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[addendum II travaux prép convention a]

ADDENDUM II CDBI/INF (2000) 1

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

ADDENDUM II

(Document prepared by the Directorate General of Legal Affairs)

Official reports¹ of debates
by the Parliamentary Assembly of the Council of Europe
on the draft Convention on Human Rights and Biomedicine

¹ In the reports, speeches in English are reported in full and speeches in other languages are summarised. Speeches in German and Italian are reproduced in full in a separate document.

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE
1995 SESSION

(First part)

excerpt from the OFFICIAL REPORT

Sixth sitting
Thursday 2 February 1995 at 10 am

Mr Martinez, President of the Assembly, took the Chair at 10.03 am.

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The PRESIDENT (Translation).- The first item of business this morning is the debate on the report on giving an opinion on the draft Bioethics Convention (Doc. 7124) presented by Mr Palacios on behalf of the Committee on Science and Technology (Doc. 7210) with an oral opinion presented by Mr Daniel on behalf of the Social, Health and Family Affairs Committee and an opinion presented by Mr Schwimmer on behalf of the Committee on Legal Affairs and Human Rights (Doc. 7223).

The list of speakers closed at 6.30 pm yesterday.

Forty-five names are on the list, and 12 amendments and one sub-amendment have been tabled.

In view of the time available and the number of speakers on the list, I propose that speaking time in the debate be limited to five minutes.

In order to finish by 1.00 pm, we must conclude the general debate by about 12 noon to allow time for the reply and the vote.

(Continuing in summary) he urged delegates to be brief in their speeches and reminded them that they could submit their speeches in writing to be printed in full in the official report if they were unable to speak during the debate. He expressed his thanks for the work of the Rapporteurs in producing the reports and was hopeful of a constructive debate.

He called on Mr Palacios, Rapporteur to the Committee on Science and Technology, to present the report on the draft Bioethics Convention (Doc. 7124).

Mr PALACIOS (Spain) (Rapporteur of the Committee on Science and Technology) said that he would be brief. After the Assembly's debate on 5 October 1994, it was clear that some issues had needed to be re-examined. Following meetings with Mr Schwimmer, Rapporteur of the Committee on Legal Affairs and Human Rights, they had come to a mutual understanding of their differing opinions. He believed that the amendments to the draft Bioethics Convention set out in the report would enrich it. He thanked all members of the Assembly, the committee, and officials and translators for their rigorous efforts. He thanked the objectors for their input, but hoped that the draft convention would be voted through without difficulties. Further protocols were needed on embryo research, but the convention represented consensus and maturity.

The PRESIDENT thanked Mr Palacios for his outstanding work and called Mr Daniel, Rapporteur of the Social, Health and Family Affairs Committee, to present the committee's oral opinion.

Mr DANIEL (France) (Rapporteur of the Social, Health and Family Affairs Committee) said that the convention was the fruit of long work in the Council of Europe. He paid tribute to the Rapporteur and the advisers.

Despite legal and scientific difficulties, Mr Palacios had guaranteed that the main concern of the convention was human beings. There must be a long-lasting positive outcome. The principles and objectives of human rights had always been respected and safeguarded by the convention. He said that, together with the amendments, it represented a balanced consensus; he hoped for ratification and signature to the convention by the maximum number of states.

France had already adopted some texts on bioethics, but he was happy to say that these did not conflict with the text of the convention.

The convention was designed for human action in order to preserve human dignity and he stressed the importance of a positive vote.

Mr SCHWIMMER (Austria) (Rapporteur for an opinion of the Committee on Legal Affairs and Human Rights) maintained that the areas of medicine research and technology were now offering new approaches capable of eradicating ills which had beset mankind for centuries. Researchers were always keen to extend their knowledge. But there was a potential danger that they might break certain limits. As a result, he felt that there must be ethical standards imposed on medical research.

Fifty years after the liberation of Auschwitz he took the opportunity of reminding the Assembly that it was not just science and technology which could exceed ethical limits. In conjunction with the development of science and technology, the state was also capable of breaching those norms. He reminded the Assembly of the misguided scientists who carried out mass medical experimentation during the Nazi regime. There had also been mass experimentation in the Soviet military. Even the United States, a western democracy had been involved in experimentation using uninformed military personnel.

This convention should protect individuals from abuse and a breach of ethical limits. It was designed to safeguard human rights and the dignity of individuals in relation to the application of biology and medicine. As a result, he welcomed the convention, since the protection of human rights was the key duty of the Committee on Legal Affairs and Human Rights.

He acknowledged that there had been some criticism of the convention both within the Assembly and from outside. Criticism had focused on the fact that research could perhaps be carried out on people who were unable to express themselves. There had been criticism of the vague wording about intervention in the human germ cell line and criticism regarding the admissibility of research on embryos which had been created specifically for artificially assisted procreation.

He concluded by thanking the Chair and the Rapporteur for the constructive dialogue that had developed regarding the convention and emphasised that the goal of the Committee on Legal Affairs and Human Rights was to have a European framework convention prepared so that human rights and individual dignity in biology and medicine could be recognised without restrictions.

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Mrs LENTZ-CORNETTE (Luxembourg), speaking on behalf of the European People's Party Group, said that she would concentrate on the implications of bioethics research on mankind. She raised two questions. First, what would happen if the scientific revolution did not lead to a moral revolution? Secondly, how was society morally bound to make progress?

In the last 50 years there had been prodigious progress in science. The age of electronics had been followed by an era of biogenetic evolution. She doubted that the full implications of scientific information could be assimilated properly by researchers. Twenty years of progress had produced legal, moral and social problems.

Attitudes in Council of Europe member states differed from extreme liberalism to greater restriction. Many European countries had not drafted legislation, but there was an awareness about what was at stake. In conclusion she said that the challenges of genetic research presented both a risk and an opportunity.

Mr DENIAU (France) said he had read the reports with interest and would devote his brief remarks to the articles of the draft convention. He said that Article 15 on embryo research was unacceptable. He was unhappy with the texts of Articles 6 and 7 concerning degenerative tissue. A provision should be added to Article 3 to enable conscientious objection to be made.

Mr HEGYI (Hungary):- Our Rapporteurs have worked long and hard so that this draft convention could come to the Assembly. Two things are certain. Human rights and the dignity of human beings should be respected in the application of biology and medicine. Written regulations can only be a framework for European biology and medicine. The draft convention is an important step forward for European integrity. It shows everybody that we

Europeans - eastern and western Europeans, Christians and free thinkers, ordinary people and experts - share common ethical values.

The draft convention is important for central and eastern European member states. As Mr Schwimmer underlines in his opinion, our countries have no regulations in this area. The need for regulation has become even greater in recent years. The state-owned health care, the state-owned health industry and the state-ruled scientific institutions work at a low, but more or less solid and well-controlled level. The entry of market forces, in many cases overseas market forces, into this area could destroy even those relatively low ethical values unless there is proper regulation.

Central and eastern European citizens and patients do not learn how to raise questions, how to choose and how to decide in the area of medical experiments and treatment. In these new times of market competition, human rights and dignity can and should be enforced through such conventions. The operation of the market means not only free competition, but the right and the knowledge to choose, to understand the conditions and to say a well-founded yes or no in the important moments of human life.

The framework convention can help us to set up a proper system of regulation. I do not want to touch on the hot ideological issues of the convention. In central and eastern European countries we are hungry not for more ideologies but for a practical approach and common sense. That does not mean that we no longer trust ideologies. However, in our conditions, we need ethical regulation to control the blind market forces and interests in the important fields of biology and medicine. That is why I welcome the draft convention and I am sure that the Assembly will accept the convention.

Ms ÖZVER (Turkey) welcomed the fact that the Council of Europe was examining this issue and stressed that new developments in medicine and biotechnology could lead to the infringement of human rights and dignity. Genetic research without guidelines could have the same results. Co-ordination of action across Europe was essential and the Council of Europe provided the perfect forum. The establishment of legal instruments at an international level would enable national regulations to be harmonised.

She stressed that Article 6 would need constant vigilance if the rights of those under 18 or with some form of mental handicap were to be protected and she therefore supported Mr Schwimmer's Amendment No. 3. With the completion of the convention a great achievement would have been made.

Mr DEES (Netherlands) said that the convention was necessary to safeguard human rights. In this respect those with a mental handicap needed special attention and protection. The convention was a milestone in safeguarding the rights of patients. He supported the amendments to Article 6 from Mr Schwimmer and Mr Cox, as well as Amendment No. 12 in the name of the three Rapporteurs.

The principle of tolerance was essential. This convention was intended to apply to all human beings and therefore the majority in this instance must pay attention to the needs of the minorities.

In the Netherlands the National Council for Public Health had given a favourable response to the draft convention with the proviso that they foresaw the need for a right for the individual to complain.

Sir Andrew BOWDEN (United Kingdom)- I pay tribute to the dedication of the Rapporteurs. They have had an enormously difficult task, and I believe that their work is now beginning to bear considerable fruit.

I shall be brief, because I set out my views at the Assembly meeting on 5 October, and I shall quote briefly from the speech that I made then. It is still relevant. I said:

"We are making decisions that will have long-term consequences for the human race. What is the fundamental matter about which we are talking? It is, when does life begin ... Life does not begin after 14 days. Life begins at fertilisation and conception and the fact is that some scientists are already arguing that 14 days is not a long enough period."

So the debate is about the fundamental principles of human existence. I must say that I still have considerable reservations about the draft convention. But we have to be practical and realistic, and doing nothing is not an option. We know that it is difficult to control scientific activities. Inevitably, among some scientists, there are people who are extremely arrogant and who believe that they have the right to do what they want, whenever and however they want to do it. Such individuals must be controlled.

The convention represents a step forward. I believe that it will be vital to ensure that in our respective countries, through our national parliaments - we all have a role to play in this - the convention is fully implemented and effectively operated. Indeed, I believe that in some national parliaments it will be strengthened.

To debate this matter in detail is not possible in a short speech. That has been done in committee. We who are here today must make the overall decision. If we are convinced that the convention is right and that it can be applied and enforced, and, if necessary, strengthened in future, I believe that we shall have carried out our responsibilities. We owe this to the human race.

Mr ANTRETTTER (Germany) said that the debate concerned the further protection of the human individual in bio-sciences. He asked whether this was defining an ethical taboo zone.

He had reservations over the draft convention. Article 6, for instance, made provisions for a period of experimentation on persons who had no legal capacity. The section of the convention dealing with foreseeable risks fell far short of what had been agreed in the Helsinki Agreement.

He asked the Assembly why the convention did not have the full consensus of the international medical profession. One answer was that a set of values was needed to establish the rights of the human individual from birth to death. As a corollary of that, embryo research should be prohibited.

He was also troubled by Articles 17 and 18. More thought was needed on the release of test information, the approval of medicines and the problem of unethical tests outside Europe. He said that a new form of Hippocratic Oath was needed.

