2000

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 28 June 2000 CDBI/INF (2000) 1

[cdbi/plénier/docs publics/inf/travaux préparatoires Conv (2000.1)a] Provisional

STEERING COMMITTEE ON BIOETHICS (CDBI)

CONVENTION ON THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE:

CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE

(ETS N° 164)

PREPARATORY WORK ON THE CONVENTION

(Document prepared by the Directorate General of Legal Affairs)

- This document prepared by the Secretariat of the Steering Committee on Bioethics (CDBI) assembles the relevant parts of the meeting reports of the plenary Committee (CAHBI/CDBI) and its Working Party responsible for drafting (CDBI-CO-RED) until the adoption of the Convention. It must be noted that the meeting reports and the abstracts contained in this document constitute a synthesis of debates but not the proceedings of each meeting concerned.

- In order to clarify matters, where the numbering of the Articles of successive drafts of the Convention has changed during the course of the work, the Secretariat has specified each time in brackets, the current Article of the Convention to which the text refers.

- Addendum I to this document contains all draft Conventions as decided at the end of the different meetings of the CDBI-CO-RED and CDBI. The date appearing in the header of each draft is the date of the above-mentioned meeting.

- Addendum II to this document contains the official reports of debates by the Parliamentary

Assembly of the Council of Europe on the draft Convention.

Preliminary remark

CAHBI 24-27/03/92

The Committee decided by a majority to use general terms in the framework Convention and to avoid giving overly precise definitions therein, it being understood that the Protocols could provide the necessary precision in their respective fields.

In particular, the Committee decided:

- to specify that the term *"human being"* should be understood in its widest sense and to avoid, at the present stage, the inclusion in the framework Convention of a definition of the human being;

- not to specify whether the framework Convention applies to the human being only after birth or also before;

- not to specify whether the framework Convention also applies to gametes and genetic engineering;

- not to include a definition of bioethics, the difference between the latter and medical deontology being sufficiently well established. Nevertheless, the Explanatory Report should give some details on the concept of bioethics.

Title of the Convention

CORED 16-18/06/92

i. concerning the reference to human rights

The Working Party unanimously regarded the use of the words *"human rights"* in the title as highly appropriate, since this underlined the connection between the protection system established by the text and the general philosophy of human rights.

Several participants stressed the progress made by the biomedical sciences since the European Convention on Human Rights had been concluded; the principles embodied in the present draft text might make it easier to interpret the Convention in a manner which took into account scientific progress.

ii. concerning the term *"protection"* of human rights

One participant pointed out that, when a French Act of 1988 had referred to *"protection"* with regard to scientific application, this had been taken to imply a certain distrust of the latter.

Other participants pointed out, however, that the term was used in several other Council of Europe conventions, such as Convention No. 108 (data protection), and in the English version of the Convention on Human Rights.

The Working Party decided to keep the term *"protection"*.

iii. concerning the phrase *"application of biology and medicine"*

The Working Party decided to keep the phrase *"application of biology and medicine"*, thinking it preferable to *"life sciences"* (which was thought too broad and capable of taking in disciplines such as psychology and sociology), *"biomedical sciences"* or *"bio-medicine"* (whose content was not clearly defined).

The phrase "application of biology and medicine" also appeared in the first Article. Under this Article, the Explanatory Memorandum should indicate that it covered medical application employed for preventive, diagnostic, therapeutic and research purposes. Moreover the Working Party will examine at its next meeting whether the draft Convention should cover medical application in fields such as life insurance.

iv. concerning the phrase *"Bioethics Convention"*

The Co-ordinator thought that, according to instructions received, the Convention might have a double title: the first, very short title, *"Bioethics Convention"*, would serve to identify it rapidly; the second would be longer and serve as a sub-title, giving a fuller idea of what the text was about.

Several participants thought that the content of the term *"bioethics"* was not clear, even to specialists, and that certainty regarding the content of the Convention was needed in the title.

The Working Party did not accept the Co-ordinator's suggestion, but decided to put it to the Steering Committee.

CORED 9-12/11/92

The Co-ordinator reiterated his opinion, stating that the Convention should have a dual title. The Working Party noted this comment and referred to the previous meeting report.

CDBI 24-27/11/92

The CDBI decided after discussion to adopt the following title:

"Convention for the Protection of Human Rights and Dignity of the human being with regard to the Application of Biology and Medicine: Bioethics Convention".
The new title thus takes into account the concern of some delegations to see all human beings brought within the scope of the Convention.

CORED 8-12/03/93

The Working Party carefully examined Dr Palacios' proposal for the addition of the following subtitle to the title of the Convention: *"Preliminary draft Convention for the protection of human rights with regard to the application of biomedicine and human biotechnology"*.

The experts considered that the title proposed by the CDBI was more readily comprehensible and preferred for the time being to keep to the Convention title accepted by the CDBI at its previous meeting.

CDBI 27-30/04/93

Following the amendment suggested by Dr Palacios, the Committee decided to keep the title unchanged. However, the Working Party was instructed to clarify the Explanatory Report on this item in the light of Dr Palacios' remarks.

CORED 1-3/06/93

Following the instructions of the CDBI on this point, the Working Party kept the title unchanged but decided to clarify the title in the Explanatory Report, as suggested by Dr Palacios, representative of the Parliamentary Assembly.

It was therefore decided to make it clear in the report that the scope of the Convention was confined to human biology, thereby excluding animal and plant biology when it was not relevant to the biology of the human being. It was further recalled that the expression *"Bioethics Convention"*, which was merely an abbreviation of the title, was used only for reasons of convenience.

CDBI 26-30/06/95

The CDBI decided not to give a final opinion on the sub-title of the draft Convention until completing its work on the content of the provisions.

CORED 24-26/04/1996

The Working Party noted that the Committee of Ministers' instructions to draw up a Convention[1] did not refer to a *"Bioethics Convention"*. It further noted that the term *"bioethics"*, although widely used in English-speaking countries and in France, had a pejorative connotation in certain states. It was noted that the Convention was referred to as the Bioethics Convention and it was likely that this would continue, nevertheless the Working Party considered it preferable to keep to the title *"Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine"*. Consequently, it recommended that the CDBI delete the abridged title.

CDBI 4-7/06/1996

Several delegations considered that the term *"bioethics"* had negative connotations in the German-speaking countries and furthermore did not adequately emphasise the legal (apart from ethical) nature of the provisions in the text.

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[1] The CDBI received the following terms of reference to prepare: "a framework Convention, open to non-member States, setting out common general standards for the protection of the human person in the context of the biomedical sciences".

By 24 votes in favour and 8 against, with no abstentions, the Committee decided to replace the abridged title *"Bioethics Convention "* with the title "*Convention on Human Rights and Biomedicine*" proposed by a delegation.

Preamble

CORED 16-18/06/92

The Working Party agreed on the Preamble.

CORED 9-12/11/92

The Working Party decided to refer in the Preamble to the International Covenant on Civil and Political Rights of 19 December 1966.

The experts proposed rewording the fourth sub-paragraph of the Preamble.

The Working Party decided, with some reservations, to add a new sub-paragraph submitted by the Special Adviser.

CDBI 24-27/11/92

Some delegations suggested that there be express mention of the embryo in order to bring the embryo explicitly within the scope of the Convention.

It was accordingly proposed that a specific provision be included in the Preamble. This was not agreed to by the Committee.

It was then suggested that the Preamble could indicate that the term *"human being"* should be understood in the broadest sense. The Committee did not adopt that proposal for the Preamble but agreed that this would be included in the Explanatory Report.

A delegation expressed its regret that, in rejecting the suggestion for a specific provision to this effect in the text, the CDBI had gone back on what had been decided at its previous meeting.

The Committee amended the eighth paragraph of the Preamble as follows: *"Affirming that the progress of biology and medicine shall be used for the benefit of present and future generations".*

One delegation proposed the addition of a new paragraph: *"Convinced that human genes are the common heritage of mankind".* Another delegation suggested adding the following paragraph: *"Considering that ethics require that limits be imposed on the acceleration of developments in biology and medicine".* These suggestions were referred to the Working Party.

CORED 14-16/12/92

At the CDBI meeting, one delegation had suggested adding the following paragraph: "*Convinced that human genes are the common heritage of mankind*".

The Working Party considered the suggestion and accepted the inherent principle to the extent of its implication that in genetic manipulations performed on human beings it is imperative to preserve the human species and refrain from combinations with other species.

It was pointed out that the idea under discussion was already partially embodied in paragraph 7 of the Preamble. However, a new wording of the paragraph would be proposed in order to take account of the suggestion.

Another delegation had suggested the addition of a further paragraph:

"*Considering that ethics require that limits be imposed on the acceleration of developments in biology and medicine*".

It was pointed out that what had to be ethical was the use made of advances in medicine and biology and that the idea already occurred in paragraph 8 of the Preamble.

The Working Party, after discussion, accordingly decided not to include this provision.

CORED 8-12/03/93

Following a discussion, the Working Party decided to retain paragraph 5 of the Preamble which referred to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.

The Working Party considered amendment N° 2 by Dr Palacios aimed at introducing the concepts of biomedicine and human biotechnology in the sixth paragraph of the Preamble.

The experts considered that it was not desirable to refer to those concepts in the Preamble as they had not been adopted for the title of the Convention. Furthermore, some experts considered that the concepts were ill-defined.

The Working Party decided to insert a reference to human dignity in paragraph 7 so that the Preamble would stress the need to ensure the dignity of the human being, which was referred to in the title of the Convention.

With regard to paragraph 8 of the Preamble, the Working Party decided to replace "*Mindful*" by "*Conscious*".

The experts also preferred to replace the phrase *"acts contrary to human dignity"* with *"acts endangering human dignity"*.

In his amendment N° 3, Dr Palacios had proposed the insertion in paragraph 9 of the Preamble of the phrase *"... and medicine, as part of the human heritage, shall be used...."*

The Working Party did not accept this proposal because it felt that the idea in question was already contained in the Preamble, having being added in a new version of the text of which Dr Palacios had had no knowledge when drafting his proposals.

On the other hand, the Working Party felt that the Preamble should include the additional paragraphs set out in amendments N° 4 and 5 by Dr Palacios, concerning the work of the Parliamentary Assembly. Indeed, the experts thought it important to emphasise the role of that body in the study of bioethics within the Council of Europe.

The Working Party therefore decided to add a fifteenth paragraph to the Preamble on the role of the Parliamentary Assembly.

CDBI 27-30/04/93

The Committee approved the Preamble. However:

- the Working Group should examine the appropriate order in which the different international and European texts should be mentioned;

- the Explanatory Report should also contain a reference to the Helsinki Declaration;

- the paragraph which reads *"Recognising the importance of promoting a public debate .... etc."* should appear in brackets until a decision is taken on Article 22;

- the Working Group should examine the wording of the paragraph which reads: *"Wishing to remind all members of society of their rights and responsibilities."*

CORED 1-3/06/93

The Working Party examined the suggestions of the plenary CDBI and decided:

- to classify the different international texts in chronological order;

- to place the paragraph beginning with the words *"Recognising the importance of promoting a public debate …"* in square brackets;

- not to mention the Helsinki Declaration in the text of the Explanatory Report, but to include a general reference in that report to the texts adopted by other organisations and to give examples in a footnote. The Working Party felt that there were many international texts to which reference could be made and that it was not desirable to give emphasis to a single text in the Explanatory Report.

In accordance with the instructions of the CDBI, the Working Party examined the following paragraph *"Wishing to remind all members of society of their rights and responsibilities",* but did not consider it advisable to change the wording.

CDBI 6-9/07/93

The Committee approved the Preamble. However:

- one delegation proposed combining the paragraph *"Conscious of the accelerating developments in biology and medicine"* with the one beginning with the words *"Affirming that progress in biology …".* The Working Party was instructed to study this suggestion;

- the square brackets in the paragraph beginning with the words *"Recognising the importance of promoting a public debate"* could be deleted, as Article 22 had in principle been approved by the CDBI.

CDBI 26-30/06/95

The CDBI approved the amendments made by the Working Party and therefore adopted the Preamble.

CORED 24-26/04/96

Several participants pointed out that the CDBI had decided to include in the Preamble a reference to the 1966 International Covenant on Economic, Social and Cultural Rights. The Working Party incorporated this reference.

CDBI 4-7/06/1996

The Committee decided by consensus to make reference in the Preamble to the International Covenant on Economic and Social Rights, several of whose provisions were of relevance, particularly for Article 3 of the draft Convention.

CHAPTER I - General provisions

Article 1 (Purpose and object)

CORED 16-18/06/92

i. concerning the reference to protocols

The Working Party decided to mention the Protocols to the Convention in this Article for the purpose of underlining the unity of the whole and the *"consubstantiality"* of the Protocols and the Convention itself.

ii. concerning the terms *"human being"* and *"person"*

The definition of the Convention's purpose consisted of two elements: protecting every human being, which implied protection of the unborn human being; and guaranteeing the rights and freedoms of every person, only persons being regarded as having rights.

iii. concerning the terms *"identity, integrity and dignity"* of the human being

These terms were taken from the wording adopted by the CAHBI at its 15th meeting.

With regard to the term *"identity"* of the human being, the Working Party noted that it could be ambiguous and agreed that the Explanatory Memorandum would have to indicate that this covered both membership of the human species (so ruling out hybrids) and the individual's genetic identity.

Some participants preferred to see this double meaning embodied in the text of the Convention itself.

iv. concerning the phrase *"in the territory of each Party"*

As in the Convention on data protection[2], the phrase *"in the territory of each Party"* was used to indicate the responsibilities of each State Party.

v. concerning the phrase *"whatever his nationality or residence"*

This phrase was also repeated from the data protection Convention.

It emphasised that the guarantees provided applied to anyone coming, however briefly, within the jurisdiction of a State Party; for example, an alien in transit who submitted to a medical examination; transplantation of an organ removed in an outside country; etc.

CDBI 24-27/11/92

The Committee decided to remove the reference to the Protocols since the term *"Convention"* included the Protocols.

It was also decided to delete the words *"in the territory of each party"*. It was made clear that the application of the conventional rules of international law sufficed to obtain the same result.

The CDBI also decided to replace the words *"whatever their nationality or residence"* by the words *"without discrimination",* thereby incorporating the provisions of the former Article 20[3].

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[2] Article 1 of Convention N° 108: "The purpose of this convention is to secure in the territory of each Party for every individual, whatever his nationality or residence, respect for his rights and fundamental freedoms, and in particular his right to privacy, with regard to automatic processing of personal data relating to him ('data protection')."

[3] This Article no longer appears in the text of the Convention.

CORED 14-16/12/92

At its last meeting the CDBI had asked the Working Party to reword Article 2 of the Convention so as to highlight the fact that the Convention constituted a framework to be supplemented by protocols.

The Working Party's opinion was that the best way of achieving this purpose would be the inclusion of a reference to the protocols in Article 1. The Working Party therefore recommended that both existing and future protocols be mentioned so as to avert any difficulty should no protocol exist at the time of signature of the Convention.

CORED 8-12/03/93

The Working Party decided to amend this Article so as to bring out clearly the fact that it lay with the Parties to the Convention to take the necessary measures to protect human beings and guarantee respect for the rights and freedoms of all individuals.

The experts observed that, in accordance with the CDBI's decision, the reference to the Protocols in this Article had been deleted, since the term "*Convention*" included the Protocols.

CDBI 27-30/04/93

The Committee decided to maintain this Article unchanged. In particular, it rejected a proposal to replace the words *"shall protect"* by the expression *"undertake to take such measures as are necessary to protect."* However, the Committee agreed that the Explanatory Report should make it clear that the Convention contained some provisions which could be self-executing, while other provisions required States to take internal measures to make them applicable.

One delegation proposed that the second sentence of the Explanatory Report under Article 1 should read: *"induding human embryos"*. This proposal was supported by some delegations, while a number of other delegations opposed it.

One participant asked for the reason for using two different terms (*"human being"* and *"individual"*) in Article 1 if the two terms were to be understood as having the same meaning. Should it not then be indicated in the Explanatory Report that the term *"human being"* includes the embryo?

The Secretariat suggested that the following sentence be included in the Explanatory Report: *"The purpose of the Convention is not only to guarantee the respect of the rights and fundamental freedoms of the person already born but to protect the dignity, identity and integrity of the human being, this being understood in its largest sense."*

One delegation suggested including in the Explanatory Report the expression *"in the largest sense compatible with national law"*.

For the Explanatory Report, one participant suggested indicating: *"... human being, including the human embryo"*, and adding: *"The principle of protecting the human being accepted by all the Contracting States, it goes without saying that this does not prejudice the various national levels of protection, particularly with regard to abortion."* The Secretariat and other participants expressed the fear that this proposal would weaken the text even further: For what purpose would the States bind themselves to a Convention which protects the human being if they reserve the right to freely define the content of this protection themselves? The very purpose of an international convention is to define a minimum level of protection which the States should respect.

Dr Palacios, representative of the Parliamentary Assembly felt that abortion should not be mentioned in this context.

The Chairman noted that the Committee had decided to maintain the text of Article 1 unchanged. The Working Party was instructed to make alternative proposals as far as the text of the Explanatory Report is concerned.

CORED 1-3/06/93

At its last meeting, the CDBI had instructed the Working Party to put forward alternative proposals concerning the Explanatory Report while maintaining the Article unchanged.

However, the Working Party made the following comments: Article 1 used two different terms: *"individuals"* and *"human beings",* and the CDBI had decided that the term *"human being"* should be understood in its broadest sense, ie as not being limited to the person already born.

In fact, Article 1 affirmed that the integrity of the human being had to be guaranteed. The members of the Working Party therefore took the view that there might be a contradiction between this wording and national legislation concerning embryos. Indeed, States had very different sets of laws concerning the level of protection of the embryo, whether in regard to abortion or research.

In the circumstances, the Working Party found it difficult to make proposals concerning the Explanatory Report without amending the text of Article 1 itself.

Accordingly, the great majority of the participants proposed the following alternative for Article 1: *"Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their rights and fundamental freedoms, particularly their integrity, with regard to the application of biology and medicine"*. It was observed that this new wording did not leave the embryo unprotected since the requirements of respect for dignity and identity were clearly maintained.

The Co-ordinator, Professor S. Puglisi, asked that note be taken of his disagreement with regard to the presentation of an alternative for Article 1, in as much as the terms of reference assigned to the Working Party by the CDBI had concerned the submission of proposals for the Explanatory Report.

With regard to the English version of the text, the Working Party decided to replace the words *"all individuals"* by *"everyone",* thereby taking up the wording of Article 2 of the European Convention on Human Rights and bringing the French and English versions into line with each other.

The Working Party also decided to mention in the Explanatory Report that the term *"everyone"* meant a *"human being already born"*.

With regard to the term *"discrimination",* the Working Party considered, after discussion, that it should remain unqualified and that it could be pointed out in the Explanatory Report that this term referred to a situation where equal cases were treated unequally.

CDBI 6-9/07/93

At its last meeting, the CDBI-CO-RED had decided to submit alternative wording for this Article to the plenary CDBI.

Several delegations expressed themselves in favour of alternative II. Indeed, according to the delegations concerned, if Article 1 was maintained in its previous wording (alternative I), which provided that *"Parties to this Convention shall protect the dignity, identity and integrity of all human beings",* it could be understood as prohibiting abortion. However, national legislation on this subject differed widely and many countries authorised abortion.

The Committee decided by 17 votes to 7, with 1 abstention, to give Article 1 the wording proposed in alternative II.

In addition, several delegations took the view that, in respect of this Article, the Explanatory Report on the Convention should confine itself to stating that the Committee had not reached unanimous agreement on the definition of the terms *"everyone"* and *"human being",* a task which should be left to the national legislation of each Party to the Convention. The CDBI agreed not to define these terms in either the Convention or the Explanatory Report.

CORED 27-29/09/93

The Working Party noted that the CDBI had accepted the second alternative for the wording of this Article and that it had been decided not to define the terms *"person"* or *"human being"* in the Explanatory Report to the Convention.

One expert was of the opinion that embryos came within the scope of the Convention and that, although the definition of human being varied from one country to another in accordance with social, cultural, legal, philosophical or religious traditions, the dignity of the embryo must be protected.

CDBI 29/11-3/12/93

The CDBI referred to the CDBI-CO-RED, for consideration, the Secretariat proposal to amend the wording of Article 1 as follows: *"... guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms ..."*.

CORED 24-27/01/94

In accordance with the instructions of the CDBI, the Working Party examined the Secretariat proposal to amend the wording of Article 1 as follows:

"Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms, with regard to the application of biology and medicine".

The CDBI-CO-RED approved this amendment, and noted that this wording was more readable and that, while mentioning the right to integrity, it did not give secondary status to other fundamental rights.

With regard to the Explanatory Report, the Working Party decided to incorporate the following ideas:

- the dignity of the human being must be respected from the earliest stage of life;

- however, it was for the legislation of each country to give a status to the embryo, where appropriate;

- mention should be made of the difficulty of defining the terms *"human being"* and *"person"* and the consequent lack of a definition. In this connection, it should be recalled that the European Convention on Human Rights also offered no definition.

CDBI 18-22/04/94

The CDBI slightly altered the French version of this Article, replacing the words *"les autres droits et libertés fondamentales"* by *"ses autres droits et libertés fondamentales"*.

Paragraph 23 (former paragraph 2) of the Explanatory Report would have to be revised by the CDBI-CO-RED in the light of the discussions in the plenary Committee. In particular, the sentence, *"It was also observed that some national laws specified the point at which they conferred the status of human being, while others did not"* could be deleted in order to obtain a generally agreed text.

CDBI 26-30/06/95

Having closely examined the proposed amendments to Article 1 and the responses suggested by the CDBI-CO-RED, the CDBI decided to maintain the Article unchanged by 27 votes in favour, 1 against and 1 abstention.

The Explanatory Report would nonetheless be amended to reflect certain comments.

Article 2 (Primacy of the human being)

CDBI 24-27/11/92

After discussion, bearing in particular on whether the interests of the individual should take precedence over the interests of society, the Committee decided to maintain this Article without change.

CORED 14-16/12/92

The Working Party considered that the expression "whenever the need arises" should be deleted and replaced by a phrase making reference to the body with authority to propose the drafting of further protocols.

CDBI 27-30/04/93

The Committee accepted the content of this Article. Certain comments on the wording, which the Working Group should examine, were however made, i.e.:

- speak of the "pre-eminence of the human being" instead of the "welfare of the human being";

CORED 1-3/06/93

The Working Party considered the comments made by the CDBI.

It decided first of all to maintain the expression "welfare of the human being" and not to replace it by "pre-eminence of the human being". The experts noted that the term "welfare" was an ethical concept which in this context was opposed to the term "ill", not the term "evil".

One expert observed that the welfare of the human being was the intended objective, while the term "pre-eminence" placed human beings in relation to other species.

CDBI 6-9/07/93

The Committee accepted the first paragraph of this Article without amendment.

CDBI 29/11-3/12/93

With regard to the first paragraph of Article 2, a delegate proposed transposing it to Article 14 (new Article 15) which dealt with scientific research. This suggestion was explained by the fact that this paragraph was drawn from Recommendation No. R (90) 3 concerning medical research on human beings. It therefore appeared desirable to keep it in the research context. The CDBI-CO-RED was instructed to study this proposal.

CORED 24-27/01/94

The Working Party studied the proposal made by a delegation at the December meeting of the CDBI, which was to transpose the first paragraph of Article 2 to Article 14 (new Article 15) which dealt with scientific research.

Participants noted that this Article was of a general nature and was not limited to the concept of research; consequently, it was advisable to keep the Article unchanged.

CDBI 18-22/04/94

The CDBI kept the first paragraph of this Article virtually unchanged, merely reversing the order of the words *"society"* and *"science"* in the first paragraph.

One participant nevertheless expressed doubts about the concept of the *"interests"* of the human being, which were to prevail over the interests of science and society, a concept which might cause confusion. The participant felt that it was not in a person's interests to submit to non-therapeutic research. On the other hand, participation in such

research, subject to certain conditions, was not contrary to human dignity. The delegate therefore proposed an amendment of paragraph 1 of Article 2 to read: *"The welfare and dignity of the human being shall prevail over the sole interest of society and science"*.

The CDBI, while recognising the value of this proposal, nonetheless decided not to take it up, so that the wording of this provision matched that of the Declaration of Helsinki, from which it had been taken. The Committee decided, however, to make it clear, in the Explanatory Report, that Article 2 was not intended to prohibit research on healthy persons.

CORED 30/05-2/06/94

The Working Party questioned the Human Rights representatives, MM. Nørgaard and Walsh, on the desirability of authorising restrictions on the exercise of the rights set forth in the Convention for reasons relating to national security.

They took the view that national security, which could no doubt justify restrictions on freedom of expression for example, should hardly be included in a context concerned with the application of medicine and biology. They considered that an explicit reference to national security in this context could give rise to abuse.

Following this discussion and taking into account the opinion expressed, the Working Party agreed to delete this exception.

CDBI 26-30/06/95

The CDBI accepted the Working Party's proposal to divide in two former Article 2 of the draft Convention (see DIR/JUR (94) 2).

The CDBI approved the present wording of new Article 2.

Article 3 (Equitable access to health care)

CORED 8-12/03/93

Following the proposals of one expert and the decision taken at their previous meeting, the experts decided to include an article concerning the obligation for Parties to the Convention to recognise equity of access to applications of biology and medicine.

It was pointed out that the meaning conveyed by the Article was that the *"resources"* available in a given State should be apportioned among individuals according to their needs, but that States were obviously not obliged to meet everyone's demands.

CDBI 27-30/04/93

The following observations were made on this Article:

- Should one refer to *"equitable access"* or to *"equality of access"*? Most delegations were in favour of the former.

- Should access cover all applications of biology and medicine (including research) or rather diagnostic and clinical applications only?

The Chairman noted the Committee's agreement with the principle and instructed the Working Party to look again at its formulation.

CORED 1-3/06/93

The Working Party reviewed the wording of this Article, as requested by the CDBI.

The experts laid emphasis on the fact that the meaning of the Article was not that everyone should systematically obtain the benefit of the applications of biology and medicine when he so requested, but that it was necessary to take account of everyone's needs. The Group wished to make clear that availability of resources had to be taken into account.

Two alternative solutions were proposed for Article 4 (new Article 3), both of which employed the term *"equitable access"* in accordance with the CDBI's wishes, avoiding the term "equality of access" which would mean that a person would be entitled to have access to applications which he did not need.

The first alternative was drafted as follows: *"Parties promote the principle of equitable access [for everyone] to applications of biology and medicine"*.

The second alternative, which was finally adopted, was the following: *"Parties recognise equitable access to applications of biology and medicine for health care with [due] regard to medical needs and available resources"*.

The second solution had the advantage of making it clear that States were under no obligation to meet everyone's demands.

The Working Party pointed out that the phrase *"for health care"* restricted the scope of this Article to preventive, diagnostic and therapeutic interventions, thereby excluding research.

CDBI 6-9/07/93

The Committee agreed with the principle contained in this Article, but one delegation expressed doubts with regard to the term *"equitable access"* and would have preferred the use of the expression *"parties undertake to enable everyone to benefit equitably from applications..."*

One delegation emphasised that the phrase *"en matière de soins de santé" ["for health care"]* in the French version was clumsily worded. It was suggested that it be replaced by *"à des fins médicales", ["for health care purposes"]*, which was the phrase used in Recommendation No R (92) 3 of the Committee of Ministers on genetic testing and screening for health care purposes.

These two questions were referred to the Working Party.

The Committee decided to delete the square brackets around the word "due".

CORED 27-29/09/93

The Working Party began examining this Article. The experts were divided over the appropriateness of either alternative proposed. Some found the first version too theoretical and preferred the second, which imposed positive obligations. Others, on the other hand, had doubts about the possibility of States *"undertaking to enable everyone to benefit…" since this would be an impossible commitment to meet.*

The Working Party's attention was drawn to Articles 13 and 14 of Part I of the Social Charter, according to which: *"anyone without adequate resources has the right to social and medical assistance"* and *"everyone has the right to benefit from social welfare services".*

The Working Party instructed the Secretariat to try to combine these two alternatives in the wording of Article 4 and decided to reconsider it at its next meeting.

CDBI 29/11-3/12/93

In the opinion of the participants, the following questions had to be answered before a form of words could be adopted for this Article:

- was it necessary to formulate a general principle which in fact would constitute no more than a declaration of intent, or was it desirable to adopt a provision which imposed genuine obligations on States?

- if the latter solution was preferred, would the obligation relate to the means employed or the result obtained?

The CDBI leaned in favour of a principle which would be binding on States but agreed that there would have to be an obligation as to the means employed. In other words, States should make appropriate means available for the achievement of the aim in view.

The Secretariat proposed the following wording for this Article: *"Parties shall, according to conditions they shall determine and taking into account medical needs and available resources, take appropriate steps with a view to [providing] [promoting] equitable access to applications of biology and medicine".* This proposal was a compromise between the two variants set out in the previous draft: the first variant provided for little more than a prohibition of non-discrimination; the second variant enunciated what was practically an individual right. The Secretariat proposal, without going so far as to recognise an individual right which would entail an obligation to produce a certain result, formulated an obligation with regard to the means employed by requiring parties to *"take appropriate steps with a view to …".* The aim was to secure equitable access to applications of medicine and biology. This wording was inspired by the Social Charter recently adopted by the European Union.

One expert did not consider this wording satisfactory. In her view, it authorised a degree of discrimination, whereas no discrimination should be possible.

Several participants indicated that they could accept the proposed wording. Some felt that the word *"promoting"* was too weak; others considered *"providing"* to be too strong.

Some participants said that they would prefer the scope of the Article to be restricted to necessary medical services only. The following wording was therefore proposed: *"The necessary medical services must be available to everyone on an equitable basis and in accordance with medical needs".*

Others thought that the concept of *"necessary medical services"* was impossible to define. Moreover, if necessary medical services were to be understood as referring to basic medical services, there would be an omission with regard to all the other medical services.

Following this discussion, the CDBI decided:

- to refer in this Article to *"medical services"* (20 in favour, 2 abstentions) without listing them or limiting them in any way whatsoever;

- to include a reference to *"available resources"* in the Article;

- considering that an indicative vote resulted in the expression of a preference for the term *"providing"* by 10 delegations, with 4 abstentions and none in favour of the term *"promoting"*, to instruct the CDBI-CO-RED to find an expression halfway between *"providing"* and *"promoting"*.

CORED 24-27/01/94

The CDBI-CO-RED undertook a thorough examination of this Article.

In accordance with the decision taken by the CDBI, the Working Party agreed that this Article should set out, for the attention of States, an obligation to use their best endeavours to achieve the desired result.

A discussion ensued on the question whether the Article should be limited to "*necessary medical services*".

In one participant's view, the Article was to be understood as meaning that the State should at least provide necessary medical services on an equitable basis, since it concerned only services made available by the State.

Other experts objected to this proposal, either because the State, in their case, did not itself supply medical services which were in fact financed by private insurance funds, while the State confined itself to establishing priorities, or because the State did not define what was meant by necessary medical services.

It was also observed that the concept of *"necessary medical services"* was a difficult one to define, as the necessity might come to light only after the event.

The Working Party decided therefore not to refer to the concept of necessity, since what counted was that everyone should have access to available medical services on an equitable basis.

One participant proposed replacing the term *"medical services"* by *"health care"* which was more precise.

In the wake of this discussion, the Working Party adopted the following wording for this Article:

"Parties shall take appropriate steps with a view to providing equitable access to health care, taking into account available resources and medical needs".

The CDBI-CO-RED thought that it would be wise to include the following points in the Explanatory Report:

- the purpose of the Article was not to recognise a personal or individual right. Rather, it affirmed an economic and social objective which could not be used by individuals as a basis for legal action against the State;

- it was necessary to lay stress on the restriction imposed by the reference to available resources, such resources being those of the State, whereas the medical needs referred to were those of each individual;

- the Article was not aimed at meeting everyone's demands, but at applying a principle of justice in the light of needs, and this did not rule out the possible existence of waiting lists, for example for organ transplants.

CDBI 18-22/04/94

The CDBI held a detailed exchange of views on this Article and on the corresponding part of the draft Explanatory Report.

One participant raised inter alia the question of co-operation between States, wondering to what extent this Article applied to persons wishing to obtain health care in a State in which they were not resident and of which they were not citizens.

The CDBI agreed that the obligation incumbent upon the Parties to provide equitable access applied within the limits of their jurisdiction. The experts instructed the CDBI-CO-RED to make this clear in the Explanatory Report.

Where the Explanatory Report was concerned, the CDBI decided, after an indicative vote (by 20 votes to 2), to retain paragraph 47 (former paragraph 25) unchanged, in order to make it clear that Article 4 (new Article 3) did not create individual rights.

The CDBI also agreed to replace the term *"medical needs"* by "*health needs*".

CDBI 26-30/06/95

The CDBI considered the CDBI-CO-RED's proposal to include the idea that the care provided must be of appropriate quality.

The CDBI agreed that it would be advisable to include this concept in Article 4 (new Article 3), so as to comply with the spirit of one of the Parliamentary Assembly amendments.

Regarding the terms of the Article, one delegation suggested rewording the text as follows:

"Parties shall take appropriate measures to secure, within their jurisdiction and having regard to health needs and available resources, health care of appropriate quality according to its assessment".

The CDBI decided to reconsider the Article at its next meeting in order to adopt a final text.

CDBI 5-7/09/95

The CDBI discussed the proposal to add the following words: *"... equitable access to health care of appropriate quality, having regard to its assessment*". It concluded that the idea of assessment was already embodied in the expression *"of appropriate quality"* and that the proposed addition was unnecessary. It therefore agreed on the text.

Article 4 (Professional standards)

CORED 8-12/03/93

The Working Party decided to include an article in the Convention designed to ensure that a doctor carrying out an intervention respects professional standards. In other words, the doctor must not only respect legal and technical rules, i.e. the prevailing scientific standards, but also take into account the person undergoing the intervention and therefore adapt the technique at his disposal to the requirements of the patient.

In this connection, the Working Party decided to include in the Explanatory Report on the Convention an explanation of the phrase "*professional standards*", stipulating that the clinician providing treatment should act in accordance with the practice accepted at the time by a responsible body of medical opinion skilled in the particular form of treatment in question.

CDBI 27-30/04/93

The Committee expressed its agreement with the principle enunciated in this provision: an intervention was not admissible unless it met professional standards (scientific and technical). In other words, the intervention was subject to the twofold condition of competence and humanity.

The following remarks were made about the wording:

- It should be specified that the term "*intervention*" covered diagnostic, preventive, therapeutic, rehabilitation and research interventions.

- What were the "*relevant*" professional standards: national standards or international standards?

- The provision concerned was aimed not only at doctors but at all health professionals. Should it also be extended to non-professionals (parallel medicine)?

CORED 1-3/06/93

In accordance with the wishes of the CDBI, the Working Party decided to make it clear in the Explanatory Report that the term "*intervention*" covered diagnostic, preventive, therapeutic, rehabilitating and research interventions.

With regard to the "*relevant*" professional standards, the Working Party considered that both national and international standards were applicable, in order to take account of different approaches in different countries.

The Working Party decided to include in the Explanatory Report the definition of "*professional standards*" which it had given in its previous report, stipulating that the clinician providing treatment should act in accordance with the practice accepted at the time by a responsible body of medical opinion skilled in the particular form of treatment in question. The intervention was therefore made subject to the twofold condition of competence and humanity.

With regard to the CDBI's third comment concerning the question whether this provision should be extended to non-professionals, the Working Party's reply was negative. On the other hand, it decided to point out in the Explanatory Report that Article 3 (new Article 4) applied not only to doctors but to all health professionals.

CDBI 6-9/07/93

The Committee agreed on the principle expressed by this Article.

However, a delegation expressed doubts about the French version of the Article and proposed the following wording: *"Toute intervention en matière de santé doit être faite dans le respect des règles de déontologie et conformément aux données acquises de la science et aux règles de conduite applicables en l'espèce"* (any intervention in the health field must be carried out with respect for the rules of ethics and in accordance with the prevailing scientific standards and the relevant rules of conduct).

The Working Party was therefore instructed to revise the wording of the French version of this Article in the light of the proposal put forward by this delegation.

