BELGIAN ADVISORY COMMITTEE ON
Bioethics

Opinion No 2 of July 7th 1997 concerning the Convention Human Rights and Biomedicine of the Council of Europe

Request for an opinion from Ministers Colla and De Clerck concerning the Draft Convention on Bioethics of the Council of Europe, together with an analysis of the consequences of ratifying this text for Belgian Law.

Preliminary observations

The Committee was unable to reach consensus on how it ought to approach and implement the assignment issued by Ministers Colla and De Clerck.

Two groups have evolved, both aware of the fact that neither the Convention nor the explanatory report can be amended. Both are concerned about the consequences for Belgium of a potential signing and ratification of the Convention. One group, however, reacted in a generally positive manner to the Convention and broadly endorsed the text thereof. This group thus preferred to focus primarily on an analysis of the consequences of a potential signing and ratification of the Convention for Belgian law. The remaining group considered it necessary to explore the text of the Convention from an ethical and philosophical perspective above all else. This group had reservations with respect to some of the articles of the Convention, and was thus also more inclined to express reservations concerning the consequences of potential signing and ratification.

Although they did not concur with the *modus operandi* of the latter group, the other members of the Committee finally agreed to a limited analysis of the content of the Convention, focusing in particular on clarifying ideologically different approaches evident in the text.

Three different approaches thus emerged within the Committee. The first focused on the "analysis of the consequences of signing the text for Belgian law." The remaining two approaches are to be situated within the context of the philosophical and ethical analysis of the Convention.

The Committee also addressed its attention to the explanatory report, which does not constitute an integral part of the Convention and was thus not approved *qua tale*. It is the custom nevertheless to refer to it in interpreting the Convention. The explanatory report occasioned such frequent debate, however, that the decision was made not to refer to it in the present recommendations. This does not alter the fact that the report accompanying the present recommendations occasionally refers to the explanatory report in its study of some of the articles of the Convention.

1. An analysis of the consequences of signing this text for Belgian law (requested by the Ministers on August 6th 1996)

As observed in the Minister's second letter (November 28th 1996), the members who focused their attention on an analysis of the juridical consequences of potential ratification are of the opinion that this Convention can serve as a basis for possible legislation in relation to the domains treated therein.

They believe that the Convention reflects and confirms the already established resolve to endeavour to articulate the minimal consensus that exists in the various member states of the Council of Europe with respect to a variety of bioethical problems across national boundaries as well as the boundaries presented by religion and other fundamental life options. To an important degree, the Convention is also (no more than) a codification of already existing convictions. For member states in which reflection on these issues has hitherto been nominal or even non-existent (e.g. the new member states from the former Eastern Bloc, and also to a certain extent Belgium), the Convention can be considered as an incentive to implement such a reflection process at the national level.

From both perspectives (codification, incentive for further discussion), the Convention responds to an exigency endorsed by the Parliamentary Assembly of the Council of Europe.

As with the European Convention for the Protection of Human Rights of the Council of Europe, the present Convention is also destined to become a "living" instrument. What is meant here is that the Convention's provisions can be interpreted and applied to situations that did not exist when the Convention itself was approved. It is possible to specify the repercussions of potential ratification for Belgian legislation. Such an article by article analysis can be found in the Report accompanying these recommendations.

2. An ethical-philosophical analysis: an ethical recommendation in diversity

2.1.The fundamental orientations of the Convention

While no one questions the principle of this Convention, a study of its content makes clear nevertheless that various interpretations are possible and that deep-seated differences of opinion exist as to whether the fundamental ethical orientations of the Convention are well-founded.

2.1.1. Human Rights, Freedom, Dignity of the Human Person

Some recall that the spirit of the Declaration of Human Rights in whose name the Convention has been promulgated set out to protect persons as postpartum individuals, whether adult or not. The protection of the embryo, or of entities further removed from the individual such as the human genome, was never a matter of discussion in the basic texts on Human Rights. The fundamental value of these basic texts concerning human rights was, in the first instance, the freedom of the individual (see, in particular, the Declarations of 1789 and 1948: Art. 1); the fundamental value of the Convention is the dignity of the human person. If we presume that the individual is entitled to determine what is unique to his or her dignity, then continuity is guaranteed. But if one is inclined to argue that one has a duty to protect individuals and entities against assaults on the dignity of the human person, in spite of themselves and even against their will, then every form of restriction becomes conceivable in the name of the so-called "authentic values". The danger exists that a segment of society, or of humanity, such as a religious community, for example, or an ideological faction, will be able to force its vision of human dignity on others. Determining priority between freedom and dignity is less important than their mutual integration: the exercise of freedom based on respect for the dignity of the other and the determination of dignity based on respect for the autonomy of the other.