Mrs GRZESKOWIAK (Poland) thanked the Rapporteurs for their excellent reports on the draft convention, which she felt was very necessary. She restricted her remarks to two specific problem areas. First, she shared the idea contained in Amendment No. 12. Polish law recognised the fact that an embryo was a human being, and human identity was present from fertilisation. She felt that a great deal of thinking had to be done about the implications of determining when life actually began.

Her second point related to Amendment No. 11, which she had tabled. The text of Amendment No. 11 related to point 38 of the explanatory memorandum to the draft convention, but it did not appear in the legislative text. She felt that it was extremely important to have a conscience clause inserted in Article 3, allowing doctors and other medical staff to refuse to participate in medical interventions on ethical grounds. She concluded by urging the Assembly to support both amendments.

Mr MONFILS (Belgium) said that the draft convention was a major step forward in the protection of human rights and the integrity of the individual. He congratulated Mr Palacios on the quality of his work and for his determination.

He welcomed the decision by Mr Palacios, Mr Daniel and Mr Schwimmer, set out in Amendment No. 12, to deal with the sensitive issue of embryos in a protocol to the draft convention, rather than in just one line.

He stressed that individuals should not be deprived of the results of advances in medical research as a result of the draft convention. If research was blocked as a result of potential abuse, this would make the convention inoperable in certain states and would result in Europe lagging behind in the field of medical research.

There was still much to be done in the form of protocols to the draft convention, and he saw the need for, in particular, appropriate legislation in member states which would provide for sanctions against violations.

Mr GÜL (Turkey)- Scientific and technological advances have at last targeted human beings. The early stages of human life and anatomy are being subjected to biological analysis. That has produced the inevitable clash between religious values and the insatiable appetite of science and technology. In other words, human beings, the creators and initiators of science and technology, find it necessary to dwell on the ethical, social and legal implications of scientific and technological research now that they have become the subjects of those scientific endeavours.

The ethical, social and legal implications of scientific and technological advances in human biomedicine and biotechnology have been under review by the Council of Europe for a long time. The draft Bioethics Convention represents the sublimation of those efforts.

In that way, various national approaches to bioethics will be harmonised on the basis of the principles and values of the Council of Europe.

Human life is God-given and divine. Accelerating developments in biology and medicine, if misused, endanger human dignity and contravene basic religious precepts. Therefore, measures against the misuse of biology and medicine should also be considered within the scope of the general mechanism of the Council of Europe for the protection of human rights and fundamental freedoms.

I welcome the convention as a pioneering effort. I equally acclaim the Parliamentary Assembly's contribution to its materialisation. The convention conforms with Turkish legislation. We have difficulties only with Article 6, which allows interventions on persons who have no legal capacity without the prior consent of their legal representatives. That formulation is against basic human rights and in that context I welcome and support Mr Palacios' proposal for redrafting Article 6.

Mr SOLÉ TURA (Spain) expressed his thanks to all the Rapporteurs and congratulated Mr Palacios on his exemplary work.

The draft convention was the first ever development on such lines. It would open up possibilities and also close loopholes. The draft convention set out the major principles and correctly left details to subsequent protocols. Given the pace of scientific research it was necessary to define areas that science should not move into. It was the Assembly's task to reach consensus. Even with respect to Articles 6 and 15, which were the most controversial, there was general agreement that there should be full protection of human rights.

Mr BIANCHI (Italy) said it was no easy task to consider ways of giving clear and unequivocal statements of rights to human beings. Rules for bioethics had to be in line with the social and ethical rules of society.

A crucial consideration was the distinction between the dignity of the human being and the rights of the person. The dignity and identity of human beings was derived from the point of fertilisation whilst other facets were derived later through the capacity of the individual. There were problems on the issue of consent. The convention had to deal with the protection of the human being and to protect from scientific research incapacitated individuals who were unable to give their consent. Article 15 which related to research on embryos in vitro was very topical in Italy where a lively debate had been generated amongst the general public.

In conclusion he said that it was vital to set standards for everyone; otherwise standards should not be set.

Mr de Puig, Vice-President of the Assembly took the Chair in place of Mr Martínez.

Mr LIE (Norway).- First, I wish to emphasise the importance of having a convention on bioethics. In many ways, it will be a new approach and an enlargement of the convention on human rights. I am impressed by the work that the Rapporteur, Mr Palacios, has done and the constructive way that he has greeted new proposals from the committee's members and other committees.

However, some of the articles are, in my opinion, not satisfactorily formulated. I shall return to that subject later. Let me stress two important aspects. First, the purpose of the convention is to ensure that human rights are protected, and therefore it is better to have a convention than nothing at all. If Amendment No. 9, which I strongly support, is adopted, the Parliamentary Assembly will have the opportunity to give a final opinion, if necessary.

Secondly, the convention proposed is a framework and each country has the right and opportunity to grant a wider measure of protection than is stipulated in the Bioethics Convention. In Norway, a number of laws have been passed already. In the national Norwegian law covering the medical use of biotechnology, research on embryos in vitro is forbidden, and that prohibition has no limitation in time. It is therefore important for me to emphasise that each country has a right to grant a wider measure of protection than is stipulated in the Bioethics Convention. I therefore support Amendment No. 6 - alternatively Amendment No. 12.

In Doc. 7210, which is the result of committee meetings in December and January, there have been changes in many articles. In general, I support the new proposal, except for Article 15 paragraphs 1 and 6. I have already commented on Article 15, paragraph 1 by showing that Norwegian law forbids research on embryos in vitro.

As regards Article 6, it is very important that all relevant information is sufficiently clearly worded and understandable to a layman. The definition of "incapacitated persons" might not be distinct and precise enough when saying "persons who have a reduced capacity of understanding." I therefore support Amendment No. 3, from the Committee on Legal Affairs and Human Rights.

Finally, I strongly emphasise my support for the intention laid down in the convention on bioethics. It is necessary to safeguard human dignity and the fundamental rights of the individual with regard to the application of biology and medicine. I will support the convention as it now stands.

Mr POZÉLA (Lithuania):- The achievements of research in genetic engineering have opened up new horizons and new effective approaches to the improvement of human life and health. I believe that biochemical and genetic regulation is the only way to improve the quality of human life and health.

Experiments on embryos are most important for genetic engineering. Without those experiments, this discipline could not realise its scientific and technical potential. The basic research objective for experimentation with human embryos is the development of medical diagnostic, therapeutic science.

Those experiments give rise to complex legal and ethical problems. I agree that the freedom of research is the fundamental right of a scientist, but, in the case of genetic engineering, that right must be limited. It is a very delicate question. The right must be limited, but not prohibited. That is a reason why I strongly oppose the proposal for the first paragraph of Article 15, which is formulated in Amendment No. 6, that the research on embryos is forbidden. That would mean the end of the development of genetic engineering, with many practical consequences. That means a loss for our European common culture.

I also believe that the first paragraph of Article 15 must be deleted from the convention, as it is proposed in Amendment No. 12. I think it is the best solution in the present circumstances.

Mr VALLEIX (France) recognised the importance of the debate. The draft convention was a sensitive issue. Article 6 provided for experimentation on the legally incapacitated. But the text of this article was not finalised. It was unacceptable to ask the Assembly to accept a report on such a sensitive issue that had not been finalised. He urged the Parliamentary Assembly to refer the text back for a final version to be drawn up. The report proposed that the draft convention became part of internal law; in France legislation was already in place which gave protection above and beyond that provided by the convention. It was not just the question of conflicts in law to which he objected but the slackness of some of the articles within the convention itself.

Mr LEONTE (Romania) said that great progress had been made in the last few years. Everyone had had to think about the legal and ethical issues dealt with in the draft convention, which had been very accurately and professionally prepared.

A thorough knowledge of the laws of nature was needed. Genetic engineering could produce miracles by increasing crop production and improving breeds of animals. It would make possible the use of micro-organisms and the production of new food and medicines. His country took an active interest in the matter; in 1994 Romania had acceded to the International Biotechnology Centre, and he wanted to encourage others to follow this path.

Mrs MIHAYLOVA (Bulgaria):- Mr President, ladies and gentlemen, parliamentarians, I should like to share with you some of the thoughts which this project for a convention on bioethics has provoked in me as a citizen who is neither a doctor nor a lawyer. I divide into three groups the problems which arise from such a convention - medical, legal and ethical problems. The medical practitioner has to define to what extent interventions on humans or embryos can be undertaken and whether a person is capable of expressing his will. That is why the report correctly groups the first set of questions with the legal criteria.

It was a pleasure to notice that, overall, the report gives priority to ethical principles and the dignity and value of the human individual. In the few minutes available to me I should like to focus the Assembly's attention on the proposals made by Mr Palacios in Article 6. It refers to persons who are recognised as incapacitated. In all

countries incapacitated persons are represented by a legal tutor. The report proposes a definition of incapacitated persons, but it is necessary to make the definition more complete.

Let us keep it in mind that the convention will be applied by countries which have different legal systems. It might be better if the convention referred to national legislation, the application of which would be subordinate to a more general definition of incapacitated persons which could not be interpreted either intensively or extensively.

The proposed Article 6 provides for obligatory respect for the refusal of the incapacitated person. I believe that the article should be more precise. I agree that one should always accept the refusal of a person who has reduced capacity to understand, but when a person who is absolutely incapable of acting refuses treatment, the will of his legal tutor should be taken into account. I believe that that should be the case because the eventual refusal is not the result of conscious evaluation and freely expressed will.

I also cannot accept the proposal in Article 6 under which an incapacitated person can undergo medical research when it will have a direct and significant benefit to his health. It is obvious that medical intervention can and should occur for the benefit of an incapacitated person in an emergency or when the agreement of his tutor cannot be obtained. Medical research, however, is something else. For me as a non-professional, it means carrying out an experiment. The result of one experiment cannot always be predicted and that is why I would prefer the words "medical research" in paragraph 2 of Article 6 to be replaced by the words "medical intervention". I thank the Assembly for its attention.

Mrs ARNOLD (Denmark).- In the Danish parliamentary delegation, we have had discussions about the important subject of a common set of principles guiding the rapidly developing field of biomedical research. Let me put it straight. We find it extremely important to construct internationally agreed principles in this area, especially as biomedical research is international. Communication between scientists across borders is intense, swift and open. A new treatment, a new remedy for a given disease and new tools in diagnostics are available for many individuals soon after the publication of the results in international scientific journals.

The text of the draft convention was released half a year ago and the consideration phase is now concluding. The Danish Ministry of Health, under which these issues are dealt with in Denmark, has sent a detailed answer to the steering committee. In short, the Danish response to the draft convention is positive, especially to the fundamental principle laid down in the text, but the Ministry found that many details needed clarification. My delegation agrees that the text of the draft convention needs further discussion and that the convention is far from perfect although it will represent a major step forward for countries that have no national legislation in this area.