CORED 27-29/09/93

The Working Party examined the wording of this Article in the light of a delegation's proposal.

The experts were not happy with the expression "*règles de déontologie*" ("rules of ethics"). Although this was a well-known concept for some of them, it was not familiar to other delegations using French as a working language. It was further pointed out that the expression was principally suggestive of the code of ethics for the medical profession, whereas the Article had a broader application, covering all health professionals. Consequently, the participants preferred the expression "*obligations professionnelles*" ("*professional obligations*") which seemed to cover every situation.

A majority on the Working Party was also against including the expression "*in accordance with the prevailing scientific standards*," which seemed to be already included in "*professional standards*" and, moreover, did not seem appropriate when applied to research.

On the other hand, the Working Party did base itself on the proposal in altering the beginning of the sentence in the French version.

The Working Party also amended the English version to bring it in line with the French version. It was noted that the French expression "*obligations professionnelles et règles de conduite*" primarily imposed a duty to act on professionals, while also suggesting how to act. The English expression "*professional standards*", however, did not necessarily imply that the professional had to act. Participants therefore changed the English expression to "*professional standards and obligations*", to include the notion of duty to act.

CDBI 29/11-3/12/93

The CDBI examined the wording proposed by the Working Party, as well as the Secretariat's proposal to replace the phrase "*obligations professionnelles et règles de conduite*", in the French version, by "*normes professionnelles*".

Several delegations expressed a preference for the expression "*normes professionnelles*" (standards), which they considered broader in scope than "*obligations*". The same experts thought it necessary to establish clearly the twofold dimension of any intervention:

- first of all, the intervention had to conform to scientific and technical criteria, and the professional/practitioner had to act on the basis of technical knowledge and know-how: the “prevailing rules";

- secondly, the intervention had to be carried out in a humane manner. The practitioner should adapt his approach to the patient, as each case was unique. He had to take account of the circumstances and personality of his patient.

In the opinion of the delegations in question, these two requirements in respect of any intervention were not fully covered by the term "*obligations professionnelles*". In addition, it was noted that the expression "*normes professionnelles*" was the exact translation of the English term "*professional standards*". In reply to an objection concerning the supposedly written nature of a standard, it was stated that a standard was not necessarily set out in written form.

Other participants expressed doubts about the French term "*normes*", as in their view it implied a measure of "automaticity" which was precisely what it was wished to avoid.

In conclusion, the CDBI decided to supplement the existing wording of the French text, through the addition of a reference to "normes professionnelles": *Toute intervention en matière de santé doit être effectuée dans le respect des normes et obligations professionnelles et des règles de conduite applicables en l'espèce"* (Any intervention in the health field must be carried out in accordance with relevant professional standards and obligations).

The Committee also agreed that this Article should apply only to health-care professionals. It did not apply to non-professionals who were called upon to provide care, for example in emergency situations.

CORED 24-27/01/94

The CDBI-CO-RED kept the wording of this Article unchanged but made the following observations for the purposes of the Explanatory Report.

One participant noted that, in the French version, the phrase "*normes et obligations professionnelles*" referred to the texts to which the practitioner was obliged to conform, whereas "*règles de conduite*" extended the practitioner's obligation by requiring him to be humane in his behaviour and to establish a genuine relationship with his patient. In other words, the Article covered both written and non-written rules.

The Working Party decided to make it clear that the term "*intervention*", in the context of this Article, meant any act carried out on a person for health purposes, thus covering diagnosis and therapy as well as research and prevention.

The CDBI-CO-RED recalled that this Article applied only to health professionals. It did not, therefore, concern non-professionals who might be called upon to provide care in emergency situations.

Participants felt that practitioners had a twofold obligation: to act as a reasonable practitioner would act in the same circumstance and to take account of the patient's rights.

The CDBI-CO-RED noted that there might be a conflict of duties explaining why a health-care professional did not respect a particular professional standard, but he should then be prepared to justify his conduct and explain the reasons which had led him to ignore the standard in question. By way of example, the Working Party referred to the case of a doctor who, in particular circumstances, would not communicate all available information to his patient, thereby failing to comply with the obligation imposed on him by Article 12 (new Article 10) of the Convention, in the interests of the patient himself.

Mention was also made of the disclosure of information to third parties without the patient's consent, if for instance the latter was carrying an infectious disease. In this connection, the experts stressed the fact that national customs varied and that it was important to respect them.

One participant emphasised that professional standards and obligations were by definition evolutionary in nature, and that they were therefore subject to new developments.

CDBI 18-22/04/94

The CDBI decided to specify in this Article that the word "*intervention*" also encompassed research; it amended the Article accordingly.

One participant proposed the addition of a new article dealing with the conscience clause. It was pointed out that a vote had been taken on this question at the November 1992 meeting, when it had been decided not to include such a clause. In another vote (2 votes for, 18 against and 4 abstentions), the CDBI rejected the proposal.

CDBI 26-30/06/95

The CDBI studied this Article, which had not been amended by the CDBI-CO-RED. In particular, it re-examined the proposal to introduce a reference to the general clause of conscience into the draft Convention. Certain delegations recognised the expediency of such a clause in respect of specific acts and under certain conditions, but

viewed a general clause as inexpedient. The CDBI was opposed to its inclusion (5 votes in favour, 22 against, 2 abstentions).

CHAPTER II - Consent

Article 5 (General rule)

CORED 9-12/11/92

The Working Party decided to draft a general article on the need for consent.

The requisite consent had to be free and informed. The experts stressed that qualification "*informed*" encompassed the concept of specific consent. There was therefore no need to mention it. Furthermore, one expert added that if express consent were required, this would exclude implicit consent. It seemed difficult to demand express consent for every medical act.

The second sub-paragraph laid down the patient's right to withdraw his consent at any time. This wording had been preferred to another version which required the doctor to stop the intervention when the patient asked him to do so.

One expert pointed out that consent under any form should be required for all interventions on a person and hence his tissues, even when these had been removed and were no longer attached to the person, for example tissues which were left over after an operation. The Working Party felt that this last proposal should be re-examined.

CORED 14-16/12/92

The members of the Working Party observed that there were exceptions to the principle of consent even where the person concerned was capable of understanding, for instance in cases of compulsory psychiatric treatment.

The Working Party decided to mention this exception in the Explanatory Report on the Convention, and with a reference to the Hawaii Declaration of the World Psychiatric Association of 10 July 1983.

CORED 8-13/03/93

The Working Party adopted this Article, albeit with the replacement of the phrase "*in the medical or biological field"* by "*in the health field*". It read as follows: "*No intervention may be carried out in the health field without the free, informed consent of the persons undergoing it. The persons concerned may freely withdraw consent at any time*".

The Co-ordinator drew the Working Party's attention to the corresponding Article in the Protocol on medical research, which called for informed, free, express and specific consent.

Other experts observed that it was not desirable to require express and specific consent for all interventions in the health field, although this requirement - which provided supplementary protection - appeared to be well-founded in the research field, especially when the research did not directly benefit the person undergoing it.

They considered that there was no conflict between the Convention and the Protocols, but that the latter could be more rigorous.

The Working Party considered amendment N° 7 by Dr Palacios, but it was observed that, in the field of epidemiological research in particular, the requirements in question might not necessarily be respected. However, the Explanatory Report could explain what was meant by "*free and informed consent*" and point out inter alia that the information should be presented in intelligible terms to the person required to give his consent.

CDBI 27-30/04/93

- *First paragraph*

The Committee expressed its agreement with the principle of free and informed consent.

Dr Palacios, the Assembly's representative, thought that the Explanatory Report should be more explicit about the concept of "*informed*" consent and the content of the information to be given.

One delegation suggested also using the expression "*express consent*". Other delegations pointed out that the doctor/patient relationship should not be made too juridical: it was impossible to require a document for each of the many acts of everyday medicine.

The Chairman noted that the Committee was in favour of emphasising the need for appropriate information. What mattered was that the information should be provided; its form was of less importance. However, written information might be required by the law in the case of some acts of special importance.

- *Second paragraph*

Dr Palacios reiterated his remarks concerning the phrase *"withdraw his consent at any time"*. In a number of cases it was impossible to interrupt an intervention already under way without detriment to the patient's health. He therefore proposed deleting the words *"at any time"*. Another delegation suggested saying *"at any reasonable time"*.

Other delegations considered that the phrase *"at any time"* was useful in a general provision for emphasising that the patient retained his freedom of choice throughout an intervention. Naturally, the doctor would not have to interrupt an intervention already begun if the interruption would be prejudicial to the patient's health, as implied by Article 3 concerning the relevant professional standards.

The Committee decided to keep the second paragraph unchanged and instructed the Working Party to include the necessary particulars in the Explanatory Report.

CORED 1-3/06/93

In accordance with the instructions of the CDBI, the Working Party decided to clarify the term *"informed"* in the Explanatory Report, by indicating that the information given should stress the advantages and drawbacks of the proposed treatment and the existence of any alternative treatment, so that the person could give his consent with full knowledge of the facts.

The Working Party then carefully considered the comments of a delegation on the need for written consent, but it considered that written consent did not always provide the greatest protection for the individual's rights and that the possibility of such consent should merely be mentioned in the Explanatory Report.

CDBI 6-9/07/93

The Committee accepted this Article without amendment.

One expert observed, however, that doctors sometimes did not give their patients all available information before carrying out an intervention.

Another expert took the view that the information supplied to the patient could in some cases be limited, but that this did not impair the terms of consent.

The majority of Committee members, however, were of the opinion that the information should be as comprehensive as possible inter alia deal with the consequences of the intervention, including the possibility of failure.

Lastly, it was observed that the case of compulsory vaccinations which might be carried out without the consent of the person concerned was covered by the reference to public health in the second paragraph of Article 2.

CORED 24-27/01/94

In accordance with the decision taken by the plenary Committee at its meeting in July, the CDBI-CO-RED maintained this Article without amendment. It was suggested that Articles 5 to 10 (new Articles 5, 6, 7, 8, 9 and 17) be incorporated in a single chapter dealing with consent issues.

With regard to the Explanatory Report, the following observations would have to be taken into account:

- the adjective *"informed"* should be understood to signify that the information provided should include all the elements which could influence the person's choice, including where appropriate the alternatives to treatment and the risks of failure. Such information need not therefore be exhaustive but it had to be relevant. The information "mix" could vary in relation to the individuals concerned. In some cases, it could be supplemented by written information;

- it would be worthwhile in this context to establish a link between Article 5 and Articles 2 and 3 (new Article 26); in other words, to look at cases where the person's consent to an intervention need not be obtained;

- it might be a good idea to refer to the Explanatory Reports on the various texts prepared by the CAHBI which contained a clause relating to consent, in order to check their contents;

- it was not worth mentioning the future protocols to the Convention in this context.

CDBI 18-22/04/94

The CDBI retained this Article as it stood.

The experts agreed to add a paragraph to the Explanatory Report describing the different forms that consent might take.

CDBI 26-30/06/95

The CDBI held a detailed discussion of this Article. In particular, several delegations stressed the need to clarify the concept of *"informed consent"* by specifying the content of the information to be given to the person concerned.

Certain delegations felt that it would be useful to make it plain in the wording that the Article set forth a general principle nevertheless subject to exceptions.

Others did not consider this legally expedient because the Articles derogating from Article 6 (new Article 5) immediately followed it, and furthermore because it would be inappropriate for restrictions to appear in the text of the Article itself. The Committee agreed to take up a suggestion aiming to collect all the relevant Articles in a Chapter dealing with consent, Article 6 (new Article 5) being entitled *"general rule"*. The Convention would thereby gain in readability, and Article 6 (new Article 5) would not need to specify that there were exceptions to the general rule which it contained.

After this discussion, an alternative version of Article 6 (new Article 5) incorporating the terms suggested by another delegation was proposed:

"An intervention in the health may only be carried out after the person concerned has been given appropriate information as to the purpose and nature of the intervention, its consequences and risks, and after the person has given free consent to it".

The CDBI decided to examine at its next meeting a new Secretariat wording based upon this latter proposal.

The CDBI also considered the Parliamentary Assembly proposal that Article 6 (new Article 5) stipulate the condition not only of free and informed, but also of express and specific, consent. The CDBI agreed with the Assembly that this stipulation was necessary for certain interventions, in particular research and removal of organs and tissues. The condition of express consent would on the other hand obstruct daily medical practice as consent was always implicit for many routine medical procedures such as taking temperature, blood pressure and so on. As

for the stipulation of specific consent, the idea was conveyed in the proposed reformulation of the Article with the emphasis on information to the person concerned. However, since its coverage of all types of interventions gave Article 6 (new Article 5) a very wide scope, the CDBI agreed to retain the wording of the Article without mentioning the condition of express and specific consent which would, however, be stipulated where necessary, eg. for research and organ transplantation.

CDBI 5-7/09/95

In the first paragraph of this Article, the Committee considered it preferable to refer to *"free and informed"* consent, which is the usual expression, even though the second paragraph deals with informing the person whose consent is required.

With regard to the second paragraph, some delegations thought that the substance of the information to be given to the person concerned should be detailed in the text of the Convention. It was thus proposed by a delegation that the paragraph should be reworded as follows: *"This person shall be informed beforehand the elements which may influence his or her decision as to the purpose and nature of the intervention as well as its consequences and risks, including the risks and consequences of refusing the intervention"*.

Several participants pointed out that the expression *"all the elements which may influence his or her decision"* implied a subjective judgement of what was important to the person concerned and would be difficult to apply in practice. They added that, not only was it difficult to itemise all data without forgetting any, but such itemisation might have the effect, as was sometimes the case in North America, of encouraging defensive medicine, consisting of a multiplicity of acts designed to guard against any liability suits.

In the end, 26 delegations voted in favour of the expression *"appropriate information"* and 3 against.

By 19 votes to 2 with 8 abstentions, the CDBI also decided not to include in the text of the Convention the phrase *"including the risks and consequences of refusing the intervention"*. It was agreed, however, that the Explanatory Report might specify that the information to be supplied to the person whose consent to the intervention was required included not only the data expressly mentioned in the Article but also the risks and consequences of refusal of the intervention, as well as any alternatives to the intervention. With regard to the risks of the intervention, the information supplied should cover not only the risks inherent in the type of intervention envisaged but also individualised risks (ie risks due to the person's characteristics such as his or her age or the existence of other pathologies).

A delegation emphasised that the information supplied should be comprehensive, objective, intelligible and understood. Other participants considered that the requirement of comprehensive information was unrealistic if *"comprehensive"* meant *"exhaustive"*. On the other hand, they emphasised the importance of such information being given in the context of the doctor-patient relationship, as the provision of information in writing was not usually a substitute for that relationship. Such a requirement enabled the patient to ask the practitioner to provide further details, if he or she so wished.

After these amendments, the CDBI agreed on the text.

CORED 24-26/04/96

An expert proposed adding the words *"in particular"* in paragraph 2, which would thus read as follows:

"This person shall beforehand be given appropriate information, in particular as to the purpose and nature of the intervention as well as on its consequences and risks".

The CDBI-CO-RED noted that it had no mandate for amending Article 6 (new Article 5), which had already been adopted, and decided to keep the Article in its present wording. It nevertheless envisaged specifying in the Explanatory Report that the items of information mentioned in Article 6 (new Article 5) were not exhaustive and that informed consent might entail the provision of additional items, according to circumstances.

Article 6 (Protection of persons not able to consent)

CORED 9-12/11/92

The Working Party then examined the situation of persons who were legally incapacitated. This concerned three categories of people: minors, adults who were under legal constraint and mentally disabled adults.

Domestic legislation should provide a substitute decision-making mechanism as well as specific measures for these categories.

One expert proposed that this Article include persons who were materially or morally dependent. However, other participants felt this was not necessary.

The Working Party added a second sub-paragraph stating that the consent of minors was required if they were capable of understanding. The proposal to add the term *"also"* before *"be required"* was rejected because some experts said that in some cases the minor's own consent would be adequate. In any case the States could provide additional protection here.

The wording of the whole Article was only provisional and could include other aspects.

CDBI 24-27/11/92

With regard to Article 6, paragraph 2, the majority of the Committee was prepared to accept the idea reflected in this provision provided the provision was reworded. The delegations put forward proposals to this effect, which the Working Party would take into account. One delegation suggested inter alia that Article 6 paragraph 2 be worded as follows: *"In any case, if the minors are capable of understanding, their consent must be sought, without prejudice to the option Parties have of stipulating that, in some cases, such consent must be obtained"*.

CORED 14-16/12/92

The Working Party examined the proposal made by a delegation at the last CDBI meeting concerning Article 6, paragraph 2.

The experts noted that with regard to minors, two ideas should be stated. Wherever possible, the minor should be involved in the decision-making process, in other words consulted. Furthermore, in certain cases, to be prescribed by national law, the minor's prior consent to the intervention should be obtained for it to be permissible. This second eventuality would depend in particular on the type of intervention and the minor's age and ability to understand. One participant stressed that for the intervention to be permissible, the minor must not have objected to it.

In this connection, the Secretariat was instructed to keep the Working Party informed of progress in the activities of the Working Party of the Committee of Experts on Family Law (CJ-FA) responsible for preparing a draft Convention on the exercise of rights by persons below the age of 18.

At a more general level, the Working Party noted that two different situations should be distinguished in Article 6: persons incapable of understanding and persons momentarily or more lastingly deprived of their judgement by a circumstance such as a coma. The Working Party considered it expedient that the Explanatory Report to the Convention should clearly indicate the relevance of Article 6 to both these situations.

As to presentation, the experts suggested reversing the order of Articles 5 and 6 to make it clear that the Article concerning emergency situations also applied to legally incapacitated persons.

CORED 8-12/03/93

The Working Party listed the categories of persons for whom an exception to the general principle of free and informed consent should be allowed.

In this connection, and in line with the suggestions made by Dr Palacios, mention was made of legally incapacitated persons, that is to say minors and adults recognised as lacking legal capacity, as well as adults who, though legally capable, are incapable of understanding.

The Working Party decided that interventions could be carried out on such persons only under protective conditions provided for by national law, conditions which included the consent of the legal representative of the person concerned or of a competent authority.

The experts added another condition, namely that the intervention should directly benefit the person concerned.

The Working Party then considered whether or not an exception to this condition should be authorised; in other words, should interventions be authorised, under certain conditions, on persons incapacitated in law or in fact, when they would derive no direct benefit therefrom? It was pointed out that the authorisation of interventions only in cases of direct benefit to the persons concerned would exclude non-therapeutic research on those persons as well as the removal of organs, while for the time being the Protocols under preparation did not prohibit such interventions but laid down guidelines for them.

Conversely, one expert cited Article 7 of the International Covenant on Civil and Political Rights which provides that no one shall be subjected without his free consent to medical or scientific experimentation. The expert recalled that, in the preparatory documents of the Covenant, it had been proposed by that means to ban non-therapeutic research on minors.

The Working Party decided to refer the question of principle to the CDBI: should non-therapeutic research and removals of organs be authorised in respect of legally incapacitated persons and persons who, though legally capable, are incapable of understanding?

The experts decided that the third paragraph of Article 6 should stipulate that the legally incapacitated persons referred to in the first paragraph, who were not able to give their consent, should nevertheless be involved, as far as possible, in the consent procedure. That meant, for example, that it would be necessary to explain the intervention to the person who was to undergo it and to obtain his/her opinion, even if it was not the deciding factor. The Explanatory Report could point out that this was desirable irrespective of the strict legal position.

The Working Party decided that adults who were capable of understanding, though legally incapacitated, should be required to consent to the intervention in order for it to be able to take place, as a means of ensuring respect for the principle of personal autonomy.

Lastly, the participants stressed that the consent of a minor should increasingly be taken into consideration as he advanced in age and capacity of understanding, in accordance with Article 12 of the United Nations Convention on the rights of the child.

CDBI 27-30/04/93

- *First paragraph*

The Committee agreed to keep the three categories of legally incapacitated persons referred to in this provision: minors, legally incapacitated adults and de facto incapacitated adults.

The following observations were made:

- A delegation thought that the third category (de facto incapacitated adults, ie those unable to understand and take a decision) should be divided into two sub-categories, viz:

  3 a. persons permanently incapacitated (eg persons suffering from senile dementia);

  3 b. persons temporarily incapacitated (eg road traffic victims who lost consciousness);

- The same delegation also suggested using the word *"assent"* instead of *"consent"* in the case of minors.

- Another delegation thought that this provision was unwieldy as it covered widely differing categories of incapacitated persons and enunciated several conditions. The delegation suggested treating the different categories of incapacitated persons separately.

- Another delegation thought that the legal representative's consent should be expressly mentioned, as the implicit reference *"protective conditions approved by national law"* was not sufficient.

- *Second paragraph*

This latter delegation felt that the consent condition should be supplemented by a reference to the protective conditions approved by the law.

The Committee approved the substance of the other provisions of Article 6 and instructed the Working Party to consider the possibility of dividing the Article into several articles.

CORED 1-3/06/93

The Working Party considered the various proposals made at the CDBI meeting.

The experts decided to divide Article 6 into two articles for the sake of easier readability and, hence, accessibility.

With regard to the terminology used and as far as de facto incapacity was concerned, the Working Party agreed with the Co-ordinator that the phrase *"persons who, though legally capable, are incapable of understanding"* was vague. The experts therefore decided to use the phrase *"persons who, though legally capable, have a reduced capacity of understanding"*.

With regard to the proposal of a delegation to divide the category of persons suffering from de facto incapacity into two sub-categories (persons temporarily or permanently incapacitated), the Working Party decided to refer that question to the CDBI for a decision on the desirability of making such a distinction in the actual text of the Convention.

The same delegation also proposed that the term *"assent"* should be used instead of *"consent"* in the case of minors. One expert supported that idea because he did not think it desirable for the term *"consent",* which referred to free and informed consent, to be applied to minors and incapacitated adults. The same expert thought that the term *"consultation"* would be even more appropriate in the case of minors. Another expert, however, considered that the idea conveyed by the term *"assent"* was contained in the third paragraph of Article 6 and the second paragraph of Article 7, but that the word *"consent"* was more appropriate.

The Working Party endorsed the latter opinion by majority and accordingly decided to retain the term *"consent"*.

The Co-ordinator observed that the current wording left unsolved the problem of the conflicting wishes of a minor and his legal representative. In other words, what happened when a minor capable of understanding gave his consent to an intervention, while his legal representative refused, or vice versa?

While noting the relevance of this remark, the Working Party took the view that only national legislation could resolve any such contradiction.

With regard to a delegation's position that the legal representative's consent should be expressly mentioned in the first paragraph of Article 6, the Working Party considered that this was not necessary and that it was sufficient for this point to be mentioned in the Explanatory Report.

The Working Party went on to examine a contradiction between the second paragraph of Article 6 of the Convention and the Protocol on organ transplantation. Indeed, Article 6 of the Convention required that interventions on incapacitated persons should be carried out for their direct benefit. Exceptions to the principle of direct benefit were possible only when the risk incurred by the incapacitated person was a minimal risk.

On the other hand, the Protocol on organ transplantation authorised the removal of organs from incapacitated persons. However, removal was an intervention which was carried out for the benefit not of the incapacitated donor but of the recipient, and which frequently entailed, for the donor, a greater than *"minimal risk"* (if only because of the general anaesthetic which was often necessary).

The Working Party therefore decided to reword the Article to take account of this contradiction between the Convention, which required that interventions not directly benefiting the incapacitated person should present only a minimal risk, and the Protocol on organ transplantation which authorised an incapacitated person to act as an organ donor despite a greater than minimal risk.

However, the Working Party disagreed with the Protocol on organ transplantation which authorised removals from legally incapacitated persons under certain conditions but required no close personal or family relationship between the incapacitated person and the recipient, since the transplantations concerned were of bone marrow or other regenerative tissues.

The Working Party decided therefore to adopt a form of words restricting the possibility of removal from incapacitated persons to cases where the recipient was a close relation or friend of the incapacitated person. The CDBI would therefore be required to take a decision on the question whether a removal from an incapacitated person could be carried out for the benefit of any recipient or whether the latter should be a close relation or friend of the incapacitated person.

The new wording adopted specified the cases where the condition of direct benefit could be waived, namely cases of research and organ transplantation.

The Working Party accordingly expressed itself in favour of the following text for the second paragraph of Article 6:

"Exceptionally, for research purposes in the health field representing a minimal risk or burden for the individual or for purposes of transplantation of regenerative tissues between close relations and friends, national law may authorise non-beneficial interventions on incapacitated persons, in cases where there is an overriding interest, provided that sufficient protection is guaranteed and that there is no possible alternative subject nor any equally effective alternative method".

With regard to the third paragraph of Article 6, the Working Party favoured the replacement of the word *"should"* by *"shall",* since the conditional mood was sufficiently expressed by the phrase *"as far as possible".*

CDBI 6-9/07/93

The CDBI accepted the first paragraph of Article 6 without amendment.

With regard to the second paragraph, the following problems arose.

First of all, the members of the CDBI-CO-RED had expressed the view that the removal of an organ from an incapacitated person should only be carried out for the benefit of a close relation or friend. However, this position was at variance with the provisions of the Protocol on organ transplantation, Article 6 of which laid down no requirement of a relationship between an incapacitated donor and a recipient, since the transplantation concerned regenerative tissues.

The Working Party had therefore referred to the CDBI the question whether a removal from an incapacitated person could be carried out for the benefit of any recipient or whether the latter should be a close relation or friend of the incapacitated person.

The Committee decided by 14 votes to none, with 5 abstentions, to allow such a restriction.

However, a debate ensued on the scope of the restriction: should there be a close personal or family relationship between the incapacitated donor and the recipient, or should the restriction be ever narrower, requiring a family relationship between the two persons concerned?

Thirteen delegations were in favour of the requirement of a close personal or family relationship; 7 were in favour of a family relationship exclusively and there were 2 abstentions.

In the text of the Convention, the phrase *"close relations and friends"* was therefore replaced by *"persons having close personal or family relations"*.

Secondly, some delegations wondered about the concept of overriding interest which justified the application of national law.

With regard to research, it was observed that this concept limited non-therapeutic research on incapacitated persons.

Another delegation felt that, while the concept of overriding interest was understandable in relation to research, it was less clearly relevant to the subject of organ transplantation where there was always an altruistic interest in improving the state of health of another person.

In order to clarify this expression in relation to organ transplants, it was decided to include in the Explanatory Report the text of the third paragraph of Article 9 of the Protocol on organ transplantation which required that no organ should be removed when the risk to the health of the donor was disproportionate in relation to the expected benefit to the recipient, and to make it clear that, in the case of incapacitated donors, the proportionality rule required the expected benefit to the recipient to be particularly great.

Thirdly, with regard to the stipulation that there should be no possible alternative subject, the addition of a clarifying phrase was suggested: *"no possible alternative subject possessing full legal capacity"*.

Fourthly, one delegation proposed inserting the phrase *"or group of subjects"* after *"another subject"*.

Finally, the CDBI accepted a proposal to change the textual position of the third paragraph of Article 6, making it the first paragraph of Article 7 (Consent of incapacitated persons).

The Co-ordinator reminded the CDBI of the comment he had made at the meeting of the Working Party, namely that the current wording of Article 7 left unsolved the problem of the conflicting wishes of a minor and his legal representative.

In this connection, the CDBI accepted the position of the Working Party which, while noting the relevance of this remark, had taken the view that only national legislation could resolve any such contradiction.

However, several delegations considered that it would be necessary to explain in the first paragraph of Article 6 that the protective conditions approved by national law included the consent of the legal representative.

Other experts observed that not all countries allowed legal representation for all the circumstances envisaged by the Article.

In order to emphasise the fact that protective conditions applied to consent, one delegation proposed the following wording for the new first paragraph of Article 7 (former third paragraph of Article 6): *"The individual undergoing the intervention shall, as far as possible, be involved in the consenting procedure under protective conditions approved by national law"*. The delegation in question felt that the protective conditions referred to in the first paragraph of Article 6 would concern cases where an intervention could be carried out on an incapacitated person, whereas in Article 7 they would concern consent and would cover the consent of the legal representative, where necessary.

The Co-ordinator proposed an alternative solution, namely the insertion of the following additional paragraph in Article 7: *"National law shall determine the conditions of consent applicable to incapacitated persons."*

Other experts favoured keeping the text unchanged.

The CDBI decided therefore to return to this question at its next plenary meeting in order to give delegations time to consider the problem. However, the Working Party would examine the problem at its September meeting, and for that purpose delegations were invited to transmit any suggestions to the Secretariat.

With regard to the second paragraph of Article 7 concerning the consent of minors, several delegations considered that the criterion of the seriousness of the intervention should be added to that paragraph: in other words, the more serious the planned intervention, the greater should be the requirement of the minor's consent. A vote was taken and the result was six delegations in favour of adding this criterion, five against and eleven abstentions. Accordingly, the CDBI referred the question to the Working Party for more detailed consideration.

CORED 24-27/01/94

The first paragraph of this Article remained unchanged in accordance with the decision of the CDBI.

With regard to the second paragraph, the Secretariat wondered about the merits of the proposal to authorise the removal of regenerative tissue from an incapacitated person for the benefit of a person with whom he had merely close personal relations. Would it not be more desirable to limit the exception to cases where there was a family relationship between the incapacitated donor and the recipient? The exact scope of the exception on behalf of a recipient having close personal relations with the donor was not very clear.

Other participants recalled the decision taken by the plenary CDBI at its July meeting, when it had expressed itself in favour of the requirement of a close personal or family relationship.

The Working Party reworded this paragraph in order to make it more readable without, however, altering its meaning. Account was also taken of the suggestion made by one delegation at the July meeting, which was to insert the phrase *"or group of subjects"* after *"another subject";* the new wording for the paragraph concerning research on incapacitated persons used the expression *"other subjects possessing full capacity"*.

The Working Party considered the alternative proposals put forward at the plenary meeting in July, one of which was to insert the phrase *"under protective conditions approved by national law"* in the first paragraph of the Article, while the other called for the insertion of the following additional paragraph in the Article: *"National law shall determine the conditions of consent applicable to incapacitated persons"*.

The members of the Working Party considered that it was sufficient for the first paragraph of Article 6 to refer to protective conditions prescribed by national law, as those conditions included, where appropriate, the consent of the legal representative or the authorisation of a court. The Working Party did not therefore see any need to add this condition to Article 7 (Consent of incapacitated persons).

The CDBI had asked the CDBI-CO-RED to consider the advisability of adding the criterion of the seriousness of the intervention to the paragraph concerning the consent of minors.

The Working Party examined this question, but agreed that the criterion concerned was already implicitly covered by the text and that it was not necessary to spell it out.

The experts also discussed whether the term *"consent"* was appropriate in relation to a minor. One expert noted that the text was concerned with the legal effects of such consent.

Following this exchange of views, the Working Party decided to retain the expression *"the consent of minors",* as the term *"consent"* carried the twofold connotation of assent or refusal.

The CDBI-CO-RED also looked at the observations submitted by a representative, concerning Articles 6 and 7.

With regard to the title of Article 7, the Working Party noted that the problem would be solved if Articles 5 to 10 were grouped together in a single chapter entitled *"Consent issues"*.

Regarding comments on the consent of the legal representative and the authorisation of a court, the experts observed that the situation was covered by Article 6 paragraph 1 which referred to *"protective conditions approved by national law"*.

Lastly, at the suggestion of the Secretariat, the CDBI-CO-RED reversed the order of the second and third paragraphs in order to graduate the effects of the opinion of incapacitated persons. Thus the first paragraph required the individual to be involved. The second paragraph made the consent of minors an increasingly determining factor and the third paragraph established the consent of legally incapacitated adults who were capable of understanding as an essential requirement.

CDBI 18-22/04/94

The CDBI agreed on the content of this Article and slightly amended its wording, replacing the phrase *"national law may authorise"* by "*in accordance with national law*", in thus avoiding the implication that a formal law is necessary.

One delegation pointed out that the words *"un risque et une charge minimaux"* in the French text were slightly clumsy, and proposed that they be replaced by *"un risque négligeable et une contrainte minimale"*. This proposal was referred to the CDBI-CO-RED to be studied in detail, the criteria of *"risque minimal"* and *"risque négligeable"* seeming at first sight not to be identical.

The CDBI agreed on the substance of this Article, but amended the French version of the text, replacing the phrase *"être impliquée dans la procédure de consentement"* by "*être associée à la décision*".

CORED 30/05-2/06/94

The CDBI-CO-RED examined the expression *"where there is an overriding interest"* in the second paragraph of this Article. Participants agreed that it was less than clear and could give rise to confusion. It was therefore decided to replace it with the phrase "*where a significant benefit may be derived*", which had the advantage of being more specific and of having been used in other international texts.

With regard to research, the experts considered the question whether one of the criteria for the authorisation of research should be the existence of a "*minimal risk*" or rather a "*negligible risk*". The Working Party decided that, in the case of non-beneficial research on incapacitated persons, the strictest criterion should be selected in order to ensure the protection of such persons. The Working Party consequently adopted the concept of "*negligible risk*".

CDBI 27/06-1/07/94

The CDBI examined this Article in the light of the comments submitted by a delegation. This delegation drew the Committee's attention to the following problems:

- the expression *"legally incapacitated persons"* gave rise to problems because it was difficult to find a corresponding term in German and there seemed to be a risk of confusion between incapacitated persons and handicapped persons, which could include physically handicapped persons as such. It was therefore proposed that it be replaced by *"persons who have no legal capacity to give consent"*. The Secretariat supported this proposal: the notion of incapacity being relative (minors, for example, were legally incapacitated for a contract of sale of real estate, whereas they might be considered to be capable for certain transactions in personal or family life), the type of incapacity concerned should be stated. In the opinion of several delegations however, it was necessary to maintain the two notions of legal and de facto incapacity.

- the principle in research should be that research could be undertaken on an incapacitated person only if a direct personal benefit for this person was to be expected. The exceptions to this principle must strictly set the conditions for the protection of the incapacitated person;

- the value of research which did not directly benefit the incapacitated person should clearly appear in the text of the Article. In other words the Article should state that in the case of research which was not for the

direct benefit of the incapacitated person, significant benefit for the group of persons to which he or she belongs must be expected. This clarification would strengthen the protection of incapacitated persons.

- it would be desirable to combine Articles 6 and 7 into a single article, in order to bring together the provisions relating to the incapacitated person's consent and the conditions relating to his or her protection.

It was also pointed out that the present draft did not deal with the question of objection by the incapacitated person, whereas Recommendation R (90) 3 of the Committee of Ministers stated in Principle 5, *"... national law may authorise research involving a legally incapacitated person which is not of direct benefit to his health when that person offers no objection..."*.

The CDBI noted these comments and admitted their pertinence. The Committee decided for the time being not to amend the Article, but to discuss it again in detail at its next meeting, after the necessary consultations. It was therefore agreed to put several parts of this Article between brackets in order to draw attention to the fact that the wording of this text was still provisional. A footnote would give the necessary explanations.

CDBI 26-30/06/95

The CDBI examined the Article, completely rephrased by the CDBI-CO-RED. It approved of the Working Party's decision to set the question of consent apart from that of research and organ transplantation. The CDBI also agreed that it was advisable to include one paragraph concerning minors and another concerning adults unable to consent, thereby enhancing the clarity of the text.

The CDBI agreed that the incapacity to which this Article referred should be understood as relating to a given intervention. This was in line with the preoccupation that only for acts genuinely necessitating it should a person be deprived of his self-determining capacity (see conclusions to the 3rd European Conference on Family Law, April 1995). The Committee nevertheless took into account the diversity of legal systems in Europe: while in some countries the inability to consent must be verified for every single intervention, the rules in force in other states were founded on the institution of legal incapacity, ie. a declaration of a person's incapacity with more or less general effect (according to the legal incapacity technique, a person may be declared incapable of consenting to one or more classes of acts).

As the Convention's aim was not to institute standard European legal rules on incapacity but to protect persons designated by domestic law as unable to consent, reference to domestic law for the determination of incapacity appeared necessary; domestic law must determine, by its own distinctive technique, whether or not a person was capable of validly consenting to an intervention. On that basis, the Convention laid down a series of protective rules.

The CDBI therefore agreed that the definition of incapacity should be derived from domestic law (understood as constituting the legal system as a whole and thus encompassing statute law, case law and possibly custom). However, in the opinion of several delegations, the paragraph concerning adults should state the grounds (illness or mental disability) for depriving a person of his/her capacity to consent to the intervention; this would safeguard the fundamental rights of the human person. In addition, domestic law should be induced to associate the person in the process of decision, even if incapacitated.

