17); it also regulates research on embryos and prohibits the production of embryos solely for the purpose of research (Article 18). The sixth chapter regulates the taking of organs, particularly from persons who cannot give their consent (Articles 19 and
But since a detailed analysis of the 14 chapters and 38 articles of the convention would take too much time I will restrict myself to a discussion of the regulations on genetic diagnosis and gene transfer in chapter 4. In this chapter article 11 prohibits discrimination on the grounds of genetic make-up and Article 14 the choice of gender. These prohibitions are a direct result of the protection of individual dignity in Article 1. For if human beings have dignity and if dignity signifies a worth which, according to Kant, unlike a price has no equivalent by which it could be substituted, then any value judgement which made the worth of human beings dependent on their genetic make-up or their (genetically determined) gender would violate that dignity, which they have simply by virtue of being human beings.

Similarly in Article 13, the prohibition of any genetic manipulation of the germ cell line, results from a personís right to self-determination. For if a manipulation of the genome affects all future carriers of that genome we would have to be able to presume their consent beyond reasonable doubt. The defence of this type of genetic manipulation for therapeutic reasons claims that that consent may be presumed where the manipulation of the genome is directed precisely at a gene which is responsible for an inherited disease of a grave nature. However, the regulations of Article 13 of the convention do not allow for even that exception. If one is looking for reasons beyond the risks of such an intervention and the fact that it could only be established on the basis of research on persons who cannot give their consent, one could argue that the therapeutic goals in question are neither universal nor precise enough to justify an intervention which is as far-reaching as the genetic manipulation in the germ cell line.

On the other hand, in Article 12 the convention relies on the notion of a medical teleology to limit the use of predictive genetic testing for diseases to, as it is called, health purposes. It also ties such testing to genetic counselling and thus to the principle of self-determination, which entails a personís right to know as well as not to know. Both conditions: the presence of health purposes and of genetic counselling, effectively bind predictive genetic testing to the doctor-patient relationship and a relevant diagnosis, i.e. to medical indications.

There is no other area than the regulation of predictive genetic testing for disease dispositions where the convention restricts the right to self-determination so directly by reference to medical teleology. It is obvious that the convention assumes that genetic diagnosis is an intervention which is no less in need of justification than any other medical intervention and that therefore the patientsí wishes alone are not a sufficient justification.
Here the convention follows the self-regulation imposed by the recommendations and guidelines of several national professional bodies. Future developments will show whether these restrictions continue to meet with a consensus strong enough to avoid the obvious potential for the abuse of existing or newly developed diagnostic kits in drug stores.

The significance of the convention’s approach to the regulations on human genetics becomes apparent in a comparison with the regulations of the UNESCO declaration. In the first draft of this declaration, the human genome is regarded as a 'common heritage of mankind' and as such worthy of protection. Regardless of whether 'the human genome' exists as a specific genome other than in the form of an abstraction from the many individual genomes, this raises the question whether the notion of a 'common heritage of mankind', which was developed with respect to the ocean floor or the moon in order to prevent individual property claims, can be meaningfully applied to the human genome. The desire that all countries should participate in the results of genetic research is understandable; and the protection of minorities threatened by genetically determined diseases is important. Yet the protection of the human genome can only be guaranteed via the protection of the individual’s dignity and rights. For the protection of the specific genome can only be justified as an integral part of the protection of the individual genome. If the protection of the specific genome were the primary goal, eugenics or other interventions which neglect the interests of the individual could not be ruled out. Consequently, the draft of the UNESCO convention underwent significant corrections, which had the effect that the classical notion of individual human rights has become its pivotal point. In its individual regulations, too, the final version of that declaration is formed along similar lines of the convention.

Because the convention of the Council of Europe defines only a framework it contains no further regulations on human genetics. For instance, it does not deal with the problems of prenatal diagnostics or of the genetic screening of entire populations. Neither does it deal with the problem of passing on the results of predictive genetic tests. All those questions are the subject of a protocol on human genetics, which the Committee of Ministers has requested and which meanwhile is in preparation.

IV.

What relevance does this European and international process of consensus formation and its results have for the moral and legal handling of human genetics? Will limitations based on the doctor-patient relationship be effective? And will the two aforementioned complexes of moral and legal principles resist the spiral of want which results from the demands of the people and the supply of the market?
Only by being bound to medical practice and the notion of disease can the use of genetic diagnostics be protected from an unfettered commercialisation, and also from its wanton use in the labour market and the insurance industry. It is precisely the notion of disease which allows us to distinguish gene transfer for the purpose of therapy from that of enhancing a particular trait.