I now turn to the Palacios' report from the Committee on Science and Technology and the report by Mr Schwimmer from the Committee on Legal Affairs and Human Rights. The Palacios' report, as currently presented, will not get the support of the Danish delegation because it suggests a number of amendments to the draft convention text which will make later ratification by Denmark difficult. One example is amendment viii to Article 16 which would, in the wording suggested by the Palacios' report, in practice prohibit chemotherapy treatment for cancer. We know that this therapy influences genetic material and that it is not possible to exclude influence on the germ cell line. The cancer treatment is the key issue and the risk of intervention in the germ cells must be taken.

Another example is amendment vi to Article 15 which would allow research only on non-viable embryos. That would effectively stop research into and treatment by in vitro fertilisation. Not even research that aimed to improve the embedding of the fertilised ovum in the uterus would be possible. We prefer the text of the draft convention as it is. On the other hand, we find that amendment iii presents a much better text than the draft convention on the very important subject of informed consent.

Mr Schwimmer's report will not get the votes of the Danish delegation either. We agree with many of the general views expressed in the report, but we cannot accept the proposed total ban on research in human embryos, however young - not even less than two weeks. The two-week limit has been law in Denmark for some years and research is limited to improvement in the treatment of infertility. The Danish delegation has carefully studied the amendments proposed to the Palacios' report. We will vote according to the principles I have stressed.

I hope that work on the convention can continue within the planned time schedule. I hope that the result will be a convention that respects human rights and human dignity, but which makes it possible for mankind to benefit from therapeutic and diagnostic progress.

Mr Martínez, President of the Assembly, took the Chair in place of Mr de Puig.

Mrs VERSPAGET (Netherlands) congratulated the Rapporteurs on their contributions. The draft convention was one of the most important subjects currently being dealt with by the Council of Europe. It complemented the European Convention on Human Rights, although the questions with which the draft convention dealt were not exhaustive.

She drew the Assembly's attention to one issue which was not provided for in the draft convention, namely DNA research among indigenous peoples. The consent procedure provided for in Article 3 of the draft convention was not followed in this instance and there was no direct medical interest for the indigenous peoples involved.

She said that the draft convention was a good start but that there should be efforts to draft a global convention, possibly with the United Nations as the depository power.

Mr DEGUARA (Malta):- While welcoming and recognising the urgent need for an international framework to provide clear guidelines for eventual legislation at a national level, I feel that certain proposals should sacrifice neither fundamental rights or beliefs nor moral and spiritual values. The basic denominator of past and future conventions has always been total and committed respect for the human being. We should be aware at all times that what is scientifically and medically possible and feasible today is not necessarily ethical.

With that conviction in mind, I believe that certain recommendations in the draft convention will fail to rally an international consensus. Any convention from the Council of Europe, even if accepted only at draft level, represents a sign of international acceptance of its basic principles.

The draft convention fails to answer one fundamental question - the basic question: when does life begin? Many members here today believe that life begins at the very moment of conception, and that is a non-disputed fact in medical circles and publications all over the world.

It is true that the proposed research will be limited to non-viable in vitro embryos less than 14 days old, but why should those be labelled as anything other than human beings, enjoying all the rights of otherwise healthy embryos progressing and developing normally? If they are so labelled, could that mean that in future, if a developing foetus is found not to be developing normally it could eventually be targeted as a non-human being?

Given the present high failure rate of IVF methods, we are running the risk of overproduction of such embryos, who although not primarily intended for research, would eventually end up as material to be experimented on. On the other hand, if we were to accept that life begins at the moment of conception, abortions, even where legal, would have to stop. The purpose of the convention is to ensure that human rights are protected, so it is inconceivable to me that we can condemn research on animals while at the same time contemplating research on human beings, whether in vitro or not.

The convention, if accepted, would have to be updated by others as further progress was made. If the proposed benefits are to be derived from research on in vitro embryos, will it not naturally follow that at a later date that knowledge will be extended to in vivo embryos to ensure that they are progressing normally? And if they were not progressing normally, would the next step not be to abort them?

In scientific circles sexing of the foetus was also hailed as a breakthrough, but its only practical application was the aborting of female foetuses in countries where males enjoy higher status. Would not the logical next step be to start screening all embryos beyond 14 days, and to label those found defective as incapacitated embryos, and therefore, according to what we are contemplating today, liable to be subject to further research? Who would have to give consent for such research? Certainly not the incapacitated embryo. We must be vigilant at all times, and fully conscious of our limitations in medical matters. We must progress slowly, especially when the outcome is so uncertain.

What we are discussing today will have a direct bearing on the two protocols being planned that deal with medical research and organ transplants. Before proceeding further we should harmonise our aims and thoughts. At our present limited level of knowledge, genetic research and experimentation should be limited exclusively to other forms. Only in that way can we learn to avert mistakes such as those made in the past, when mankind felt that it had progressed and evolved so far that it was infallible. I am afraid that events proved otherwise, and we human beings were rudely awakened to the reality of our limitations.

Mr MARUFLU (Turkey)- Today we are discussing a most interesting and vital subject. On the eve of a new millenium, our world is witnessing a rapid and unprecedented series of technological developments and innovations in various aspects of our life. Naturally, health is no exception. Mankind has gained much from the continuous and devoted work of researchers and scientists aiming to cure all kinds of illnesses and to improve the physical condition of human beings.

The magnitude of our progress in health, especially in biomedicine and biotechnology, has reached a point that will inevitably require our utmost attention to be paid to the ethical, social and legal implications of the application of such scientific and technical advances.

As is rightly stated in the report, creating common consent covering applications of biomedicine and biotechnology will be of special value for the standardisation of measures dealing with such applications. I believe that harmonisation of the principles and norms or bioethics can establish a common stance against the misuse of biology and medicine that could otherwise lead to actions that endanger the dignity of the human being.

I am happy to see that the draft convention has been thoroughly revised with regard to the dignity of the human being, following the decision taken in the previous session of our Assembly. The amendments to the convention set out in Mr Palacios' report, Doc. 7210, appear to contribute to preserving the dignity of the human being. In particular, the amendments to Article 6 and Article 15 show that our concerns about the contents of those articles were shared by the relevant committees and the rapporteurs who drafted them.

Before finishing, I thank our Rapporteur and all the others who have generously contributed to a convention so important for mankind. I hope that the convention will soon come into force, and that we shall see its concrete outcome.

Mr ROBLES (Spain) said he would be brief since his views were well known.

He applauded the efforts that the committees had made to reach a successful compromise. He considered that they had dispelled any remaining doubts. The Council of Europe had to send out a clear message to the scientific community and to society as a whole. The convention would protect the principle of life and the rights of human beings. The Assembly should support the draft convention. It would be the starting point for action in the field of bioethics.

The PRESIDENT apologised to Mr La Loggia for missing his name on the list of speakers and now called him to be the last speaker.

Mr LA LOGGIA (Italy) said that it was essential that regulations be found to govern biotechnology and medical ethics and appreciated the great effort that had been made by the Rapporteurs. However, he did not think that the effort had been enough. The road to hell was paved with good intentions. The guidelines proposed were far too broad and the definitions of terms not clear enough. Article 6 should be removed completely. He agreed that it was sensible to remove the first part of Article 15, but not enough attention had been paid to the consequences this raised. Human dignity must be maintained and the purpose of the convention was not to benefit pharmaceutical enterprises. The Council of Europe could not accept this and the draft convention should be referred back as it did not go far enough towards the protection of human rights and dignity.

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As I have already said, I must now interrupt the list of speakers. I remind colleagues that members who are on the list and present in the Chamber but who were not able to speak may submit their speeches in writing for publication in the official report.

I now call Mr Schwimmer, Rapporteur for an opinion from the Committee on Legal Affairs and Human Rights, for two minutes.

Mr SCHWIMMER (Austria) (Rapporteur of the Committee on Legal Affairs and Human Rights) said that the debate reflected how much caution was needed in dealing with such a complex and sensitive issue. There had been a level of confusion regarding the use of terminology which had not helped the debate. He emphasised that research had no place in therapy and that they were wholly distinct functions. He supported the amendments tabled by the Rapporteurs and hoped that the Ministers would agree to the report.

The PRESIDENT.- I now call Mr Daniel, Rapporteur of the Social, Health and Family Affairs Committee.

Mr DANIEL (France) (Rapporteur for an opinion of the Social, Health and Family Affairs Committee) said that the issue of Article 5 had been raised several times during the debate. This served to reflect what a sensitive issue it was, but he hoped that the Rapporteurs' amendments would satisfy the delegates.

The PRESIDENT.- I now call Mr Palacios, the Rapporteur of the Committee on Science and Technology, to reply.

Mr PALACIOS (Spain) (Rapporteur for the Committee on Science and Technology), replying to the various criticisms made during the debate, said that Amendment No. 6 forbade research and experimentation on human embryos, and that there was therefore no reason to vote against the draft convention on these grounds. He stressed that no part of the human body could be marketed. Article 17 ensured that genetic research should be only for the health of the individual concerned. Some speakers had suggested that non-members of the Council of Europe should be invited to subscribe to the convention. Provision for this had been made in Article 28. He was also adamant that the draft convention offered protection against the commercial exploitation of bioethics.

On the subject of the protection of legally incapacitated persons, he said that the draft convention went further than French legislation, and that in any case Article 22 stipulated that any state was free to improve on this legislation. He said that he had taken great care not to conflict with the Helsinki Declaration or with any other significant document, because he wanted today's draft convention to get the widest possible support. The root of the matter was the dignity of human beings.

He believed that Mrs Arnold had misunderstood Article 17.

The PRESIDENT thanked Mr Palacios for his work, which was of unusual importance.

The PRESIDENT.- Last week I paid an official visit to the Holy See. This specific item appeared on the agenda of our debate. It gave me great satisfaction that a body which had previously expressed reservations, and had contacted me to express those reservations, no longer had those reservations and expressed satisfaction and respect for the work that had been done.

When one starts such a very long debate, and when many people, many countries, many politically-orientated colleagues, want black coffee, and many people, many colleagues, want milk, it is very difficult to drink anything but white coffee. The debate has been very long so that we may have a fair amount of coffee and a fair amount of milk so that the document is acceptable to all.

I would be very frustrated if we had missed, as a result of a last minute lack of consensus, the great opportunity that is before us today.

I remind you that 10 minutes remain for the voting procedure for the judges of the Court of Human Rights.

The debate is now closed.

The Committee on Science and Technology has presented a draft opinion to which 12 amendments have been tabled. They will be taken in the following order: 1, 2, 11, 10, 3, 4, 5, 8, 12, 6, 7 and 9 to which there is a sub-amendment. If Amendment No. 12 is agreed to, Amendment No. 6 falls.