One delegation considered it necessary to stipulate, as in the July 1994 version, the consent of adults capable of understanding though incapacitated; another delegation saw no need to mention general legal incapacity at that point because it did not enter into the concept of incapacity understood as specific to each intervention.

The CDBI further considered it unnecessary to include in the Article a provision, such as the paragraph in the CDBI-CO-RED draft, on the right to appeal against the legal representative's decision. Indeed, according to the letter of the first two paragraphs of the Article, no intervention may be performed *"without the authorisation of the representative or an authority or any person or body provided for by law"*, already implying a possibility of appeal to an authority; moreover, Article 21 (new Article 23) and the provisions of the European Convention on Human Rights made adequate legal protection arrangements.

Following the discussion, and taking into account the numerous comments by the delegations, the Secretariat proposed that the Article be reformulated as follows:

Article 7 (new Article 6) (Persons not able to consent)

1. Where, according to law, a minor does not have capacity to consent to an intervention, the intervention may not be carried out without the authorisation of his or her representative or an authority or any person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor, in proportion to his or her age and degree of maturity.

2. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or any person or body provided for by law.

The person concerned shall as far as possible take part in the [decision] [authorisation procedure]. [The consent of an adult capable of understanding is required even if he or she is legally incapacitated].

3. The representative or authority mentioned in the preceding paragraphs shall be given, under the same conditions, the information referred to in Article 6 (new Article 5). [They shall act in the [best] interests of the person concerned].

Article 7 bis (Protection of persons not able to consent)

No intervention may be carried out, subject to Articles 16 (new Article 17) and 18 (new Article 19) paragraph 4 below, on a person who does not have the capacity to consent, except for his or her [direct] personal benefit."

Remarks: Bold type is used for words not appearing in the version proposed by the CDBI-CO-RED. Phrases in square brackets were suggested by one or more delegations and have not yet been decided upon by the CDBI. The terms of paragraphs 1 and 2 have been harmonised. In either case, the incapacity meant is incapacity with regard to a specific intervention, relying on domestic law to determine capacity or incapacity to consent. It is proposed to collect in Article 7 (new Article 6) the provisions concerning the consent of minors and adults, together with those concerning the representative and, considering that the rule of direct benefit does not involve consent, to place it in a separate article where it would be more conspicuous.

CDBI 5-7/09/95

The CDBI considered this Article in conjunction with draft Article 7 bis.

The Committee thought it was preferable to make the text of Article 7 bis the first paragraph of Article 7 (new Article 6). It was also considered advisable to use in this new paragraph 1 the expression *"direct benefit"*, as it is more customary than *"personal benefit"*.

With regard to the third paragraph, relating to persons having reached the age of majority, 21 delegations to 4 (with 1 abstention) voted in favour of enumerating the reasons for which a person could be regarded as not having capacity to consent. Such an enumeration was considered to make for greater protection of the individual by specifying the only grounds on which an individual could be deemed unable to consent. The expression *"or for similar reasons"* refers to such situations as an accident or conditions in which the patient cannot formulate or communicate his or her will.

A delegation pointed out that the second paragraph, relating to minors, should also mention the grounds on which a minor could be deprived of capacity to consent, as age was not the only conceivable ground, albeit the most common one. However, the Committee was unable to accept this proposal for the text of the Convention itself, though it did note that the Explanatory Report might provide some examples, (such as a mental disability in an adolescent), where factors other than age might result in a minor being regarded as unable to consent to an intervention.

The same delegation, referring to the use of the term *"law"*, wondered whether it would not be better to refer to *"national law"*. The CDBI noted that, with one exception, *"law"* was the term routinely used by the European Convention on Human Rights. In the opinion of the European Court of Human Rights, the term should be construed broadly as denoting a state's internal legal system, with the inclusion not only of statutes, regulations, customs and case law but also any international texts, such as Community law, that had been incorporated in the system. It therefore seemed desirable to use this term in the text of the draft Bioethics Convention.

By 22 votes in favour, with 5 abstentions, the CDBI agreed to add to this Article a paragraph on withdrawal of authorisation so as to establish a parallel with the third paragraph of Article 6 (new Article 5), which enables a capable person to withdraw his or her consent at any time. The CDBI nevertheless decided, by 20 votes to 5 with 4 abstentions, to limit this option by stipulating that authorisation could be withdrawn only in the best interests of the person concerned.

CDBI 20-22/11/95

a. As to the term "intervention"

Article 6 (new Article 5), the opening provision of Chapter II, employed the expression "*intervention in the health field*". To the extent that this Article formed the general rule on consent, the CDBI considered that the word intervention, where used in the following Articles of that Chapter, was to be similarly construed as intervention in the health field.

The Explanatory Report (para. 53) in any case adequately defined the situations covered (see also, with reference to Article 7 (new Article 6), paragraph 65 of the Explanatory Report).

b. As to the expression "direct benefit"

Regarding the proposal to replace the expression *"direct benefit"* by *"best interests"*, it was pointed out that the latter was less precise and consequently afforded less protection. By 23 votes to 1 (with 7 abstentions), the Committee decided to retain the expression "*direct benefit*".

c. As to paragraph 5

Regarding the proposed deletion of this paragraph, the CDBI decided by 29 votes to 1 (with 2 abstentions) that it should stand.

The CDBI further considered it unnecessary for the person or body with authority to withdraw authorisation to be identified at this point. It would rest with national law to define the correct procedures of decision and appeal for the various persons concerned (the patient, the legal representative, the doctor, etc). In that respect, paragraphs 2 and 3, supplemented by paragraph 5, were worded with sufficient flexibility to be applicable to the various possible situations.

d. As to the whole of Article 7 (new Article 6)

The Committee adopted Article 7 (new article 6) as a whole by 30 votes in favour and none against, with 2 abstentions.

Article 7 (Protection of persons who have mental disorder)

CORED 8-12/03/93

The Working Party decided to include a new Article in the Convention to deal with the problem of patients suffering from a mental illness who were required to undergo compulsory treatment for that illness.

The experts pointed out that this Article applied to persons who, though suffering from mental illness, were capable of understanding the intervention and its implications and could therefore give their consent.

The Article thus enabled doctors to disregard the refusal of such patients to undergo the intervention in question, but only in relation to the treatment of mental illness when there was a serious risk to their health, and on the basis of respect for the protective conditions defined by national law.

One expert said that the intervention should be confined to what was strictly necessary for the protection of a patient's health. In other words, if the patient refused an intervention not designed to treat his mental illness, his objection had to be respected, regardless of the consequences.

The experts decided to include a reference in the Explanatory Report to the Hawaii Declaration of the World Psychiatric Association of 10 July 1983, in accordance with the proposal made at the previous meeting.

The Working Party pointed out that it would be desirable, in its view, to prepare a protocol on this question.

CDBI 27-30/04/93

The Committee accepted the principle laid down in this Article.

It was nevertheless agreed that the Working Party should take account of the following remarks:

- It should be specified whether mental illness denoted mental disabilities or only psychiatric treatment.

- It should be stated in the Explanatory Report that the reason why this Article was confined to cases of risk to the patient's health was that the danger to others was already covered in Article 2.2 (new Article 26.2).

An observer proposed the following wording:

"Where there is a higher interest and a court has ordered a diagnosis or treatment, a patient who cannot decide what is in his interests may be subjected to an intervention without his consent on conditions stipulated by national law, provided that:

- there is little likelihood of his health improving without treatment;

- such treatment improves his health and is not a danger to him; and

- there is no other method of comparable effectiveness.

The protective conditions should include monitoring and appeal procedures."

CORED 1-3/06/93

Following the comments of the CDBI, the Working Party pointed out that the term *"mental illness"* within the meaning of Article 10 (new Article 7) covered only treatment of psychiatric illness. Furthermore, in accordance with the CDBI's wishes, it would be specified in the Explanatory Report that the reason why this Article was confined to cases of risk to the patient's health was that the danger to others was already covered by the second paragraph of Article 2 (new Article 26.2).

In accordance with the wishes of the CDBI, the Working Party carefully considered the wording proposed for Article 10 (new Article 7) by an observer. The experts nevertheless considered that it was more desirable to maintain the current wording of the Article, inasmuch as there was no reason for court intervention in such cases and this solution would hardly be workable in practice.

CDBI 6-9/07/93

One delegation wondered about the relationship between this Article and Article 7 (new Article 6) .

It was explained that Article 10 (new Article 7) concerned persons capable of giving their consent but that doctors were given the possibility, under certain conditions, of disregarding the refusal of the persons concerned *"where, without treatment for this mental illness, serious harm is likely to result to their health"*. One delegation raised questions about that part of the Article.

The CDBI noted that the Working Party had decided to restrict the scope of the Article to persons suffering from a mental illness, but the Committee decided to extend it to persons with mental disorders. In this connection, it was noted that alcoholics and drug addicts might be included in the category of persons suffering from mental disorders and could therefore come within the field of application of this Article.

One participant suggested that consideration should be given to Recommendation N° R (83) 2 on protection of persons suffering from mental disorders placed as involuntary patients.

CORED 24-27/01/94

The CDBI-CO-RED adopted this Article without amendment.

However, the Working Party raised questions about the concept of *"mental disorder",* particularly insofar as it related to alcoholism or drug addiction.

Most members of the Working Party thought that alcoholics and drug addicts did not automatically come within the field of application of Article 10 (new Article 7) on account of their alcoholism or drug addiction. On the other hand, alcoholism and drug addiction could impair the mental faculties of certain persons and thus lead to the application of Article 10 (new Article 7). In other words, Article 10 (new Article 7) was made applicable by the existence of mental disorders which prevented the individual from deciding what was in his best interests, irrespective of the origin of those disorders: illness, old-age, alcoholism or drug addiction.

One participant expressed doubts about this interpretation which did not allow care to be given to an alcoholic or a drug addict against his will, whereas deprivation of liberty was authorised by Article 5 of the European Convention on Human Rights.

CDBI 18-22/04/94

The CDBI, while agreeing on the substance of this Article, amended its wording in order to make it clear that the Article made it possible to proceed without the consent of a person afflicted by mental disorders, but capable of understanding, only in respect of intervention for the purpose of treating the said mental disorders.

The CDBI decided not to make an explicit reference in the Explanatory Report to the case of alcoholics or drug addicts, to whom Article 10 (new Article 7) might apply insofar as they suffered from mental disorders (7 votes for an explicit reference, 16 against and 2 abstentions). The CDBI took the view that it was preferable to state clearly that this Article would be applied on the grounds of mental disorders from which a person suffered, whatever the origin of those disorders.

CDBI 5-7/09/95

A delegation was doubtful about the relevance of this Article, which seemed to offer no additional protection to the person concerned.

The majority of the CDBI, however, thought that the Article was necessary, as it protected individuals suffering from a mental disorder in that the number of cases in which the disorder could be treated without the person's consent was limited by the subjection of treatment to precise conditions. In the Common Law countries, a person suffering from a mental disorder was not often regarded as generally incapable of consenting to an intervention; in respect of the Common Law system, Article 8 (new Article 7) strictly limited compulsory treatment while maintaining the general presumption of capacity. In the case of several continental countries governed by a system of legal incapacity accompanied by guardianship or administration ("tutelle", "curatelle"), Article 8 (new Article 7) added further protection to that resulting from guardianship by limiting the possible cases of compulsory treatment of mental disorders. Article 8 (new Article 7) was thus effective in respect both of the Common Law systems and of the continental systems, as, on the one hand, it protected the individual's health (insofar as compulsory treatment was acceptable when the absence of such treatment would be seriously detrimental to the individual's health) and, on the other, it protected the individual's autonomy (insofar as compulsory treatment was precluded whenever the absence thereof did not involve a serious health risk).

After examining the terms of this Article, the CDBI decided by 13 votes to 7 (with 9 abstentions) to delete the phrase *"whose ability to decide what is in his or her best interests is severely impaired"*. The reason for this was that, although the ground for intervening without the person's consent was the fact that he or she was incapable of grasping the need for treatment, the phrase might suggest that the person was incapable in general of understanding and consenting, whereas persons suffering from a mental disorder often understood the significance of medical interventions except that of the very ones aimed at treating their own disorder. The Committee therefore agreed to refer in this Article to "a person who has a mental disorder of a serious nature" while deleting the above-mentioned phrase.

Two delegations proposed rewording the text as follows:

"Only under protective conditions prescribed by law including supervisory, control and appeal procedures a person suffering from a mental disorder of a serious nature which is without treatment likely to result in serious harm to his or her health, and he or she is therefore not able to consent he or she may be subject to an intervention aimed at a necessary treatment of this mental disorder."

Several participants were against this wording as the person concerned was not necessarily incapable of consenting.

Following this discussion, the CDBI proposed to re-examine the following wording at its next meeting:

"Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating the disorder only where, without such treatment, serious harm is likely to result to his or her health".

CDBI 20-22/11/95

a. As to the principle of Article 8 (new Article 7)

A few delegations thought the Article should be removed pending progress in the work of the ad hoc Committee on Psychiatry and Human Rights (CAHPS). Some among them also considered that the problem addressed in Article 8 (new Article 7) could be adequately dealt with under national law.

The majority of the Committee (25 votes in favour and 2 against, with 4 abstentions) felt that the principle of Article 8 (new Article 7) was necessary to the Convention insofar as it afforded essential protection in the cases not governed by Articles 7 (new Article 6) (incapacity) or 9 (new Article 8) (emergency situations).

b. Treatment of a somatic complaint

Article 8 (new Article 7) permitted treatment without consent for the purpose of treating a *mental disorder*, an expression regarded as unduly restrictive by a delegation which therefore proposed that it should be possible for such treatment to extend to somatic complaints where non-treatment would be liable to imperil the life or health of patients suffering from mental disorders. Other delegations endorsed this opinion and suggested devising formulae which would take in such diseases; one proposal referred to "*mental and physical disorders*".

The CDBI considered that the situations of risk to the physical health of mentally ill persons were already provided for either under Article 7 (new Article 6) (authenticated inability to consent) or under Article 9 (new Article 8) (emergency situations), Article 8 (new Article 7) being of use precisely in cases where the person, though theoretically capable of consenting to a physical intervention, was incapable of understanding the need for strictly psychiatric treatment.

The Committee accepted the proposal of the Chairman of the CDBI-CO-RED, to include the following paragraph in the Explanatory Report under Article 8 (new Article 7):

"A number of member States have legislation on treatment of patients in administrative internment suffering from serious mental illness and also an urgent medical condition which puts their lives in danger, for example a woman with a serious psychotic disorder who undergoes interruption of an extra-uterine pregnancy. In such a situation the law permits treatment with the object of preserving life, in this case surgery, provided that the practitioner concerned is convinced that such action is in order. This procedure is covered by Article 7 (new Article 6) or Article 9 (new Article 8) of the Convention".

c. Treatment in a criminal justice framework

A delegate recapitulated his observations embodying the request that the Article provide for court-ordered psychiatric treatment of an accused person who, failing such treatment, would be unfit to stand trial, with the object of enabling the accused to make a proper defence. He pointed out that the law of his country attached a large number of safeguards to court-ordered treatment.

The CDBI agreed that such treatment, intended not to ward off a serious danger to the health of accused persons but to enable them to recover their faculties, memory in particular, for the purpose of defending themselves in criminal proceedings, was outside the scope of Article 8 (new Article 7).

On the other hand, it came within the scope of Article 3 (new Article 26) where specific reference was made to necessary measures for the fair administration of justice *("prevention of crime")* which, in a democratic society, included the defence of the accused. The Committee agreed that the Explanatory Report should mention such treatment in the above terms under Article 3 (new Article 26).

Article 8 (Emergency situations)

CORED 9-12/11/92

This Article concerned interventions in the case of patients who were not able to give their consent.

It provided an exception from the requirement for the patient's consent only in cases where the latter's own health was involved. It therefore fell within the field of the individual's subjective rights. It therefore differed from sub-paragraph 3 of Article 4 (new Article 26) which applied at collective level and set out exceptions to individual rights for the purposes of the protection of public health and the rights of others.

The experts emphasised that a derogation of this kind was only permissible in the case of interventions which were strictly necessary in medical terms.

CDBI 24-27/11/92

One delegation pointed out that the provisons of the two paragraphs of Article 5 (new Article 8) could conflict and that the question arose whether the wishes of patients should always be respected when they were known. It also touched on the problem of a change in circumstances between the time when the patient expressed his point of view and the time when his opinion needed to be ascertained for an intervention in an emergency situation.

After discussion as to the deletion of paragraph 2 of Article 5 (new Article 8), the Committee finally decided to maintain that Article unchanged.

CORED 8-12/03/93

With regard to emergency situations, the experts decided to make it clear that this Article applied both to persons normally capable of giving their consent and to the legally incapacitated. For this purpose, it was decided to place this Article after Articles 5 and 6.

In addition, the experts adopted the formula "When because of an emergency situation the appropriate consent cannot be obtained ...", thereby referring to the consent of the person who is to undergo the intervention if he possesses legal capacity or the consent of the legal representative if he is legally incapacitated. In other words, in this situation, the appropriate consent procedure cannot be followed.

It was also pointed out that the phrase *"the appropriate consent cannot be obtained"* meant that such consent was not available and was not at all intended to make it possible to disregard a refusal.

Examples of emergency situations might include a state of coma afflicting the person required to consent to the intervention or the impossibility of contacting the legal representative of a legally incapacitated person on whom on an intervention was to be carried out.

The Working Party examined amendment N° 8 by Dr Palacios but thought that the Article was not applicable exclusively to situations of absolute and vital emergency.

CDBI 27-30/04/93

The Committee approved this Article. It was agreed that the Explanatory Report should define the expression *"immediate benefit"* as being something that needed to be done straight away (even if the benefit did not become apparent until later).

CORED 1-3/06/93

The Working Party took note of the instructions of the CDBI and would therefore define the expression *"immediate benefit"* in the Explanatory Report as referring to something that needed to be done straight away (even if the benefit did not become apparent until later).

CDBI 6-9/07/93

The CDBI noted that the Working Party, in accordance with the instructions it had received, had decided to define the expression *"immediate benefit"* in the Explanatory Report as referring to something that needed to be done straight away, even if the benefit did not become apparent until later.

CORED 24-27/01/94

The CDBI-CO-RED kept this Article unchanged.

CDBI 18-22/04/94

The CDBI amended this Article in order to make it clear that, in an emergency situation, intervention may be carried out "*immediately*", the benefit itself possibly following later. The Article thus reads as follows;

"When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned".

CDBI 5-7/09/95

The CDBI approved this Article as it stood. However, an observer raised the question of non-therapeutic research in emergency situations, wondering whether this Article, which authorises only medically necessary interventions, did not prohibit such research.

Following an observation by a delegate, the CDBI agreed that Article 9 (new Article 8) related only to medically necessary interventions; with regard to research (eg on comatose patients), reference should be made to the provisions of Articles 15 and 16 (new Articles 15, 16, 17).

Article 9 (Previously expressed wishes)

CORED 8-12/03/93

The Working Party decided to add a new article so that the wishes previously expressed by a patient who was to undergo an intervention should be taken into account when the patient was no longer in a fit state to express his wishes.

The Article thus referred to emergency situations, but also to cases where a person lost his capacity of understanding, temporarily or permanently. The Working Party considered that it demonstrated respect for the principle of autonomy.

The experts pointed out, however, that previously expressed wishes could not always be taken into account, especially if they had been expressed long before the intervention and the scientific conditions of the intervention, for example, had changed.

CDBI 27-30/04/93

Several speakers emphasised that this Article did not relate solely to emergency situations (as referred to in Article 7 (new Article 8)) but also to other cases where the patient had foreseen the possibility of being unable to express his opinion (eg senile dementia). The Explanatory Report should be amended accordingly.

It was also pointed out that the phrase *"wherever relevant"* was vague. Did it mean:

- in cases where wishes had been expressed,

- where the type of treatment had not changed, or

- that the wishes could be acted upon or otherwise?

Several delegations felt that the expression *"respect the previously expressed wishes"* was too categorical in view of the changes that might occur in the meantime. In this connection it was suggested saying: *"the wishes shall be duly considered."*

The Working Party was instructed to revise the wording in the light of the above remarks.

CORED 1-3/06/93

The Working Party endorsed the views expressed by certain delegations at the CDBI meeting and accordingly decided to replace the expression *"the previously expressed wishes … should be respected"* by *"the previously expressed wishes … shall be taken into account",* in order to soften this provision.

The experts also decided to specify in the Explanatory Report the point which had been emphasised at the meeting of the CDBI, namely that the Article in question did not relate solely to emergency situations (covered by Article 8) but also to other cases where the patient had foreseen the possibility of being unable to express his opinion (eg senile dementia). In other words, the Article concerned not only accident cases but also cases of progressive disease for example.

In addition, the term *"intervention"* used in the Article should be understood in that context in its broadest sense, thus including medical research.

CDBI 6-9/07/93

Some experts raised questions about the exact scope of this Article.

The Chairman of the Working Party explained that the Article concerned the instructions given in advance in respect of an intervention by a person capable of understanding who envisaged circumstances where he would be incapable

of expressing an opinion on the intervention at the time when it was to be carried out. For example, a person might envisage a situation where he would be afflicted by senile dementia and indicate in advance whether or not he wished to participate in research on that disease when he was so afflicted.

It was pointed out, however, that the Article provided no details on the way in which wishes should be expressed or how the doctor should ascertain those wishes.

Another expert stated that, in his view, the doctor should take account of the knowledge available to him and was not therefore required to carry out any special research. In the light of these explanatory remarks, the following proposals were referred to the Working Party:

- reword the Article as follows: "The wishes relating to a medical intervention expressed previously by a patient who is not in a state to express his wishes shall be taken into account", in order to make it clear that this Article was applicable only to cases where the patient was not able to express his consent;

- combine Articles 8 and 9.

One delegation proposed that the Explanatory Report should specify that, if the doctor respected the wishes of the patient in accordance with the terms of this Article, he was absolved of all responsibility.

Other participants opposed this proposal since they considered that the doctor always bore responsibility. It was pointed out in addition that another Article of the Convention dealt with the question of liability.

CORED 24-27/01/94

The Working Party examined the proposal made at the July meeting of the CDBI to the effect that the Article should be reworded as follows: *"The wishes relating to a medical intervention expressed previously by a patient who is not in a state to express his wishes shall be taken into account".*

The participants endorsed this reworded version by majority, with the addition of the phrase *"... who, at the time of the intervention, is not in a state ...",* in order to make the Article more readable.

The CDBI-CO-RED rejected the proposal aimed at combining Articles 8 and 9, since it considered that the Articles in question dealt with two separate matters.

The Working Party decided to make it clear in the Explanatory Report that the Article concerned the instructions given in advance in respect of an intervention by a person capable of understanding who envisaged circumstances where he would be incapable of expressing an opinion on the intervention at the time when it was to be carried out. For example, a person might envisage a situation where he would be afflicted by senile dementia and indicate in advance whether or not he wished to participate in research on that disease when he was so afflicted.

CDBI 18-22/04/94

The CDBI retained this Article without amendment.

The participants rejected by 16 votes to 4 the proposal that *"all other factors which may clarify the patient's present wishes"* be added to the elements of which account must be taken when a person was in a state in which he cannot express his wishes. The CDBI took the view that this Article covered only those situations in which a patient had previously expressed a wish.

CDBI 26-30/06/95

The CDBI held a discussion on the amendment rephrasing the Article so as to stipulate not only consideration of previously expressed wishes but also compliance with them. The Committee echoed the CO-RED's objection that this was inadvisable because the wishes might no longer be valid. It was therefore necessary to leave the medical practitioner some discretion. The CDBI accordingly decided to include in the Explanatory Report the text proposed by a delegation: *"However, the practitioner must ensure that the patient's wishes apply to the situation in hand and are still valid, bearing in mind the particular progress in medical techniques".*

The Committee also considered a proposal which wanted it to be made clear that the Article did not cover wishes regarding euthanasia or medically assisted suicide. The CDBI was not in favour of adding this, since it would be tantamount to adopting a stance on a complex and sensitive issue which could be fittingly addressed only after a detailed study.

The Committee, like the CDBI-CO-RED, nevertheless noted that only wishes not contrary to the law should be taken into consideration.

Several participants suggested replacing the expression *"medical intervention"* with *"intervention in the health field"* so as to use the terms appearing in the other Articles of the Convention, in particular Article 6 (new Article 5) embodying the general rule on consent. Other delegations opted to retain the present wording, which they considered more exact. The CDBI agreed by 20 votes in favour, 6 against and 4 abstentions to maintain the expression *"medical intervention".*

CHAPTER III - Private life and right to information

Article 10 (Private life and right to information)

CORED 9-12/11/92

Some participants said that this Article provided no more than the European Convention on Human Rights because it was too vague.

One expert proposed adding the right not to be informed, particularly in the field of genetic engineering.

One participant raised doubts regarding the term *"appropriate measures"*.

The Secretariat would propose a new version at the next meeting.

CORED 14-16/12/92

The Working Party queried the usefulness of this provision as currently worded, and decided to await the outcome of the proceedings of the Working Party on data protection in the medical field.

CORED 8-12/03/93

The Working Party decided to add an article on patient information, thus incorporating in the text a proposal by an expert in accordance with the agreement reached at the previous meeting.

To this end, the experts thought it necessary to lay down a general principle concerning respect for privacy, although such a principle already appeared in the European Convention on Human Rights. The two following paragraphs affirmed the right of individuals to know any information concerning them, or not to be so informed.

One expert observed that the principles in question were not absolute and that, apart from the general exceptions provided for in Article 2 (new Article 26), there could be cases where the doctor considered it his duty to inform or not to inform the patient, contrary to the latter's wishes. The same expert took the view that the doctor should then resolve the problem on the basis of the theory of "conflict of duties", and that in any case his actions should be guided by respect for his professional standards.

CDBI 27-30/04/93

- *First paragraph*

The Committee agreed with the principle enunciated in the first paragraph. One participant, however, preferred referring to *"confidentiality"* instead of *"privacy"*.

It was pointed out that the right of an individual to respect for his privacy in health matters might conflict with the rights of others - for example, in the case of contagious diseases. It was observed that this hypothesis was covered by the second paragraph of Article 2 (new Article 26), which permitted exceptions to the principles laid down in the Convention for protecting public health or the rights of others.

- *Second paragraph*

Several delegations supported the principle enunciated in this paragraph. One delegation, however, thought that the expression *"entitled to know any information"* was too categorical: a great deal of information was kept about a large number of people, and it would be very inconvenient to have to provide everyone with all information concerning him. It would be better to say that *"everyone has a right of access to information"*.

One delegation thought that this provision was worded in too categorical terms compared, for example, with the French Code of Ethics, whose wording was more qualified.[4]

Several participants emphasised that the patient's *"right to know"* as proclaimed in this paragraph was supplemented and, where appropriate, qualified by the obligation imposed on the doctor by Article 3 (new Article 4) to act in accordance with the relevant *"professional standards"*. These rules of conduct required the doctor, in certain cases, to evaluate the possible effect on the patient's health of communicating a grave item of information concerning him. Consequently, there was not necessarily a contradiction between the Convention, which set out the patient's rights, and the Code of Ethics, which was aimed at the doctor: in a way, did not the Code of Ethics detail the substance of the *"Professional Standards"* (Article 3 (new Article 4) of the Convention) with regard to *"the right to know"* in the context of a given country?

The Chairman noted that the Committee accepted the principle in paragraph 2. The Working Party should take account of the observations made with a view to improving its formulation, if appropriate.

- The third paragraph was accepted without any comment.

CORED 1-3/06/93

Contrary to the proposal by one participant at the CDBI meeting, the Working Party preferred to retain the accepted term "privacy" and did not therefore consider it necessary to replace it by *"confidentiality"*.

With regard to the first paragraph, the Working Party, while sympathising with the fears expressed at the CDBI meeting, pointed out that the expression *"information collected about their health status"* had been selected to show that an individual was not entitled to receive any and all information but that his entitlement was limited by respect for the privacy of third parties.

The second paragraph of the Article gave rise to a discussion within the Working Party. Some experts felt that the doctor should supply information to his patient but that he had the authority to assess how the information should be transmitted. Conversely, some participants felt that the doctor should have the possibility of not divulging all information to his patient, for example in the cases provided for in Article 42 of the French Code of Ethics, ie cases of serious diagnosis or prognosis.

In addition, one participant felt that the Article applied to access to the file, while others suggested that it was a matter of receiving information during treatment.

Lastly, the experts were divided on the question whether the second paragraph placed an obligation on doctors to divulge all information as soon as it was known or whether they were only obliged to provide the information requested by the patient.

The Working Party decided to return to this Article at its next meeting.

The Working Party instructed its Rapporteur, Mr Jean Michaud, to add to the Explanatory Report the comments that had been made at the meeting.

CORED 27-29/09/93

The Working Party discussed this Article in detail, having been unable to examine it at its previous meeting.

The Working Party approved paragraph 1 without amendment, feeling that it should be kept notwithstanding its general nature.

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[4] Article 42 of the French Code of Ethics:
"For legitimate reasons conscientiously assessed by the doctor, a patient may be left unaware of a serious diagnosis or prognosis. A fatal prognosis should be revealed only with the greatest circumspection, but the family should generally be informed thereof, unless the patient has previously forbidden such disclosure or designated third parties to whom it is to be made."

As for paragraph 2, the experts agreed that it should be reworded to provide for exceptions. The Working Party agreed that doctors sometimes ought not to inform their patients of certain facts, for humanitarian reasons, but that such cases nevertheless remained exceptional.

Another problem raised by the experts was that of divulging information contained in patients' medical files but also concerning third parties. On this point, the following remarks were made:

- there was a conflict of principle between the right to know and the right to confidentiality for which a general solution was difficult to find;

- paragraph 2 of Article 12 limited the right to know to information about the person's health status;

- paragraph 1 of the Article, recognising everyone's right to privacy, offered a solution to this problem since it entitled individuals to have access to information provided that doing so did not unacceptably invade someone else's privacy.

Having considered all these remarks, the CDBI-CO-RED decided leave the wording of paragraph 2 also unchanged.

However, an amendment to paragraph 3 was proposed. The Working Party found it inappropriate to use the word *"request"* which appeared to be too strong in this paragraph. The experts therefore preferred the following wording for this paragraph: "*The wishes of individuals not to be so informed shall be respected*" and would re-examine it at their next meeting.

CDBI 29/11-3/12/93

The following comments were made with regard to this Article:

- In the second paragraph, the expression *"health status"* was perhaps too restrictive in as much as it could be understood to refer to the current state of health, and it might be desirable to replace it by the phrase *"about their health";*

- There were a number of situations where it might not be advisable to make known to patients information which could damage their health. As matters stood, however, the only exceptions to the Article were the general ones provided for in Article 2 (new Article 26) of the Convention, which did not include the health of the patient. Some participants suggested that the matter should be clarified in the Explanatory Report which could contain a cross-reference between Article 3 (professional standards), (new Article 4) and the second paragraph of Article 12 (new Article 10). To this it was objected that the professional standards referred to in Article 3 (new Article 4) did not signify an exception to the second paragraph of Article 12 (new Article 10), and that the Explanatory Report could not validly justify an exception to a right recognised in the Convention if the Convention itself did not authorise such an exception.

An indicative vote produced the following result: 7 delegations in favour of a clarification of this exception in the Convention, 12 against and 4 abstentions. The CDBI-CO-RED was therefore instructed to find a solution enabling States which so desired to subscribe to this additional exception. In this connection, the Secretariat suggested that, if it was impossible to find a formula acceptable to all, consideration should be given to the possibility of authorising States to make an interpretative declaration in respect of the second paragraph of Article 12 (new Article 10).

- With regard to the third paragraph, one expert wondered whether it would not be advisable to insert the adjective *"express"* before the word *"wishes"*. Others felt that, if there was no expression of the wish not to know, it was the right to know which applied.

- Several delegations wanted the right to know and the right not to know to be placed on the same footing and, if possible, combined in a single paragraph. An observer proposed the following wording: *"Individuals are entitled, in accordance with their wishes, to know or not to know any information collected about their health"*.

The CDBI instructed the CDBI-CO-RED to reword the second and third paragraphs of this Article, taking into account the above comments.

CORED 24-27/01/94

The CDBI-CO-RED considered the proposals made at the December meeting of the CDBI.

In particular, the Working Party looked at the problem of the therapeutic exception, which enabled a doctor not to disclose all information to his patient if he thought that such disclosure might damage the patient's health. The experts were of the opinion that this problem could be solved by a cross-reference between Article 3 (new Article 4) and the second paragraph of Article 12 (new Article 10), in as much as it involved a conflict of duties for the practitioner.

With regard to the proposal to insert the adjective *"express"* before the word *"wishes",* the Working Party agreed that this was not advisable since there might be cases where wishes were not explicit.

On the other hand, the participants decided to replace the phrase *"about their health status"* by *"about their health"* which was broader in meaning since it covered, for example, a predisposition to illness.

The CDBI-CO-RED also decided to combine the second and third paragraphs so as to place the right to know and the right not to know on the same footing.

CDBI 18-22/04/94

The CDBI examined this Article carefully. Two delegations proposed including in the Article itself an exception to the right to know and the right not to know. The participants concerned believed that these rights could not be absolute and that it was necessary to make provision for an exception in the interests of the patient's health.

Fourteen delegations were in favour of this solution. Six delegations would have preferred the Article not to contain an individual right not to know, but to include a firm recommendation that the patient's wishes be taken into consideration. Two delegations abstained. It was therefore decided to express an individual right.

The Committee also decided that the restriction would refer to national law, thus allowing for the position of certain States which might not wish to introduce an exception based upon the patient's interests to the rights recognised in this Article, particularly the right to know.

CORED 30/05-2/06/94

In accordance with the CDBI's instructions, the CDBI-CO-RED examined the third paragraph of this Article concerning restrictions which may be placed on the right to know and the right not to know.

The Working Party amended the wording of this paragraph so that restrictions could be justified by the patient's interests in general, not just by his health. Participants considered a number of possibilities and cited as an example that, in some cases, when the doctor considered such an option to be warranted by family circumstances, it might be desirable to reveal to a patient a fatal prognosis of which he had not wished to be informed, in order to enable him to settle certain affairs.

CDBI 20-22/11/95

a. first paragraph

It had been proposed earlier to make specific reference in the body of the Article to the Convention for the protection of individuals with regard to automatic processing of personal data (ETS N° 108). The Chairman of the CDBI-CO-RED observed that paragraph 81 of the Explanatory Report already mentioned this Convention, and the fact that medical data were subject to special rules. Furthermore, any reference in the actual operative provisions of the Bioethics Convention to another international legal instrument would be sure to raise difficulties over its applicability to non-ratifying Parties.

b. paragraph 2

A representative found paragraph 2 of Article 11 (new Article 10) on every person's right to information too broadly formulated, and suggested replacing the terms *"is entitled to … information"* by *"shall have access to … information"*. Attention was drawn to the fact that this expression tended rather to be employed by texts concerning data protection in the sense of access to the medical files stored in computerised databases. In the present context, the Bioethics Convention stated a more general principle covering any data concerning a person which might be gathered, whether or not registered. This general principle should be further amplified by rules suiting the form of registration, particularly by computer.

c. paragraph 3

The CDBI considered a proposal to define in the Article itself the permissible restrictions to a person's basic rights and fundamental freedoms regarding information on his/her health. Several participants felt that it was too detailed an amendment for an outline Convention and would be more suitably placed in the Protocols.

Furthermore, many restrictions proposed were already embodied in Article 3.

The delegation thereupon suggested amending paragraph 3 of Article 11 (new Article 10) as follows:

"In exceptional cases, restrictions in the patient's interests may be prescribed by law under the relevant data protection legislation".

The CDBI rejected this text by 4 votes in favour and 26 against, with 3 abstentions, and decided to retain the initial wording without inclusion of the reference to data processing.

A delegation considered that paragraph 1 could not be subjected to restrictions without the risk of infringing Article 8 of the European Convention on Human Rights.