Others are of the opinion that the invocation of the concept of the "dignity of the human person" – within the context of international cooperation – is in line with the robust tendency to protect the human person in all his/her dimensions and relationships. While ethics tends to define these different dimensions in different ways, most boil down nevertheless to fundamental values such as unicity, intersubjectivity and solidarity. These essential dimensions of the human person need to be accounted for when we endeavour to determine whether legislation or a given law is morally acceptable; i.e. whether it supports the promotion of the human person in an integral way. The concept "dignity of the human person" is thus a pre-eminently ethical concept, which can be used to temper the sometimes excessive emphasis on self-determination. The Convention, which has the development of the human person at both the moral and physical level as its goal, determines the required exceptions when such developments might be to the detriment of others. These members of the Committee point out that the concept "dignity of the human person" is also postulated as a foundational principle of "freedom, justice and peace in the world" in the basic texts dealing with human rights, more specifically the Preamble to the Universal Declaration of Human Rights (1948) and the international conventions on civil and political rights as well as economic, social and cultural rights (both dating from 1966). The theory of human rights deploys the concept "dignity" to express the unique and irreplaceable character of the human being. Given the unique and irreplaceable character of every human being, this same dignity likewise constitutes the basis of the principle of inviolability (important for physical integrity) and the principle that the human person in society must always be recognised as an end in him/herself and never as the subject of any form of instrumentalisation (or commercialisation).

2.1.2. The application of general principles

Some observe that the Convention is immersed in the dynamics of the Universal Declaration of Human Rights, i.e. that it sets out to situate itself within a universalistic vision, in which one searches for principles that can serve as the subject of broad consensus at the level of European culture, and even, where possible, at the global level. This goal is in itself absurd, since conflictuality and the generation of value conflicts is a characteristic feature of bioethical issues. Bioethics is a reflection process intended to offer solutions to conflict-bearing problems that are the product of the biological sciences and the techniques associated therewith. The least one can say on a general reading of this document is that it has been unable to engage in such an ambitious process. The text touches on many domains that are doubtless very important, but it does not give the impression of having facilitated a structured and universal approach. Concretely, certain important and prominent issues are either not mentioned or discussed in such vague terms that only broad interpretations are made possible and no clear direction is given. It is also possible to argue that the Convention will probably have no real impact on the ground. In other places, by contrast, the Convention very explicitly takes sides where consensus has not yet been reached.

Others confirm that the Convention consists of a compilation of topics, but have questions concerning the logic and coherence thereof. Certain themes (such as organ donation after death and the medical decisions associated with the end of life) are not discussed at all, while others (such as medical-scientific research and the human genome) are discussed in depth. Nevertheless, they consider this acceptable within the context of a dynamic ethics that sets out to concretise human happiness to the best possible degree. A normative ethics, after all, will focus attention on the development of the human person in all his or her dimensions and relationships. Reality remains limited and relative, however, which implies that we must strive after the “most human possible”. This dynamic is present in the convention, specifically in the fact that it is open to revision every five years.

2.2.General observations on the chapters and articles of the Convention

Since the Report contains commentary on each of the articles of the Convention, we will not review them here in detail. Two observations can be made nonetheless with regard to the said commentary: consensus exists on some articles, while others have given rise to dissensus.

2.2.1. Articles on which consensus exists

The Convention stipulates at length and in a satisfactory manner:

- the permission of the patient for a medical intervention (chapter 2), also when performed on persons not able to consent and in emergency situations
- the permission of a test subject for medical scientific research (chapter 5), also in relation to persons not able to consent
- the removal of organs and tissue from living donors for transplant purposes (chapter 6).

Both the level of detail of these stipulations and the options chosen therein were considered opportune by the Committee and were approved.

The Committee is also of the opinion that the Convention has specified a number of interesting lines of reasoning, although for some of its members they are still too vague and general and are thus unlikely to have any concrete influence. We refer here in particular to the following articles: the priority of the human subject (art. 2), equal access to healthcare (art. 3), professional obligations and rules of behaviour (art. 4), privacy and the right to information (art. 10), non-discrimination and the use of predictive testing (art. 11 and 12) and the prohibition against financial gain from (parts of) the human body (art. 21).

2.2.2. Articles on which no consensus exists

Some are of the opinion that the Convention has adopted positions on certain points that are unacceptable in a pluralistic world and that certainly do not square with the consensus standpoints of our western society. Other members do not agree here, and are of the opinion that the Convention adopts clear and unequivocal standpoints that make a minimal consensus within our pluralistic society explicit. The latter are convinced that the Convention represents an endeavour to realise broad consensus at the level of the fundamental values that go hand in hand with bioethics.

The most important points on which no agreement exists:

- *the absence of the recognition of the obligation to research (chapter 5)*
  For some, the Convention should have confirmed the ethical value of research as a necessary phase in our endeavour to further alleviate human suffering. Others argued that the text of the Convention urges the elaboration of legislation in relation to medical scientific research, also in Belgium.

- *granting the same status to the right to know as to the right not to know (art. 10)*
  Some insist that the duty to know should be confirmed, together with the duty to collect

all useful information from the available data in order to promote the health of the subject and of associated third parties. In their opinion, the right not to know, which has recently been proclaimed in the world of bioethics, should only be invoked ‘exceptionally, rooted in the autonomy of the citizen’, since it can lead to obscurantism and irresponsible behaviour.