We come to Amendment No. 1, proposed by Mr Schwimmer, which is:

In the draft opinion, after paragraph 8.i, add a new sub-paragraph worded as follows:

"In Article 2, paragraph 2, delete the following words:

`in the interest of public safety, for the prevention of disorder or crime, for the protection of public health or'"

I call on Mr Schwimmer to support the amendment.

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that Amendment No. 1, like Amendments Nos. 2 - 8, had been tabled by the Committee on Legal Affairs and Human Rights as a result of certain limitations of the draft convention, which could lead to compulsory isolation or compulsory treatment of certain groups. He urged the Assembly to accept the amendment.

The PRESIDENT.- Does anyone wish to speak against the amendment?

Mr PALACIOS (Spain) (Rapporteur of the Committee on Science and Technology) announced that the Committee on Science and Technology was against Amendment No. 1 for reasons which had already been explained during the debate. The text of the amendment was the same as language already enshrined in the Universal Declaration on Human Rights, and he stressed that many countries already had legislation designed to protect public health.

The PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

The amendment is not adopted.

The PRESIDENT.- We come now to Amendment No. 2, proposed by Mr Schwimmer, which is:

In the draft opinion, after paragraph 8.i, add a new sub-paragraph worded as follows:

"At the end of Article 3, add the following text:

'in the context of the development of the biomedical sciences and their practical applications.'"

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that Amendment No. 2 was designed to strengthen the text of the draft convention by stipulating that all interventions should be in accordance with normal medical standards and laying down an obligation to keep abreast of the latest developments in scientific knowledge.

The PRESIDENT.- Does anyone wish to speak against the amendment?

Mr PALACIOS (Spain) (Rapporteur of the Committee on Science and Technology) said that the Committee on Science and Technology was against Amendment No. 2 on the basis that it merely repeated the title of the convention.

The PRESIDENT.- For the following debate, Mr Palacios, I shall ask every time who is against, so that one of our colleagues has a right to speak against the amendment. Then I will ask for the position of the committee. If you speak against every time - which is all right - and you say at the same time that the committee has that opinion, we save one intervention but I would prefer you to speak against the amendment explaining the arguments against, so that we can order the debate properly.

We have heard a speech in favour. Against that, we have had the opinion of the committee.

I shall now put the amendment to the vote by a show of hands.

The amendment is not adopted.

We come to Amendment No. 11, proposed by Mrs Grzeskowiak and Mrs Suchocka, which is:

In the draft opinion, after paragraph 8.i, insert a new sub-paragraph worded as follows:

"At the end of Article 3, add the following text:

'Doctors and, generally speaking, all professionals involved in carrying out a medical act are subject to ethical and legal requirements and must be competent and careful.'"

I call Mrs Grzeskowiak to support the amendment. You have defended it already in your speech.

Mrs GRZESKOWIAK (Poland) reiterated the reasons she had given for moving Amendment No. 11 during the debate, namely, the need to include a conscience clause in Article 3 of the draft convention, and she urged the Assembly to approve it.

The PRESIDENT.- Does anyone wish to speak against the amendment? That is not the case. What is the opinion of the committee?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) told the Assembly that the Committee on Science and Technology did not feel that Amendment No. 11 was necessary since the substance of the amendment was present in other areas of the draft convention.

The PRESIDENT.- I now put the amendment to the vote by a show of hands.

The amendment is not adopted.

We come to Amendment No. 10, proposed by Mr Cox, which is:

In the draft opinion, paragraph 8.iv, after the first sub-paragraph, insert the following text:

"In exceptional cases and in accordance with national law, where there is an overriding interest and provided that sufficient protection of the incapacitated person is guaranteed, non-beneficial interventions may be carried out on an incapacitated person in the case of removal of regenerative tissues for transplantation purposes between persons having close personal or family relations, provided that there is no donor with full capacity nor any equally effective alternative method."

I understand that the Committee on Science and Technology is willing to accept Amendment No. 10 with a sub-amendment. The sub-amendment reads:

"In line 5, leave out the words `personal or'"

Although I am normally reluctant to call oral sub-amendments, in this case I am prepared to make an exception if no one has any objection, with the aim of achieving the highest possible consensus. Is that acceptable, Mr Daniel?

Mr DANIEL (France) (Rapporteur of the Social, Health and Family Affairs Committee) said that the amendment had been proposed by the committee. It took account of the consent of incapacitated persons whilst protecting their integrity.

The PRESIDENT.- Mr Palacios, do you want to move your sub-amendment on behalf of the Committee on Science and Technology?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) moved the sub-amendment and said that the committee would accept the amendment as sub-amended.

Mr DANIEL (France) (Rapporteur of the Social, Health and Family Affairs Committee) said that in his opinion the sub-amendment should be accepted.

The PRESIDENT.- I now put the sub-amendment to the vote by show of hands.

The sub-amendment is adopted.

We now come to the vote on the amendment. Do you wish to speak to the amendment, Mr Schwimmer?

Mr SCHWIMMER (Austria) (Rapporteur of the Committee on Legal Affairs and Human Rights) said he was against the amendment as a whole. There were similar provisions in the text of the draft convention and the committee felt that the problem should be dealt with indirectly to avoid a public outcry.

The PRESIDENT.- Now that we have finished the discussion, we will vote on the amendment, as amended. Will those in favour of the amendment please raise their hands. Will members of the Assembly please

show clearly whether they are in favour of the amendment? I hope that soon we will find the finances for an electronic system of voting. Will those against the amendment please raise their hands.

The amendment, as amended, is not adopted.

We come to Amendment No. 3, proposed by Mr Schwimmer, which is:

In the draft opinion, paragraph 8.iv, before the paragraph beginning "For the purposes of the present Convention", add a new paragraph worded as follows:

"At national level a body (an independent multidisciplinary ethical committee) has to be set up to oversee any intervention involving mentally handicapped persons."

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that the question of incapacitated persons had played a large role in the debate. There was much concern that protection would not be sufficient. The Committee on Legal Affairs and Human Rights thought it would be necessary for a monitoring instrument to be established.

The PRESIDENT.- Does anyone wish to speak against the amendment? That is not the case. What is the opinion of the committee on the amendment?

Mr ROSETA (Portugal) (Chairman of the Science and Technology Committee) said that the committee had not voted on the amendment. It was not against the amendment in substance, but felt that it was too restrictive. At a national level the scope of the body would have to be increased.

The PRESIDENT (Translation).- I shall now put the amendment to the vote by a show of hands.

The amendment is adopted.

...

We now come to Amendment No. 4, proposed by Mr Schwimmer, which is:

In the draft opinion, after paragraph 8.v, add a new sub-paragraph worded as follows:

"In Article 7, at the end of paragraph 3, add the following words:

`and no intervention may be undertaken without their consent.'"

I call on Mr Schwimmer to support the amendment.

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that the purpose of the amendment was to strengthen the convention in its role of protecting the rights of the incapacitated.

The PRESIDENT.- Does anyone wish to speak against the amendment?

Mr PROKE_ (Slovakia).- I am not against the idea of the amendment, but I believe that the original text is strong enough. Consent is required under the original text so the amendment would do nothing more than repeat the original text.

The PRESIDENT.- What is the opinion of the committee on the amendment?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) said that the committee felt that the amendment was unnecessary.

The PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

The amendment is adopted.

We come to Amendment No. 5, proposed by Mr Schwimmer, which is:

In the draft opinion, after paragraph 8.v, add a new sub-paragraph worded as follows:

"In Article 9, replace the words 'taken into account' by the word 'determinant'."

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that the concern here was whether previously expressed wishes of patients should be accounted for. The Committee on Legal Affairs and Human Rights felt that they should be.

The PRESIDENT.- Does anyone wish to speak against the amendment?

Mr PALACIOS (Spain) (Rapporteur of the Committee on Science and Technology) apologised for speaking against the amendment.

The PRESIDENT reminded Mr Palacios that he did not need to apologise for speaking against amendments.

Mr PALACIOS (Spain) said that he knew his rights as a member of the Council of Europe. He felt that it was inappropriate that the prior wishes of patients should have to be adhered to as doctors sometimes needed to change the course of action during an operation and if they were not able to do this some patients might die.

The PRESIDENT.- What is the opinion of the committee on the amendment?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) said that the committee was not in favour of the amendment.

The PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

The amendment is not adopted.

We now come to Amendment No. 8, proposed by Mr Schwimmer, which is:

In the draft opinion, after paragraph 8.v, add a new sub-paragraph worded as follows:

"In Article 13 the words 'only if this is done in conformity with appropriate information and consent procedure' are to be clarified."

I call upon Mr Schwimmer to support the amendment.

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that the amendment was concerned with insuring that the words chosen in the convention were clear and appropriate. He felt that it was currently too vague.

The PRESIDENT.- Does anyone wish to speak against the amendment? That is not the case. What is the opinion of the committee on the amendment?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) said that committee was not in favour of the amendment.

The PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

The amendment is adopted.

Amendments Nos. 12 and 6 are to the same paragraph. If Amendment No. 12 is passed, Amendment No. 6 will fall. Amendment No. 12 is in the names of all three Rapporteurs and has the support of all three committees.

We come to Amendment No. 12, proposed by Mr Schwimmer, which is:

In the draft opinion, replace paragraph 8.vi, by a new sub-paragraph worded as follows:

"Delete the first paragraph of Article 15."

I call on Mr Schwimmer to support the amendment.

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that all three Rapporteurs had agreed to this amendment which would result in a separate protocol governing the protection of embryos.

The PRESIDENT.- Thank you. Does anyone wish to speak against the amendment? No. What is the opinion of the committee?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) said that the committee was in favour of the amendment and that the protection of embryos should have a dedicated protocol. This was done in the spirit of compromise.

The PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

The amendment is adopted.

Amendment No. 6 therefore falls.

We come to Amendment No. 7, proposed by Mr Schwimmer, which is:

In the draft opinion, after paragraph 8.viii, add a new sub-paragraph worded as follows:

"At the end of Article 18, add the following words:

`and in accordance with the national legislation about data protection.'"

Will Mr Schwimmer please support the amendment?

Mr SCHWIMMER (Austria) (on behalf of the Committee on Legal Affairs and Human Rights) said that the communication of results of genetic testing outside the health field could only be allowed in accordance with the provisions of Article 2, but that this allowed far-reaching exceptions and restrictions such as the protection of public safety and prevention of crime. He believed that this was a very dangerous way to proceed and that national laws on data protection should apply.

The PRESIDENT.- Does anyone wish to speak against the amendment?

Mr MONFILS (Belgium) said that the amendment was unnecessary.

The PRESIDENT.- What is the opinion of the committee on the amendment?

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) said that he also believed that the amendment was unnecessary. There was a choice here between the proverbial alternatives "quo abundat non nocet" or "invtilia truncant" but that he would leave that choice to the Assembly.