In order to determine the scope of paragraph 3, the CDBI took three consecutive votes on the following questions:

- did the restrictions provided for in paragraph 3 apply to the principle of the first paragraph? - 30 delegations replied in the negative and 2 abstained;

- did the restrictions provided for in paragraph 3 apply to the first sentence in the second paragraph, ie the right to information about one's health? - 16 delegations replied in the affirmative, 12 in the negative, and 4 abstained;

- did the restrictions provided for in paragraph 3 apply to the second sentence in the second paragraph, ie the right not to be informed? - 15 delegations replied in the affirmative, 6 in the negative, and 9 abstained.

In conclusion, the CDBI confirmed that paragraph 3 must make reference to paragraph 2 in its entirety, as indicated in the initial text.

The CDBI put the whole of Article 11 (new Article 10) to the vote and approved it by 22 votes in favour and 1 against, with 9 abstentions.

CHAPTER IV - Human genome

Article 11 (Non discrimination)

CDBI 26/2-1/3/96

The Committee considered a proposal to include in the Convention an article prohibiting any form of discrimination against an individual on grounds of his or her genetic heritage.

Certain participants wondered whether such a clause was necessary, because non-discrimination already appeared in Article 1, and this included any reason for the discrimination. Other participants wondered whether the words *"any form"* of discrimination were appropriate.

The Secretariat said that to ensure consistency with the objective of the Convention, the non-discrimination clause might be defined in respect of the provisions of the Convention, along the lines of Article 14 of the European Convention on Human Rights[5]. In any event, the scope of application of the Convention was very vast, and one of the most important applications of the principle of non-discrimination would probably be equitable access to health care, set forth in Article 4 (new Article 3): Parties could not refuse a disabled person equitable access to health care even if such care cost much more than on average. Thus, not only was it guaranteed, under Article 6, that the decision to give birth to a child was to be taken without the interference of the State, but it must also be ensured that there was no discrimination in access to health care, thereby preventing indirect but no less powerful pressure from being exerted upon the parents.

By 29 votes in favour and 2 against, with 2 abstentions, the Committee approved the Article on non-discrimination and decided to draft a precise wording at a later time.

CORED 24-26/04/96

The Working Party considered Article 11a (new Article 11), for which the CDBI had not adopted a precise wording. An expert suggested widening the scope of this Article in order to preclude discrimination based not only on genetic heritage grounds, but also on health reasons. While acknowledging the relevance of this proposal, the Working Party did not adopt it as it considered that discrimination for health reasons was not of the same kind as discrimination on genetic heritage grounds.

The Chair pointed out that the term *"discrimination"* always had a negative connotation in French, whereas this was not necessarily the case in English where one must use the expression *"unfair discrimination"*. He considered, however, that the concept of discrimination was precisely defined by the case-law of the European Court of Human Rights and that it was preferable to keep the expression *"discrimination"* used in the European Convention on Human Rights. The Chair suggested, however, that a clarification of this distinction appears in the Explanatory Report.

Several members of the CDBI-CO-RED wondered if it was possible to replace *"Discrimination is prohibited …"* by "*Any form of discrimination is prohibited …"* without widening the scope of Article 11a (new Article 11) beyond the actual scope of the Convention itself. The danger was that the words *"any form of discrimination"* on their own might also include so-called positive discrimination; on the other hand, neither the CDBI nor the CO-RED had been mandated to legislate beyond the scope of the Convention.

Several participants pointed out that the scope of the Convention was defined by its first Article and that Article 11a (new Article 11) was a specific application of the general principle in Article 1. Accordingly, the Working Party retained the wording proposed, viz *"Any form of discrimination …"*.

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[5] Article 14 of the European Convention on Human Rights:
"The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status".

CDBI 4-7/06/96

The Chairman of the CDBI-CO-RED explained that the term *"discrimination"* invariably had a negative connotation in French but not necessarily in English, where the expression *"unfair discrimination"* should be used instead. He nevertheless considered that the concept of discrimination was precisely established by the case-law of the European Convention on Human Rights and that it would be preferable to retain the term *"discrimination"* without qualification, as used in the European Convention on Human Rights.

The Committee agreed to make the above distinction clear in the Explanatory Report by specifying that the prohibition applied to negative discrimination *("discrimination against …")* and not to any positive measures taken by States in order to even up the chances of genetically disadvantaged persons.

The Committee also agreed that the Article in question had exactly the same scope as the Convention and therefore prohibited any form of discrimination in any area covered by the Convention.

Article 11 was adopted by 25 votes in favour and none against, with 3 abstentions.

Article 12 (Predictive genetic tests)

CORED 9-12/11/92

The participants had a preliminary discussion on these Articles.

The Working Party believed that they presented at least three types of problem:

- the problem of tests conducted on products of the human body without the knowledge of the person concerned. Was consent always necessary?
- the question of genetic tests required by insurance companies,
- the question of the need for consent to these tests in the context of legal proceedings (particularly in criminal cases).

The Working Party decided to investigate these problems and return to them at the next meeting.

It decided not to keep the present Article 17[6] which read as follows:

"No identifiable personal data resulting from the processing of genetic tests or any other scientific means may be communicated or even stored, unless the said communication or storing corresponds to the purposes mentioned in Article [16]".

CORED 8-12/03/93

At the meeting of December, the Working Party had decided to include an article designed to restrict applications of biology and medicine for non-medical purposes.

Following discussion, the Working Party decided to restrict this Article to genetic tests which are predictive of genetic diseases.

The experts agreed to limit such tests to the health field exclusively, thereby barring insurance companies or employers from obliging an individual to submit to such a test.

The Working Party pointed out that this Article did not entail a ban on tests ordered by a court in the course of criminal proceedings or paternity tests, for example, since such tests were not aimed at detecting genetic diseases.

In addition, the experts recalled that the exception provided for in Article 2 (new Article 26), which was a general exception, also applied to this Article and that it was therefore possible to ask an individual to submit to such a test, outside the health field, for the protection of public health or the rights and freedoms of others.

Thus, for example, a would-be pilot could be asked to undergo such a test.

CDBI 6-9/07/93

It was pointed out that, in the French version, the phrases *"tests prédisant des maladies génétiques*" and "*raisons de soin de santé"* were rather awkwardly worded and should be replaced.

It was observed that, apart from genetic diseases proper, which in any case were bound to propagate at a given point in time, there were certain predispositions which developed only in a specific environment or specific circumstances; there were also cases of accidental genetic illnesses, brought on by radiation for example. Did the Article refer to all these situations or should distinctions be drawn?

It was noted that this Article did not seem to cover tests designed to detect positive predispositions or qualities: should not such cases also be mentioned?

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[6] This article no longer appears in the Convention.

CORED 24-27/01/94

The Secretariat questioned the Working Party in order to ascertain whether the difference between Articles 17 (new Article 12) and 18 (Article concerning the communication of results) was intentional or fortuitous. Article 18 allowed the communication of results of genetic testing outside the health field when there was an overriding interest, whereas Article 17 (new Article 12) did not authorise testing in such a situation. The effect of this difference in treatment would be that persons who had already undergone a test would be required to communicate the results, whereas persons on whom no test had been performed would be under no obligation to submit to one.

Participants identified two situations which might justify wider exceptions to Article 17 (new Article 12) than those provided for in Article 2 (new Article 26). The first would concern cases where an employer obliged a candidate for a post to submit to a test in his own interests, for example in order to determine the existence of an allergy to a certain environment. The other situation would concern the insurance field where, in order to avoid problems of anti-selection, genetic tests could be carried out for insurance contracts exceeding a certain sum of money.

One expert recalled that the prevailing rule in the insurance field was freedom of contract, so that there was no obligation on an insurer to enter into a contract. In the circumstances, he saw no need for an exception to this Article for the benefit of insurers, especially since it would be unethical to force someone to disclose that he was predisposed to a disease merely because his insurer wished to be informed.

The Working Party decided, therefore, not to amend the Article in order to introduce an exception. However, it was noted that, by virtue of Article 2 (new Article 26), certain tests in the employment field could be performed in order to safeguard the rights of others. For example, a pilot could be required to submit to a genetic test in order to determine whether he could safely practise his profession.

As far as genetic testing for research purposes was concerned, the Working Party considered that it was necessary to restrict the scope of the Article in order to prevent research which, far from benefiting the person who submitted to it, could be detrimental to him.

However, the experts wished neither to stop research on diseases which could be genetically determined nor to prevent epidemiological research.

The CDBI-CO-RED therefore reworded the Article in order to include a reference, on the one hand, to *"health purposes*" (rather than just health care, as before) and on the other hand, to scientific research *"linked to health purposes*".

Some experts noted that it might be desirable, in due course, to elaborate a protocol to the Convention on problems connected with genetics.

CDBI 27/06-1/07/94

The CDBI discussed Articles 17 (new Article 12) and 18 (Article concerning the communication of results) in detail.

The Committee decided to extend the scope of this Article by adding to tests predictive of genetic diseases those permitting the detection of a genetic predisposition to a disease. The problems which could result from these tests were in fact similar to those which could result from tests predictive of genetic diseases.

A delegation pointed out the importance of genetic counselling both before and after the tests, a principle endorsed by the Committee of Ministers in its Recommendation R (92) 3 on genetic testing and screening for health care purposes.

Another delegation informed the Committee that it reserved its position on this Article, having been unable to contact all the ministries concerned.

CDBI 20-22/11/95

a. Against the Article in its present form

Certain delegations objected to the rule embodied in this Article prohibiting the performance of genetic testing for other than health purposes.

A delegation raised the following arguments:

i. genetic tests presented no peculiarity by comparison with other tests of predictive medicine; if the latter were authorised outside the health field, why should genetic testing be prohibited?

ii. the text was unclear in that the Explanatory Report (see para. 97) had to be consulted in order to apprehend that genetic testing was nonetheless permissible in employment situations;

iii. why should a genetic test be prohibited as long as the person concerned agreed to undergo it? Was this not paternalistic?

Another delegation raised the following argument:

iv. certain persons belonging to groups at risk (eg with negative family antecedents) could obtain insurance only on condition of a test establishing that they did not carry the gene causing the illness afflicting other members of the family. To prohibit the application of the test, notwithstanding the readiness of the persons concerned to undergo it, would be tantamount to penalisation of these persons by denying them insurance or by compelling them to pay extra premium.

b. In favour of the Article in its present form

Several delegations upheld the prohibition of genetic testing for other than health purposes. Some delegations contended that:

i. genetic tests had a high predictive potential regarding asymptomatic diseases which would be higher still in future, far more so than any other test, hence the need for very stringent regulation of genetic tests;

ii. Article 12 was very precise: it did not restrict genetic tests to a medical context, but stipulated that they could be conducted for health reasons only. Health reasons could also exist in an occupational context, particularly a pathogenic one. In this respect, the Explanatory Report did no more than to illustrate what was already embodied in the terms of the Article;

iii. the patient's consent was a central principle in the practice of medicine nowadays; only in that context did the question of paternalism arise. Article 12, however, dealt precisely with genetic testing for other than health purposes, and in that context the person's consent did not in itself constitute an adequate guarantee as the parties involved (employer-job applicant, for instance) had a very unequal power relationship;

iv. this provision went beyond the sole context of personal relations. In certain cases, admittedly not at all numerous, such as the one described in point iv. above, the prohibition of genetic testing for other than health purposes could have unfortunate individual repercussions. However, these should be set against and compared with the far more adverse social effects of permissiveness. Indeed, those States having passed legislation in the matter all had a very restrictive approach.

CDBI 26/2-1/03/96

Some experts believed that there was nothing that distinguished genetic tests from other medical tests. Other participants considered that, on the contrary, genetic tests had a predictive potential that no other medical test had to the same degree. In their opinion, this made special rules necessary, just as the development of computer technology twenty years previously had made it necessary to adopt special rules for the protection of computerised personal data.

The Committee intended to cover all possible ways for predicting a disease through a genetic test, irrespective of whether dominant or recessive diseases or healthy carriers were involved.

The Committee decided, by 23 votes in favour and 9 against, with no abstentions, to include a reference to the need for genetic counselling. It rejected (by 7 votes in favour and 20 against, with 6 abstentions) a reference to the need for consent, because Article 6, which applied to all medical interventions, was also applicable here.

The Committee adopted Article 12.1 (new Article 12) by 28 votes in favour and 2 against, with 1 abstention.

CORED 24-26/04/96

At the CDBI's last meeting there was no general vote on new Article 12; several participants asked that paragraph 2 of this Article should once more become the sole paragraph of Article 13 (use of results), which would read as follows:

Article 13 (Use of results)

"The use of the results of the genetic tests referred to in Article 12 is allowed, subject to receiving the free and informed consent of the person, only for the purposes mentioned in that Article."

Article 12 bis (Communication of results)

(This Article no longer exists in the Convention).

CORED 8-12/03/93

This Article concerned the communication of results of genetic testing outside the health field.

The experts thought it necessary for such tests to be authorised by national law and added the requirement of the existence of an overriding interest. One participant mentioned by way of example the requirement of the communication of the results of such tests for an insurance contract exceeding a certain sum of money, although the insurer could not require the person concerned to submit to the test.

The Working Party thought it important to indicate in the Explanatory Report that this field was undergoing rapid development and that it seemed desirable for the CDBI to monitor this question and review the situation after a certain period of time, say five years.

The experts observed that in any case, the field covered by Articles 16 (new Article 12) and 17 (former Article 12bis) could be the subject of a protocol to the Convention. In this connection, the Working Party noted amendments N° 16 and 17 presented by Dr Palacios and thought that they would be better placed in such a protocol.

CDBI 6-9/07/93

In connection with this Article whose purpose was to regulate the use of genetic testing, particularly in the fields of employment and insurance, the following remarks were made:

- insurance contracts and employment contracts also, in some cases, were based on the good faith of the contracting parties. Did not such good faith oblige the candidate for insurance to give the insurer all information about his state of health or any predisposition to develop a disease which had come to his knowledge as the result of a genetic test, just as he was currently obliged to provide particulars of his family background?

- some participants wondered whether a distinction should not be made between the communication of the results of a test with the consent of the person concerned, which in their view should be authorised, and the communication of results without such consent, which should be prohibited.

In connection with the two preceding remarks, the Secretariat indicated that the purpose of the Article was not just to protect the confidentiality of genetic data, a task already performed by the first paragraph of Article 12, by means of a reference to the consent of the person concerned. It went much further, by prohibiting the possibility of a request for the communication of the results of a test to a person, even if the person concerned consented thereto.

Moreover, in as much as this prohibition existed, the person concerned was exempted from the obligation which might be placed on him by virtue of the contractual principle of good faith, to communicate the results of a test with which he was already familiar.

- The expression *"... shall only be possible ..."* seemed inappropriate; it should be replaced by *"shall only be allowed"* or another equivalent expression;

- What was meant by *"an overriding interest"*? Some delegations found this concept too vague. It was pointed out that this Article was not concerned with concepts (such as judicial proceedings to establish paternity) covered by the exceptions already contained in the second paragraph of Article 2 (new Article 26), but rather with an idea which could go well beyond the cases covered by Article 2 (new Article 26). One specific example mentioned by the Chairman was the fact that in other organisations it had been considered that genetic testing should not be authorised in the field of health care insurance but that it could be accepted in other insurance fields. With regard to life insurance, the Secretariat suggested that genetic tests should not be authorised for capital guarantees of an amount considered customary in

comparable cases; on the other hand, consideration could be given to the possibility of accepting such tests for exceptionally large sums.

The Chairman took a vote: 3 votes were cast in favour of the proposal to clarify the concept of *"overriding interest"* in the text of the Convention; 15 votes were cast in favour of the text as it stood; 5 delegations abstained. The text was maintained. The Explanatory Report should contain the necessary points of clarification, and delegations were invited to transmit their ideas, in writing if necessary, on the question of possible exceptions to the principle of a ban on testing.

CDBI 27/06-1/07/94

The CDBI considered the expediency of authorising the communication of the results of a genetic test outside the health field. It studied in particular the question of communication in the fields of insurance and employment. Certain delegations considered that under certain circumstances such communication could be legitimate and that it was thus necessary to provide for an exception to the rule permitting communication only in the health field.

In this connection, the Article allowed the possibility of communicating results where there was an overriding interest. However, several delegations questioned this notion. For instance, it was pointed out that this was an imprecise notion for which there was no commonly accepted interpretation. It was therefore suggested that it should be replaced by the expression *"legitimate interest provided for under the law"*. This proposal was rejected on an indicative vote (9 votes for, 11 against and 3 abstentions).

Certain participants considered that it was not necessary to provide for an exception in the case of insurers or employers, who would be sufficiently protected from the risk of fraud by the general principles of the law, such as those concerning the abuse of right and good faith.

After this discussion, the CDBI held a vote in order to find out whether the only exceptions which should be allowed to the principle according to which communication of the results of a genetic test was prohibited outside the health field were those of Article 2 (new Article 26) paragraph 2. 17 delegations voted in favour of this solution, 3 against and 3 abstained. The Article was thus reworded accordingly and the reference to an overriding interest was deleted.

Following this decision by the CDBI, a member of the CDBI and of the CDBI-CO-RED, voiced her doubts to the Committee: "the reference to Article 2 paragraph 2 (new Article 26) in Article 18 (former Article 12bis) is not legally correct, insofar as Article 2 does not cover the exception which takes into consideration the legitimate economic interests of insurance companies (an exception aimed at preventing insured persons deriving undue advantage from the knowledge they have of their genetic make-up), whereas such was the intention of the Article (as was explained in paragraph 123 of the explanatory memorandum)".

Several delegations saw this Article as the application of the general principles governing the protection of data, and thought it would be dangerous to open the door to exceptions other than those of Article 2 paragraph 2 (new Article 26).

A delegate proposed substituting the term "use" for "communication". The CDBI rejected this idea (10 votes for, 11 against and 1 abstention).

A delegation informed the Committee that it reserved its position on this Article.

Another delegation made the following declaration:

"Recent conclusions in a (…) government and experts committee have shown that a distinction between genetic tests and other medical tests - i.e. a distinction by method - is that the same information can be obtained by different methods. Instead you must regulate what purposes can legitimate medical tests of any kind, whether genetic tests or other.

The (…) delegation must make a strong reservation in substance concerning Article 17 and 18 (new Article 12 and former Article 12bis). What the Committee has shown that such a method of regulation will at the the same time fail to fulfil the purpose, which is protection of personal integrity, and cause serious and unacceptable risks for society at large".

An observer regretted that Articles 17 (new Article 12) and 18 (former Article 12bis) had been voted upon without prior consultation with the representatives of insurance companies. It was replied that it would then also be necessary to consult representatives of the consumers. The Secretariat reminded the meeting that the CDBI had organised the 2nd Symposium on Bioethics on the topic "Ethics and human genetics" in December 1993. One of the main subjects had been the protection of privacy and, in this context, the CDBI had invited a representative of the insurance companies to give their view. This representative had submitted a written report and had spoken, as was apparent from the Proceedings of the Symposium.

CDBI 20-22/11/95

It was recalled that in June 1994 the CDBI had opposed by a substantial majority the disclosure of results of genetic tests outside the health field except in the situations covered by the present Article 3 (new Article 26). The Parliamentary Assembly had subsequently requested the addition of a reference to the data protection legislation, which the current wording did include, but with the further addition of possible exceptions founded on the concept of overriding interest. The draft of Article 13 (former Article 12bis) thus permitted the communication, outside the health field, of results of genetic testing when there was an overriding interest and subject to the consent of the person concerned, and provided that the safeguards defined by law, particularly with regard to data protection, were observed.

The delegations in favour of the Article as it stood, the concept of overriding interest included, stressed the relevance of individual self-determination in this context. A delegation considered that the Article would thus provide the basis for national legislation which, for its part, should introduce provisions specific to each situation.

Several delegations criticised the use, in this context, of the concept of overriding interest. The concept was regarded as most inadequate as the situations where it could apply (eg employment, health insurance, life insurance) differed widely and the expression *"overriding interest"* did not embody the necessary to distinguish between them. These delegations drew attention to the danger of serious social discrimination which might result from the application of the concept. A delegate stressed the difficulties of linkage between the concept and Article 3 (new Article 26).

The Secretariat shared the apprehensions expressed by several delegations regarding the very imprecise concept of overriding interest, which offered no criterion on which to class a specific interest as overriding or otherwise; there was a striking contrast with Article 3 which exhaustively specified the interests in question (public health, etc) and hedged them with safeguards (expediency, proportionality, etc) not found in Article 13 (former Article 12bis)[7].

In the Secretariat's opinion, Article 3 (new Article 26) should remain the basic reference for restrictions to the principles of the Convention. This Article permitted restrictions inter alia *"for the protection of the rights and freedoms of others"*. Certain experts found this expression ineffective when it came to safeguarding the interests of insurance companies, on the ground that it did not cover commercial interests. The Secretariat disagreed with this interpretation and held that peaceful enjoyment of possessions was not only a legitimate right but also a fundamental right of every natural and legal person[8]. Judgements of the European Court of Human Rights confirmed that the protection of commercial interests could indeed warrant restrictions on another fundamental personal right such as the right to respect for private life and the right to freedom of expression[9]. As to insurance companies, they clearly had a legitimate right, worthy of protection, to have their assets safeguarded against a potential policy-holder seeking personal gain by deceit and at their expense. In order to enforce this right, States had a duty to provide solutions through legislation or court practice in accordance with the requirements of Article 3

[7] In this respect the draft UNESCO Declaration is more precise in that it mentions general interest.

[8] See Protocol N° 1 to the European Convention on Human Rights, Art. 1: Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

[9] See judgments: Chappell case (17/1987/140/94) and case of Markt intern Gmbh and Klaus Beerman (3/1988/147/201).

(new Article 26). This Article was therefore held to provide a far more suitable framework for such solutions than the mere concept of overriding interest. Moreover, if the Bioethics Convention included the concept of overriding interest, it might be come into conflict with Article 8 of the European Convention on Human Rights unless this concept carried the same guarantees as those set out in paragraph 2 of the Article. In the last place, the Secretariat considered that if the CDBI were to take the view that the prohibition of communicating the results of genetic tests should be subject to more precise controls than those which could result from the straightforward application of Article 3 (new Article 26), it might decide to delete Article 13 (former Article 12bis) and leave this question to be dealt with in the future protocol.

According to a straw vote (21 for and 2 against, with 7 abstentions) the CDBI favoured the retention of an Article 13 (former Article 12bis) in some form, leaving its content to be defined at the next meeting if it was finally maintained.

CDBI 26/02-1/03/96

Several participants criticised draft Article 13 (former Article 12bis), arguing that the words *"overriding interest"*, which were too imprecise, would allow a wide variety of exceptions to the principle of the prohibition of communication. Other delegations were of the opinion that the concept of overriding interest might be the basis for appropriate legislation. The Committee decided, by 8 votes in favour and 20 against, with 4 abstentions, not to use the concept of overriding interest.

Concerning insurance, a representative refers to several European directives[10].

The Secretariat said that the use of the results of genetic tests for purposes other than health (employment, health insurance, life insurance etc.) was a very complex and difficult question, certain points of which were still highly controversial in the member States, and wondered whether, instead of addressing this in a single article in the Convention, it might not be better to set it aside so as to adopt more precise rules in a future protocol.

The Committee decided, by 23 votes in favour and 6 against, with 4 abstentions, to include in the Convention an article addressing the use of genetic information outside the area of health.

At a later stage of the discussion, a delegation submitted a draft Article 12, paragraph 2, to replace Article 13 (former Article 12bis). The draft read as follows:

"The use of the results of genetic tests is allowed, subject to receiving the free and informed consent of the person, only for the purposes mentioned in the preceding paragraph".

It was adopted by 23 votes in favour and 4 against, with 5 abstentions.

For its part, another delegation submitted a proposal to insert a third paragraph in Article 12, which would read as follows:

"Exceptionally, to preclude the misuse by a person of genetic information in his or her possession, such information may be requested, in accordance with conditions prescribed by law, including safeguards relating to data protection".

This proposal received 6 votes in favour and 18 against, with 8 abstentions, and thus was rejected.

CDBI 4-7/06/96

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[10] - Council Directive 92/49/EEC of 18 June 1992 on the co-ordination of laws, regulations and administrative provisions relating to direct insurance other than Life Insurance and amending Directives 73/239/EEC and 88/357/EEC (OJ L 228, 11.8.1992, p. 1)

- Council Directive 92/96/EEC of 10 November 1992 (...) relating to direct Life Insurance and amending Directives 79/267/EEC and 90/619/EEC (OJ L 360, 9.12.1992, p. 1)

- Agreement between the European Economic Community and the Swiss Confederation on direct insurance other than Life Insurance (OJ 205, 27.7.1991, p. 3).

The Committee discussed whether it would be expedient to keep this provision in the framework Convention or to remove it. Certain delegations felt that it should stand because of its importance for protecting both the privacy and the health of the persons concerned. In the view of other delegations, the subject embraced numerous fields (employment, insurance, etc) and was clearly too complex to be properly dealt with in a general provision.

By 18 votes in favour and 8 against, with 5 abstentions, the Committee decided to leave in the draft Convention a provision on the use of results of genetic tests. It then considered an amendment presented by a delegation and, by 19 votes in favour and 9 against, with 2 abstentions, adopted the following wording:

"The use of the results of the genetic tests referred to in Article 12 is allowed only for the purposes mentioned in that Article, subject to the exceptions prescribed by law".

The adoption of the above amendment obviated examination of the amendment presented by the Secretariat[11].

Later in the proceedings, a delegation stated that the draft Article as adopted raised serious legal and political difficulties for its government, and therefore requested that it be deleted. Another delegation considered that a draft article approved the day before should not be put to the vote the next day with a view to its deletion. After taking an indicative vote, the Committee decided by 21 votes in favour and 2 against, with 8 abstentions, to delete the Article.

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[11] The amendment called for the adoption of a paragraph to read as follows:
"The above provision shall apply without prejudice to any appropriate measures which may be taken by Parties to ensure respect of the principle of good faith in contracts."

Article 13 (Interventions on the human genome)

CORED 9-12/11/92

The Working Party wished interventions on the human genome to be limited to cases necessary for the protection of health. It was hoped this would avoid non-therapeutic interventions.

Such interventions should only be made on somatic cells, ie not on germ cells. Some experts felt that we should not take the risk to create human beings who were genetically different from one generation to the next.

CORED 14-16/12/92

The Working Party held a detailed discussion concerning this provision.

Several experts were in favour of maintaining the Article in its existing terms which prohibited interventions on the germ cell line, as they felt it necessary in the present state of scientific knowledge to prohibit such interventions considering the unpredictability of their effects on subsequent generations. It was further pointed out that, at the present time when defective genes are manipulated it could not be certain that only these genes and their functions are affected by the manipulation.

Other participants felt that the option should nevertheless be left open and that it might be possible to authorise germ cell therapy, although the intervention would need to carry a certain number of guarantees which were not available at the present stage of scientific knowledge. If on the other hand such therapy proved its worth and reliability, these experts might be able to accept it under certain conditions.

The two following alternatives were proposed:

1. Maintain Article 10 (new Article 13) unchanged and include in the Explanatory Report a passage with the following substance:

The Working Party discussed the possibilities for exceptions to this provision in the light of recent or anticipated progress in the medical field, relating for instance to the prospect of eliminating the genes which cause diabetes, Huntington's chorea and haemophilia. However, the difficulty of taking into account all the implications and the existing uncertainties prompted the Working Party's decision to admit no exceptions for the time being.

2. Redraft Article 10 (new Article 13) along the following lines:

An intervention on the human genome shall only be undertaken for therapeutic purposes. No interference with the germ cell line shall be permitted for the purpose of perfecting human existence (rendering human beings more intelligent, musical, athletic, etc.). An intervention on the germ cell line may nevertheless be permitted in exceptional cases (where there is no conceivable alternative) in order to correct recognised abnormalities provided that it is carried out for the purpose of ending or alleviating severe human suffering and that strict standards of reliability and safety are observed.

Include in the Explanatory Report the following passage:

The Working Party appreciates how difficult it is to draw the line between attempting to perfect the human being and attempting to eliminate recognised abnormalities and diseases. The latter proposition includes the elimination of the genes which cause diabetes and Huntington's chorea.

Before the proposed therapy is applied, an independent body, preferably a national ethics committee, should ascertain whether it complies with the standards in respect of reliability and safety.

Developments in this area should be closely monitored by the CDBI and the relevant national bodies, and special attention should be paid to the possibility of revising this Article should the need arise.

The Working Party concluded this discussion by approving the first approach and accordingly maintained the current version of the Article prohibiting germ cell therapy. It nevertheless agreed unanimously to specify that the provision would need to be reviewed within a certain time (eg five years after the entry into force of the Convention) having regard to the current progress in knowledge.

CORED 8-12/03/93

The Working Party adopted this Article with no change and kept to its decision of the previous meeting.

CDBI 6-9/07/93

a. with regard to the therapeutic requirement

Several delegations wished to insert the words *"or diagnostic"* in the phrase *"An intervention on the human genome shall only be undertaken for therapeutic purposes"*. One participant considered that this would not be necessary since therapy necessarily implied diagnosis.

b. with regard to the germ cell line

In order to keep the current debate open on this point, one delegation proposed the addition of the phrase *"given the current state of scientific knowledge"*. Other participants considered that such an addition would give rise to uncertainty about the applicability of the Article: scientific knowledge was developing constantly; from what point (and by whom) should it be judged to have made sufficient progress to render the provision no longer applicable? While accepting the idea behind the proposal, these participants preferred the solution already put forward at an earlier date within the Working Party which was to include in the operative part of the Convention a clause providing for the periodical review of certain Articles, including this one in particular. The Secretariat indicated that a draft version of such a clause would be submitted to the Working Party.

Several delegations took the view that the phrase *"and as long as there is no interference with the germ cell line"* would have the effect of prohibiting interventions, such as certain types of cancer treatment, which could have the side effect of interfering with the germ cell line. They therefore proposed that it be replaced by the following phrase: *"and as long as the aim is not to interfere with the germ cell line"*. An expert pointed out that the current cancer therapies did not have the effect of interfering with the germ cell line. Certain other delegations wondered whether the possible decision to authorise gene therapies with the side effect of interfering with the germ cell line would not amount to opening a Pandora's box.

In reply to a question asked by one delegation, it was pointed out that the draft Article prohibited inter alia research aimed at modifying the germ cell line of the human foetus.

The Chairman noted that no delegation was opposed to this Article. The words *"or diagnostic"* could be inserted. The Working Party would have to examine the proposal to replace the phrase *"there is no interference"* by *"the aim is not to interfere"*.

CDBI 29/11-3/12/93

The CDBI considered a proposal by a representative to supplement Article 16 with the following sentence: "*Any injury to the human genome caused by man-made mutagens should be regarded as intervention on the human genome*".

The CDBI thanked the delegate for this very interesting proposal, but considered that its purpose lay outside the scope of the Bioethics Convention. The CDBI took the view that this suggestion could be used in other Council of Europe instruments.

On behalf of the Parliamentary Assembly, it was observed that - without reference to the suitability or not of its being part of a convention on bioethics - the above-mentioned proposal would be very much welcome. It spelt out in detail some of the concerns behind a proposal which the Parliamentary Assembly had already made [Recommendation 1168 (1991)] with a view to updating and strengthening the Council of Europe's Social Charter.

An observer drew attention to the work of the International Commission for Protection Against Environmental Mutagens and Carcinogens. That body, which had been partly financed by the Institut de la Vie in Paris, had included among its members specialists from the Commission of the European Communities, WHO and the International Agency for Research on Cancer. The final reports of the Commission and its Committees had been published in the journal Mutation Research and could be made available to interested members of the CDBI and observers.

CORED 24-27/01/94

The Working Party undertook a detailed consideration of this provision, particularly the proposal to replace the expression *"there is no interference with"* by *"the aim is not to interfere with"*.

In this connection, the following comments were made:

- interference with the germ cell line occurred in three types of situation:

. where the purpose of the intervention was to affect the germ cell line and it was in fact affected;

. where the purpose was somatic but there were side effects with a known likelihood of occurrence, which affected the germ cell line;

. where the purpose of the intervention was somatic and the germ cell line was affected by an unforeseeable side effect;

- what it was wished to prohibit was an intervention on the human genome with the aim of interfering with the germ cell line, not the objective results of such an intervention;

- in other words, Article 16 (new Article 13) should be aimed at prohibiting only the first possibility;

- one argument in favour of this solution was the fact that, for the time being, interventions in this field were still at an experimental stage and therefore had to be approved by ethics committees. It was thus to be anticipated that the latter would not authorise an intervention which was known in advance to have the potential side effect of interfering with the lineal descent.

Following this debate, the Working Party reworded the Article to read:

"An intervention on the human genome shall only be undertaken for therapeutic or diagnostic purposes and as long as the aim is not to interfere with the germ cell line".

The members of the Working Party stressed the need for this Article to be reviewed after a certain period of time.

CORED 30/05-2/06/94

The Working Party added prevention as a possible justification for intervention on the human genome, since it was not covered by the other two terms used (therapeutic and diagnostic purposes).

CDBI 27/06-1/07/94

A delegate proposed rewording this Article as follows: *"An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes and as long as the aim is not to interfere with the germ cell line, in the light of scientific knowledge".* The CDBI did not accept this suggestion for the text of the Convention, but noted that the idea was contained in the explanatory memorandum.

A delegation for its part suggested the deletion of paragraph 112 of the explanatory memorandum as it mentioned as the sole reason for prohibiting germ cell therapy the insufficiency of scientific knowledge, whereas other reasons, notably ethical ones, might be relevant.

In view of the results of the vote (9 delegations in favour of deleting paragraph 112, 9 against and 4 abstentions), the CDBI decided to keep this paragraph but to make a number of amendments to it.

CDBI 20-22/11/95

Article 14 (new Article 13) was briefly discussed at the end of the meeting, and raised three groups of comments.

a. indirect modifications of the germ cell line

Many of the delegations felt that this Article ought not to rule out already long-standing techniques such as chemotherapy or radiotherapy for cancer of the ovaries or testicles. In point of fact the amendment suggested by the Parliamentary Assembly, stipulating *"without any intervention in the human germ cell line",* would seem to exclude these therapies too, as the CDBI-CO-RED had noted.

b. prohibition of any modification of the germ cell line

A delegation advised against reopening discussion on the actual principle of this prohibition.

The Committee was informed that draft legislation in a member State envisaged prohibiting modifications of the germ cell line but permitted such modifications where intended to eradicate severe genetic diseases.

c. revision clause

A representative of the European Community Working Group on Human Embryo and Foetus Protection, agreed that while it was reasonable in the present state of scientific knowledge to prevent all intervention on the reproductive cells, it was nevertheless expedient to insert a revision clause so that technical advances could be taken into account.

d. should research on the germ cell line be allowed?

Several delegations were of the opinion that germ cell therapy should be prohibited, at all events in the present state of knowledge, owing to its incalculable inherent risks. They considered, however, that such research ought not to be totally prohibited, precisely in order to make room for improvement in this hitherto very inadequate knowledge. Article 14 (new Article 13) as it stood nonetheless prohibited any intervention aimed at modifying the germ cell line, research included.

In the Secretariat's opinion, Article 14 (new Article 13) could be construed as also prohibiting research since it did not supply a definition of the germ cell line. Should the prohibition be deemed to cover the modification of any germ cell whatsoever (including ova, spermatozoa and stem cells)? If so, then all germ cell research would become unlawful under Article 14 (new Article 13). If, on the other hand, the prohibition applied solely to modification of *characteristics transmissible* to descendants[12], then research on non-procreative germ cells remained possible. If the Committee's wish was for genetic research on germ cells to be permitted on condition that they were not used for procreation, it should specify this - perhaps on the French model - rather than settle for a reference to the germ cell line.

The second sentence in Article 14 (new Article 14) might thus be formulated according to the following alternatives:

a. Any intervention with the aim of modifying <u>the genetic characteristics in the germ cell line</u> is prohibited.

b. Any intervention with the aim of modifying <u>genetic characteristics transmissible to descendants of the person</u> is prohibited.

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[12] French Act no. 94-653 of 29 July 1994 concerning respect for the human body, amends Article 16-4 of the Civil Code and stipulates in particular that "...genetic characteristics shall not be modified for the purpose of modifying the descendance of the person".

The Secretariat further supported the proposal that the restrictions provided for in Article 3 (new Article 26) should not be deemed applicable to Article 14 (new Article 13).