For others, speaking in terms of rights in relation to ethics is an expression of a rationalistic and individualistic approach. For them, autonomy is not the only fundamental value; intersubjectivity and solidarity should also be accounted for. All legislation should be judged in light of its promotion of the person in all his or her dimensions and relations. They maintain, moreover, that an individualistic approach cannot distinguish between the right to know and the right not to know, since both are legitimate from the perspective of respect for the autonomy of the individual.

- *the exaggerated emphasis on patient self-determination (art. 5 to 10, 16, 17, 19 and 22)*

  For some, the fundamental value is respect for the autonomy of the individual. The Convention is inclined to extend itself to include entities that are not persons in the sense of individuals already born. In their opinion, the Convention employs exceptionally vague and problematic terminology when it speaks, without demarcation, of “the person, or the individual, or the human being.”

  Others are of the belief that there is a danger of exalting the autonomy of the subject to such a degree that procedures of exception (exception with respect to the principle of permission) will need to be put into place. As a result, the traditional mechanism for the protection of the patient – the inviolability of the human body, whereby only those interventions that benefit the subject are justifiable – is likewise in danger of disappearing.

- *an oversimplified disapproval of germ line gene therapy (art. 13)*

  For some, the very broad consensus not to permit stem cell therapy at the present time is inspired by a concern to avoid running health risks. This consensus can also disappear in the future. Others are of the opinion that the Convention allows for such an evolution. The fact that the Convention is open to a five-yearly review allows for the possibility of revising the article in question.

- *limiting research on embryos (art. 18)*

  The Committee was only able to observe variety in the interpretation of the provisions in the first paragraph.

  The second paragraph (prohibiting the creation of embryos for research purposes) exposed more profound differences of opinion. For some, the creation of human embryos for research is unavoidable in certain instances, e.g. in providing assistance to patients with fertility problems or genetic disorders. For others, the creation of human embryos for research would give expression to a radically utilitarian approach: human life would no longer be respected, indeed it would be instrumentalised.

- *oversimplified prohibition against the retrospective use of bodily material for research (art. 22)*

  For some, article 22, although correct in its intention, is formulated in an excessively categorical manner and has the potential to lead to absurd situations. It could imply, for example, that retrospective research might become completely impossible. Others are of the opinion that a modification of scientific research in Belgium can easily allow for the integration of this possibility.

- *the notion of broader protection whereby the conflict of values associated with bioethics and its conflictual character are denied (art. 27)*

  Some reject the protectionist character of this article, arguing that it suggests that increasing protection against medical science, which is too often considered dangerous, is always ethically justifiable and even desirable. Others are of the opinion that boundaries need to be drawn to facilitate reflection. This will allow us to better integrate progress in medical science in our western society.

- *choice of gender (art. 14)*

  Article 14 (choice of gender) was not discussed in great detail because another limited commission (96/2) has been charged with providing recommendations in this regard. The Committee thus refers to the recommendations of select commission 96/2.

3. Conclusions

3.1. It should be underlined that some members were of the opinion that the Committee should not comment on whether it believes potential ratification of the Convention to be opportune or not. They presume that this is a juridical-political matter for which the Committee is not competent. They point out, in addition, that this was not part of the Ministers' brief.

3.2. For the other members, the lack of consensus sketched above leads to a different assessment of a potential ratification of the Convention in Belgium. The absence of consensus and the criticism related to certain important provisions of the Convention inclined some to argue that ratification could have potentially negative consequences for scientific research and for the development of science and biomedical techniques in Belgium. The interests of certain patients could thus be placed at risk. The members in question support, rather, the integration of the interesting and consensus segments of the Convention (cf. 2.2.1.) into law via specific legislation approved at the appropriate legislative level.

Others were of the opinion that the Belgian government – by ratifying the Convention – would demonstrate that it understands the importance thereof for international and humanitarian development in the domain of bioethics. They thus support the integration of the Convention into Belgian law. As a matter of fact, Belgium has little if any legislation in relation to bioethical issues upon which basis reservations can be expressed concerning one or other article of the Convention. The members in question thus consider it more appropriate to insist that legislators develop legal provisions on issues such as “medical experiments on human subjects”, “patient rights”, “quality norms for centres specialising in fertility technology” or the actualisation and extension of existing legal provisions concerning “animal experiments”.

A third possibility also exists, however, namely the invocation of article 36 of the Convention. On the most important points of disagreement, the Belgian legislator is free to search for acceptable compromises and, by approving them in advance into law, could do the necessary reservations prior to ratification of the Convention.

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The opinion was prepared by select commission 96/6, consisting of:

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The working documents of the select commission 96/6 – the question, personal contributions of the members, minutes of the meetings, documents consulted – are kept on file at the Committee's Documentation Centre where they are available to be consulted and copied.

The opinion is available to be consulted at **www.health.belgium.be/bioeth**