The PRESIDENT.- Thank you. Now you see, Mr Roseta, that in our languages, which are of Latin origin, we can find proverbs for any use.

I shall now put the amendment to the vote by a show of hands.

Will those who are for the amendment please raise their hands.

Will those who are against the amendment please raise their hands.

Are there any abstentions?

It was the first proverb that was right, Mr Roseta - quod abundat non nocet.

The amendment is adopted.

We come to Amendment No. 9, proposed by Mrs Lentz-Cornette, which is:

In the draft opinion, paragraph 9, before sub-paragraph (i), insert a new sub-paragraph worded as follows:

"transmit the final revised text for a final opinion to the Parliamentary Assembly"

I call on Mrs Lentz-Cornette to support the amendment.

Mrs LENTZ-CORNETTE (Luxembourg) said that she believed that the revised text of the convention should return from the Committee of Ministers for a final opinion from the Parliamentary Assembly.

The PRESIDENT.- We come to Sub-amendment No. 1 to Amendment No. 9, proposed by Mr Roseta, which is:

At the end of the amendment, add the words:

"except in the event of the Committee of Ministers accepting the changes proposed by the Assembly."

The PRESIDENT called on Mr Roseta to support Sub-amendment No. 1.

Mr ROSETA (Portugal) (Chairman of the Committee on Science and Technology) said that it would be more logical, if the Committee of Ministers accepted the recommendations, not to return the draft convention to the Assembly.

The PRESIDENT.- I shall now put the sub-amendment to the vote by show of hands.

The sub-amendment is adopted.

Does anyone wish to speak against the amendment, as amended?

No.

I shall now put the amendment to the vote by show of hands.

The amendment, as amended, is adopted.

We will now proceed to vote on the whole of the draft opinion contained in Doc. 7210 (as amended).

Mr BIANCHI (Italy) called for a roll-call vote on the matter.

The PRESIDENT.- Do you, Mr Bianchi, have the support of nine other colleagues? They must stand up so that they can be counted. The number of colleagues standing does not meet the required number for a vote by roll-call, so the Assembly will therefore vote by a show of hands.

The draft opinion contained in Doc. 7210, as amended, is adopted with a two-thirds majority.

Mrs GRZESKOWIAK (Poland) said that following the President's earlier remarks, she understood that the Holy See was prepared to withdraw its reservations on the draft convention, only if sub-amendments were introduced.

The PRESIDENT.- Perhaps you have had some reason to be in contact with the Holy See. I had no such reason, but I was in contact. I met the responsible people at the Holy See and heard their comments. I have done my job and ensured that the amendments were introduced. Therefore I stand by what I said. I am glad that the document has been adopted.

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE

OPINION N_184 (1995)²

***on the draft bioethics convention
(draft convention for the protection of human rights
and dignity of the human being
with regard to the application of biology and medicine)***

1. The Assembly has undertaken a considerable amount of work since 1976 with regard to the bioethical aspects of human biotechnology and biomedicine.
2. This work, based on principles designed to protect human dignity and the corresponding fundamental human rights relating to human biology and medicine, led to Recommendations 1100 (1989) and 1160 (1991) which contained proposals for the preparation of a comprehensive European bioethics convention intended as a legal instrument open to non-member states.
3. Resolution No. 3 of the 17th Conference of European Ministers of Justice (1990), recommended that the Committee of Ministers instruct the CAHBI (now the CDBI, the Steering Committee on Bioethics) to examine the possibility of preparing a framework convention and, if so decided, to draft it.
4. The Assembly considers that Recommendation 1160 proposes a convention of a general nature and a series of protocols on specific subjects that can be extended to other subjects if this is considered to be advisable and necessary in the future. This convention should allow codification of existing but fragmented work and fill a legal vacuum. The Assembly is aware that the incorporation of certain principles into the European Convention on Human Rights, which affords better protection, albeit limited to the member states, should be borne in mind for the future.
5. The Assembly has closely followed the various stages in the drafting of the texts of the convention and of the protocols within the CDBI, in which the Parliamentary Assembly has been represented since 1990, and its contributions and suggestions have been largely taken into account and incorporated into the texts.
6. There has been excellent co-operation between the Parliamentary Assembly and the CDBI and the latter has carefully considered the work carried out by the Parliamentary Assembly over the last twenty years, which largely inspired the text of the draft convention.
7. The Assembly notes the fact that the Committee on Science and Technology, the Social, Health and Family Affairs Committee, and the Committee on Legal Affairs and Human Rights have been kept permanently informed by their representative in the CDBI during these years of drafting the convention.
8. The Assembly therefore recommends that the Committee of Ministers review thoroughly the text of the draft bioethics convention as transmitted to the Assembly and set out in Doc. 7124, and amend it as indicated below before opening it for signature:
 - i. At the end of Article 1, add the following new sentence:
"They shall introduce the substantial provisions of this convention into their national legislation."
 - ii. In Article 4, add a new paragraph to read as follows:
"Services offered to the public involving the use of the biomedical services and techniques shall be subject, in the interest of the protection of the persons concerned, to control of their quality."
 - iii. Amend Article 5, paragraph 1, to read as follows:

²1. *Assembly debate* on 2 February 1995 (6th Sitting) (see Doc. 7210, report of the Committee on Science and Technology, rapporteur: Mr Palacios; and Doc. 7223, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Schwimmer). *Text adopted by the Assembly* on 2 February 1995 (6th Sitting).

"No intervention may be carried out in the health field without the informed, free, express and specific consent of the person undergoing it."

iv. Replace Article 6 by the following text:

"Interventions may be carried out on persons who have no legal capacity of giving consent and those who, though legally capable of giving consent, have a reduced capacity of understanding, only for their direct benefit and with the consent of their legal representative or an authority or an individual authorised or designated under his national law.

A legally incapacitated person may not undergo medical research unless it is expected to produce a direct and significant benefit to his health.

Any refusal by the incapacitated person must always be respected.

At national level a body (an independent multidisciplinary ethical committee) should be set up to oversee any intervention involving mentally handicapped persons.

For the purposes of this convention, "incapacitated persons" means:

- persons who have a reduced capacity of understanding;
- persons whose capacity to possess rights and to be bound by obligations is limited, either for reasons of age or because of mental illness;
- persons having a de facto incapacity".

v. In Article 7, at the end of paragraph 2, add the following words:

"and also the free and informed consent of the parent(s) or legal guardian(s) is necessary".

vi. In Article 7, at the end of paragraph 3, add the following words:

"and no intervention may be undertaken without their consent."

vii. In Art 13 the words: "only if this is

done in conformity with appropriate information and consent procedures" are to be clarified.

viii. Delete the first paragraph of Article 15.

ix. In Article 15, paragraph 2, delete the word "solely".

x. Replace Article 16 with the following text:

"An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes without any intervention in the human germ cell line."

xi. At the end of Article 18, add the following words:

"and in accordance with the national legislation about data protection."

xii. In Article 20, delete "according to the conditions and procedure prescribed by law".

xiii. In Article 26, paragraph 2 (and elsewhere), replace "European Community" by "European Union".

xiv. In Chapter V, add a new article worded as follows:

"For the purpose of observing the application of the convention on the territory of the Contracting Parties and of interpreting the text of the convention, a monitoring body in connection with the European Court of Human Rights is hereby set up".

xv. In Article 28, paragraph 1, delete "and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers".

xvi. In Article 30, at the end of the first paragraph, add:

"No reservations may be made in respect of Articles 15 and 16."

9. The Assembly also recommends that the Committee of Ministers:

i. transmit the final revised text for a definitive opinion to the Parliamentary Assembly except in the event of the Committee of Ministers accepting the changes proposed by the Assembly;

ii. invite member states and non-member states (according to the procedure provided for in Articles 27 and 28 of the draft convention) to sign and ratify the reviewed and amended convention and to implement it as soon as possible;

iii. invite the CDBI to continue with the preparation of the four draft protocols concerning medical research, organ transplantation, protection of the human embryo and foetus, as well as genetics, in the light of the opinion of the Parliamentary Assembly;

iv. transmit for opinion to the Parliamentary Assembly each draft protocol as soon as it is finalised.

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE
1996 ORDINARY SESSION

(Fourth part)

excerpt from the OFFICIAL REPORT

Thirtieth sitting

Thursday 26 September 1996 at 9.45 am

Mrs Fischer, President of the Assembly, took the Chair at 9.49 am.

THE PRESIDENT.- The first item of business this morning is the debate on the report on giving an opinion on the draft Convention on Human Rights and Biomedicine presented by Mr Plattner on behalf of the Committee on Science and Technology (Doc. 7622), with an opinion presented by Mr Daniel on behalf of the Social, Health and Family Affairs Committee (Doc. 7664) and an opinion presented by Mr Schwimmer on behalf of the Committee on Legal Affairs and Human Rights (Document 7654).

The list of speakers closed at 6 pm yesterday.

Thirty-four names are on the list, and 15 amendments and one sub-amendment have been tabled.

In view of the time available, and the number of speakers on the list, I propose that speaking time in the debate be limited to five minutes.

It is proposed to conclude the general debate at noon today, when we hear the address of Mr Forné, head of the government of the Principality of Andorra and to have the votes on the draft opinion and amendments at the sitting this afternoon.

Are these arrangements agreed?

They are agreed to.

I call Mr Plattner to present his report. You have 10 minutes, Mr Plattner.

Mr PLATTNER (*Switzerland*) (*Rapporteur of the Committee on Science and Technology*).-The Convention on Human Rights and Biomedicine is a very important matter. If adopted by this Assembly, it could enter into force possibly next year, after almost a decade of difficult political and technical work. It will have far-reaching consequences for the further development of human rights, which will be extended to fundamental aspects of human dignity and ethics in the context of modern medicine and biology. This convention will be a milestone.

The convention is - and I quote from the report of the Steering Committee - "the fruit of observation and concern: observation of the radical developments in science and their applications to medicine and biology, concern about the ambivalent nature of many of these advances. Science, with its new complexity and extensive ramifications, thus presents a dark side or a bright side, according to how it is used."

The convention attempts to ensure that the bright side prevails. It rests solidly on the basis of human rights as defined in the famous European convention. The two conventions share their underlying approach, their ethical principles and legal concepts.

The new convention sets out only the most important principles. Additional standards and detailed questions shall be dealt with in additional protocols. Thus, the bioethics convention will be further developed in the years ahead. The present version is a first step, not the definitive truth. Just as was the case with the human rights declaration, it will take time and experience to develop the relation between human dignity and biomedical ethics. Rome also was not built in one day.

Since the subject matter is so complex and controversial, it has received great public attention. This was and is very welcome, since public attention has led to very careful, cautious and responsible work. I have deep respect for those whose questions, criticisms, doubts and proposals have helped greatly to perceive difficult issues, find novel solutions and bring the convention to its present high standard. We all know, Europe having seen not long ago such terrible abuse of human dignity by a cruel, ideologically misguided medicine, that scepticism in this matter is a virtue and not a vice.