The CDBI postponed its discussion and decision to the next meeting.

CDBI 26/02-1/03/96

The Chair noted that there was substantial agreement on the substance of the various proposals submitted by certain delegations, as well as by the Secretariat. She proposed that the Committee should first state its position on the substance and only then on the wording.

a. Regarding the substance:

She noted that the Committee agreed on the following principles, identified in a proposal submitted by two delegations:

1. An intervention including research aiming at altering the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes.

2. Any alteration, including research, of a person's germ cells shall be prohibited unless an effect on his or her descendants is ruled out.

3. Inoculation, radiation, chemotherapy or other interventions with unintended alteration of the genetic constitution of germ line cells are not prohibited.

b. Regarding the form:

A number of delegations preferred that no express reference be made to research. The Secretariat observed that an express reference to research in the framework of a prohibition on modifying the germ cell line had the result of strengthening this prohibition, not weakening it.

The Committee preferred (by 24 votes in favour and 5 against, with 4 abstentions) a more general wording to a more detailed wording that specified exceptions.

In a straw vote, the Committee decided, by 30 votes to none, with 3 abstentions, in favour of the following wording:

"An intervention seeking to modify the human genome may only be undertaken if its aim is not to modify the genetic characteristics of descendants and only for preventive, diagnostic or therapeutic purposes".

A speaker specified that in preparation of therapeutic gene strategies it is sometimes required to do so called *"gene marking"* studies in patients, i.e. a diagnostic procedure prior to therapeutic steps. This has for example been done in patients with tumours (eg. S. Rosenberg, NIH, U.S.A.). It is consequently advisable to keep the word *"diagnostic"* as one of the reasons why the intervention can be undertaken.

CORED 24-26/04/96

The CDBI-CO-RED proposed keeping to the present wording, while nevertheless replacing *"if its aim is not to modify <u>the</u> genetic characteristics of descendants"* by *"if its aim is not to modify <u>any</u> genetic characteristics of descendants".*

CDBI 4-7/06/96

The Committee reconsidered this question in the light of the proposal made by the CDBI-CO-RED. There were two aspects: definition of the aims (preventive, diagnostic or therapeutic) of any intervention seeking to modify the human genome, and protection of the genome of any descendants by prohibition of interventions seeking to modify it.

Certain experts stated a preference for the expression *"genetic constitution of the descendants"* over the one appearing in the proposed text, namely *"genetic characteristics of the descendants"*, which might prove too restrictive insofar as it could be construed as not covering those parts of the genome without any known specific function. Other participants considered that "*genetic constitution"* was not a usual expression and would raise problems of interpretation. The Committee finally agreed to use the term *"genome"* which was well-accepted, comprehensive in meaning, and consistent with the same term used at the beginning of the sentence.

Following the discussion the Secretariat, in consultation with several delegations, presented the following drafts for Article 13 and the Explanatory Report:

"Any intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants".

The Committee adopted Article 13 by 23 votes in favour and 4 against, with 2 abstentions.

The corresponding paragraph of the Explanatory Report could read as follows:

"In addition, the article prohibits interventions which aim at the modification of any part of the genome of any descendants. Therefore it is forbidden to genetically modify the totipotent cells of an embryo to be used for procreation as well as the modification of spermatozoids or ova destined to be used for fertilisation.

On the other hand this prohibition does not apply to inoculation, radiation, chemotherapy or any other treatment not aiming at the modificaiton of the genetic constitution of any descendants".

Several delegations indicated that they accepted the proposal relating to the Explanatory Report, as clarifying what the Article was intended to authorise and prohibit.

Article 14 (Non-selection of sex)

CORED 24-26/04/96

The Secretariat pointed out that the selection of sex could be effected either by means of a technique of medically assisted procreation (before conception or before the implanting of the embryo) or subsequently, by means of an induced abortion.

The CDBI-CO-RED agreed on the following text:

"The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided."

The Explanatory Report would specify that one of these techniques was artificial insemination.

CDBI 26/02-1/03/96

The Committee considered the proposal of a delegation to include an article prohibiting the predetermination of the sex of the future child, unless for health reasons. It adopted this principle by 27 votes to none, with 3 abstentions.

At a later date, the Committee considered the scope to be given to this principle: should it, as was the case with principle 1.2 of the report of the CAHBI of 1989 on human artificial procreation (CDBI/INF (97) 5)[13], be confined to the area of techniques for medically assisted procreation, or should it be broader, also including the case of a voluntary termination of pregnancy on account of the unborn child's sex?

Certain participants noted that it would be wrong to speak of *"predetermination"* of sex in the case of voluntary termination of pregnancy. Other participants thought that the Committee was far from having reached a consensus on this latter subject.

The Committee agreed to postpone until its next meeting a decision on an exact wording.

CDBI 4-7/06/96

The Chair of the CDBI-CO-RED presented the wording proposed by the Drafting Group.

The phrase *"except where serious hereditary sex-related disease is to be avoided"* was discussed. Who should be competent to assess the seriousness of a disease, the legislator or another official body, or else the two parents insofar as perception of the seriousness of an illness was subjective in many cases? It was agreed that the Explanatory Report would make reference to the current procedures in several countries (ethical committees or other bodies) for identification of the diseases justifying the possibility of choosing sex, and also to the importance of genetic counselling in this area, enabling the couple to be properly informed as to the available choices.

Article 14 was adopted with the wording proposed by the CDBI-CO-RED, by 27 votes in favour and 1 against, with no abstentions.

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[13] "The techniques of human artificial procreation must not be used for obtaining particular characteristics in the future child, in particular for the purposes of selecting the sex of the child except where, in conformity with sub-paragraph a. of the preceding paragraph, a serious hereditary disease linked with the sex is to be avoided".

CHAPTER V - Scientific research

Article 15 (General rule)

CORED 9-12/11/92

The Working Party agreed on the inclusion of an article stating that research in the field of biology and medicine should be carried out freely, but that this freedom should not be absolute.

The experts believed that research should be limited by respect for the dignity, identity and integrity of the human being, including the necessity of the person's consent.

The term *"pursuit of scientific knowledge"* referred here to all scientific activity, ie both to scientific research involving human beings and basic research in the field of biology and medicine. The question of patents on the human genome should also be considered.

CDBI 24-27/11/92

The Committee adopted this Article. The Working Party was instructed to examine the following proposals:

- insert *"responsibly"* after *"freely";*

- include the idea of sharing scientific knowledge.

CORED 14-16/12/92

The Working Party considered the proposal made by a delegation at the CDBI meeting to add the expression "*and responsibly*" after "*freely*". The experts did not approve of its inclusion which, they felt, added nothing beyond what was already conveyed by the rest of the sentence.

Another delegation had suggested including in the Article the idea of sharing scientific knowledge. The Working Party held that the idea was already embodied in paragraph 13 of the Preamble and need not be reiterated in Article 8 (new Article 15).

CORED 8-12/03/93

One participant proposed that this Article should be deleted or at least amalgamated with another provision.

The Working Party nevertheless preferred to adopt it with the wording contained in the previous text, while replacing the phrase *"the pursuit of scientific knowledge"* by *"scientific research"*.

CORED 27-29/09/93

The experts noted that the present wording, mentioning the integrity of the human being, might go even further than Article 15 (new Article 18) in preventing research on embryos.

The Working Party therefore decided to bring this Article into line with Article 1 of the Convention and thus delete all reference to the integrity of the human being.

The Working Party ultimately proposed deleting *"with respect for the dignity, identity and integrity of the human being and"* since, in any case, Article 1 of the Convention applied to all the other Articles including Article 14 (new Article 15).

CDBI 29/11-3/12/93

One expert wondered about the usefulness of such an article in a Convention which dealt with the protection of the human being with regard to the application of biology and medicine.
Another participant proposed the deletion of the adverb *"frœly"*.

These two statements elicited the majority view that it was important for the Convention to recognise freedom of research while laying down limits to such freedom based on respect for the human being. That also made it possible to strike a balance in the text between individual rights and the rights of researchers. Lastly, this Article laid the foundation for the draft Protocol on medical research. Four delegations voted in favour of the deletion of the word *"frœly",* 17 delegations voted against and 2 abstained.

One delegation suggested that a reference to ethics committees be made in this context.

One participant suggested that explicit reference should be made to the Bioethics Convention as one of the texts ensuring the protection of the human being, which had to be respected by researchers.

Following this discussion, the CDBI amended Article 14 (new Article 15) to read as follows:

"Scientific research in the field of biology and medicine shall be carried out freely in accordance with this Convention and with the other legal provisions ensuring the protection of the human being."

The CDBI also decided to instruct the CDBI-CO-RED to review the order of Articles 13 (new Article 22) and 14 (new Article 15).

CORED 24-27/01/94

The CDBI-CO-RED adopted this Article without amendment.

CDBI 27/06-1/07/94

The CDBI adopted this Article as it stood.

CDBI 26-30/06/95

The Committee endorsed the CDBI-CO-RED's decision to insert an article containing provisions on protection in respect of research in general. Such an article had the twofold advantage of providing a normative framework for all research projects and a clearer insight into the specific provisions concerning research on incapacitated persons.

i. paragraph 1

A few experts considered this paragraph superfluous and unrelated to the aim of the Convention, namely protection of the human being.

However, in the view of most delegations (21 votes in favour, none against and 7 abstentions) it was important for the Convention to uphold the free exercise of medical research, subject to the necessary protection of individuals. This freedom, according to one speaker, had its foundation and limitations in human dignity. Many participants considered medical research justified principally by the benefits which its findings were expected to bring for human health and well-being.

ii. paragraph 2

Among the conditions set out in the CDBI-CO-RED draft the Committee, at an expert's suggestion, distinguished the *"formal"* conditions (consent of the subject and examination of the project by an independent committee) from the *"substantive"* conditions. Another expert thought that as certain important conditions were liable to be omitted, the draft Convention should not mention the substantive conditions and should leave them to be covered by the future protocol. A straw poll indicated that 9 delegations favoured a text containing both substantive and formal conditions while 17 others would prefer to have formal conditions only (1 delegation abstained).

Concerning examination of the research project by an independent committee, the sole condition of *"examination"* was considered insufficient because approval was also required. A discussion ensued as to whether the opinions of ethics committees should be purely advisory or rather decisive. In many states the opinion was purely advisory where in favour of a project and decisive where unfavourable; in certain countries, however, it was in all cases advisory, the administrative authority having sole power to authorise or prohibit a research project. The Committee accepted the following wording proposed by the Secretariat: *"the project must have been approved [by the competent authority] after independent examination..."*

In the opinion of some experts, ethical examination would necessarily entail an examination of scientific merit, since it would be unethical to accept research of no scientific merit.

Without denying the soundness of this argument, for the sake of greater clarity in the text the majority of the CDBI (18 votes in favour, 10 against, 1 abstention) wanted an explicit mention of the project's scientific merit.

Regarding the subject's consent, the Committee agreed that it must be express and specific. Certain experts considered that where possible it should be certified in writing.

CDBI 5-7/09/95

Following a statement by Mr Mahoney, Deputy Registrar of the European Court of Human Rights, on Article 16 (new Article 17), several delegations expressed the view that the first paragraph of this Article, concerning research in general, should include a provision on the conditions to be fulfilled by domestic law regarding research. It was suggested adding the following sentence as a first step: *"The Parties shall ensure that these provisions are clearly stated and accessible"*.

This wording was not, however, regarded as satisfactory, and the Secretariat proposed altering it by the inclusion of a reference to the informing of persons undergoing research, as follows: *"Individuals undergoing research shall be informed of their rights and the safeguards prescribed by law for their protection"*.

The CDBI decided to reconsider this sentence at its next meeting.

The CDBI then examined the conditions set out in the second paragraph. It agreed on the substance of the three conditions raised during the last meeting of the CDBI. With regard to the first one, concerning approval of the research project by an authority, the CDBI chose the expression *"competent body"*, as it covers the various arrangements existing in the states.

CDBI 20-22/11/95

At the proposal of two delegations, the CDBI decided to move the sentence in square brackets *[Individuals undergoing research shall be informed of their rights and the safeguards prescribed by law for their protection]* and include it in the conditions which must be fulfilled in order to subject a person to research.

The Committee members unanimously approved (32 votes in favour) the proposal of a delegation to turn the first sentence of paragraph 1 into a separate article embodying a general principle regarding research.

Paragraph 2, more specific in that it stated the conditions under which research could be performed on a person, became Article 15 bis (new Article 16).

Article 16 (Protection of persons undergoing research)

CDBI 20-22/11/95

a. Proportionality of benefit to risk

A delegation felt that the present formulation of Article 15 (new Article 16) did not convey a vital aspect of the protection of persons undergoing research: the test of proportionality between the risks and benefits thereof. It suggested adding the following extra condition to be placed in paragraph ii):

"the risks which may be incurred by the person undergoing research are not disproportionate to its expected benefits and the importance of its aim".

The proposal was accepted by all members of the CDBI, but with the expression *"expected benefits"* (11 votes in favour) replaced by the expression *"potential benefits"* (12 votes in favour).

Furthermore, in compliance with a suggestion by a delegation, the CDBI decided by 24 votes to 12 to move the expression *"the importance of its aim"* to paragraph iii), which would thus read as follows:

"the research project has been approved by the competent body after independent examination of its scientific merit, including the importance of its aim, and of its ethical acceptability".

b. Written consent

In accordance with a proposal by a delegation, it was added to the final condition that the consent must be *"documented"* (in French, *"consigné par écrit").*

With the change in the order of the various conditions, Article 15 bis (new Article 16) now read as follows:

Article 15 bis (new Article 16) (Protection of persons undergoing research)

Research on a person may only be undertaken if all the following conditions are met:

i) there is no alternative of comparable effectiveness to research on humans,

ii) the risks which may be incurred by the person undergoing research are not disproportionate to its potential benefits,

iii) the research project has been approved by the competent body after independent examination of its scientific merit, including the importance of its aim, and of its ethical acceptability,

iv) individuals undergoing research are informed of their rights and the safeguards prescribed by law for their protection, and

v) the necessary consent provided for in Article 6 has been given expressly and specifically and documented. Such consent may be freely withdrawn at any time.

The CDBI unanimously adopted the above text (33 votes in favour).

Article 17 (Protection of persons not able to consent to research)

CORED 8-12/03/93

The Working Party decided that interventions could be carried out on such persons only under protective conditions provided for by national law, conditions which included the consent of the legal representative of the person concerned or of a competent authority.

The experts added another condition, namely that the intervention should directly benefit the person concerned.

The Working Party then considered whether or not an exception to this condition should be authorised; in other words, should interventions be authorised, under certain conditions, on persons incapacitated in law or in fact, when they would derive no direct benefit therefrom? It was pointed out that the authorisation of interventions only in cases of direct benefit to the persons concerned would exclude non-therapeutic research on those persons as well as the removal of organs, while for the time being the Protocols under preparation did not prohibit such interventions but laid down guidelines for them.

Conversely, one expert cited Article 7 of the International Covenant on Civil and Political Rights which provides that no one shall be subjected without his free consent to medical or scientific experimentation. The expert recalled that, in the preparatory documents of the Covenant, it had been proposed by that means to ban non-therapeutic research on minors.

The Working Party decided to refer the question of principle to the CDBI: should non-therapeutic research and removals of organs be authorised in respect of legally incapacitated persons and persons who, though legally capable, are incapable of understanding?

CORED 1-3/06/93

The Working Party accordingly expressed itself in favour of the following text for the second paragraph of Article 6 (new Article 17):

"Exceptionally, for research purposes in the health field representing a minimal risk or burden for the individual or for purposes of transplantation of regenerative tissues between close relations and friends, national law may authorise non-beneficial interventions on incapacitated persons, in cases where there is an overriding interest, provided that sufficient protection is guaranteed and that there is no possible alternative subject nor any equally effective alternative method".

CDBI 6-9/07/93

Secondly, some delegations wondered about the concept of overriding interest which justified the application of national law.

With regard to research, it was observed that this concept limited non-therapeutic research on incapacitated persons.

Another delegation felt that, while the concept of overriding interest was understandable in relation to research, it was less clearly relevant to the subject of organ transplantation where there was always an altruistic interest in improving the state of health of another person.

Thirdly, with regard to the stipulation that there should be no possible alternative subject, the addition of a clarifying phrase was suggested: *"no possible alternative subject possessing full legal capacity"*.

Fourthly, one delegation proposed inserting the phrase *"or group of subjects"* after *"another subject"*.

CORED 24-27/01/94

The Working Party reworded this paragraph in order to make it more readable without, however, altering its meaning. Account was also taken of the suggestion made by one delegation at the July meeting, which was to insert the phrase *"or group of subjects"* after *"another subject";* the new wording for the paragraph concerning research on incapacitated persons used the expression *"other subjects possessing full capacity"*.

CDBI 18-22/04/94

One delegation pointed out that the words *"un risque et une charge minimaux"* in the French text were slightly clumsy, and proposed that they be replaced by *"un risque négligeable et une contrainte minimale"*. This proposal was referred to the CDBI-CO-RED to be studied in detail, the criteria of *"risque minimal"* and *"risque négligeable"* seeming at first sight not to be identical.

CORED 30/05-2/06/94

The CDBI-CO-RED examined the expression *"where there is an overriding interest"* in the second paragraph of this Article. Participants agreed that it was less than clear and could give rise to confusion. It was therefore decided to replace it with the phrase "*where a significant benefit may be derived*", which had the advantage of being more specific and of having been used in other international texts.

With regard to research, the experts considered the question whether one of the criteria for the authorisation of research should be the existence of a "*minimal risk*" or rather a "*negligible risk*". The Working Party decided that, in the case of non-beneficial research on incapacitated persons, the strictest criterion should be selected in order to ensure the protection of such persons. The Working Party consequently adopted the concept of "*negligible risk*".

CDBI 27/06-1/07/94

The CDBI examined this Article in the light of the comments submitted by a delegation. This delegation drew the Committee's attention to the following problems:

- the principle in research should be that research could be undertaken on an incapacitated person only if a direct personal benefit for this person was to be expected. The exceptions to this principle must strictly set the conditions for the protection of the incapacitated person;

- the value of research which did not directly benefit the incapacitated person should clearly appear in the text of the Article. In other words the Article should state that in the case of research which was not for the direct benefit of the incapacitated person, significant benefit for the group of persons to which he or she belongs must be expected. This clarification would strengthen the protection of incapacitated persons.

- it would be desirable to combine Articles 6 and 7 (new Article 17) into a single article, in order to bring together the provisions relating to the incapacitated person's consent and the conditions relating to his or her protection.

It was also pointed out that the present draft did not deal with the question of objection by the incapacitated person, whereas Recommendation R (90) 3 of the Committee of Ministers stated in Principle 5, *"... national law may authorise research involving a legally incapacitated person which is not of direct benefit to his health when that person offers no objection..."*.

The CDBI noted these comments and admitted their pertinence. The Committee decided for the time being not to amend the Article, but to discuss it again in detail at its next meeting, after the necessary consultations. It was therefore agreed to put several parts of this Article between brackets in order to draw attention to the fact that the wording of this text was still provisional. A footnote would give the necessary explanations.

CDBI 26-30/06/95

Subject to certain editorial changes and possible additions, the Committee (26 votes in favour, 2 against, no abstention) approved the provisions of this Article concerning research on incapacitated persons, including research not directly benefiting the subject.

The delegations made the following remarks:

- the first sentence should specify potential benefits instead of *"expected benefits";*

- the second sentence, instead of directly mentioning an exception to the principle of benefit for the incapacitated person, should state that the Parties may authorise additional research subject to statutory safeguards and the following provisions;

- specify that an incapacitated person should not be subjected to more than one type of research at a time. However, in the opinion of the CDBI-CO-RED Chairman, the number of research projects authorised was less important than the concept of minimal burden inherent in the project;

- replace the phrase *"where this research may significantly improve understanding of disease or disorder"* with the phrase *"where this research is beneficial to persons with the same age, disease or disability profile";* similar wording was proposed by another delegation, the gist of both proposals being that the expected benefits of research related to the same group or category of persons as the subject;

- should a specific monitoring system for research on incapacitated persons be instituted? Several participants expressed misgivings over a solution of this kind, involving the creation of cumbersome machinery of dubious effectiveness.

Several delegations pointed out that the removal of the *"substantive"* conditions from Article 15 (new Articles 15 and 16) had the effect of rendering Article 16 (new Article 17) incomplete. For instance, the condition concerning non-existence of an alternative to research should be stated here if not shown in Article 15 (new Articles 15 and 16).

CDBI 5-7/09/95

The CDBI held an exchange of views on the first paragraph of this Article, which lays down the general principle regarding research on persons incapable of consenting.

An observer pointed out that, in the case of so-called therapeutic research, there could be a benefit for the person concerned or for persons belonging to the same category as she or he. He therefore proposed referring in this first paragraph not only to the potential benefit for the person concerned but also to the benefit for other individuals. The majority of the CDBI, however, did not share this opinion, as the Article did not distinguish between therapeutic research and non-therapeutic research but between research of potential benefit for the person undergoing it and research without such potential.

The Committee then considered the wording of this first paragraph. Eleven delegations stated their preference for wording it as follows: *"A person who is not able to consent according to Article 6 may not undergo research unless it is expected to produce a significant benefit to his or her health"*. Following a proposal by a delegate, however, 18 delegations voted in favour of the following text: *"A person incapable of consenting may not undergo research unless it has the potential to produce a significant benefit to his or her health"*. In the opinion of these delegations, the concept of potential reflected the reality of research more accurately.

The CDBI then studied the second paragraph of this Article, which authorises research that is not for the direct benefit of a person not able to consent.

One delegation disagreed with the principle of this paragraph, which it considered to call in question the Article 2 principle of the primacy of the human being over the interests of science and society. The delegation was worried that the text might allow researchers to carry out research on a human being incapable of consenting, solely in order to satisfy their scientific curiosity.

The majority of the CDBI, while understanding these fears, thought that the text allowed persons incapable of consenting to benefit from the contributions of science while ensuring their protection. But for research of that kind, such persons might be victims of discrimination. The Committee agreed that it was essential to make it clear in the text that research on a person incapable of consenting must, where it was not for his or her direct benefit, be aimed at benefiting the category to which he or she belonged. It must be designed to investigate or improve the

treatment of a disease or a disability; it could also be aimed at improving understanding of a disease or a health condition with a view to sooner or later benefiting persons suffering from that disease or falling in the same age group, for example.

With regard to the actual wording, several participants thought that stipulating that *"it may be prescribed by law"* that research is authorised would mean that in the absence of a law, in the broad sense of the term, such research was prohibited. Other participants, on the other hand, thought that, even in the absence of law, research could be authorised if the country applied the principle that anything not prohibited was permitted. After hearing the explanation of the Deputy Registrar of the European Court of Human Rights, the CDBI decided by 20 votes to 7 (with 2 abstentions) to refer to law in this text, without deciding on the exact terms of the paragraph.

After this discussion, the following text was proposed for this paragraph:

"Exceptionally and only if there is negligible risk and minimum burden for the individual concerned, research which does not have the potential for immediate direct benefit may be permitted if this research:

a. may improve knowledge of the individual's disease or disorder and be beneficial to persons suffering from the same disease or disorder, or

b. may improve knowledge of growth, development or health condition, provided the following conditions are met, in addition to those in Article 15:

i) the necessary authorisation as provided for under Article 7 (new Article 5) has been given expressly and in writing. Such authorisation may be freely withdrawn at any time;

ii) any refusal by the individual or his or her representative must always be respected,

iii) equally effective research cannot be carried out on individuals capable of giving consent."

Several participants criticised the addition of the adjective *"immediate"* to qualify the benefit insofar as it created a divergence between the scope of paragraph 1 and that of paragraph 2. Moreover, one delegation considered that combining this text with paragraph 1 might have the result of authorising only research of benefit to the person concerned, whether the benefit was immediate or delayed, whereas paragraph 2 was in fact intended to cover cases where there was not necessarily any benefit to that person.

The CDBI decided to reconsider this first sentence of paragraph 2 at its next meeting. The Secretariat proposed discussing the following text:

"Exceptionally, under the protective conditions prescribed by law, research without direct benefit may be permitted on an individual who is not able to consent where this research may significantly improve the understanding of his or her health condition, disease or disorder, and aims to benefit persons with the same age, growth, disease or disorder profile, provided that, in addition to those contained in Article 15, the following conditions are met:

i. research of comparable effectiveness cannot be carried out on individuals capable of giving consent,

ii. there is only negligible risk and minimum burden for the individual concerned,

iii. the necessary authorisation as provided for under Article 7 (new Article 5) has been given expressly and in writing. Such authorisation may be freely withdrawn at any time;

iv. any refusal by the individual must always be observed".

Note bene: The proposed order of the conditions matches the way in which the question arises in practice; it also emphasises that there can be no question of carrying out on persons incapable of consenting any research that could be carried out on a capable individual.

CDBI 20-22/11/95

Paragraph 1:

A delegation thought it preferable to revert to the previous wording, as follows: *"is expected to produce a significant benefit to his or her health"*; it considered that the expression *"unless it has the potential to produce a significant benefit to his or her health"* had been replaced too hastily by the above expression. The majority of the CDBI disagreed, as the concept of potential, which had gained preference at the last meeting reflected better the reality of research.

Attention was also drawn during the discussion to a risk of inconsistency in that two different adjectives were used to describe the benefit (*"significant"* in the first paragraph and *"direct"* in the second paragraph), whereas the two concepts should be made uniform.

The CDBI debated the exact meaning of the expression *"direct benefit"*. The conclusion was that the term referred to the benefit which a person could derive from the potential results of the research undergone; therefore it also applied to persons undergoing blind tests by administration of a placebo as they could supposedly benefit from the direct result of such research. Consequently, benefit could accrue directly either through participation in the research or through its results. A delegation pointed out in this connection that the benefit referred to in paragraph 1 could be immediate or mediate but must always be derived from the research itself.

The CDBI, having put to the vote the alternative phrases *"significant benefit"* (7 votes), *"direct benefit"* (12 votes) and *"significant direct benefit"* (13 votes), accordingly opted for the third expression.

In addition, the CDBI confirmed that refusal by an incapable person, including a minor at an early age, to undergo therapeutic research, even where considered capable of conferring significant benefit, must always be respected for two reasons:

- because benefit in connection with even therapeutic research was never assured;
- in order to conform to the terms of Article 7 of the International Covenant on Civil and Political Rights stipulating: *"... no one shall be subjected <u>without his free consent</u> to medical or scientific experimentation* ".

Paragraph 2:

The CDBI agreed that paragraph 2 should form an exception to paragraph 1 and apply specifically to cognitive research unlikely to be of other than indirect benefit (whether to the person undergoing research or to other persons in the same category), for instance through better understanding of disease processes. Some delegates however criticised the notion of *"indirect benefit"*.

A delegation suggested deleting the words *"may significantly improve the understanding of his or her health condition, disease or disorder"* so as not to restrict, even unintentionally, the scope of the Article. However, the majority of the CDBI members disagreed.

The same delegation suggested replacing the conjunction "*and*" by "*or*" before *"aims to benefit persons who may have the same (...) profile",* which would also obviate restriction of the scope of the Article.

One delegation asked that the term *"minimum risk"* be given preference over *"negligible risk"*. The proposal was supported by several experts who felt that a risk should never be considered negligible. The CDBI agreed to this amendment by a majority (22 votes in favour of "minimum" and 6 votes in favour of *"negligible",* with 4 abstentions).

A delegate observed that the condition laid down in paragraph 2.i) *("research of comparable effectiveness cannot be carried out on individuals capable of giving consent")* logically applied not only to paragraph 2 (research without direct benefit) but also to paragraph 1. Indeed, if comparable results were obtainable from research on capable

persons, it ought not to be conducted on incapable persons even if they were expected to derive direct benefit from it. The Secretariat was instructed to take account of this observation for the reformulation of the Article.

At the close of discussion, the text of paragraph 3 appeared as follows:

"exceptionally, under the protective conditions prescribed by law, research without direct benefit may be permitted on a person who is not able to consent where this research may [produce a significant indirect benefit to his or her health] or significantly improve the understanding of his or her health condition, disease or disorder [and] [or] aims to benefit persons with the same age, growth, disease or disorder profile. In addition to the conditions contained in paragraph 1 above and in Article 15 bis (new Article 16), the following conditions must be met".

A delegate made a new contribution to Article 16 (new Article 17) (not discussed in the meeting):

"Research which, by improving understanding of the person's condition, illness or disorder, has the potential to produce benefit for the person and/or for someone in the same condition or afflicted with the same illness or disorder, may be permitted provided that, in addition to the principles contained in Article 16 i) to iv), the following conditions are met: (...)".

The Secretariat was instructed to make suggestions on this Article in the light of the observations made during discussion.

CDBI 26/02-1/03/1996

The CDBI considered this Article on the basis of a proposal made by the Secretariat, which took into account the results emerging from the Committee's discussion in the course of its ninth meeting.

a. Paragraph 1

Bearing in mind a delegation's comments, the Committee adopted paragraph 1 by 30 votes in favour and none against, with 2 abstentions.

b. Paragraph 2

The Committee introduced some of a delegation's amendments to the second paragraph. It should be pointed out in the Explanatory Report that the research on *"the individual's condition"* under paragraph 2 (i) might cover, with regard to research on children, not only diseases or abnormalities peculiar to childhood or certain aspects of common diseases that are specific to childhood, but also the normal development of the child.

An observer said that paragraph 2 was a good description of the conditions and terms of research without direct benefit and met the highest national and international standards for protecting the individual.

Many delegations stressed that the long-term goal of any research was to improve a medical application (diagnostic, preventive, therapeutic etc.) but that to attain this goal, the results of certain research, in particular so-called cognitive research, had to be rounded out by other research. In certain cases, it might be hoped (but could not be reasonably assured) that the individual who consented to research could benefit from the results himself; in others, such benefit could be ruled out straightaway (for example when testing a new method of diagnosis on a patient for whom an illness had already been diagnosed by the usual method).

Subparagraph 2 (i) makes provision for these two possibilities, because it addresses research capable of conferring a benefit *"to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition".*

A delegation proposed replacing, in the phrase *"to the person concerned or to other persons"* the word *"or"* by *"as well as" ("ainsi que").* This proposal was rejected by 5 votes in favour and 27 against, with 1 abstention.

The Committee adopted paragraph 2 by 27 votes in favour and 4 against, with 2 abstentions.

CDBI 4-7/06/1996

The Committee voted on Article 17 as a whole, which had been discussed during the previous meeting. It was adopted by 24 votes in favour and 1 against, with 2 abstentions.

Article 18 (Research on embryos *in vitro*)

CORED 9-12/11/92

Several experts felt that it was necessary to include such an article which prohibited the creation of embryos solely for research purposes (paragraph b).

One expert said that this concerned the dignity and integrity of the human being and that authorising creations of this kind risked reducing the human being to a mere object. This expert felt that this Article raised the problem of the scientific creation of human life for purposes other than human life, a problem which went much further than the question of the embryo.

It was also mentioned that parents might conceive a child for a different purpose than its birth (for example to take the bone marrow for another child of the couple).

Another participant mentioned the problem of euthanasia, but it was pointed out that the reason for drafting the Convention had been to take account of medical progress, and progress in medicine and biology was mainly being made in areas which concerned the start of life. This question must be reexamined.

The Special Adviser reminded the Working Party of the fact that a similar provision had contributed to the Recommendation on human artificial procreation being rejected by the Committee of Ministers. He therefore considered such an article as inopportune.

The Working Party decided to submit this Article to the CDBI to obtain the plenary body's opinion on the need for this Article.

The Co-ordinator, aware of the fact that the CAHBI has discussed, on many occasions, such a problem without reaching a uniform opinion on the point, and in order to facilitate the rapid progress of the works of the Convention, expressed his dissenting opinion on the decision to submit, once again, the question to the Committee in plenary.

CDBI 24-27/11/92

Several delegations thought that Articles 9.a (new Article 18) and 9.b[14], which concerned research on embryos, would be better dealt with in a special protocol on embryos. It was pointed out, however, that such a protocol would for the time being have little chance of success and that these provisions provided a minimum of protection for embryos.

After a discussion, the majority of the Committee (11 votes in favour, 6 votes against, 2 abstentions) were in favour of including in the Convention an article designed to protect embryos in research work.

The Working Party was instructed to suggest a wording for Article 9.a (new Article 18) that took account of the CAHBI's previous work, as set out in the report on artificial procreation.

One delegation expressed the desire that the Convention should expressly prohibit keeping the embryo for more than fourteen days.

The Committee accepted the idea contained in Article 9.b[15], but two delegations said that this provision was not acceptable in the light of the legislation in force in their countries.

With regard to Article 9.c[16], the Working Party would consider the possibility of including it in Article 10 (new Article 13).

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[14] This paragraph no longer exists in Article 18.
[15] This paragraph no longer exists in Article 18.
[16] This paragraph no longer exists in Article 18.

Other delegations would like to have seen Article 9.c amplified in the light, inter alia, of Parliamentary Assembly Recommendations 1046 and 1100.

CORED 14-16/12/92

At the last CDBI meeting, the plenary Committee had asked the Working Party to reformulate Article 9.a (new Article 18) so as to take into account the content of the report on human artificial procreation.

After examining the report, the Working Party expressed the opinion that it was preferable to retain the present wording of Article 9.a (new Article 18) and to mention the report on artificial procreation in the Explanatory Report to the Convention.

Having discussed Article 9.b, the Working Party decided to delete it.

It was decided to delete Article 9.c after consideration of Parliamentary Assembly Recommendations 1046 and 1100. However, these two Recommendations would be mentioned in the Explanatory Report to the Convention concerning the stipulation in Article 8 (new Article 15) that the pursuit of scientific knowledge shall be carried out with respect for the dignity, identity and integrity of the human being, in view of the fact that Article 9.c had been designed to prohibit certain types of research affecting the identity of the human being.

CORED 8-12/03/93

Following a discussion concerning inter alia the problem of the transfer of embryos which have been the subject of manipulation, the Working Party decided to add the phrase *"and shall be restricted to research aimed at treating infertility"*.

Some experts felt that, when research on embryos was authorised, it should not be capable of being developed in any direction or for any purpose.

However, the Working Party decided to refer to the CDBI, for a decision of principle, the question whether research on embryos, when it is authorised by national law, should be restricted to the treatment of sterility.

CDBI 6-9/07/93

The Chairman asked each delegation in turn to give its opinion on the desirability of including in the text of the framework Convention an article dealing with research on the human embryo and, if the opinion was favourable, on its possible content.

The views expressed showed that a large number of delegations favoured the inclusion of such an article in the framework Convention.

With regard to its possible content, a number of delegations preferred the following wording:

- *"Where research on embryos in vitro is allowed by national law, such research may only be authorised in the case of embryos which are not more than fourteen days old".*

Several delegations pointed out that this wording, which was taken from the Council of Europe report on artificial procreation (1989), was appropriate in as much as it was confined to imposing a restriction on research on embryos *where such research is allowed by national law*, thus taking into account and regulating a practice already established in several countries, without however expressing a view on the merits of such a practice.

Some delegations wished to add the following phrase to the above text:

- *"…and shall be restricted to research aimed at treating infertility".*

Some delegations were in favour of the inclusion of a second paragraph in the same Article, as already proposed by one delegation at the Committee's April meeting and also supported on several occasions by another delegation. It would read as follows:

- *"The creation of human embryos solely for research purposes is prohibited".*

An observer said that he would be in favour of a provision banning all research on human embryos. Failing such a provision, research should be made subject to a large number of additional conditions. In this connection, the same observer pointed out that the Council of Europe's report on artificial procreation had already laid down several restrictions: embryos should not be created for research purposes exclusively; they should not be more than fourteen days old; the couple should have consented to the research; there should be no alternative method and an ethics committee should have authorised the research.

Furthermore, some delegations proposed that the CDBI should ask the Committee of Ministers to give it the task of preparing a protocol to the Convention dealing with the various problems associated with the human embryo. Indeed, these delegations took the view that the draft terms of reference reproduced in the report of the previous meeting did not faithfully reflect the intention of all the delegations which had voted to adopt them, as they were restricted exclusively to the field of organ transplantation, whereas the initial proposals had aimed at obtaining terms of reference for a general protocol on the embryo.