To be sure, there remain questions and grave problems. Does not an understanding of health as general well-being, embraced by the World Health Organisation, make it illusory to use the concept of health as a moral and legal criterion? Even if the delineation is not always entirely clear, medical practice and its largely uncontested reliance on the diagnosis of diseases suggests that the delineation is workable and that any concept of health which does not recognise this will indeed remain illusory. That is why the combination of the two criteria can rule out the abuse of new techniques for the purposes of eugenics understood as a deliberate improvement of the genetic pool. For such an improvement regards the individual only as a means and does not care about the individual but only the common good.

However, can the two criteria of self-determination and presence of health purposes counter the spiral of want which results from the unfortunate combination of conflict situations, technical possibilities, economic interests and social pressure? Nothing presents the problem of that spiral more clearly than prenatal diagnostics and inheritable genetic manipulation, i.e. genetic manipulation of the germ cell line. On the one hand prenatal diagnosis frees parents from unnecessary fear, allows them to have children even if they have a disposition to a severe disease, and can possibly contribute to that disease no longer being passed on to future generations. On the other hand there is the grave burden which is the knowledge of a positive diagnosis, the connection with abortion, which contradicts the protection of life, and effectively a preventive eugenics. However, the proponents of the genetic therapy of the germ cells argue that all these could be avoided if a timely diagnosis of the genetic disposition to a severe disease allowed a targeted therapy of the gene in which the disease is coded.

Indeed, the therapeutic goals appear to justify the magnitude of the intervention, in contrast to the gene transfer for the purpose of enhancement. Yet, it is not only the fact that effects and side-effects cannot be controlled but also the far reaching causality which casts doubt on the moral legitimacy of such an intervention. For none of the future carriers of the altered gene can be asked for consent; yet the distinction between disease dispositions for which the consent of future gene carriers can be assumed and others for which that is certainly not the case is not as clear
as is necessary to assume that consent. In the 1980s the Council of Europe therefore rightly guaranteed future generations the right to an unmanipulated genetic heritage; and in the human rights convention on biomedicine it rightly prohibits the gene transfer in the germ cell line even for therapeutic purposes.

However, will not the knowledge from the human genome project still lead to a scenario in which human beings become creatures which can be biologically perfected, the scenario of 'Wonderwoman and Superman' (J. Harris): ageless, free of disease, endowed with all desirable dispositions, yet deprived of their own humanity?

What makes the dream of producing the perfect human being appear realistic in the first place is the widespread idea of genetic determinism or essentialism, which reduces all relevant causes to the genetic code. However, as all human geneticists know very well, molecular genetic has destroyed nothing more comprehensively than that idea. If difference is normal and not sameness, if diversity is normal and not universality, if a polygenetic causal mechanism is normal and not a monogenetic one, then the concepts of genetic normality and genetic health are equally obsolete.

So it is science itself which shows us the limits at the same time as it opens up new possibilities. Molecular genetics is integrating its insights into broader, more complex patterns of explanation. All this confirms the insight that the same evolutionary mechanism which through mutation caused our possibilities and our potential is also the cause of our limitations and defects; and that therefore by nature disease is part of health ó like death is part of life ó as much as death and disease must be understood as challenges.

The scientific results refer us back to the dialectic which is part of the human condition itself. As a being which is both restricted by its body and able to control it, the human being is facing a nature with which it is at once identical. It is this 'excentric position' (H. Plessner) which makes human beings artificial by nature; it allows them to view their bodies as objects ó a condition which makes medical diagnosis and therapy possible in the first place; at the same time it puts limits on objectifying the body and rules out arbitrary interventions. Human beings are not merely alive, they have to lead their lives; and as such they must master those limits, not be mastered by them. That is why informed consent to a medical intervention and its binding to a disease diagnosis play the role I have described above.

V.

To sum up. No doubt, the development of molecular biology during the second half of this century has opened up new worlds and thrown up new
challenges. It has given us knowledge about the foundations of life on which we cannot go back and which will play a key role in all future understanding and treatment of life. That knowledge has turned life into an object of technology which goes far beyond, for example, the traditional techniques of breeding. It has also made human beings themselves the object of actions in a way which was hitherto unknown. What will become of these possibilities depends on whether human beings will succeed, on the strength of their own discernment, to limit the technically possible to the humanly beneficial. The new knowledge itself will be crucial here. For the new understanding of life as a complex network of interactions clearly indicates the limits of the old understanding of nature as a linear causal process of a technomorphic kind. The understanding of life as a complex network must be combined with an appreciation of the limits of nature. In the end, however, we ourselves must strike the right balance between intervention and restriction. That balance is not handed to us by nature, nor can it be enforced against it. We have to find and apply it ourselves. Only self-imposed, transnational limits will counter the temptation into which our own knowledge may lead us.