On the other hand, no matter how critical public attention, in the end those called upon to vote must assume their responsibility. The time is now ripe for a European Convention on Human Rights and Biomedicine. A number of countries have done their internal work on this topic and are awaiting from us, the keeper of human rights, the Council of Europe, an authoritative guideline, which sets a high common standard in this area. It is evident that, if we have no convention, we shall be in a far worse situation than if we have one, even though it may be one that still can and must be improved. To have no convention would spread uncertainty, open the door to anarchy in respect of biomedicine, and lead to trafficking of doctors, patients and researchers across borders to the countries with the least restrictive laws. These are developments that we must avoid.

For this morning's deliberations to end in a deadlocked Assembly, would be the worst possible outcome, both for the convention and for the Council of Europe. So we are all condemned to compromise, unless we want to succumb to the same bewildering confusion that befell the European Parliament, when it proved unable to reach an agreement in this matter and lost a great deal of its credibility on the way. I am confident, however, that we shall pass a reasoned judgment on the draft convention, amended according to our decisions this morning. As I said: Rome was not built in one day. But there was a day when Romulus had to start building it, or it would never have been built at all. Our starting day is today.

The draft convention has already been approved by the representatives of the European governments in the Steering Committee, by a vote of 31 against one - Germany - with two abstentions. The German Government - known to be extremely diligent in its respect for human rights - has explained its vote by stating that it did not want to agree before the internal German debate on the matter had finished, but that the new draft was much improved over the previous version and that, anyway, there was a strong German interest in an international convention. So there is still good reason to hope that the last country, Germany, too, will eventually decide to sign the convention.

Please remember in that context that the draft convention explicitly allows every signatory state to have stricter provisions than the convention requires as the common standard, so that no state must go back below its own standard because of the convention.

Both committees of the Assembly, to which the draft convention has been referred for an opinion, speak well of it. Of course, even so, 15 amendments have been proposed. I am glad to report that my committee considers two thirds of them to be very helpful and well conceived and will hence suggest their adoption. This demonstrates that everyone is willing to seek a good compromise. We shall have the opportunity to discuss the amendments and examine some of the core issues of the convention in more detail this morning.

The topic which has raised most concern in the context of the bioethics convention is medical therapy and research on persons unable to consent. In this matter the present draft is so well conceived that neither of your committees has proposed further amendments. Let me explain.

Articles 6 and 7 now limit the permissible cases of interventions on persons unable to consent to ethically unobjectionable therapeutic interventions in their direct personal interest. Both articles are formulated with such rigour that no loopholes remain. Articles 16 and 17 deal similarly with medical research, and Articles 19 and 20 with organ and tissue transplant. In these cases a narrow door is left open for interventions beyond the direct interest of those concerned, but it is strictly regulated by a set of restrictive conditions which must be simultaneously fulfilled. The rigour with which this core issue of the convention is treated has led the critical German Government to state approvingly that a considerable and satisfactory increase of the protection of persons unable to consent has been achieved.

I want to point out to the sceptics among you that a complete ban of such research - as is advocated by many - would in itself be highly unethical. It would render research on children's diseases, on Alzheimer's or on Creutzfeld-Jacob's diseases impossible. Also, a total ban on, for example, a skin transplant between a healthy boy of 12 and his seven-year-old sister, severely burnt in an accident, would have little to do with ethical standards. It is evident to me, that those requesting a total ban of interventions on persons unable to consent and claiming to be the only persons with high ethical standards, should beware of the danger of righteousness. In this matter, as in most,

truth is not simple, and ethical ideals are best served by a careful and balanced debate not of one but of all the issues involved.

I should point out the inclusion in the draft convention of a powerful new provision. It is beautifully simple, as are all great ideas. I am speaking of Article 11 on non-discrimination on the ground of a person's genetic heritage. In my eyes, that article is a tremendous asset of the convention and may well turn out to have been the shiniest pearl found during the work of the past six years. It strengthens the other articles in a particular and commendable way and will greatly influence the legal interpretation of the convention.

In conclusion, I strongly recommend that we accept the draft Convention on Human Rights and Biomedicine today by adopting the draft opinion of my committee, amended as you may deem reasonable.

I thank all those who have helped me, in particular the committee's president, Mr Roseta, the secretary, Mr Perin, and the experts of the Steering Committee. I was very much impressed by the responsible earnestness with which they went about their difficult task of finding a common European denominator - and not the smallest one, I trust - of the many different concepts of human rights and human dignity which have evolved on our continent in the course of history. They have done a commendable task. Now it is up to us to take the next step.

THE PRESIDENT.- Thank you very much for your report, Mr Plattner. I call on Mr Daniel to present the opinion of the Social, Health and Family Affairs Committee. You have seven minutes, Mr Daniel.

Mr DANIEL (*France*) (*Rapporteur of the Social, Health and Family Affairs Committee*) said that there had been substantial progress in medical research over the past 20 years. Many lives had been saved by transplants and genetic intervention. In congratulating the committees involved, he said that the report now allowed the adoption of the convention. The table contained in the report was a good complement to the report and allowed better understanding of the technical issues. The framework convention was not a final position, but allowed further discussion on the status and nature of embryos.

The debate would help that discussion and assist in clarifying positions such as that taken by the UK Government in its decision to order the destruction of embryos after a certain period. He supported the convention which would strengthen the individual trust in this difficult subject and urged its adoption.

THE PRESIDENT.- I call Mr Schwimmer to present the opinion of the Committee on Legal Affairs and Human Rights.

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*) said that the draft convention was a very sensitive and important undertaking. It dealt with the protection of human rights and human dignity and had to look to the most vulnerable members of society, which included those in contact with medicine. It was crucial to ensure that the rights and dignity of all were protected, that protection to cover the will of the patient.

Those who had contributed ideas to the committee were thanked for their efforts. It was noted that few other topics had raised such interest which served to highlight the enormous responsibility on the Council of Europe. The convention document was not in itself legally effective. It still needed to be adopted into domestic legislation. States with higher levels of protective legislation would be able to retain those standards. It was noted that Austria, in particular, had very high standards.

The issue required great caution. The draft convention, which was not yet finalised, had to be accepted by the Committee of Ministers. However, it would be wrong to have no convention.

Protection provisions had to be on a Europe-wide basis to prevent possible migrations of researchers and doctors who might seek to avoid such regulation. The issue was one of human rights and human dignity. The use of embryos raised the issue of dignity very clearly. The Council of Europe had an important contribution to make in this area.

THE PRESIDENT.- The first speaker on the list, Mr Lenzer, was supposed to speak on behalf of the European Peoples' Party but he is delayed in traffic. I shall give him the floor as soon as he arrives. I call Mr Valleix.

Mr VALLEIX (*France*) welcomed the convention as it established basic rules of biomedicine. It was looking to define the foundation of values in this area. It was crucial to be stringent in any matters relating to human life.

Although there had been remarkable progress in human medicine it was necessary to set certain limits by establishing a code of rights for embryos and incapacitated people. It was uncertain whether the current text of the draft convention took account of all the problems but the corrections that had been made since the earlier draft represented a step in the right direction. The provisions relating to experiments on embryos however, did not match up to the level of debate in 1995.

He could not approve a draft opinion which endorsed a convention that did not deal fully with all the issues. To approve such a document would give the wrong signal. Before deciding which way he would vote, he would wait to see whether the points on which changes were required were addressed in the debate and whether amendments relating to the protection of embryos and incapacitated persons were approved.

THE PRESIDENT.- For the sake of equilibrium, I will allow five minutes to other speakers, even if they do not speak on behalf of their group. I call Mr Antretter.

Mr ANTRETTTER (*Germany*) (*on behalf of the Socialist group*) said that there was considerable public interest in this subject. The recent decision to destroy human embryos which were no longer required raised the question whether it was acceptable to treat human life purely in scientific terms. The issue was whether limits should be set on the scope of modern medicine and research. Embryos developed as human beings and not towards humanity. There was no room for compromise on this issue. All human life must be treated alike. The protection of human life was given a fundamental status in the German constitution which ruled out any intervention on human beings incapable of giving consent. Ethical distinctions needed to be made even at the risk of being accused of scientific ignorance. The German delegation was therefore seeking improvements to the report and could not endorse Mr Schwimmer's draft as it stood. He regretted that an extension of time for consideration of this subject had not been available.

[*Interruption.*]

THE PRESIDENT.- There should be no comments from the tribune, please. I call Mr Christodoulides of Cyprus.

(*Mr Bársony, Vice-President of the Assembly, took the Chair in place of Mrs Fischer.*)

THE PRESIDENT.- As Mr Christodoulides does not appear to be in the Chamber, I call Mr Olrich.

Mr OLRICH (*Iceland*).- The way to today's debate has been neither easy nor straight but a long and tortuous path characterised by heated controversy. That is understandable, considering that the issue touches on religious convictions and difficult questions such as deciding when human life begins or at what stage of embryo development a human being is entitled to enjoy the rights for which the Council of Europe stands.

Time is an important factor, and it is running against us. The need for common general standards for the protection of the human being in the context of biomedical sciences is felt more acutely each year. If we do not take this opportunity to make up our minds, the Assembly is not likely to arrive at a decision. One of our distinguished colleagues asserted on Monday that work on the draft convention in its present form had taken us backwards, but I firmly oppose that view. Substantial improvements have been made to the text's structure and content, and further improvements are embodied in the amendments that we will consider today. I want to express my warm thanks to all the members who have contributed to that work - especially, in the final stages, our rapporteurs Mr Plattner and Mr Schwimmer.

Two fundamental questions remain to be answered. Does the draft provide sufficient freedom in research to ensure scientific and medical progress for the benefit of present and future generations? If so, does the text guarantee basic standards for the protection of man's dignity and identity? I am convinced that the draft convention does provide ample dimensions for scientific development and progress. The crucial dilemma is whether scientific *lebensraum* is so generously defined as to undermine the Assembly's purpose and willingness to protect fundamental human rights. The protection of the individual is acceptably formulated in most respects in the draft convention but some of its wording lacks accuracy or is even intended to be vague. That is true of Article 18 in

chapter 5 on "scientific research", which does not take a stand on the admissibility of the principle of allowing research on embryos in vitro.

The article does not deal sufficiently with the problem of embryos created for procreation purposes that are not used as such. Furthermore, the text of the draft convention, including the amendments to the provisional report with which we are dealing today, seems to go too far in prohibiting organ transplants. As we know, organ transplants have been carried out on dying children who cannot be saved and who have not been declared legally dead. This has been done with the generous consent of their grieving parents with the noble intention of saving other children's lives. That problem will be dealt with in a protocol.