The Chairman decided to give the Committee time for reflection in order to enable delegations to consider the various proposals put forward.

At a later stage of the meeting, the Chairman requested the Committee's opinion on the voting procedure to be observed. By 12 votes to 7, with 2 abstentions, the Committee decided to vote first on the draft Article of the Convention, and then on the draft terms of reference for the elaboration of a protocol.

The Committee decided by 18 votes to 2, with 4 abstentions, that the framework Convention should contain an article concerning research on the human embryo. One delegation pointed out that it was not in a position to express an opinion at that time.

With regard to the content of the Article in question, the Committee decided as follows:

- with 14 votes in favour, it adopted the following wording: *"Where research on embryos in vitro is allowed by national law, such research may only be authorised in the case of embryos which are not more than fourteen days old";*

- there were 4 votes in favour of the phrase *"...and shall be restricted to research aimed at treating infertility"* and five abstentions. It was not adopted;

- the proposal for a second paragraph was adopted (16 votes in favour, 4 against and 2 abstentions) with the following wording: *"The creation of human embryos solely for research purposes is prohibited".*

One delegate expressed a reservation with regard to the whole of Article 15 (new Article 18). Another delegate said that his country reserved the right to raise an objection with regard to the second paragraph of Article 15 (new Article 18) at any subsequent time, even possibly in the Committee of Ministers.

The Committee then took a vote on the following wording proposed by one delegation and amended by another delegation:

"Given the ever growing importance of the ethical problems raised by the application to the embryo and the foetus of progress in biology and medicine - whether in the field of scientific experimentation, organ removal, or gene therapy etc - the CDBI decided to request the Committee of Ministers to give it specific terms of reference for the preparation of a protocol to the Bioethics Convention on the protection of the embryo and the human foetus."

There were 17 votes in favour, 5 against and 1 abstention. The proposal was adopted.

CDBI 29/11-3/12/93

The CDBI referred to a proposal made by a delegation to the Working Party which aimed at rewording the first paragraph of this Article to read: *"Where research on human embryos is [allowed] by law, such research may only be authorised in the case of embryos which have not been developed for more than 14 days"*.

Several speakers came out in favour of this proposal, which clarified the meaning of the provision.

CORED 24-27/01/94

The CDBI-CO-RED examined and adopted the proposal by a delegation aimed at rewording the first paragraph of Article 15 (new Article 18) without affecting its meaning.

The first paragraph of Article 15 (new Article 18) was therefore reworded to read:

"Where research on human embryos is allowed by law, such research may only be authorised in the case of embryos which have not been developed for more than 14 days".

The Working Party considered the order of the paragraphs and decided to leave it unchanged, in as much as the first paragraph dealt with the very principle of research on embryos, which was the primary condition.

CDBI 27/06-1/07/94

The CDBI examined a delegation's proposal to reword the Article as follows: *"Research on embryos which is not for their benefit and the creation of embryos for other purposes than bringing about a pregnancy are prohibited"*.

In the course of an exchange of views, several delegations said they were in favour of deleting Article 15 (new Article 18). One delegation for its part considered that at least the second paragraph of this Article should be deleted, in particular because in the draft Convention submitted by the CDBI-CO-RED it was the only one in respect of which States could formulate a reservation.

The CDBI held a vote on the proposal to reword the Article. 9 delegations were in favour, 15 against and one abstained. The amendment was therefore rejected.

The CDBI agreed to reconsider the suggestion that Article 15 (new Article 18) or its second paragraph should be deleted under the heading of reservations.

CDBI 20-22/11/95

The CDBI, by 26 votes in favour and 4 against, with 2 abstentions, approved the principle of including in the Convention an article covering research on embryos.

One delegation reiterated its proposal, reading as follows:

"Research on human embryos which does not serve the purpose of their preservation shall be prohibited. Also prohibited shall be the generation of embryos for purposes other than inducing a pregnancy."

A vote taken by the CDBI indicated that the inclusion of this text in the Convention was accepted by 8 delegations and rejected by 19 delegations, with 5 abstentions.

The CDBI discussed whether, in accordance with the wish of the Parliamentary Assembly, the first paragraph of this Article, permitting research on embryos up to the fourteenth day of life, should be deleted.

Certain delegations wished to confirm the deletion outright. An observer felt that such confirmation should not imply that the Convention henceforth permitted research on embryos, but that the matter was simply left to be dealt with in a subsequent protocol.

Among those in favour of maintaining the paragraph, some would rather avoid mention of the 14 days and confine themselves to drafting a more general text which would leave it for the future protocol, or otherwise for domestic law, to make the requisite clarifications.

The Committee took a stance as to whether it would be preferable to adopt a general or a specific text on embryo research (the first paragraph of former Article 15, mentioning the 14 day rule, being a specific text): 27 delegations were in favour of a general text, 4 delegations preferred a specific text, and there were 3 abstentions.

An observer put the following proposal to the Committee:

"The Parties shall protect human dignity as soon as life begins. Any research on human embryos shall respect the dignity and identity of the human being and comply with the legal rules affording such protection".

He pointed out that the text covered, in general terms, research on embryos both in vitro and in vivo, and implicitly acknowledged the existence of domestic law in the matter.

A delegation shared the idea of respect for the dignity of the embryo in the observer's proposal, but objected to the use of the expressions *"as soon as life begins", "embryo"* and *"human being"* as if they were equivalent. It put forward its own text as follows, and the observer said he could agree to the first paragraph:

"1. Any research on human embryos shall respect their dignity and comply with the rules ensuring their protection.

"2. The generation of embryos for research purposes is prohibited."

The Secretariat for its part proposed:

"Where the law allows research on embryos in vivo or in vitro, it shall ensure adequate protection of the embryo".

A delegation proposed:

"Where research on embryos in vivo or in vitro is allowed by law, it must always be founded on prevalent national existential and cultural values pertaining to the earliest stages of human life".

The CDBI agreed to reconsider these alternatives at its next meeting.

CDBI 26/02-1/03/96

a. Paragraph 1

The Chair proposed holding a vote to see which of the various following proposals the Committee preferred:

- the July 1994 version[17], which read as follows:

"Where research on embryos in vitro is allowed by law, such research may only be permitted in the case of embryos which have not been developed for more than 14 days".

Two delegations voted in favour. The proposal of the Parliamentary Assembly to delete paragraph 1 was thus approved.

- a delegation's proposal, which read as follows:

"Research on human embryos which does not serve the purpose of their preservation shall be prohibited. Also prohibited shall be the generation of embryos for purposes other than inducing a pregnancy".

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[17] Article 15.1 of the draft Convention of July 1994.

Five delegations voted in favour; the proposal was rejected.

- another delegation's proposal, which read as follows:

"Where research on embryos in vivo or in vitro is allowed by law, it must always be founded on prevalent national existential and cultural values pertaining to the earliest stages of human life".

Three delegations voted in favour; the proposal was rejected.

- a third delegation's proposal, which read as follows:

"Any research on human embryos shall respect their dignity and comply with the rules ensuring their protection".

One delegate voted in favour; the proposal was rejected.

- the Secretariat's proposal, which read as follows:

"Where the law allows research on embryos in vivo or in vitro, it shall ensure adequate protection of the embryo".

This proposal, amended to confine it to embryos in vitro, was approved by 24 votes in favour and 3 against, with 5 abstentions.

b. Paragraph 2

The Chair of the CDBI-CO-RED reminded delegates that virtually all member states permitted in vitro embryo creation to treat infertility. However some member States have legislation which forbids the creation of embryos for research purposes, whilst other member states legislation permits the creation of embryos for limited research purposes under strict protective conditions. There is a third group of member States which has no legislation on the subject.

He considers that given that the purpose of creating embryos in vitro is to treat infertility, it is surely important to ensure that the best way of creating and preserving these embryos is established as well as ensuring so far as possible that they are safe to implant. Here desirable conditions can only be achieved by suitable research. The critical ethical question therefore is whether the Article should, in line with this view, be phrased to permit research subject to protective conditions or whether the Article should be negative and forbid research in which case these aims could not be achieved.

Mr Englert, Chair of the HEF Group of the European Commission, stressed that although the use of surplus embryos might make certain research possible, the results of research on this embryo population were distorted. Embryos with the best potential naturally had priority for implantation in patients, because they gave them the best chance of becoming pregnant. Hence, the other embryos were not representative of the entire population, and this posed certain problems of interpretation.

Speaking as a practitioner, he referred to the difficulty that this type of prohibition would place him in *vis-à-vis* his patients: either he would stop developing new therapies (which was difficult for a physician to do) or he would have to introduce them without having conducted all possible assessments as to effectiveness and safety. It therefore appeared that a strict prohibition would not take into account the legitimate interests of patients and children.

The Committee was asked to decide between the two versions of paragraph 2:

A. The version proposed by one delegation and amended by another read as follows:

"The creation of human embryos for research purposes not serving the production of advances in reproductive health care or the prevention of severe genetic or congenital diseases or malformations is prohibited".

In a straw vote, this proposal received 10 votes in favour and 15 against, with 7 abstentions. It was considered to have been rejected.

B. The version of the draft of July 1994 contained two alternatives:

- alternative 1: In a straw vote, *"The creation of human embryos solely for research purposes"* received 11 votes in favour and 9 against, with 10 abstentions.

- alternative 2, which was in keeping with the wishes of the Assembly, and which read: *"The creation of human embryos for research purposes is prohibited"* received 10 votes in favour and 9 against, with 13 abstentions.

The result of the votes showed that none of the alternatives received the required two-thirds majority. But a number of delegations considered that version B had probably not received the required majority because the votes were dispersed between the two alternatives of this version.

The Chair therefore proposed, and the Committee approved, the following procedure:

i. vote on the principle of having a paragraph 2 containing the prohibition to create embryos for research purposes: 22 delegations voted in favour of this principle and 6 against, with 4 abstentions.

ii. straw vote on the following alternatives:

a. prohibition to create embryos *"solely"* for research purposes: 4 votes;

b. prohibition to create embryos for research purposes without the word *"solely"*: 15 votes;

c. abstentions: 13 votes.

iii. vote on alternative B, which had received the most votes and which read as follows:

"The creation of human embryos for research purposes is prohibited"

21 delegations voted in favour and 8 against, with 4 abstentions.

iv. vote on Article 17 as a whole, which read as follows:

"Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.
The creation of human embryos solely for research purposes is prohibited".

17 delegations voted in favour and 11 against, with 3 abstentions.

The Chair noted that the two-thirds majority (the abstentions not being counted[18]) was 19 votes and that this majority had not been attained. Thus, as matters stood, there was not a sufficient majority for Article 17 (new Article 18) as a whole.

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[18] Rules of procedure for Council of Europe committees (Appendix II to Resolution (76) 3 of the Committee of Ministers on Committee structures, terms of reference and working methods):
Article 14 - Voting
a. Each member of the committee shall have one vote ; however where a government designates more than one member, only one of them is entitled to take part in the voting.
b. Subject to any contrary provisions in these Rules, decisions of the steering committees are taken by a two-thirds majority of the votes cast.
c. Except on procedural matters, other committees shall not take decisions by voting. They shall state their conclusions in the form of unanimous recommendations, or, if this proves impossible, they shall make a majority recommendation and indicate the dissenting opinions.
d. Procedural matters shall be settled by a majority of the votes cast.
e. Where the question arises as to whether or not a matter is procedural in nature, it may not be so regarded unless the committee decides to that effect by a majority of two thirds of the votes cast.
f. For the purposes of these Rules "votes cast" shall mean the votes of members cast for or against. Members abstaining shall be regarded as not having cast a vote.

CORED 24-26/04/96

The CDBI-CO-RED took note of the situation regarding Article 17 (new Article 18), especially the fact that at the previous meeting it had not obtained a two-thirds majority. As things stood, therefore, there was no article concerning research on embryos. Without discussing the content, the Working Party considered that it was for the CDBI to decide whether it wished to include in the Convention a general article on the protection of embryos or whether it preferred leaving this subject for a future protocol, without reopening a substantive discussion.

CDBI 4-7/06/96

The Committee voted on the entire Article, which had been discussed at the previous meeting. It was expressly agreed that paragraph 2 neither allows nor forbids research on surplus embryos. The Article was adopted by 17 votes in favour and 3 against, with 7 abstentions.

CHAPTER VI - Organ and tissue removal from living donors for transplantation purposes

Article 19 (General rule)

CDBI 26-30/06/95

The Committee, on its first examination of this Article, agreed with the ideas formulated. There were nevertheless several remarks:

First paragraph

- the French expression for *"cadaveric organs" ("organes d'origine cadavérique")* was inappropriate; it would be better to use *"organs removed from deceased persons"* as including persons in a state of brain death;

- add the condition that corresponding results cannot be achieved by an alternative method (tissue culture or xenografts, for instance). In this connection several participants felt that even though dialysis enabled patients to compensate for renal failure, the results of such therapy were inferior to those of a successful transplant;

- include in the first paragraph the following principle: *"removal of organs from a living person may be carried out solely for the direct therapeutic benefit of the recipient"*. This principle would make it possible to guard against trafficking in organs.

Paragraph 2

- Phrase the beginning of the paragraph as follows: *"No organ may be removed from a living donor except …";*

- under (a): delete *"personal"* and restrict organ donation to members of the same family; outside the family, donation should be subjected to the approval stipulated in (b);

- add the need to conduct immunological analyses before transplantation .

Paragraph 4

- add *"bone marrow or other regenerative tissues"*.

CDBI 5-7/09/95

The CDBI discussed whether this Article should cover organs only or might also apply to tissues.

Several delegations thought that, while the future Protocol on organ transplantation should cover both cases, the draft Convention, which lays down a general rule, should deal only with organs. On the other hand, the draft Convention, should, for the purposes of the text, equate bone marrow to an organ, as is the case with many countries' laws. The CDBI agreed on this latter proposal, as the removal of tissues calls for significantly different rules and it is not necessary to go into these details in the draft framework Convention. One delegation expressed the view that a separate protocol on tissue banks should be drawn up.

A delegation and an observer wondered whether xenotransplantations came within the scope of the Convention. In its present state, the text refers only to organs removed from a living donor, which precludes xenografts. On the other hand, it would be for the Protocol, to deal with this question if the Committee so decided.

The Committee also decided, following a proposal by a delegation, to include in this first paragraph the requirement of the absence of a comparably effective alternative therapeutic method, a requirement which previously appeared only in the Article on the removal of organs from persons incapable of consenting. The CDBI regarded this safeguard as valid for all removals, not just for those effected from incapable persons.

The Committee then examined the second paragraph as appearing in the report of its previous meeting. Several delegations proposed authorising removals of organs without it being necessary to obtain the permission of an authority, not only where there were family links between the donor and the recipient but also where there were personal relations between them. In these delegations' opinion, in the case of removal of organs from a capable person it was necessary to respect the person's autonomy and enable him or her to give an organ if he or she so wished without having recourse to a procedure deemed cumbersome. Other delegations, on the other hand, felt that, outside cases where there were family links between the donor and the recipient, it was necessary to be extremely cautious so as to avoid any trafficking or pressure; consequently, the intervention of an independent authority seemed to them to be a necessary safeguard.

In the end, following an observation by a delegate, the CDBI agreed that this question was more a matter for the Protocol than for the actual Convention and did not need to be dealt with at the present juncture. The Committee therefore decided to delete this paragraph. The Committee also deleted paragraph 4 of this Article, concerning immunological analyses, as it was considered too detailed.

With regard to the last paragraph, concerning consent, the CDBI agreed that, in the case of such an important intervention, it was necessary to obtain the express consent of the person concerned. Two delegations, however, felt that the expression "*written consent*" was too restrictive, as in some countries consent was obtained by an authority such as a court or by a law officer such as a notary. The Committee agreed that requiring consent to be obtained in these forms was just as protective as demanding written consent.

In conclusion, in order to cover all these situations, the CDBI decided to refer to consent *"given in written form or before an official body"*.

CDBI 26/02-1/03/96

The Committee considered a delegation's proposal that Article 18 (new Article 19) should not cover *"organs and bone marrow"* alone but *"organs and tissues"*.

Some delegations had reservations about this proposal and argued that both from the point of view of risk and from an ethical point of view, the problems posed by the removal of tissue were not comparable to those posed by the removal of organs.

The Committee decided to include tissue by 26 votes in favour and 4 against, with 3 abstentions.

The Committee then considered various proposals on the inclusion of specific conditions.

At a later stage of the discussion, the Committee instructed the CDBI-CO-RED to make proposals on this Article.

The Secretariat was of the opinion that it did not seem advisable to have very detailed provisions in the Convention on a subject that was highly dependent on the state of science at a given moment and that it would be better for the Convention to be restricted to essential principles.

CORED 24-26/04/96

The Working Party examined this Chapter with the participation of an organ transplant specialist in the British Department for Health and a representative of the French Ministry of Health, who had both been invited by the Secretariat. However, because of their individual availability, they were not able to be present at the meeting at the same time.

The Working Party decided not to include in the Convention any definition of organ or tissue, on the understanding that the Explanatory Report might give some examples instead.

With regard to the therapeutic benefit of the recipient in the event of the donation of organs or tissues, it was emphasised that the benefit needed to be *"direct"* only in the case of the donation of organs, not in the case of the donation of tissues. The Working Party decided to delete the adjective *"direct"* from the Convention, on the

understanding that the Explanatory Report might provide relevant details. In particular, the CO-RED decided to mention in the Explanatory Report that the storage of tissues in tissue banks was permissible.

The wording of paragraph 2, concerning the form of the consent, was amended in order to bring it into line with that of the Article on research.

The CO-RED agreed on the following text:

Article 18 (new Article 19) (General rule)

1. Removal of organs or tissues from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 6 must have been given expressly and specifically either in written form or before an official body.

CDBI 4-7/06/96

The CDBI voted on the entire Article in the form proposed by the CDBI-CO-RED.

It was adopted unanimously by 29 votes in favour and none against, with no abstentions.

Article 20 (Protection of persons not able to consent to organ removal)

CORED 8-12/03/93

The Working Party decided that interventions could be carried out on such persons only under protective conditions provided for by national law, conditions which included the consent of the legal representative of the person concerned or of a competent authority.

The experts added another condition, namely that the intervention should directly benefit the person concerned.

The Working Party then considered whether or not an exception to this condition should be authorised; in other words, should interventions be authorised, under certain conditions, on persons incapacitated in law or in fact, when they would derive no direct benefit therefrom? It was pointed out that the authorisation of interventions only in cases of direct benefit to the persons concerned would exclude non-therapeutic research on those persons as well as the removal of organs, while for the time being the Protocols under preparation did not prohibit such interventions but laid down guidelines for them.

The Working Party decided to refer the question of principle to the CDBI: should non-therapeutic research and removals of organs be authorised in respect of legally incapacitated persons and persons who, though legally capable, are incapable of understanding?

CORED 1-3/06/93

The Working Party examined a contradiction between the second paragraph of Article 6 of the Convention and the Protocol on organ transplantation. Indeed, Article 6 (new Article 17) of the Convention required that interventions on incapacitated persons should be carried out for their direct benefit. Exceptions to the principle of direct benefit were possible only when the risk incurred by the incapacitated person was a minimal risk.

On the other hand, the Protocol on organ transplantation authorised the removal of organs from incapacitated persons. However, removal was an intervention which was carried out for the benefit not of the incapacitated donor but of the recipient, and which frequently entailed, for the donor, a greater than *"minimal risk"* (if only because of the general anaesthetic which was often necessary).

The Working Party therefore decided to reword the Article to take account of this contradiction between the Convention, which required that interventions not directly benefiting the incapacitated person should present only a minimal risk, and the Protocol on organ transplantation which authorised an incapacitated person to act as an organ donor despite a greater than minimal risk.

However, the Working Party disagreed with the Protocol on organ transplantation which authorised removals from legally incapacitated persons under certain conditions but required no close personal or family relationship between the incapacitated person and the recipient, since the transplantations concerned were of bone marrow or other regenerative tissues.

The Working Party decided therefore to adopt a form of words restricting the possibility of removal from incapacitated persons to cases where the recipient was a close relation or friend of the incapacitated person. The CDBI would therefore be required to take a decision on the question whether a removal from an incapacitated person could be carried out for the benefit of any recipient or whether the latter should be a close relation or friend of the incapacitated person.

The new wording adopted specified the cases where the condition of direct benefit could be waived, namely cases of research and organ transplantation.

The Working Party accordingly expressed itself in favour of the following text for the second paragraph of Article 6 (new Article 17):

"Exceptionally, for research purposes in the health field representing a minimal risk or burden for the individual or for purposes of transplantation of regenerative tissues between close relations and friends, national law may authorise non-beneficial interventions on incapacitated persons, in cases where there is an overriding interest, provided that sufficient protection is guaranteed and that there is no possible alternative subject nor any equally effective alternative method".

CDBI 6-9/07/93

With regard to the second paragraph, the following problems arose.

First of all, the members of the CDBI-CO-RED had expressed the view that the removal of an organ from an incapacitated person should only be carried out for the benefit of a close relation or friend. However, this position was at variance with the provisions of the Protocol on organ transplantation, Article 6 (new Article 17) of which laid down no requirement of a relationship between an incapacitated donor and a recipient, since the transplantation concerned regenerative tissues.

The Working Party had therefore referred to the CDBI the question whether a removal from an incapacitated person could be carried out for the benefit of any recipient or whether the latter should be a close relation or friend of the incapacitated person.

The Committee decided by 14 votes to none, with 5 abstentions, to allow such a restriction.

However, a debate ensued on the scope of the restriction: should there be a close personal or family relationship between the incapacitated donor and the recipient, or should the restriction be ever narrower, requiring a family relationship between the two persons concerned?

Thirteen delegations were in favour of the requirement of a close personal or family relationship; 7 were in favour of a family relationship exclusively and there were 2 abstentions.

In the text of the Convention, the phrase *"close relations and friends"* was therefore replaced by *"persons having close personal or family relations"*.

Secondly, some delegations wondered about the concept of overriding interest which justified the application of national law.

With regard to research, it was observed that this concept limited non-therapeutic research on incapacitated persons.

Another delegation felt that, while the concept of overriding interest was understandable in relation to research, it was less clearly relevant to the subject of organ transplantation where there was always an altruistic interest in improving the state of health of another person.

In order to clarify this expression in relation to organ transplants, it was decided to include in the Explanatory Report the text of the third paragraph of Article 9 of the Protocol on organ transplantation which required that no organ should be removed when the risk to the health of the donor was disproportionate in relation to the expected benefit to the recipient, and to make it clear that, in the case of incapacitated donors, the proportionality rule required the expected benefit to the recipient to be particularly great.

Thirdly, with regard to the stipulation that there should be no possible alternative subject, the addition of a clarifying phrase was suggested: *"no possible alternative subject possessing full legal capacity"*.

Fourthly, one delegation proposed inserting the phrase *"or group of subjects"* after *"another subject"*.

CORED 24-27/01/94

With regard to the second paragraph, the Secretariat wondered about the merits of the proposal to authorise the removal of regenerative tissue from an incapacitated person for the benefit of a person with whom he had merely close personal relations. Would it not be more desirable to limit the exception to cases where there was a family

relationship between the incapacitated donor and the recipient? The exact scope of the exception on behalf of a recipient having close personal relations with the donor was not very clear.

Other participants recalled the decision taken by the plenary CDBI at its July meeting, when it had expressed itself in favour of the requirement of a close personal or family relationship.

The Working Party reworded this paragraph in order to make it more readable without, however, altering its meaning. Account was also taken of the suggestion made by one delegation at the July meeting, which was to insert the phrase *"or group of subjects"* after *"another subject";* the new wording for the paragraph concerning research on incapacitated persons used the expression *"other subjects possessing full capacity"*.

CDBI 5-7/09/95

The CDBI readily agreed on the first paragraph.

With regard to the second paragraph, the Committee decided by 22 votes to 1 (with 4 abstentions) to authorise removal of bone marrow from a person incapable of consenting. This exception to paragraph 1 is accounted for by the requirement of compatibility between donors and recipients, which means that the only possible donor is one of the siblings. Prohibiting removal from a minor or from an adult incapable of consenting would preclude any transplantation in cases where he or she was the only person compatible with the recipient, which would usually result in the patient's death.

A delegation emphasised the importance of recognising this exception, as even if removal of bone marrow involves risks for children, the risks are probably less than the psychological consequences children might suffer if they learnt when older that one of their siblings had died because bone marrow could not be removed from them because they were under age.

The CDBI agreed by 17 votes to 6 (with 5 abstentions) to limit this exception to bone marrow and not to extend it to other regenerative tissues, on the understanding that the Convention's provisions refer in any event only to organs, including bone marrow.

Several delegations were in favour of establishing a parallel here with the Article on research and specifying that removal should involve only a negligible risk and a minimal burden for the person concerned. The majority of the CDBI were against this proposal, which would rob the paragraph of its substance as removal of bone marrow presupposes a given risk and burden that cannot be termed negligible or minimal. On the other hand, it lies with practitioners, in pursuance of the rules of conduct incumbent on them, to ascertain that the person concerned does not run, by virtue of his or her characteristics, any risks greater that those which are inherent in this type of intervention and which make removal unadvisable.

After this discussion, the Committee agreed on the text as worded.

CDBI 26/02-1/03/96

Following a proposal the Committee voted on the following options with regard to paragraph 2:

- limit the exception to bone marrow: 6 votes in favour;
- include *"bone marrow and other regenerative tissue"*: 23 votes in favour;
- include *"bone marrow, regenerative tissue and other tissue"*: 3 votes in favour.

The CDBI-CO-RED was instructed to make proposals taking into account the above results.

CORED 24-26/04/96

To take account of the rapid scientific advances in the field of organ and tissue transplants (in particular, the removal of stock cells) as well as of the variety of definitions to be found in national laws, the Working Party decided to

delete the term *"bone marrow"* and to keep to the more generic term of regenerative tissue. The Explanatory Report might specify that regenerative tissue was tissue capable of reconstituting its tissue mass and functions after partial removal[19].

To increase the protection of donors unable to give consent, the Working Party considered that removal should not be authorised for the benefit of a person having only *"a close family relationship with the donor",* but solely between brothers and sisters. This restriction was motivated by a concern to prevent any undue attempt by either the family or by doctors to find a donor at any price, even if the relationship was somewhat remote (eg a cousin) and the chances of the transplant succeeding were not very great. Moreover, the donation should be permissible only if the life of the recipient brother or sister was threatened.

The Working Party emphasised that the exceptions to the principle of prohibiting the removal of organs or tissues from someone unable to consent should be very strict, as they often affected people who were not just minors but were in the early stage of life. One participant proposed limiting the Article to minors and prohibiting removal from adults unable to give consent, but this proposal was not adopted by the CO-RED.

The wording of the condition concerning consent was amended to bring it into line with that in the Article on research.

The CO-RED agreed on the following text:

Article 19 (new Article 20) (Protection of persons not able to consent to organ removal)

1. No organ or tissue removal may be carried out on an individual who does not have the capacity to consent under Article 6 (new Article 5).

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from an individual who does not have the capacity to consent may be authorised provided the following conditions are met :

i. there is no compatible donor available who has the capacity to consent,

ii. the recipient is a sibling with the same parents as the donor,

iii. the donation must have the potential to be life-saving for the recipient,

iv. the authorisation provided for under paragraphs 2 and 3 of Article 7 (new Article 6) has been given specifically and in writing, as provided for by law,

v. the person concerned does not object.

CDBI 4-7/06/96

a. Paragraph 1

The Committee adopted paragraph 1 by 30 votes in favour and none against, with no abstentions.

b. Paragraph 2

The CDBI approved the CDBI-CO-RED's proposal that removal of tissues from persons not able to consent should not be restricted to *"bone marrow",* and opted for the generic term *"regenerative tissues"*.

[19] See Explanatory Report to the draft Protocol on organ transplantation.

With regard to the recipient, the CDBI-CO-RED advocated restricting the benefit of the donation to a sibling rather than authorise it for a person merely having a close family relationship with the donor. The three following variants were considered:

- variant 1: *"the recipient has a close family relationship with the donor"* received 11 votes in favour and 15 against, with 2 abstentions.

- variant 2: *"the recipient is a brother or sister of the donor"* received 26 votes in favour and none against, with 7 abstentions;

- variant 3: *"the recipient is a person with the same biological parents as the donor"* received 1 vote in favour and 28 against, with 3 abstentions.

The Committee accordingly adopted variant 2. An indicative vote (4 votes in favour and none against, with 6 abstentions) rejected the idea of adding that the recipient must be biologically a brother or sister of the donor. It was nevertheless agreed to specify in the Explanatory Report that even in the case of a brother or sister, removal should not be effected where the chances of success were too slim.

The proposal to add a condition concerning the possible risk to a donor following removal was also considered. The two following approaches were discussed:

- either to stipulate that the risk incurred should not exceed the normal degree of risk, which was the purport of one delegation's proposal that *"the donor's individual state of health does not pose any extraordinary risks if the procedure is undertaken"*. The proposal was not accepted;

- or to provide that the donor should be properly informed of the possible risks and that these should be assessed, as implied by the following proposal by a delegation: *"an independent examination has been carried out of the risks that the removal might cause, as well as its foreseeable consequences"*. The proposal was rejected by 13 votes in favour and 16 against, with 2 abstentions. It was agreed that the Explanatory Report would draw attention to the existence of a duty to provide information, particularly on the risks incurred.

By 11 votes in favour and 17 against, with 3 abstentions, the Committee opposed the principle of adding the concept of risk to the stated conditions.

The condition worded *"the donation must have the potential to be life-saving for the recipient"* was adopted by 31 votes in favour and 2 against, with no abstentions.

Condition iv. concerning authorisation of removal was adopted as it stood by 32 votes in favour and none against, with 2 abstentions.

The final condition, slightly amended to read *"the potential donor does not object"*, was adopted unanimously.

Paragraph 1 of Article 20 was adopted by 30 votes in favour and none against, with 1 abstention; paragraph 2 was adopted by 27 votes in favour and 2 against, with 2 abstentions.

Article 20 was adopted in its entirety by 29 votes in favour and none against, with 2 abstentions.

CHAPTER VII - Prohibition of financial gain and disposal of a part of the human body

Article 21 (Prohibition of financial gain)

CORED 9-12/11/92

The experts agreed that no person should sell parts of his or her body. In other words, profits should not be made from the human body.

One participant underlined the problem of human tissues here, adding that the problem was complex because industry was involved.

The wording of the Article took account of these views.

The Working Party decided to have another discussion on this matter at its next meeting.

CORED 8-12/03/93

The Working Party maintained this Article with no change from the previous meeting.

The Working Party pointed out, however, that the Article primarily covered the person from whom the parts were obtained.

It was then observed that laboratories and hospitals provided parts of the human body against remuneration, but that such remuneration was explained by the services rendered. Nevertheless, care had to be taken to ensure that the remuneration covered only the services rendered and was not disproportionate.

One expert noted that it might be desirable to allow States the possibility of reserving their position on this Article with regard to blood.

Lastly, some participants wondered whether this Article was appropriate for certain parts of the human body, such as nails and hair. The Working Party considered that a solution might be found in the distinction between parts of the human body which could be *"naturally"* separated from the body and others.

CDBI 27-30/04/93

The Committee accepted the principles laid down in the two paragraphs of this Article.

The following remarks were made:

- Hair, nails and other similar parts of the body should be excluded.

- Should a reservation be allowed in respect of blood?

- Did the expression *"parts of the body"* include human genes? According to a representative the expression included the human genome and, accordingly, implicitly precluded the patentability of human genes as such. On the other hand, according to another speaker, the expression *"parts of the human body"* referred to physical parts, not to the representation of those parts.

- According to the Co-ordinator, the term *"agreement"* concerning the human body should be replaced by *"disposal"*.

CORED 1-3/06/93

The CDBI had made a number of comments at its meeting which were considered by the Working Party.

Regarding the first comment to the effect that hair, nails and other similar parts of the body should be excluded from the Article, the Working Party did not consider it necessary to amend the text in order to achieve that goal. On the other hand, it decided to stipulate in the Explanatory Report that the Convention dealt with the applications of biology and medicine and that, consequently, hair and nails did not fall within the scope of the Article.

Secondly, the Working Party took the view that a reservation in respect of blood was not desirable.

With regard to the remark concerning the patentability of human genes, the Working Party considered that this was a very specific problem which deserved more detailed consideration.

On the question of the wording of paragraph 1 of the Article, the Working Party expressed the view that the term *"agreement"* was not appropriate.

One expert then proposed combining the two paragraphs of Article 11 and submitted the following text: *"The dignity of the human body and its parts shall be respected and [therefore] shall not, as such, give rise to financial gain"*.

This solution was adopted by the Working Party.

CDBI 6-9/07/93

One expert questioned the use of the expression *"as such"* which he considered to be lacking in clarity.

It was then recalled that certain organs or tissues were the subject of certain procedures (tests, conservation, transportation etc) which legitimately gave rise to a payment. The purpose of the Article was to prohibit any trafficking in organs and tissues as such, without any accrued value, not to ban normal remuneration for operations of the type previously mentioned.

Moreover, the CDBI took note of the opinion expressed by the CDBI-CO-RED which considered that the question of the patentability of the human genome should be specifically considered.

Lastly, it was proposed to reword the article as follows: *"The dignity of the human body shall be respected. The body and its parts shall not, as such, give rise to financial gain"*.

CORED 24-27/01/94

The CDBI-CO-RED adopted this Article without amendment.

CDBI 18-22/04/94

The Committee wondered about the first sentence of this Article, worded as follows: "*The dignity of the human body shall be respected*".

Some participants said that this sentence did not lay down a rule, making it superfluous. Others said that a statement should be made to the effect that the human body had to be respected, a provision which might have a great variety of applications in practice.

Following its discussion, the CDBI decided by 13 votes to 9, with 2 abstentions, to delete the sentence.

CDBI 5-7/09/95

The CDBI approved this Article as it stood.

Two delegations wondered whether the Article prohibited the patenting of the human body or its parts.

The CDBI agreed that it had not considered the question of patents in connection with this provision. Such was the complexity of the problem of patents that a detailed study was necessary before any regulations were drawn up[20]. If such a study led to the conclusion that regulations on the subject were desirable, the regulations should include principles and rules suited to the specific nature of the subject. The Committee agreed that these points should be included in the Explanatory Report.

[20] See the CDBI's similar opinion on the Parliamentary Assembly's Recommendation No. 1213 on developments in biotechnology and the consequences for agriculture, where reference is made to the question of patenting biotechnological inventions.

Article 22 (Disposal of a removed part of the human body)

CORED 14-16/12/92

The Working Party agreed to include the idea embodied in the fifth suggestion, although one expert felt that it might be more suitable for inclusion in a protocol.

The basic idea presented in the fifth suggestion was the right of every individual to be informed concerning the use of his body and body material, and to express his opinion in the matter. In this connection a system of non-objection or a system of express consent according to the intended use of the body material would be conceivable. The principle concerned living persons only.

CORED 8-12/03/93

This new Article set out ideas accepted by the Working Party at its previous meeting and affirmed that an individual had the right to examine the use made of a part of his body after it had been removed.

The experts decided in this context to use the phrase *"in conformity with appropriate information and consent procedures",* in order to take account of the different possible scenarii. In some cases, the formula of non-objection would be more appropriate than that of express consent. It was also observed that this Article also applied to the persons covered by Article 6 (new Article 17) and that, consequently, it was in some cases the consent of the legal representative which would be required.

The Working Party decided to indicate in the Explanatory Report that the system of non-objection was the minimum requirement and that it was possible, for example, to conceive of arrangements for the distribution of booklets to patients in hospitals. In some cases, on the other hand, express consent would be required.

The Working Party noted that a protocol on this subject might be useful.

CDBI 27-30/04/93

Several delegations expressed their support for the principle in this Article.

Other participants, while approving the principle, thought that its formulation was too broad. One delegation preferred limiting its scope to parts of the human body removed in the course of a therapeutic intervention.

A few delegations thought that the provision was too restrictive. They preferred it to be deleted in favour of a provision in the Articles on consent.

Some experts emphasised that, depending on the case, the consent required would be express or might be implied.

The representative of the Parliamentary Assembly, Dr Palacios, was satisfied with the Article as it stood.

An indicative vote on the principle in the Article gave the following result: 19 votes for, 2 against, 1 abstention.