Such shortcomings - and others that I shall not dwell upon due to the limited time allotted to us - are serious. However, I believe that they should be evaluated against the eventuality of having no common standards. That would leave us in a far worse situation than the one created by the several weak points found in the present draft. I firmly believe that the greatest risk we run now is that we shall not be guided by any common standards in this field in the years to come.

In conclusion, I recommend that we modestly accept the provisional report, together with the amendments with which we shall deal, on the grounds of having no better alternative and in view of our urgent need to establish common general standards in the field of biomedicine.

THE PRESIDENT.- Thank you. I call the next speaker, Mr Ramírez Péry.

Mr RAMÍREZ PÉRY (*Spain*) thanked the authors for their report and said that the debate was timely. The topic was a difficult one in which misunderstanding could not be risked. At what point did life begin, for example, and when should human rights be recognised? Such questions could be answered from a scientific, as well as a philosophical standpoint. Scientists, as recently as 1990, had attempted to establish the personal existence of an embryo and some were now suggesting the existence of pre-embryonic life.

THE PRESIDENT.- Mr Ramírez, please conclude your remarks.

Mr RAMÍREZ PÉRY (*Spain*) said that an embryo had genetic characteristics that should not be replicated. The Assembly should support the opinion.

THE PRESIDENT.- Thank you for your understanding. As Mr Kotlar is not in the Chamber, I call Mr Szakál.

Mr SZAKÁL (*Hungary*).- Thank you, Mr President. We have an excellent report by Mr Plattner which contains a detailed compilation of the previous and the present text of the convention. We also have an explanatory report and the opinion of the Committee on Legal Affairs and Human Rights. After studying those documents, I think that we are now in a position to make a decision about the draft Convention on Human Rights and Biomedicine.

I am not an expert in medicine or in biotechnics, so I do not wish to discuss the details. However, I point out the importance of the convention and the fact that a decision must be made about it without further delay.

In my country, for example, the whole health service system is undergoing radical reform, hand in hand with drastic cuts in the funds available to hospitals and other health institutions. A new health care law is in preparation.

Following the - sometimes heated - debates in my national parliament and in the press about problems in the health care system, I am convinced that the guidelines afforded by a European convention are much needed. To prove that, I offer the example of people's right to information collected about their health, defined in Article 10. As the explanatory report says, that right is important in itself but it also provides the basis for the effective exercise of the right of consent, under Article 5.

Over previous decades we built up an excessive health care system which, at least in theory, was free for all citizens. But the paternalist approach of the one-party communist state applied to the health service system too. That approach was adopted by many doctors and health care professionals, who considered themselves officials of the state authorities and thus exempt from the need to consider the wishes or rights of patients.

All these problems are widely discussed in newspaper articles in Hungary. In a recent interview, the Commissioner for Personal Data Protection declared that current regulations governing people's health care contradict our constitution, and that a new law is needed.

I hope that my fellow Hungarians will forgive me for discussing our problems, but I have personal experience of them. I believe that the situation in other former communist countries is likely to be similar or even worse. Besides, although we have well functioning democratic political institutions, it is still difficult to guarantee democracy and full observance of human rights in every aspect of social life.

As a Christian I hold the view that human life must be respected and protected at every stage. I regret the fact that Europeans are so divided over such basic values. Even if we cannot reach general agreement on specifics, it is still better to have an imperfect convention than to have no convention at all.

As I have tried to show, it is important to ensure that sick people have no fewer rights than those who are in good health. That is why I ask the Assembly to vote in favour of the draft opinion.

THE PRESIDENT.- I see that Mr Dionisi is not here, so Mr Probst is the next speaker.

Mr PROBST (*Germany*) said that the debate was of great importance because the subject was essential, ongoing, and subject to rapid change. The Assembly was grappling with a complex scientific issue in which it was not expert. It was therefore not important to seek to adopt the convention immediately. It was more important to ensure that the right decision was reached. However, while certain benchmarks could be established, much remained uncertain and subject to interpretation.

[*Interruption*]

THE PRESIDENT.- Order. I urge those attending this meeting in the public gallery, as it says in our rules, to "remain seated and silent. Any person expressing approval or disapproval shall be ejected by order of the President."

Mr PROBST (*Germany*) contemplated the uncertainty surrounding an incapacitated person and the need for his or her protection. However, if genetic assistance could help to overcome such illnesses as Alzheimer's disease, it would be the salvation of many.

It was unacceptable for medical research to infringe on human rights. National governments had to be compelled to ban certain practices when they saw abuses taking place.

Recently in Great Britain, thousands of embryos had been destroyed. This was not an acceptable response to over-production of human embryos. It was necessary to ensure that over-production did not take place. It would have been preferable had the Assembly had more time to weigh up the consequences of the draft convention. The report was not commended to the Assembly.

THE PRESIDENT.- Once again, I urge those who are sitting in the public gallery to be silent, otherwise I shall have to act with the rules of the Assembly.

The next speaker is Mr De Puig, who is not in the Chamber. That being so, the next speaker will be Mr Mészáros.

Mr MÉSZÁROS (*Hungary*). - The two most sensitive parts of the draft convention are those dealing with the issue of the human genome and the research on embryo in vitro.

Communication of the results of genetic tests to third parties seems to remain open under the draft that is before us. In drafting an important convention it is our moral and political responsibility to provide clear guidance on matters such as communication of results. The explanatory memorandum clearly states that the emergence of a new social category - a genetically inferior group of people who for reasons over which they have no control will find that they are refused jobs, loans and life insurance, for example - is a danger if we are not able to strengthen the personal data protection side of the case.

To widen the non-discrimination clause in terms of a person's genetic heritage is extremely important. Non-discrimination, however, could remain only a desire without strict data protection requirements. For this

reason I strongly support the amendment of the Committee on Legal Affairs and Human Rights that reads: "Results of genetic tests may only be communicated where they serve to determine a person's descent or as evidence in official procedures to try a criminal offence."

I cannot accept that research on embryos in vitro should be referred to a state's national legislation. The right of life cannot be the object of free choice. I cannot agree also with the idea of leaving the solution to a future protocol. That would be the postponing of the decision and would prolong the present dangerous legal vacuum. We would lose the chance of keeping biomedical science on the human rights track for a long time. The Council must accept its responsibility and take a decision at the end of the debate. The debate on whether to allow research on embryos in vitro has been taking place for a long time now and it is unlikely that any new arguments will appear in future.

The principle that the creation of human embryos for research purposes should be prohibited seems to enjoy wide support. We know, however, that the prohibition does not imply in itself the prohibition of research on embryos which were created in vitro for procreation purposes, but in respect of which there is no longer a parental project. Even the blind can see that a huge back door is open for purposes of manipulation.

It is beyond doubt that every fertilised cell can lead to human life. Therefore, any form of manipulation should be prohibited. That being so, I draw attention to Amendment No. 6, which has been presented by Mr Schwimmer. It offers an acceptable solution. It states: "The creation of human embryos for research purposes and the research on living human embryos is prohibited."

The PRESIDENT.- The next speaker is Mr Priedkalns.

Mr PRIEDKALNS (*Latvia*).- It appears that the provisional report presented by Mr Plattner represents the maximum degree of European consensus that can be achieved at present. In that light the adoption by the Assembly of the draft Convention on Human Rights and Biomedicine, as amended, is to be supported. The amendment should clearly specify, however, that the definition of the human being includes the unborn child and that appropriate rights and protection be accorded to it.

A sign of a civilised society is the way in which it deals with those of its members who are least able to defend themselves, such as the elderly and the sick, children and, above all, the unborn child. Frequently we speak nobly of the dignity of the human being and of human life yet we seldom hear of the extension of that dignity to the unborn human life. The unborn child is a human person to whom such dignity should be accorded.

I support, therefore, the proposals to amend the provisional report by according protection to every person without discrimination against the misuse of biology and medicine. Such protection is especially needed for individuals who are physically or mentally unable to consent to research on their person. That means using people who cannot speak for themselves as test objects for the benefit of others.

In that context, the first sub-paragraph of Article 17(2) should be deleted as it is in contradiction with Article 1, which claims protection for everyone. Research on embryos and fetuses without direct benefit for the individual embryo or fetus concerned is in violation of Articles 1 and 2 and is therefore contradictory. As for genetic tests before birth, to which Article 12 refers, the value of the unborn life should be considered and protected.

I propose that we support the amendments that represent the dignity of human life, and especially the dignity of those members of society who are least able to defend themselves, including the unborn child. Taking it as a whole, I propose that we support the draft convention as amended. It may represent the maximum consensus that can be achieved at present.

THE PRESIDENT.- Thank you, Mr Priedkalns. The next speaker will be Mr Mocioi.

Mr MOCIOI (*Romania*) said that the Assembly was considering a third draft convention which had been revised and improved following consultation with legal and scientific experts. Further improvements were still possible, as the amendments that had been tabled made clear. A principal outstanding problem concerned research on the human genome. Medical interventions aimed at altering the genome sequence should be banned. A protocol to the convention to this effect would help to regulate research on hereditary diseases. A convention approved by the Assembly could offer guidance to national legislators. He would vote in favour of the draft convention.

THE PRESIDENT.- Thank you, Mr Mocioi. The next speaker is Mr Bianchi.

Mr BIANCHI (*Italy*) stressed the importance of establishing a legal framework in this important area. The current text had room for improvement but should be supported. Prohibitions on the commercial exploitation of parts of the human body and on alterations to the human genome were required. Although a convention aimed only to provide a framework the current text did not contain sufficient detail on the implementation of the principles discussed. In particular it neglected consideration of artificial insemination and the selection of the sex of the child. A protocol was needed to address these and other issues, including the destruction of excess embryos, the fertilisation of single women and the conscientious objection of some medical practitioners. Some of the central terms used, particularly the use of the word "embryo" in Article 18, required greater clarification. This should be done by amendment to that article rather than by a separate protocol. All experiments which would result in the loss of embryos should be banned. He intended to vote against the draft convention.

THE PRESIDENT. -Thank you Mr Bianchi. The next speaker is Mr Szymanski.

Mr SZYMANSKI (*Poland*)- I want to make several important legal points about the draft Convention on Human Rights and Biomedicine. The draft convention concerning the protection of integrity and an individual's autonomy in the context of biomedical interventions is vital. Article 1 of the draft convention defining the scope of the application of its provisions allows those countries that are signatories to the convention to specify the meaning of the term "human being" in their national law systems. Article 1 provides different levels of protection, depending on the status of the human being. According to the convention, each human being's dignity and identity is protected. Guarantees of integrity and other fundamental rights and freedoms refer only to the human being.