On behalf of the Committee, the Chairman instructed the Working Party to look at the wording of the Article again in the light of the delegations' comments.

CORED 27-29/09/93

After further consideration, the Working Party decided to leave this Article unchanged, noting that its present wording was sufficiently flexible, in particular because of the use of the catch-all term *"appropriate"*.

CDBI 29/11-3/12/93

The CDBI adopted this Article without amendment.

CORED 24-27/01/94

The CDBI-CO-RED adopted the Article without amendment.

CDBI 27/06-1/07/94

A delegation expressed reservations about the wording of this Article because it did not appear to serve any purpose to systematically obtain a person's consent to use a part of his or her body for purposes other than those for which it had been removed. The use of waste materials from surgery for which it did not appear expedient to seek the consent of the person was mentioned in this regard.

It was therefore proposed that the Article be reworded as follows: *"When, in the course of an intervention, any part of a human body is removed it may be stored and used for a purpose other than that for which it was removed only if the appropriate procedures governing information have been observed and if, depending on the case, the person has consented or has not objected".*

The CDBI decided against this rewording since only two delegations were in favour, but took note of a delegation's reservations.

CDBI 5-7/09/95

Some delegations considered this Article too restrictive in that it required the person concerned to be informed and his or her consent obtained in all cases where a part of the body was used for purposes other than the purpose for which it had been removed.

Other participants, however, regarded the text as sufficiently flexible as it specified that the information and consent procedure should be *"appropriate"*. This term enabled the procedure to be adapted according, inter alia, to the type of human body part involved, the use envisaged and any invasion of the privacy of the person concerned. The Article therefore made it possible, in certain cases, to obtain only implied consent and inform persons by means, for example, of a leaflet.

Following a remark by a delegate, it was agreed to include in the Explanatory Report a sentence specifying that this Article should not be construed as authorising any exception to the principle in Article 18 that removal of organs for transplantation purposes can be effected only for the benefit of the recipient; thus, it would be inadmissible for an organ to be removed for transplantation purposes and then used for a different purpose (unless, with the donor's consent, only a small part of the organ was used for, say, research purposes while the main part had been transplanted).

The CDBI agreed to return to this Article at its next meeting.

CHAPTER VIII - Infringements of the provisions of the Convention

Article 23 (Infringement of the rights or principles)

CORED 9-12/11/92

Some members of the Working Party felt the second paragraph of this Article should be deleted but no agreement was reached.

The Working Party therefore decided to refer to the CDBI the question whether the Convention should include provisions on class action.

CORED 14-16/12/92

Where the second paragraph of Article 12 (new Article 23)[21] was concerned, the Working Party wished to limit collective action to the protection of persons unable to ensure their own protection (eg very old people confined to an institution).

CORED 8-12/03/93

The Working Party adopted the Article in its existing terms but preferred to use the phrase *"unlawful infringement of the principles set forth in this Convention"* in order not to give priority to any particular aspect, such as integrity.

The experts decided to mention in the Explanatory Report infringements affecting several persons, especially if they were unable to defend themselves. Thus, the appropriate judicial protection in such cases could be the commencement of proceedings by the Public Prosecutor to prevent the infringement of these individuals' rights.

Finally, the Working Party noted that this Article did not overlap with Article 20 (new Article 24) since it covered the prevention of infringements, whereas Article 20 (new Article 24) dealt with compensation for infringements.

CDBI 6-9/07/93

The following comments were made on the subject of this Article:

- it should cover not only the threat of infringement but also infringements which had already begun and were perpetuated. The following wording was suggested: *"to prevent or to put a stop to …"*. This suggestion was accepted by the Committee;

- the expression *"at short notice"* was perhaps too restrictive; could it not be deleted? In the opinion of the Secretariat, the terms *"appropriate judicial protection"* might be sufficient. The protection of some of the rights set forth in the Convention no doubt called for urgent judicial action (for example, the risk of impairment of physical integrity); while in other cases the normal procedure could be followed. For that reason, the Article should reserve the possibility of protection *"at short notice"* to cases where there was a risk of serious infringement with irreversible consequences; otherwise States would be placed under an obligation to provide for emergency procedure even in complex cases where there was no indisputable urgency. Several delegations, however, took the view that the particular value of this Article lay in the fact that it required a rapid solution. One delegation proposed the formula *"effective and timely protection"*, but this was not adopted.

CDBI 27/06-1/07/94

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[21] This paragraph no longer exists in this article.

The CDBI amended this Article by adding the term *"rights"* before *"principles",* since the Convention not only states principles but also guarantees rights.
CDBI 5-7/09/95

The CDBI agreed on this text.

Article 24 (Compensation for undue damage)

CORED 9-12/11/92

The experts felt that it was difficult to lay down a system of liability applicable to all States and preferred to leave the question of the system of liability to domestic legislation.

One expert mentioned the problem of the burden of proof which could prove to be a serious one for the victims in this case.

CORED 8-12/03/93

The Working Party adopted this Article as it appeared in the previous text, with the addition of the adjective *"undue"* before the word *"damage"*.

CDBI 6-9/07/93

The following comments were made:

- Was the Article necessary, since Article 20 (new Article 25) spoke of sanctions and compensation could be considered as a form of sanction? It was pointed out that the term "sanctions" used in Article 20 (new Article 25) had a precisely limited meaning (administrative sanctions, criminal sanctions, etc) and not a broad meaning covering compensation for victims. The text would not be clear if it merely referred to sanctions without explicitly mentioning compensation. The Committee decided, by 15 votes in favour to 9 against, to maintain the Article.

The Secretariat suggested the following change in the order of the Articles, in order to respect their sequential implications: first the current Article 19 (new Article 23), dealing with the prevention of infringements; followed by the current Article 21 (new Article 24) (compensation); and finally the current Article 20 (new Article 25) (sanctions). The Working Party could consider this proposal.

- Some delegations expressed doubts about the need to qualify the noun *"damage"* with the adjective *"undue"*: in as much as compensation had to be provided "according to the conditions defined by national law", was not the justification or non-justification of the damage one of the conditions in question? Other delegations, on the other hand, considered that this concept should be included in the text. Medical interventions frequently gave rise to damage, and it was important to emphasise, when enunciating the principle of compensation, that only undue damage warranted compensation. The Committee decided, by 16 votes to 4 with 4 abstentions, to maintain the term *"undue"*.

- Several delegations considered that it would be important for the Explanatory Report to specify that it lay with the legislator to determine the system of compensation selected, particularly as regards the choice between strict liability and fault liability. A representative said that reference should also be made to the extent of the damage covered, in particular the question of non-material damage and damages for pain and suffering ("pretium doloris").

CDBI 27/06-1/07/94

The CDBI accepted this Article as it stood.

CDBI 5-7/09/95

A delegation referring to the use of the adjective *"fair"* in connection with compensation in the English version, wondered wether it would not be better to use instead the adjective appearing in Article 50 of the European Convention on Human Rights, namely *"just"*. [This remark does not apply to the French version, which uses the term *"équitable"* in the same way as the Human Rights Convention.]

Several delegations were against deleting the phrase *"according to the conditions and procedures prescribed by law"*, as proposed by the Parliamentary Assembly. In their view, its deletion would render the text liable to be interpreted as establishing a system of strict liability.

Other participants, however, thought that the term *"undue damage"* was adequate and allowed states considerable room for manoeuvre as it would be for domestic law or the courts to define the concept. In no event did this Article opt for a particular system of liability, as already mentioned in the Explanatory Report.

The CDBI decided to reconsider this text at its next meeting.

CDBI 26/02-1/03/96

The CDBI considered the proposal of the Secretariat to link the right to fair compensation to damages resulting from failure to comply with the provisions of the Convention. Several delegations spoke out against this proposal, which might suggest that failure to comply with a given provision of the Convention might also entail the responsibility of the State.

The Committee thus decided to retain the initial version of this Article.

A delegation proposed the deletion in this version of the word *"undue"*. The Committee decided not to follow this proposal.

The Committee then considered the proposal of the Assembly to delete the phrase *"according to the conditions and procedures prescribed by law"*. However, 27 delegations spoke out in favour of retaining this phrase, and none in favour of its deletion. It was thought that the conditions and procedures of this general Article, applicable to very varied situations (diagnosis, treatment, research etc.) needed to be specified by law and, if necessary, by future protocols.

Article 23 (new Article 24) was therefore retained in its initial version.

Article 25 (Sanctions)

CORED 8-12/03/93

The Working Party adopted this Article without amendment.

CDBI 6-9/07/93

This Article was adopted without amendment. At a later stage, consideration should be given to whether the word *"Chapter"* in square brackets should be retained or replaced by the term *"Convention"*.

CDBI 27/06-1/07/94

The CDBI also adopted this Article as it stood. The question arose as to whether a State should provide for sanctions for acts perpetrated outside its territory. It was pointed out that criminal law, which is essentially of national origin, may in fact provide for this possibility, as was indeed the case with the recent French Acts on bioethics in the case of certain offences violating the principle of non-commercialisation of the human body.

CDBI 5-7/09/95

No amendment was proposed to this Article.

CHAPTER IX - Relation between this Convention and other provisions

Article 26 (Restrictions on the exercise of the rights)

CORED 9-12/11/92

The Working Party decided to examine this Article together with Article 8.

The experts stressed the need to define concrete rights and to provide additional guarantees compared to other existing texts, in particular the European Convention on Human Rights.

The Working Party then examined the counter-proposal from an expert. The problems raised in this proposal were dealt with in several different Articles (Articles 3/4/5/6/7/9).

The Working Party decided that the third sub-paragraph of should be kept, and stressed the need to determine whether the possibility of derogation it offered applied to all the rights contained in the Convention, once the content of the other Articles had been decided.

CORED 14-16/12/92

Regarding Article 3 (new Article 26), paragraph 1, one participant suggested replacing *"The law"* by *"States"*. Other members of the Working Party preferred to retain the existing version, pointing out that in this context the term *"law"* was to be construed in its broadest sense, by contrast with paragraph 3 of this Article where its technical sense was intended.

Another expert observed a discrepancy between Article 1 of the Convention and Article 3 (new Article 26), paragraph 1 in that the latter provision made no specific reference to protection of rights and fundamental freedoms.

The Working Party instructed the Secretariat to deal with the problem when editing the Articles.

The Working Party went on to consider paragraph 3 of Article 3 (new Article 26).

The experts noted that this provision was directly inspired by Article 8 of the European Convention on Human Rights but that the wording differed.

They queried the term *"health"*, and wondered whether it should be understood to mean public health alone or to include the health of the person concerned.

On this point, Mr de Salvia, Deputy Secretary to the Commission of Human Rights, took part in the discussion. He said that in fact only one decision of the Commission gave any indication about the scope of the term *"health"* within the meaning of Article 8 of the European Convention on Human Rights, viz: the decision of 10 December 1984 (Roger Almanne and others v/ Belgium, application no. 10435 (83)).

After this exchange of views, the experts, in order to make it clear that the term *"health"* in Article 3 (new Article 26) was to be taken in its broadest sense, ie. public health and individual health, redrafted Article 3 (new Article 26), paragraph 3 as follows:

"*There shall be no interference with the exercise of the rights contained in this Convention except such as is in accordance with the law and is necessary in a democratic society for the protection of health or for the protection of the rights and freedoms of others*".

Concerning this paragraph of Article 3 (new Article 26), certain members of the Working Party advocated the deletion of the expression *"democratic society"* on the ground that if a measure is necessary for the protection of health in a democratic society, it is equally so in a non democratic society. Other experts, however, were in favour of maintaining the expression, a direct borrowing from the European Convention on Human Rights.

Having concluded that the expression *"a measure which is necessary in a democratic society"* was to be understood as *"a measure which is mandatory in a democratic society",* the Working Party decided to make no further change in the wording of the Article.

CORED 8-12/03/93

Following discussion, the Working Party decided to limit the exception provided for in the second paragraph of this Article to the protection of public health, and to that end inserted the adjective *"public"* before *"health"*.

The experts thought it preferable not to include the protection of the health of individuals in the general exception but to mention it only in the Articles concerned by that exception. Indeed, if a general exception was allowed for the protection of the individual concerned, that would mean for example that it would be possible to disregard the refusal of a person possessing legal capacity and capable of understanding, and thus to waive Article 5, on the ground that his refusal could be prejudicial to his health.

CDBI 27-30/04/93

The Committee accepted the content of this Article. Certain comments on the wording, which the Working Group should examine, were however made, i.e.:

- use the expression *"principles"* instead of *"rights";*
- use the expression *"limitation"* instead of *"interference";*
- should one not add other reasons than public health, for example, public safety, etc.?
- use the expression *"in cases specified by law",* instead of *"in accordance with the law";*
- examine the comments made by the Coordinator.

CORED 1-3/06/93

The Working Party did not endorse the suggestion that the expression *"principles"* should be used instead of *"rights"*. The experts felt that this term would weaken the Convention, the purpose of which was to protect individual rights. It was also observed that the title of the Convention contained the term *"rights"*.

After discussing the terms to be employed in the second paragraph of Article 2 (new Article 26), as requested by the CDBI, the participants opted for the formula contained in Article 11 of the Human Rights Convention, while maintaining only the exceptions applicable to the scope of the Convention. The experts considered that it was indeed desirable to adopt the terminology of the Human Rights Convention, with adjustments where necessary, in order to show the links between the two texts.

Following the suggestions of the Co-ordinator, the exceptions allowed by Article 2 (new Article 26) were limited to certain fields: [national security], protection of public health or public order and protection of the rights and freedoms of others.

The experts therefore excluded a number of exceptions which appeared in the Human Rights Convention, since they felt that exceptions in the field of biology and medicine were necessarily narrower than those in the field of human rights in general. For example, the economic welfare of a country could not constitute grounds for restricting the rights contained in the Bioethics Convention. The same was true of morals. With regard to public safety and the prevention of disorder or crime, they were considered to be covered by the expression *"public order"*. The experts observed that all possible exceptions were thus covered by the new wording of Article 2 (new Article 26) and that, for example, any measures ordered by a court in civil proceedings (eg a paternity suit) which derogated from the Convention would be covered by the protection of the rights and freedoms of others, while in the field of criminal law exceptions would be authorised by public order. National security had been added to take account of situations where military personnel might be required, with or without their consent, to undergo specific interventions not made compulsory for the rest of the population.

The Working Party stressed that the conditions laid down in Article 2 (new Article 26) were cumulative and that presciption of the law was therefore required for any derogation from the rights contained in the Convention, while the restriction adopted would have to constitute a necessary measure in a democratic society for the protection of the interests enunciated. It was decided to include that comment expressly in the Explanatory Report.

CDBI 6-9/07/93

With regard to the second paragraph of the Article, delegations asked the following questions:

- What was meant by *"public order"?* Would not the concepts of public safety and the prevention of disorder and crime, referred to in Article 8 of the European Convention on Human Rights, be more appropriate?

- Was the exception relating to national security necessary? Some delegations, while agreeing on the need of an exception for the circumstances which the Working Party wished to indicate (namely situations where military personnel might be required, with or without their consent, to undergo specific interventions not made compulsory for the rest of the population), expressed doubts about the use of the concept of national security;

- Why did the Articles referring to national law not all use the same terminology? Indeed, some experts observed that the phrase *"restrictions prescribed by law"* was used in some cases, while other Articles contained the formula *"national law may authorise"* or again *"if authorised by national law"*. These delegations therefore stressed the need to harmonise the terminology employed in the different Articles. One delegation wondered whether it was necessary to use the terms *"law"* or *"national law"* or again *"domestic law"*.

Mr Mahoney, Head of Division in the Registry of the European Court of Human Rights, replied to certain questions asked by the Committee concerning the second paragraph of Article 2 (new Article 26) in relation to the second paragraphs of Articles 8, 9, 10 and 11 of the European Convention on Human Rights. A summary of his statement appears below in Appendix to Article 26.

Following this discussion, the Working Party was instructed:

- to reword the exception concerning national security in order to reduce its scope to the circumstances expressly referred to by the Working Party;

- to review the exception concerning public order in the light of the information provided by Mr Mahoney;

- to bring the different Articles into line with one another by favouring the expression "*prescribed by law*" as it appeared in the English version of the European Convention on Human Rights.

CORED 27-29/09/93

The Working Party noted that the CDBI had asked it to change the wording of the exceptions to this Article in the light of the information provided by the Head of Division in the Registry of the European Court of Human Rights.

The experts examined the European Convention on Human Rights and noted that it used the following expressions in respect of the notion of public order:

Article 8:	- public safety - the prevention of disorder - the prevention of crime
Article 9:	- public safety - the protection of public order
Articles 10 and 11:	- public safety

- the prevention of disorder
- the prevention of crime

Having examined this list of terms, the Working Party decided to employ the expressions used in Article 8 of the Convention on Human Rights, as that Article was closest to several provisions in the draft Bioethics Convention.

The expression *"public order"* used in the previous version of Article 2 (new Article 26) was therefore replaced by "*public safety, the prevention of disorder and the prevention of crime*".

As for national security, the Working Party noted that the CDBI had instructed it to change the wording of this exception. However, participants pointed out that this was the wording used in the Convention on Human Rights and that it seemed appropriate to the situation. The Working Party did nonetheless instruct the Secretariat to seek the opinion of the Human Rights Directorate of the Council of Europe or representatives of the Court or Commission on this subject in due course.

The CDBI had also asked the Working Party to use the expression *"prescribed by law"* for the sake of consistency between the different Convention Articles. Participants agreed to use this expression for Article 2 (new Article 26) but made the following remarks:

- it would be necessary to examine the appropriateness of this expression for each Article where it was to be used;

- certain experts felt that the word *"law"* contained in the expression implied that the measure had to be covered by formal statute law. Other participants reminded the Working Party of the very broad interpretation given to the idea of *"law"* by the Court and Commission of Human Rights, defining the word as including not only Statute law but also regulations and case-law.

CDBI 29/11-3/12/93

With regard to the second paragraph of Article 2, a representative approved the Working Party's choice which consisted in reproducing in Article 2 (new Article 26) the exceptions set out in Article 8 of the European Convention on Human Rights (EUROPEAN CONVENTION ON HUMAN RIGHTS). He considered this to be the most appropriate solution in as much as Article 8 bore the greatest similarity to a number of provisions in the draft Bioethics Convention.

In this connection, the Secretariat recalled that the only difference between Article 8 of the EUROPEAN CONVENTION ON HUMAN RIGHTS and the draft second paragraph of Article 2 (new Article 26) was that the latter did not mention the economic well-being of the country as one of the possible justifications for an exception to the rights recognised in the field of bioethics.

The Chairman of the Working Party informed the CDBI that the Secretariat had been instructed to seek the opinion of the Directorate of Human Rights or representatives of the Court or Commission on the exception relating to *"national security",* in order to ascertain whether they considered that formula appropriate in the context of the draft Convention.

Lastly, the CDBI took note of the Working Party's discussion on the expression *"prescribed by law".* The Steering Committee confirmed that, unless otherwise indicated, the expression *"prescribed by law"* should be taken to cover not only formal statute law but also any other standard-setting text (regulations, for example) as well as case law.

CORED 24-27/01/94

With regard to the exception concerning national security, the CDBI-CO-RED thought it necessary to seek the opinion of the representatives of the Court and Commission and the Steering Committee for Human Rights; it would therefore be desirable to include this important question in the agenda for the meeting to be held between the representatives in question and those of the CDBI.

Regarding the Explanatory Report, the Working Party took the view that it would be worthwhile to provide examples of cases covered by the exceptions contained in Article 2 (new Article 26). For information, one expert cited the example of contagious diseases in respect of the exception concerning *"the protection of public health"*.

One participant felt that mention should also be made of the criteria which states were required to apply when they envisaged authorising an exception, namely necessity and proportionality, criteria which were accepted by the European Court of Human Rights.

CDBI 18-22/04/94

Where the second paragraph was concerned, the CDBI decided to retain *"national security"* as one of the grounds which might justify restriction of the rights recognised in the Convention. The Explanatory Report would quote as examples certain compulsory acts (such as vaccinations) undergone by members of the armed forces. This matter, as previously decided by the CDBI, would be examined at the joint meeting between the CDBI-CO-RED and Human Rights representatives.

CORED 30/05-2/06/94

The Working Party questioned the Human Rights representatives, MM Nørgaard and Walsh, on the desirability of authorising restrictions on the exercise of the rights set forth in the Convention for reasons relating to national security.

They took the view that national security, which could no doubt justify restrictions on freedom of expression for example, should hardly be included in a context concerned with the application of medicine and biology. They considered that an explicit reference to national security in this context could give rise to abuse.

Following this discussion and taking into account the opinion expressed, the Working Party agreed to delete this exception.

CDBI 26-30/06/95

The CDBI accepted the Working Party's proposal to divide in two former Article 2 (new Articles 2 and 26) of the draft Convention.

The CDBI made a detailed examination of this Article and the exceptions contained in it. In particular, the Committee thoroughly discussed the amendment requiring the deletion of *"for the prevention of disorder"* as a ground for restricting the rights embodied in the Convention. A substantial majority of the CDBI members considered this exception too broad and out of place in a Bioethics Convention. It was therefore deleted.

Several delegations wondered whether it was advisable for the draft Convention to have a general provision containing exceptions. They would prefer each Article of the text to state whatever exceptions might be appropriate. In their opinion, the terms of Article 3 (new Article 26) were too broad and certain exceptions which it embodied were not applicable to all the Articles. The protection afforded by Article 3 (new Article 26) would therefore be insufficient and might leave room for possible abuses.

Other participants considered it very difficult to specify the exceptions in each Article, as some were liable to be omitted. That would prevent States from availing themselves of an exception or compel them to enter a reservation to the Article in question if the conditions for a reservation were met.

The CDBI ended the discussion by agreeing to reconsider this provision once it had finalised the text of the other provisions in the draft.

Regarding the second sentence of the Article dealing with the interpretation of its terms, several delegations objected to the mention of case law in a treaty text. Others pointed out that the provision could cause difficulty for States not Parties to the European Convention on Human Rights and consequently not bound by the decisions of the European Court of Human Rights.

In conclusion, the CDBI recommended the deletion of the sentence.

CORED 24-26/04/96

The CDBI-CO-RED considered the possible scope of Article 3 (new Article 26). It reviewed each Article of the Convention in order to draw up a list of those in respect of which no restriction should be possible.

The Working Party decided to propose the addition of a second paragraph reading as follows:

"The restrictions set out in the preceding paragraph shall not apply to Articles 11a (new Article 11), 11b (new Article 14), 14 (new Article 13), 15bis (new Article 16), 16 (new Article 17), 18 (new Article 19), 19 (new Article 20) or 20 (new Article 21)".

On a motion by an expert, the Working Party proposed moving Article 3 (new Article 26) towards the end of the Convention and including it in Chapter IX, "Relation between this Convention and other provisions". Article 3 (new Article 26) should be inserted after Article 24 (new Article 25) and will need to be renumbered appropriately.

CDBI 4-7/06/96

The Committee decided to replace the expression *"the exercise of the rights contained in this Convention"* with the more complete expression *"the exercise of the rights, and protective provisions, contained in this Convention"* to take account of the fact that certain provisions also subject to restrictions did not directly define individual rights.

The Committee then considered the proposal by the CDBI-CO-RED to include a second paragraph stipulating that certain Articles of the draft (in particular those concerning research and removal of organs and tissues) could not be subjected to the restrictions referred to in Article 3. By 24 votes in favour and 1 against, with 4 abstentions, the Committee accepted the principle of this paragraph.

After a general review of the Articles, the Committee decided by consensus to include in this paragraph Articles 11 (Non-discrimination), 13 (Interventions on the human genome), 14 (Non-selection of sex), 16 (Protection of persons undergoing research), 17 (Protection of persons not able to consent to research), 19 (General rule on organ removal), 20 (Protection of persons not able to consent to organ removal) and 21 (Prohibition of financial gain).

It decided not to include Article 15 (General rule on scientific research) since this provision carried its own restrictions on freedom of research, these being founded on protection of the human being.

The Committee also decided against the inclusion of Article 18 (Research on embryos in vitro) by 5 votes in favour and 12 against with 15 abstentions for the second paragraph, and by 11 votes in favour and 12 against with 9 abstentions for the Article as a whole.

Article 26 was adopted in its entirety by 28 votes in favour and none against, with 5 abstentions.

APPENDIX to Article 26

SUMMARY OF THE STATEMENT BY MR P MAHONEY (REGISTRY OF THE EUROPEAN COURT OF HUMAN RIGHTS) ON THE RELATIONSHIP BETWEEN THE DRAFT BIOETHICS CONVENTION AND THE HUMAN RIGHTS CONVENTION
CDBI 6-9/07/93

Mr P Mahoney, Head of Division in the Registry of the European Court of Human Rights, was asked several questions by the CDBI about the relationship between the second paragraph of Article 2 of the draft Bioethics Convention and the second paragraphs of Articles 8, 9, 10 and 11 of the European Convention on Human Rights.

After giving a brief description of the preparatory work on the Convention, Mr Mahoney indicated that the restrictions allowed by the Articles in question had to meet three requirements:

-first of all, they had to be "prescribed by law". The shape of this requirement could, however, vary according to the legal system concerned; it could be expressed in either a formal law or a rule defined by case law (see for example The Sunday Times against the United Kingdom, judgment of 26 April 1979, Series A No 30, para 47). The restrictions had to have a basis in domestic law but, according to the Commission and Court of Human Rights, the requirements derived from the expression "prescribed by law" went beyond conformity with the national law. The latter was itself required to meet several conditions: it should conform to the principle of the rule of law (by affording a measure of protection against arbitrary infringements of guaranteed rights by the public authorities); it should be sufficiently accessible to those whom it affected (not secret); and its effects should be reasonably foreseeable (see for example Malone against the United Kingdom, judgment of 28 June 1984, Series A No 82, paras 66-67);

-The restrictions should pursue one of the legitimate aims set out in the Articles concerned, the list of which was exhaustive. He pointed out that there was little case law on this point since it had not given rise to much controversy;

-They had to be "necessary in a democratic society". It was this latter condition which had given rise to the most abundant case law. The Strasbourg organs which examined an application concerning the use made of these restrictions by a State required that it should meet a "pressing social need" but acknowledged that States enjoyed some margin of appreciation in determining the need for a limitation and in the choice of the measure to be taken. Indeed, it was accepted that the justificitation for a measure could depend on social and cultural conditions which varied from one country to another; consequently, States were allowed some freedom to choose from among the range of democratic measures available, one condition being of course that the measure in question should be proportionate to the aim pursued (see also, for example, the above-mentioned Sunday Times judgment, paras 59-62).

The CDBI then put several questions to Mr Mahoney about the terminology employed in the Human Rights Convention. In particular, he was asked to explain the difference between "prevention of crime", "public safety", "prevention of disorder" and "protection of public order". Mr Mahoney replied that, according to the case law of the Court, the concept of "prevention of disorder" was broader than that of "prevention of crime" or even "protection of public order" (the French term *"ordre public"* was sometimes rendered in English by "public policy"). He pointed out, however, that the Court and Commission of Human Rights gave broad interpretations to these concepts, without making a decisive distinction between prevention and punishment.

He gave a negative reply to the question whether the case law of the Human Rights Convention organs made a distinction between the concepts of "law" and "national law". However, he recommended the use of the term "law", in view of the existence in the countries of the European Community of what might be termed a form of supranational law.
The French version of the Human Rights Convention (and Article 1 of the first Protocol thereto also) used the expression *"prévue par la loi"* in all Articles, and he recommended this formula. On the other hand, the English version of the text contained different variants which were always rendered in French as *"prévue par la loi"*. According to the case law of the Strasbourg organs, these English expressions were equivalent, but it would no doubt be preferable for the Bioethics Convention to select one of them and use it.

Article 27 (Wider protection)

CDBI 6-9/07/93

a. first paragraph

It was pointed out that, in order to bring the French version into line with the English version (which was the original for this Article), the words *"aux personnes concernées"* should be deleted.

Two delegations observed that there could be a conflict between the different rights recognised by the Convention, for example between the scientist's right to freedom of research and the rights of the person who was subjected to such research; if national law could - as stated in the Article - grant a wider measure of protection, which of the two conflicting rights could be strengthened by the law? In this connection, it was explained that the expression "wider measure of protection" had to be interpreted in the light of the very purpose of the Convention which - as defined in Article 1 - was to *"protect ... human beings ... with regard to the application of biology and medicine"*. The additional protection of the law could therefore only be understood to mean reinforced protection for the person undergoing research, not an extension of the rights of the researcher. The very terms of Article 14 (new Article 15) confirmed this interpretation, if confirmation was needed, since that Article specified that research *"shall be carried out freely with respect for the dignity ... of the human being and in accordance with the legal provisions ensuring this protection"*. The same was true with regard to any conflict between the protection of an organ donor (based on restrictions such as transplantation only between close relations and friends) and the interest of the recipient in having access to any compatible organ. The Explanatory Report should perhaps refer to these points of clarification.

b. second paragraph (disconnection clause)

A representative of the Commission of the Community, said that the so-called disconnection clause was the result of an agreement, since 1989, between the legal services of the Council of Europe and those of the Commission of the Community for the elaboration of all kinds of conventions, in cases involving "mixed" competence, ie fields in which both the Community as such and its member States had authority, so as to ensure the rule of Community law[22].

It was only effective for mutual relations between member States of the Community, without affecting in any way relations based on the Convention between EC member States and other States signatory to the Convention, whether members of the Council of Europe or third States. Since there was the implication of "mixed competence" (eg scientific research, health - at least in the preventive field -, patents, data protection, freedom to provide services), the Legal Service of the Commission of the Communities took the view that such a clause should be included in the Convention. For example, if the Community Directive on legal protection for biotechnological inventions eventually enforced a restrictive interpretation in respect of the patentability of human DNA fragments, the EC member States would not be authorised to invoke, in their mutual relations, a provision in this Convention allowing them more freedom; the reverse situation could also, at least theoretically, arise, and then, again in their mutual relations, EC member states should in his view recognise any patents which were in conformity with Community law.

The Secretariat confirmed that the text of the disconnection clause had indeed been agreed between the Council of Europe and the Community. The wording of the clause, even if it was not perfect, had hitherto served to solve satisfactorily the problem of areas of competence within the Community: when a subject came partly within the jurisdiction of the member States of the Community and partly within the jurisdiction of the Community itself, the States could not, when acting in the international sphere, deviate from Community law. It also had to be pointed out that the member States of the Community would not be the only ones concerned by this problem; the other member States of the European Economic Area, when it came into force, would also be affected. That being the case, the Secretariat emphasised that the agreement between the Council of Europe and the Community related to the actual text of the clause but did not mean that each Council of Europe convention necessarily had to contain such a clause: the decision on this point was less technical than political.

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[22] As far as he knew, the disconnection clause also implied that EC services should inform Council of Europe services about any instrument of Community law which might entail the application of a disconnection clause.

Several delegations expressed opposition in principle to a disconnection clause in the context of the Bioethics Convention. The latter was directly related to the European Convention on Human Rights; it laid down minimum standards of protection for individuals in the field of medicine and biology. To insert a disconnection clause would be to acknowledge in advance the possibility of a lesser degree of protection in the countries of the Community and those of the European Economic Area. While this was conceivable in other fields, it was unacceptable where the fundamental rights of the individual were concerned.

The Co-ordinator considered that, if a disconnection clause was to be inserted, it would be better placed in the final clauses of the Convention.

The Working Party was instructed to consider the question of the disconnection clause.

CORED 24-27/01/94

The CDBI-CO-RED adopted the first paragraph without amendment.

The experts were not in favour of the draft disconnection clause, in as much as the draft Convention dealt with fundamental rights from which not even Community law should be allowed to deviate.

Consequently, the Working Party agreed to delete this clause.

CDBI 27/06-1/07/94

Several delegations pointed out that the Convention recognised the rights of different persons and it was not clearly stated to whom national law might grant wider protection.

In response to this comment, the CDBI reworded the Article as follows:

"None of the provisions of this chapter shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention".

In addition, paragraph 134 of the explanatory memorandum already stated that the expression *"wider protection"* must be interpreted in the light of the purpose of the Convention, namely the protection of the human being with regard to the application of biology and medicine.

CDBI 26/02-1/03/96

The CDBI adopted this Article by consensus.

Concerning the place of the Article in the Convention, it was agreed that its current place, after the provisions recognising rights, seemed to be most appropriate (and was also in keeping with the model of the European Convention on Human Rights).

CHAPTER X - Public debate

Article 28 (Public debate)

CORED 16-18/06/92

The first version of this Article gave rise to the following comments:

- making public consultation compulsory in all cases was inappropriate;

- if consultation was the aim, why should the intervention of a national authority be made compulsory?

- if, however, the intention was to encourage the establishment of national authorities, why not say this clearly?

- however desirable the Working Party's members might think the involvement of a national authority, making this compulsory might provoke negative reactions, particularly in parliaments;

- involving a national authority might prove inopportune (for example, where abortion was concerned, governments did not tell parliamentarians in their parties how to vote) and indeed impossible (for example, direct tabling of a Bill by a parliamentarian).

The Working Party will examine another version submitted by the Secretariat.

CORED 9-12/11/92

The Working Party adopted this Article, the experts being aware of the need for debate which should not be restricted only to doctors and specialists.

CORED 8-12/03/93

The Working Party decided to recast this Article partially, while maintaining the intrinsic idea. It considered it useful to list a number of sectors concerned by applications of biology and medicine which should be taken into account in discussions on this subject.

CDBI 6-9/07/93

Two delegations expressed doubts about the usefulness of this Article. Other delegations, however, considered that it should be maintained.

A vote was taken. Twenty delegations voted to maintain the Article; 2 voted for its deletion. The Article was maintained.

CORED 24-27/01/94

The Working Party adopted this Article without amendment.

CDBI 27/06-1/07/94

A delegation pointed out that the expression *"public consultation"* used in this Article appeared inappropriate insofar as it could be understood as being synonymous with referenda, whereas what it was intended to refer to was public discussion.

The CDBI modified the wording of the Article to take account of this comment.

CDBI 26/02-1/03/96

The CDBI adopted this Article by consensus.
A delegation pointed out that the various Articles, some of which spoke of *"Parties to this Convention"* and others simply of *"Parties"*, would need to be harmonised.

CHAPTER XI - Interpretation and follow-up of the Convention

Article 29 (Interpretation of the Convention)

CORED 30/05-2/06/94

Possible role of the Human Rights Court with regard to the Bioethics Convention

The CDBI-CO-RED questioned the representatives of the Human Rights organs and the CDDH on the possible role of the Court of Human Rights with regard to the Bioethics Convention.

Mr Walsh said that the Court had not discussed this matter and that he was therefore speaking in his personal capacity. Mr Nørgaard also indicated that he was speaking in a personal capacity. The representative of CDDH said that the Bureau of the CDDH had recently considered the matter.

Mr Walsh and the representative of the CDDH thought that the role of the future Court should be confined to interpreting the Bioethics Convention. Mr Nørgaard, for his part, thought that it would be wrong to rule out the possibility of individual appeals (which could possibly be examined by a Standing Committee acting as a filter for the Court).

Mr Mahoney said that Mr Rolv Ryssdal, President of the Court, and MM Pettiti and Spielman, French and Luxembourg members of the Court, had personally expressed themselves in favour of an interpretative role for the Court. He mentioned in particular the statement by Mr Ryssdal to the Congress of the International Movement of Catholic Lawyers.

Furthermore, Mr Nørgaard, the representative of the CDDH and Mr Walsh all felt that the assignment of a role to the Court - whatever it might be - should only be envisaged following the entry into force of the reform of the Court's machinery (Protocol No. 11 to the Human Rights Convention), for the following reasons: desirability of not delaying the adoption of the draft Bioethics Convention; avoidance of any interference with the process of ratification of Protocol No. 11; and concern not to overburden the Court's existing machinery with new responsibilities when it already faced extremely long lead times for the implementation of its current tasks. For these reasons, the three human rights representatives considered that the role of the Court could be the subject of a later protocol to the Bioethics Convention.

The Chairman thanked the distinguished guests for their great assistance and especially for giving their views on the many issues raised by the Working Group.

CORED 13-17/02, 27-31/03/95

With regard to the monitoring of the Bioethics Convention, the CDBI-CO-RED took note of the Parliamentary Assembly's proposal to assign this task to the European Court of Human Rights. The Working Party prepared a draft, based on Article 25 of the European Convention on Human Rights, aimed at incorporating a clause into the Bioethics Convention allowing Council of Europe member states which were Parties to the Convention to make an optional declaration recognising the jurisdiction of the Court of Human Rights in matters concerning the interpretation of the Convention (see Article 28 (new Article 29)).

CDBI 20-22/11/95

The representative of the CDDH said that its Committee had not officially examined the opinion of the European Court of Human Rights. However, he personally regarded the Court's proposal as a very sound basis for the Committee's discussion. The speaker pointed out that the Court had excluded referral for a preliminary ruling, standing by its previous position on preliminary rulings in the framework of the European Convention on Human Rights. The Court had also taken care to specify that consultation should not involve a case pending before a court. Finally, he stressed that the consultation of the Court provided for in Protocol No. 11 to the EUROPEAN CONVENTION ON HUMAN RIGHTS was decided by a majority of members of the Committee of Ministers.

A delegation drew the Committee's attention to what it regarded as a twist in the wording, as a Party could request an opinion from the Court individually and without consulting the other Parties, which opinion might have an impact on those Parties not having accepted the Court's advisory jurisdiction.

The Secretariat pointed out that the Court's opinion would be purely advisory and as such would not be binding upon the requesting Party. It must nevertheless be acknowledged that such an opinion would be highly authoritative. Even so, the "twist" pinpointed by a delegation had always been present in the European Convention on Human Rights since Article 45 enabled each Party individually to recognise the Court's jurisdiction, and no major difficulties over its jurisdiction had resulted.

The Secretariat was also of the opinion that consultation of the Court by a Party on a question of interpretation would occur in practice only after the question had been discussed with the other Parties; thus it would be expedient to provide the possibility for the Committee set up under Article 30 to consult the Court by majority decision of the Parties. The CDBI decided to consider this possibility at its next meeting, together with the two others appearing in the text, for a final decision on each.

As to the question whether the Court might be consulted on any provision of the Convention or only on certain ones, the draft text from the Court left both possibilities open. Since, however, the Court had made it clear that the consultation should concern legal questions, the CDBI decided to delete the words *"certain provisions of"* to allow consultation on any legal question of relevance to the Convention.

The Chair called for a straw vote on the draft text proposed by the Court and amended as above. The results were 27 votes in favour and 4 against, with 1 abstention. Two delegations voting against explained that they found the text inadequate because they would have wished the Court's jurisdiction to extend, as provided in Article 45 of the EUROPEAN CONVENTION ON HUMAN RIGHTS, to the interpretation and *application* of the Bioethics Convention.

The Committee decided to take a decision at its next meeting on a text to be prepared by the Secretariat containing three alternatives.

CDBI 26/02-1/03/96

The Committee decided to postpone discussion of this Article until its next meeting.

CDBI 4-7/06/96

In a straw vote, the Committee approved the principle of Article 27 (new Article 29) by 26 votes in favour and 2 against, with 2 abstentions.

The Committee considered it unnecessary to mention the European Community in this connection, as it could be embodied in the concept of Party; consequently, the reference to the Court of Justice of the European Communities was also deleted.

The Committee then decided as to the various bodies able to request an advisory opinion of the European Court of Human Rights. Four variants were considered:

- the government of a Party and the Committee provided for in Article 32: 22 votes in favour, 6 against and 3 abstentions;

- the government of a Party, the Committee of Ministers and the Committee provided for in Article 32: 6 votes in favour, 19 against and 3 abstentions;

- the Committee of Ministers : 3 votes in favour, 22 against and 5 abstentions;

- the higher judicial body designated by a Party: 1 vote in favour, 24 against and 7 abstentions. This proposal, presented by a delegation, was unacceptable to many delegations in that the initiative of a judicial body might tend to change the interpretative opinion into disguised supervision of enforcement.

Several delegations considered that the retention of the optional clause *("Parties to this Convention member states of the Council of Europe may declare at any time that they accept the jurisdiction of the European Court of Human Rights to give… advisory opinions …")* was rendered all the more needless by the fact that such opinions could be requested not only by the Parties but also by the Committee provided for in Article 32. The Committee decided to delete this clause (5 votes in favour of its retention, 13 against and 14 abstentions).

Regarding requests by the government of a Party for an opinion, the Secretariat suggested adding *"after having informed the other Parties"* so that they would have the opportunity to arrive at a common interpretation without recourse to the interpretative opinion of the Court. The Committee accepted this proposal by 12 votes in favour and 2 against, with 18 abstentions.

As to requests for an opinion submitted by the Committee set up under Article 32, the CDBI decided by 23 votes in favour and none against, with 8 abstentions, that the decision must be taken *"by a two-thirds majority of the votes cast"* (abstentions not being counted).

At a later stage of the proceedings it was decided that the Committee set up under Article 32 should be the CDBI but that for the purposes of the functions mentioned in Article 29 its membership would be restricted to the Representatives of the Parties to the Convention.

The CDBI adopted Article 29 in its entirety by 25 votes in favour and 1 against, with 8 abstentions.

Article 30 (Reports on the application of the Convention)

CORED 30/05-2/06/94

The CDBI-CO-RED held an exchange of views on the desirability of incorporating in the Convention an article enabling the Secretary General of the Council of Europe to seek explanations from the Parties concerning the application of certain provisions of the Convention.

The Working Party agreed that it would be helpful for the Secretary General to have this option available. Participants noted that such a procedure would not be too onerous for States since it would involve the submission of occasional reports on specific subjects.

Standing Committee

The CDBI-CO-RED gave detailed consideration to the desirability of setting up a Standing Committee to monitor the Convention, in the light of the discussions on a possible role for the Court.

Participants agreed that it was not necessary to set up a committee with the task of expressing opinions on the application or interpretation of the Convention. The Chairman of the CDBI-CO-RED concluded that it was not opportune at the moment to consider whether the Court should be involved in monitoring or interpreting the Convention. The matter should be held in abeyance and reconsidered when the Convention has come into force. If there was to be Court involvement this could be added to the Convention, as was suggested (paragraph 22) by drawing up a suitable protocol. On the other hand, the Working Party considered that it would be useful for a committee to have competence to propose amendments to the Convention, to examine proposals for amendments and to submit them to the Committee of Ministers. Article 26 (new Article 32) of the Convention concerning amendments was therefore amended accordingly.

CDBI 26/02-1/03/96

In reply to a question by a delegation, the Secretariat said that in the framework of the European Convention on Human Rights, the Secretary General had only made use of this provision five times in nearly 50 years. Each time, the Secretary General's request had been addressed to all States, and not to one State in particular. The Secretariat also stressed that this provision was fully in line with the "preventive" policy in the area of respect for human rights defined by the Committee of Ministers in the context of the recent enlargement of the Council of Europe.

The CDBI adopted this Article by consensus, deciding to replace (in the French version) *"soumet"* by *"fournira"* to use the same wording as in Article 57 of the European Convention on Human Rights.

CHAPTER XII - Protocols

Article 31 (Protocols)

CAHBI 24-27/03/92

The CAHBI examined the following questions:

- Should signature or ratification of the framework Convention be a precondition for signature or ratification of the Protocols?

The CAHBI considered that this should be required; it should not be possible to become a Party to a Protocol without being a Party to the framework Convention.

- Should it be possible to sign or ratify the framework Convention without also being required to sign or ratify at least one of the Protocols?

Opinions appeared divided on this point. Some experts believed that it was possible, legally speaking, to become a Party to the framework Convention without being a Party to a Protocol. Other delegations felt that only the Protocols would establish practical obligations and that there was not much point in being a Party solely to the framework Convention.

CORED 16-18/06/92

The Working Party agreed to refer, at this point in the Convention, to the preparation of protocols. The formalities for proposing them and the procedure for adopting them would be detailed later in the text.

The Working Party rejected the expression *"additional agreements"*. The Secretariat pointed out that the term *"additional"* might have the effect of diminishing the protocols' actual significance.

CDBI 24-27/11/92

It was decided to delete at this stage the words *"These protocols are part of the Convention"*.

For the Committee, the main idea to be included was that the Convention was a framework Convention to be supplemented by protocols. There were so far two such protocols, but others could be drawn up. It referred that Article to the Working Party responsible for drafting the Convention in order to improve its wording.

CORED 14-16/12/92

The Working party considered that the expression *"whenever the need arises"* should be deleted and replaced by a phrase making reference to the body with authority to propose the drafting of further protocols.

CORED 8-12/03/93

The Working Party added a phrase to show the dynamics of the process of the preparation of protocols.

It was pointed out that the Articles to which this provision referred were technical articles on the preparation of protocols which would appear in the final clauses of the Convention.

The Working Party instructed the Secretariat to prepare a document containing the final clauses of the Convention and a document on the committee responsible for monitoring the Convention, as decided by the CDBI.

CDBI 6-9/07/93

On the basis of a suggestion made by a delegation, the Committee took decisions on the two following points:

a. could a State ratify a protocol without previously or simultaneously ratifying the Convention?

No delegation was in favour of this possibility. Consequently, in order to become a Party to any of the protocols, a State should accede to the framework Convention. The Secretariat indicated that the draft protocols already contained such a provision in their final clauses (see for example Article 18 of the draft Protocol on organ transplantation).

b. was a State which ratified the Convention also required to ratify a minimum number of protocols?

In favour of such an obligation, it was argued that many provisions in the framework Convention would remain excessively general principles if they were not amplified by the protocols. States should therefore undertake to ratify at least three protocols. Precedents were cited, such as the European Social Charter under which Contracting Parties undertook to respect a number of obligations from among those listed in the provisions of the Charter (see Article 20 of the Charter).

The following arguments were put forward against this proposal:

- each protocol should retain its independence. A degree of flexibility should be preserved, without which a State might not ratify the Convention because it would not be in a position to ratify a protocol;

- no commitment could be made in respect of protocols which had not yet been drafted;

- if States which ratified the Convention were also obliged to ratify a future protocol, that would mean that the protocol in question would have to be unanimously accepted by the States Parties to the Convention, with one of two results: either its adoption would be made extremely difficult, or its content would have to be too insubstantial in order to make it acceptable to all States.

A vote was taken. Twenty-one delegations were in favour of separate ratification of the framework Convention and the protocols; one delegation voted for combined ratification and one delegation abstained. Consequently, States would be able to ratify the framework Convention without having to ratify any of the protocols.

CORED 24-27/01/94

In its consideration of Article 24 (new Article 31) et seq, the Working Party was joined by a representative of the Central Division of the Legal Affairs Directorate.

The CDBI-CO-RED approved the first paragraph without amendment.

It decided to add a second paragraph for the purpose of incorporating in the text of the Convention the decision of the CDBI concerning the protocols, namely that it would not be possible for a State to ratify a protocol without simultaneously or previously ratifying the Convention.

CDBI 27/06-1/07/94

The CDBI accepted the Article 24 (new Article 31) without making any changes.

CDBI 26/02-1/03/96

One delegation observed that this provision was purely programmatic in nature and thus seemed out of place in a binding text. It was pointed out, however, that it specifically fulfilled the terms of reference set by the Committee of Ministers to draw up a framework Convention with protocols centred on a main text.

The CDBI adopted this Article by consensus.

Chapter XIII – Amendments to the Convention

Article 32 (Amendments to the Convention)

CDBI 26/02-1/03/96

The CDBI had an in-depth discussion on this Article, in particular with regard to the relations between the Committee set up under this Article (Conventional Committee) and the CDBI.

The Secretariat pointed out that according to an express decision of the CDBI during its 3rd meeting, the Conventional Committee did not have any function of monitoring implementation of the Convention. Its sole functions were those appearing in Article 30 (new Article 32), concerning possible amendments to the Convention, and in Article 27 (new Article 29), third dash, concerning the decision to request an interpretative opinion of the Court.

In theory, a distinction could always be made between a committee in charge of co-operation on bioethics within an international organisation and a committee created by the actual Bioethics Convention. The former depended on the terms of reference set by the international organisation, whereas the latter would be governed by the provisions of the Convention and by the States party thereto, independently of the international organisation itself. Hence, conventional committees usually met at the expense of each Party; but the costs of the Secretariat and interpretation were borne by the Council of Europe.

In practice, given that ultimately any amendment to the Convention must be approved by the Committee of Ministers (see Article 30 (new Article 32), paragraph 4), it was probable that a committee which reported to the Committee of Ministers, ie the CDBI, would be entrusted with drawing up any amendment to the Convention or any protocol. In fact, the CDBI had already been asked by the Committee of Ministers to prepare three Protocols.

The Conventional Committee thus risked having a purely theoretical existence, in that its functions would probably be carried out by the CDBI, which reported directly to the Committee of Ministers.

The Secretariat pointed out that it would be possible to make provision in the Convention itself for the intergovernmental committee of the Council of Europe responsible for bioethics to assume the functions of the Conventional Committee referred to in Article 30 (new Article 32). An alternative draft along these lines might be submitted by the Secretariat for the next meeting. In practice, there was scarcely any difference, regardless of which solution was adopted.

The Committee decided to postpone the decision on this Article until the next meeting.

The Committee instructed the Secretariat to submit a draft general clause making provision for a review of the Convention at regular intervals.

CORED 24-26/04/96

The CO-RED considered a Secretariat's document, which proposed the following alternative: the committee responsible for dealing with amendments would be either a Conventional Committee set up for that purpose or the CDBI or any other committee designated by the Committee of Ministers. In the former case, only the Parties to the Convention would be entitled to vote; in the latter, any Council of Europe member State as well as the Parties to the Convention that were not members of the Council of Europe would be able to vote.

The representative of the Central Division of the Legal Affairs Directorate pointed out that amendments to a Convention were uncommon in practice. He added that if the Convention was closely linked to the Council of Europe's activities, it would be wise to opt for the CDBI, but that if it was intended to be more autonomous, a Conventional Committee seemed more appropriate.

The Working Party agreed that the draft Convention's provisions were very close to those of the Convention on Human Rights and that, therefore, it was logical for the committee responsible for examining amendments to the Convention to include not only the Parties but all Council of Europe member States. It therefore proposed that the CDBI should be responsible for examining amendments (Article 30) (new Article 32) and carrying out a review of the Convention (Article 28bis) (new Article 32, paragraph 4).

CDBI 4-7/06/96

The Chairman of the CDBI-CO-RED recalled that the content of the Article was fully consistent with the model final clauses reproduced in each Council of Europe Convention. A choice was nevertheless offered as to the committee which would be responsible for examining proposed amendments to the Convention: either a committee only composed of the Parties (the other States being observers only) or a committee, such as the CDBI, comprising all Council of Europe member States and Parties not members. There were precedents for each model.

The CDBI, by 31 votes in favour and none against, with no abstentions, opted for the solution recommended by the CDBI-CO-RED to assign the examination of amendments to the CDBI.

Article 32 was adopted in its entirety by 27 votes in favour and 1 against, with 4 abstentions.

CORED 24-26/04/96

The CDBI-CO-RED examined Articles 28bis (new Article 32, paragraph 4) and 30 (new Article 32) with the participation of a representative of the Central Division of the Directorate of Legal Affairs.

The Working Party proposed making an initial re-examination of the Convention after a five-year period following its entry into force, and subsequently at such intervals as the Committee might set.

CDBI 4-7/06/96

Certain experts considered this provision superfluous. The usefulness of re-examining the Convention lay in a resultant decision to amend it but, since the terms of Article 32 paragraph 5 enabled any Party to put forward an amendment at any time, there was no reason to make express provision for periodical reviews. According to these experts, such a provision would only detract from the substance of the Convention by implying that its amendment was envisaged from the outset.

In the opinion of other delegations, it was important for a convention regulating the applications of rapidly developing sciences to take account of these trends so that its provisions would not become outmoded. They added that the outcome of a review would not necessarily be the deletion of a given provision, but equally likely the addition of others.

The Committee approved the principle of a clause on revision of the Convention by 20 votes in favour and 8 against, with 5 abstentions. It was then decided by 24 votes in favour and 6 against, with 2 abstentions, to include this provision in Article 32 as paragraph 4.

The Secretariat adverted to the following paragraph appearing in an earlier version of the Explanatory Report:

"*Some of the provisions reflect basic human rights which ought to be respected irrespective of developments in science. There are others which owe their wording to the present state of the art scientific knowledge and in their case the possibility of revision cannot be ruled out depending on developments in science. However, such developments must in no circumstances weaken the force of the first set of provisions*".

It suggested restoring this paragraph in the Explanatory Report. In order to clarify the meaning of the revision clause, it further suggested adding to the text of the Article: *"In order to monitor scientific developments, the present Convention ..."*.
The Committee agreed to the proposal by 24 votes in favour and 5 against, with 2 abstentions.

CHAPTER XIV - Final clauses

Article 33 (Signature, ratification and entry into force)

CDBI 26/02-1/03/96

The representative of the European Commission said that the latter had been represented throughout the process of drafting the Convention. The European Community should thus, ipso facto, be able to sign the Convention, as could non-member States of the Council of Europe that participated in its elaboration.

The CDBI adopted this Article by consensus, including the phrase *"and by the European Community"*.

CORED 24-26/04/96

The CDBI-CO-RED asked the Secretariat to draft an information memorandum specifying in which fields of the Convention the European Community can have competence.

Article 34 (Non-member States)

CDBI 26/02-1/03/96

The CDBI considered the amendment of the Parliamentary Assembly to delete the phrase *"and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers"*, which appears in the first paragraph of this Article.

The Committee noted that this text was a standard clause consistent with the model clauses adopted by the Committee of Ministers and used as it stood in many Council of Europe conventions. It also noted that this clause might be considered to be an application, restricted to Parties entitled to sit on the Committee of Ministers, of the rule of international law contained in the Vienna Convention on the Law of Treaties of 23 May 1969, Article 15 (c)[23].

The Committee was of the view that it was not its role to judge the whether the Parliamentary Assembly's proposal to change this rule was legally well-founded or politically desirable. Such a decision, which would probably not affect the Bioethics Convention alone, would appear to fall within the direct jurisdiction of the Committee of Ministers.

The CDBI adopted this Article by consensus in its current version, without prejudice to the decision of the Committee of Ministers on the Parliamentary Assembly's proposal.

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[23] Article 15(c) of the Vienna Convention on the Law of Treaties, 23 May 1969, (United Nations, serial treaties, vol. 1155, p. 331) :

"The consent of a State to be bound by a treaty is expressed by accession when : (…)

(c) all the parties have subsequently agreed that such consent may be expressed by that State by means of accession".

Article 35 (Territories)

CDBI 26/02-1/03/96

The CDBI decided to adopt this Article by consensus.

The Committee also agreed to include in the Explanatory Report the following paragraph, which appears in many Council of Europe Conventions.

"Since this provision is mainly aimed at overseas territories, it was agreed that it would be clearly against the philosophy of the Convention for any Party to exclude parts of its aim territory from the application of this instrument, and that there would be no need to lay this down explicitly in the Convention"

Article 36 (Reservations)

CORED 30/05-2/06/94

Several experts took a stand against the solution adopted in Article 30 (new Article 36), which provided for a reservation to a single paragraph of a Convention Article. Some would have preferred the paragraph concerned in Article 15 (new Article 18) to be deleted and no reservations to be accepted to the Convention. Others were in favour of a system allowing several reservations.

The Working Party agreed that it would be for the CDBI to take a decision on the principle of reservations and, if it agreed that reservations were possible, on the Articles to which they could be made.

CORED 13-17/02, 27-31/03/95

The Working Party discussed at length the problem of reservations. It proposed a new Article 33 (new Article 36) based on Article 64 of the European Convention on Human Rights.

CDBI 20-22/11/95

The Committee was invited to give an indication of its position on the various possibilities for reservations as formulated by the Chairman of the CDBI-CO-RED:

- a State may make a reservation to any Article of the Convention: no delegation in favour.

- the Articles to which a reservation may be made are listed: 1 delegation in favour.

- the text limits the total number of reservations allowable (eg 3 reservations permitted without further explanation): 3 delegations in favour.

- the vast majority of the CDBI members were in favour of an Article 34 (new Article 36) with wording borrowed from Article 64 of the European Convention on Human Rights.

Accordingly, Article 34 (new Article 36) would enable a State to make a reservation concerning a provision of the Convention to the extent that *"any law then in force*[24] *in its territory is not in conformity with the provision"*.

The CDBI asked the Secretariat to ascertain whether the term *"law"* as used in paragraphs 1 and 2 of Article 34 (new Article 36) should be interpreted in the broad sense, as in the European Convention on Human Rights (ie all binding rules, including customary law and case-law) or in the more restrictive sense of *"legislation"*.

CDBI 4-7/06/96

A delegate proposed that no reservations should be permitted in respect of provisions not subject to the restrictions provided for in Article 26.1.

The Committee valued this proposal but did not accept it, expressing the opinion that a reservation afforded the sole possibility of ratifying the Convention for a State unable to accept a specific provision thereof - which might not even be an essential one (example: possibility of bone marrow donation between members of the nuclear family other than brothers and sisters, Article 20). Thus the restrictions provided for in Article 26 and the reservations referred to in Article 34 (new Article 36) did not necessarily have the same object.

The Committee adopted Article 34 (new Article 36) by 31 votes in favour and none against, with 1 abstention.

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[24] Reservations may be made not only when the Convention is signed but also when the instrument of ratification is deposited.

Article 37 (Denunciation)

CDBI 26/02-1/03/96

In reply to the question of a delegation, the Secretariat pointed out that in international law a distinction could be drawn between total denunciation (of the entire Convention) and partial denunciation. The rule in the Council of Europe, particularly as concerned conventions involving principles of the European Convention on Human Rights, was not to allow partial denunciations, because this possibility was tantamount to giving each Party the power to modify unilaterally and at any time the content of its obligations deriving from the Convention.

Similarly, the possibility of formulating reservations after a State expressed its consent to be bound by a treaty was also ruled out, because that would amount to partial denunciation.

In order to allow the Convention to evolve while retaining the consistency of its content for all Parties, the text made provision in Article 30 (new Article 32) for a procedure for amending the Convention which had proved its worth for nearly 50 years, particularly as concerned the Convention on Human Rights.

The CDBI adopted this Article, as it stood, by consensus.

Article 38 (Notifications)

CDBI 26/02-1/03/96

The CDBI adopted this Article, as it stood, by consensus.

Final vote by the CDBI on the draft Convention on Human Rights and Biomedicine in its entirety

The following 31 States voted in favour of the draft Convention: Albania, Austria, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom.

Vote against: Germany.

Abstentions: Belgium and Cyprus.

Explanations of votes

Declaration by the German delegation

Germany could not but vote against the text of the Convention as it lies now before us. The German delegation recognises that the actual text is much better than earlier ones and quite a lot of Germany's concerns are met now.

The main reason for the decision to vote "no" is that at the moment it is too early for a vote. The decision of my government depends from the actual text of the Convention and of the explanatory report. These texts have to be examined very carefully by my government.

To make it quite clear: our today's "no" does not prejudice the German decisions which have to be taken in future eg. by the Committee of Ministers.

Declaration by the Italian delegation

We have worked hard and tried to consolidate our opinions as much as possible.

We have obtained a text which, given the circumstances, can be considered as a possible mediation and is in the spirit of tolerance and democracy which governs a Committee such as ours. On the whole and given these conditions, the vote should be positive.

However, I must also examine my own conscience and formally express my reserves concerning the article on the use of genetic data, the article on tissues donation, which is not bone marrow, on minors (today this is not a great problem), and especially concerning the article on the human embryo which I cannot accept! I hope that the explanatory report, the Committee of Ministers and the Parliamentary Assembly will be able to expel my worries. Thank you.

Adoption by the Committee of Ministers of the draft Convention on Human Rights and Biomedicine in its entirety (578th meeting, November 1996)

The Deputies

1. took note of Parliamentary Assembly Opinion No. 198 (1996) and of the recommendations of their Rapporteur Group on Legal Cooperation concerning the amendments proposed therein;

2. adopted the text of the draft Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine, as it appears at Appendix 6 to the present volume of Decisions;

3. instructed the Secretariat to finalise the Explanatory Report to the Convention on Human Rights and Biomedicine, in consultation with the Chairman of the CDBI, and agreed to take a decision on the authorisation to publish the said Report before the opening to signature of the Convention;

4. decided to open it for signature by member States.

Declarations made by Austria, Belgium, Germany, Liechtenstein, Portugal, Slovenia and by the Secretary General at the 578th meeting (November 1996) of the Committee of Ministers for the adoption of the Convention.

The Representative of Liechtenstein (Chairman of the Group) made the following statement:

"1. The problem raised, namely the relationship between the techniques of modern medicine, "biomedicine", and human dignity, is a very thorny issue. The rapid advances in this field call for immediate action, and it is therefore necessary to adopt a Convention which is based on the ethical consensus of a large majority and lays down generally applicable legal rules governing research.

2. This Convention already has a long history. As early as 1983, the Council of Europe had instructed a committee to lay down guidelines for biomedical research.

In 1985/86, the Committee of Ministers had planned a recommendation in this field to the member States, but it was rejected on ethical grounds by the then Permanent Representative, H.S.H. Prince Nicolas of Liechtenstein. As a result we failed to achieve unanimity, which was obligatory at the time for such a decision.

The draft Convention on Bioethics was submitted twice - which is quite exceptional -to the Parliamentary Assembly for opinion. Numerous requests for substantial amendments were once again submitted to the Committee of Ministers following the debate in the Parliamentary Assembly on 27 September 1996. After that, there were no longer any obstacles to acceptance of the report as a whole. Our two members, Büchel and Goop, abstained. The Parliamentary Assembly recommends that the Committee of Ministers accept the draft Convention and submit it to the member States for signature before the end of the year.

3. As I have already mentioned, this Convention concerns a subject with some highly problematical aspects. For me, as Ambassador, the subject is made even more difficult by the fact that we do not have a Liechtenstein expert on the Steering Committee on Bioethics. I am therefore dependent on the pronouncements and expert opinions of scientific, philosophical and even theological circles with similar views to our own.

The controversial points show how extremely sensitive this whole area is. The different mentalities and approaches to human dignity which have developed in our member States are clearly revealed here: they differ in terms of their rigour and in terms of the emphasis placed on human dignity as a universal principle.

The Convention must be a special human rights convention. That is essential for understanding and interpreting the text, firstly because it refers explicitly in its preamble to the European Convention on Human Rights and the other agreements relating to human rights, and secondly because, according to Article 29 of the draft, the European Court of Human Rights may give opinions on questions of interpretation.

Three controversial points call for detailed comments:

a) Research on embryos

Article 18 of the Convention allows research on embryos "in vitro", in the test tube, provided the national law of a member State has already authorised it. But it calls for "adequate protection" of the embryo.

Gian-Reto Plattner, rapporteur of the highly competent Committee on Science and Technology, wrote in the NZZ (Neue Züricher Zeitung) on 16 October last that a European consensus had yet to be found and that, for this reason, it had been necessary to limit the text to the lowest common denominator. The Steering Committee therefore plans to lay down definitive rules on this thorny issue in a forthcoming protocol. To start the ball rolling, a symposium will be held in December on this subject.

b) Research on persons not able to consent

I must confess that I take a keen personal interest in this aspect as my brother-in-law is the director of a large centre for handicapped people.

Research on patients not able to consent may only be carried out for their direct benefit. But to what extent is this prohibition sufficient when, for example, it is a question of carrying out research into and treating certain diseases affecting children, or of improving their chances of being cured? The draft Convention allows some exceptions here subject to the ultimate attainment of "results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition".

There is a further condition, namely that the research should entail only minimal risk and minimal burden for the patient.

c) Predictive genetic tests

In the chapter on the "human genome", the draft contains rules which go beyond the legislation in force in some member States. It authorises predictive genetic tests for health purposes only. Such tests make it possible to diagnose genetic diseases; they also serve to identify the gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease.

The use of such tests on the labour market - for example, as information for employers - or for insurance purposes was ruled out.

4. Owing to the complexity of the issues involved, the Convention cannot be exhaustive. During the lengthy discussions, many regrets and criticisms were voiced to the effect that the Convention fails to deal with whole series of important issues in biomedicine, and does not even mention them - abortion, euthanasia, care for the dying, etc.

However, it was agreed that it would be impossible to achieve something approaching a satisfactory result in these fields, and we managed in time to reach a tacit agreement to leave these issues aside in order to make better progress on the other points.

Professor Ludger Honnefelder, a member of the German delegation to the Steering Committee and, at the same time, Director of the Institute of Research and Ethics in Bonn, believes that the Convention that has just been completed could be regarded as a process of learning, opinion-forming and decision-making which will ultimately cover the fields which have not yet been taken into account at the present stage.

5. I shall now attempt an overall assessment.

To do so, I have to refer - as already mentioned - to reliable experts. I have already mentioned Professor Honnefelder. In an interview published in the 4 October 1996 issue of the newspaper "Le Parlement", he made the following statement: "For the time being, the current draft only contains what can realistically be expected from a consensus of the 39 member States. It comprises some provisions of substance, such as a ban on intervening on the human genome, restrictions on genetic tests, a ban on trade in organs and the requirement of the patient's free and informed consent".

If these minimum standards could be established with binding effect at international level, we should have taken a great step forward. Other provisions certainly leave something to be desired, such as, for example, tougher penalties for failure to comply with the Convention.

But we have now come somewhat closer to our goal, with the drawing of boundaries on a Europe-wide level between biological and medical research in the interests and for the good of human beings, on the one hand, and the preservation of human dignity, on the other, to help ensure that research does not move to the countries with the lowest standards of protection, because not only is research international, but also the market for diagnostic and therapeutic applications.

We also believe that Article 2 of the Convention must prevail: "The interests and welfare of the human being shall prevail over the sole interest of society or science."

Professor Franz Furger, who, having been entrusted with an important task relating to the educational field in Liechtenstein, is familiar with our country's ideological position, our "Weltanschauung", characterised by a long

Christian tradition attaching great importance to Christian values, and who is at the same time Director of the Christian Social Science Institute at the University of Münster (Germany), is also in favour of signing this Convention.

He told me in this connection, during a telephone conversation, that the expression "it is often better to let well alone" can also be applied to the Convention.

Conclusion:

In view of the complexity of the subject, the values at stake and the already long history of the Convention, it is obvious that this draft is a compromise, which is understandable given that 39 different States took part in the discussions. However, because of the excessive speed at which technology is moving forward in this field, the Steering Committee was unanimous on one thing: it is better to have a Convention that can be improved through additional protocols than to have no Convention at all. Gian-Reto Plattner expressed this idea in a rather more striking manner: if the Parliamentary Assembly rejects the draft again, the Convention is dead.

These observations lead me to conclude that the draft must be *accepted* despite the shortcomings which remain, but which can be remedied through additional protocols. When the fundamental values of the whole are at stake, a small State must also give its support. In these questions of values, the voice of a small State is as important as that of the larger States. It is for this reason that my statement has been rather long."

After the decisions were adopted:

The Representative of Germany made the following statement:

"The Government of the Federal Republic of Germany sees a basic need for a framework Convention for the protection of Human Rights and dignity of the human being in cases of medical intervention and in the context of biomedical research, particularly as a legal guideline for States that do not have adequate protective provisions. The Federal Government welcomes the progress made on important points in the negotiations since 1994 and would like to thank its partners for the patience and understanding always shown to German representatives with their particular sensitivities when assessing complex individual issues. The Federal Government is confident that further protective provisions can be established to strengthen the Convention's minimum standards in future protocols on medical research, organ transplantation, genetics and embryo protection.

The legal position in Germany is in tune with the protective norms established by the Convention on Human Rights and Biomedicine; in some areas, however, such as embryo protection and the protection of persons not able to consent to research, German law ensures a higher standard. Hence, it is of great importance to the Federal Government for the Convention to enable the high level of protection in Germany to be retained there in full.

The debate in Germany is not yet over as regards the Convention in the version proposed for signature. There is a need for further parliamentary and public discussion, for instance on the significance of the conditions laid down by the Convention as minimum protection of persons not able to consent to research. There is still intensive discussion in Germany regarding this question, in which both the general public and social groups are participating. Only when these discussions are over will a final decision be possible. For this reason, the Federal Government has abstained in today's vote on adopting the Convention. By doing so the Federal Government, having regard to the text now submitted, wishes to give expression to the fact that it does not want to hold up the course of proceedings.

The Federal Government would like to state that its abstentions will not prejudice the subsequent German decision on signature and ratification of the Convention."

The Representative of Belgium made the following statement:

"Belgium abstained because it is waiting for an opinion from the National Bioethics Committee and, if appropriate, the prior adoption of national legislation."

The Representative of Austria made the following declaration:

"Bearing in mind the sad experiences of recent history, Austria advocates the widest possible protection of human rights and the preservation of dignity of the human being in areas where the individual is faced with research and medicine. Austria therefore welcomes the fact that an international instrument has been established which obliges the member States to provide for appropriate protection in many ways. However, not only because Austrian law provides a number of points for protection going far beyond this Convention but also for reasons of humanity Austria regrets that the protection provided for in the Convention remains not only behind the expectations of Austria, but also of those of many people in Europe. We will therefore work for the inclusion of more extensive obligations in additional protocols."

The Representative of Portugal made the following statement:

"Portugal considers the positive outcome of this debate highly gratifying, especially in view of our constant active involvement in the process from the very start, in the Parliamentary Assembly when the committee dealing with this subject was chaired by a Portuguese parliamentarian, as well as in the committees of experts and the Rapporteur Group. We are really very satisfied to have been able to take this step as we consider that the regulation of biomedicine is a matter of great urgency and of great importance for the future of our society. Having said that, I should like to justify a reservation which I made in abstaining in the vote on Article 12 because it is a very important, very delicate and very sensitive issue with both moral and economic implications, and I should be much more satisfied if the article came somewhat closer to the Assembly's amendment, especially through the inclusion of something about the protection of data relating to predictive genetic tests. I assume that the drafting work for the additional protocol on data protection will be able to fill what we consider perhaps to be the largest gap in this document. Thank you, Mr Chairman."

The Representative of Slovenia made the following statement :

This Delegation would just like to join the statement made by the Austrian Ambassador concerning the regret that this Convention remains below expectations and that is why our Delegation will also be very active in the work on additional protocols, especially concerning the principle of prohibition of illegitimate non-medical use. Thank you very much."

The Secretary General made the following statement:

"The adoption today of the draft Convention on Human Rights and Biomedicine marks the end of several years of intensive efforts, in the Parliamentary Assembly and in the Committee of Ministers, to bring about an instrument which aims at closing a legal vacuum in order, in the words of the Assembly's rapporteur Mr. Plattner:

- "to preserve human dignity and mental and physical integrity,

- to dispel misunderstandings and unjustified fears allowing the scientific community to work in a calm and lawful environment".

The Convention adopted today is destined to become the common European standard in the area of bioethics.

The fact that no member State voted against the text can only give it greater strength.

I am very happy about this result and I wish to congratulate and thank this Committee, and its Rapporteur Group under the Chairmanship of the Ambassador of the Czech Republic, for the decision today.

Many have worked to achieve this result. If any names should be mentioned on this occasion special tribute must be paid to the Assembly Rapporteur, Mr. Marcelo Palacios, who was at the origin of the proposal for a new Convention; to the work continued by Mr. Gian-Reto Plattner and to Mr. Walter Schwimmer who took great interest in this matter as a member of the Committee for Legal Affairs and Human Rights.

I should also like to mention the excellent, pioneering work achieved by the Steering Committee on Bioethics (CDBI), successfully chaired by Mrs. Paula Kokkonen (Finland), Dr. Octavi Quintana (Spain), Mrs. Kits-Nieuwenkamp (The Netherlands) and Mr. Jean Michaud (France).

Most of the technical work done by the CDBI was prepared by its drafting Group chaired by Dr. Michael Abrams (United Kingdom).

I also wish on this occasion to add my sincere gratitude to the colleagues of the Secretariat who have also done an outstanding job leading up to the adoption today of the Convention.

Let me finally say that we now have to ensure a serious follow-up of the adoption of this Convention. This means focusing efforts on the elaboration of the four protocols envisaged to the Convention. In parallel with the entry into force of the Convention, this work will require very serious efforts which will require sufficient resources of both personnel and funds and I am confident that member States will agree on these needs for the next couple of years".