The authors of the convention avoid giving a clear position on abortion. The definition of that issue in the draft convention allows its signatories to apply their own solutions. Freedom in specifying the scope of application of the convention's regulations, as well as permission to define three basic practical solutions, raise questions of approval. The postulate to protect the dignity and identity of all human beings, which is laid down in Article 1 - and which is crucial to the whole convention - is not precise. The meaning of terms included in that article may be explained on the grounds of other convention provisions referring to the issues relating to human beings. The terms "dignity" and "identity", when applied to a human being, may be explained on the basis of resolutions expressed in other documents on bioethics issues that have been prepared and adopted by the Council of Europe in recent years.

Many important problems concerning the protection of the human embryo and foetus still arouse great controversy and it is difficult to reach consensus. We should consider laying them in a separate protocol of the convention. Indeed, several attempts to do so have already been made.

The convention's provisions include a ban on the commercial use of the human body and its parts, which makes paid blood donation a problem. If we treat blood as a part of the human body, it will mean the prohibition of paid blood donation in many countries, including Poland, where that practice is very popular. The provision may be interpreted as being a ban on selling women's milk and men's sperm. If commercial use of the products of the human body is prohibited, ratification of the convention by several countries will require changes to the provisions relating to blood donation. I have a very important question. Do we, in accordance with the convention, treat blood as part of the human body?

The draft convention includes a few separate resolutions concerning carrying out interventions on the human genome. This is the first attempt to establish international law standards in the field of medicine, which is developing dynamically. It gives hope, but at the same time poses threats. The convention regulations define limits of biomedical interventions within genetics, protect the privacy of patients undergoing genetic tests and aim at the elimination of the abuse of tests and their results.

I think that the process of ratification of the convention will be very difficult.

THE PRESIDENT.- Thank you. The next speaker is Mr Schreiner.

Mr SCHREINER (*France*) felt that the text could be improved and hoped that further dialogue would take place between the Council of Ministers and the Assembly. He did not feel that the text of the report fully lived up to the title, which aimed to protect the human rights and dignity of the human being. The convention was a backward step from the first text presented in February 1995. The choice others had outlined, between minimum standards and none at all, was unacceptable to him. The problem lay in the existence of different standards in different countries and the report, therefore, was based on the principle of the lowest common denominator. He

was particularly concerned with the articles dealing with the expression of consent for legally incapacitated persons; an area in which there was much confusion and a need for a strengthening of the law. To this end he urged the Assembly to accept the amendments put forward by Mr Schwimmer, Mr Daniel and Mr About. Without these he did not feel he would be able to support the draft convention.

THE PRESIDENT.- Thank you. The next speaker is Mr Lenzer.

Mr LENZER (*Germany*) said that the Assembly had rarely been faced with such a difficult issue. As he could not agree that the Council of Europe should have domain over individual states in matters such as this he could not, therefore, support the document. Another reason was that one of the relevant papers had only been received by the German delegation on Monday last. He urged the Assembly to delay its decision.

Germany had serious reservations about the draft convention as it stood. He himself had been involved in scientific study and policy-making and so understood reasonably well the inherent dangers of the situation. Articles 15, 16 and 17 were of fundamental importance for individuals whether they were able to give their consent to medical intervention or not.

He was concerned about some of the terms used in the report and asked what was a "minimal risk" or "appropriate protection". Were those words legally acceptable? Was the Assembly delegating to others the task of defining those terms? There was a need to weigh carefully the desirability of scientific advance against the requirement to protect the interests of the individual. Human dignity was far more important than any medical research. After quoting from a recent German newspaper article he said that those who were unable to give their consent had to suffer the consequence of scientific progress. Only those in possession of all five faculties were protected.

THE PRESIDENT.- I call Mrs Fernández de la Vega.

Mrs FERNÁNDEZ DE LA VEGA (*Spain*) said she was pleased to be able to take part in the debate. The Assembly was being asked to consider a most important legal instrument for the protection of human rights. The issue was topical and gave rise to widespread concern. The trafficking in organs and fetuses was of concern to those people involved with bioethics. There should be safeguards for the individual which would not unnecessarily block scientific advance. She was concerned about the protection of the human dignity of those who were unable to give their consent to medical intervention. It was therefore important to ensure that adequate legal protection was available. In that sense the convention provided a good balance between scientific advance and citizens' rights. She hoped that the Assembly would give a good lead by adopting the report.

People were waiting to hear whether politicians were living in reality. It was imperative that the standards should be adopted, otherwise there would be a legal void. If the convention was not adopted, there would be trade in items that infringed human rights.

Mr LORENZI (*Italy*) said that he had been dealing with research in astrophysics for 25 years, and he had occasionally crossed paths with other researchers. It was necessary to steer a course between science and morality. The convention was commended to the Assembly but with the objection that science should not be demeaned. It would be unacceptable if the convention provided a precedent for limiting freedom of scientific research in other fields. It was hoped that other conventions would not grow up on other matters. Science could not proceed in a democratic fashion. This was a hard fact of life. It was ignorance and not knowledge which should be feared.

Mr MAASS (*Germany*) accepted the need to protect freedom in science, but said the Assembly had a responsibility to set the framework for this. A consensus was better than nothing, but there were a number of weak points in the convention which could have benefited from having more time devoted to them. There were too many woolly terms, and it was argued that the Assembly was not in a position to vote on the draft convention.

THE PRESIDENT.- I call Mr Martínez.

Mr MARTÍNEZ (*Spain*) said that the Assembly had been discussing this subject for 10 years. Another two months of discussion would make no difference.

Any document could be improved. Each time it appeared that a consensus had been reached, someone would seek to re-open the debate. The dignity and credibility of the Council of Europe was at risk if the Assembly failed to vote on this document now. It was open to each member state to introduce national legislation at any time.

A convention would provide a European reference for such national legislation, and it would be a failure of the Council of Europe if it did not make such a reference available. The Assembly should enable the Committee of Ministers to adopt and ratify the draft convention. Experience had shown similar conventions - for example that on minorities - to have provided useful reference points for member states in their progress towards democracy. The present opportunity should not be lost.

Mr SERRA (*Italy*) said that taking decisions on subjects with ethical implications often required overriding economic considerations. Similar problems arose in relation to environmental issues. In any such case democratic participation was vital. Any attempt to impose limits on science could face accusations of standing in the way of progress, but the best way to remedy the adverse effects of science was to ensure that it was properly used to promote human well-being. The draft text, although imperfect, was better than nothing. The debate had established the principle that all human beings should be treated with respect regardless of their situation and level of development.

THE PRESIDENT.- The next speaker is Mr Figel from Slovakia.

Mr FIGEL (*Slovakia*).- I begin by paying my compliments to the rapporteur for his serious report, his personal openness and his co-operative manner.

I have been a member of the Assembly for more than three years, so I now understand better the importance of working actively for positive ideas in Europe. But our continent is still troubled and human rights are not always respected, either in member states or - still less - in guest states. Some people are even prepared to fight for their rights, but there are many human beings who cannot defend their right to life because they cannot speak. They are the unborn, but they are creatures with dignity and an identity. We are mandated to defend the rights of those incapable of giving their consent to scientific research which tampers with their organisms.

Since citizens are generally allowed to do whatever is not prohibited by law, we need a legal framework defining acceptable research. The draft convention should serve as such a framework. Human dignity must not be subordinated to the purposes of research, however important they might be. Hence I fully support the changes proposed to Articles 13 and 18 of the draft convention.

Something that is moral is always good but it may not always be useful. Pragmatism can lead us far from ethics. The basic and primary human right is the right to life. Unfortunately the draft convention does not even mention it.

Another omission that must be rectified concerns the right to conscientious objection in relation to research procedures in vivo and in vitro, and to techniques of medically assisting procreation. The draft shows great sensitivity to individual needs but does not acknowledge the leeway accorded to medical professionals and researchers in many countries. This is not a problem in my country; in some places, such as Italy, conscientious objection in respect of animal research is permitted.

Tom Beauchamp and James Childress, respected scholars in this field, write in their book *Principles of Bio-Medical Ethics*: "When we encounter serious conflicts of conscience in health care and elsewhere, we may legitimately rely on procedures of resolution and on virtues such as conscientiousness." This right is recognised by the universal declaration of the rights of man, by the European Convention on Human Rights and, I hope, by the constitutions of all Council of Europe member states.

For reasons of clarity, and to express our wish to preserve the integrity of professionals and their procedures, I and some others have tabled Amendment No. 15 to Article 4, which concerns professional standards.

Since I am the last speaker today from the EPP group I should like to sum up our position. A convention that improves human rights protection in health and bio-medical research is better than no legal measure. Whenever human beings are interfered with in the interests of society or by professionals, the right to life remains paramount, as does the protection of human dignity and personality.

People who are incapacitated in any way, including embryos from the moment of conception onwards, must be protected. We cannot allow research on living human embryos. Therefore we urge you, dear friends, to vote in favour of Amendments Nos. 6 and 4. If you do not, we will be unable to vote in favour of the draft opinion.

Moreover, we insist on another vote in the Assembly after the Committee of Ministers decides the final text of the convention. Following today's debate we can use our time debating and campaigning to increase public awareness of these problems.

In spite of some omissions and imperfections I believe that a properly amended draft convention can be adopted by majority consensus.

Morality cannot be replaced by conventions or laws but it can be significantly influenced by legislation, for good or ill. I hope that our Assembly will continue its work of bringing forth good fruit for the peoples of Europe.

THE PRESIDENT.- Thank you, Mr Figel. The next speaker is Mr Golu from Romania.

Mr GOLU (*Romania*) congratulated his colleagues on the Committee on Science and Technology for their work in this difficult area. In the course of their deliberations it had become clear that a ruling was necessary in the light of rapid scientific progress. Some scientific research today had obvious implications for human dignity and he hoped that the Assembly wished to avoid any abuse.

The draft convention was a clear improvement on its predecessor, thanks to the Assembly's amendments. It was now much stronger, for example, on the protection of persons not able to give consent but, although the protection of the genome was now satisfactorily regulated, he felt that it could be strengthened further. He favoured a total ban on embryo research and hoped the text would be accepted because doing nothing could have disastrous, legal and moral repercussions.

Mrs TERBORG (*Germany*) said that the convention's long lead in time was a reflection of the difficulty of this area. It had been frequently revised in ways which her cautious German colleagues had been able to approve but, having proceeded with great care up to this point, it now seemed that the draft had to be finalised in a great hurry. She was concerned about this, not least because the document had not yet been translated into any language other than English. There was also insufficient time for delegates to liaise with their national Assemblies, and the recent decision of the European Parliament made it difficult for her to see how the Assembly could approve the draft.

She said that the Assembly did not necessarily have to follow closely the actions of the European Parliament and the convention itself would benefit from the widest possible support. She opposed the use of embryo management to determine the sex of a child and thought that research should not be allowed on incapacitated persons. There should be a ban on the transplant of organs to incapacitated persons. There were too many matters of detail in the convention to which she could not give support. Deferment of consideration would produce greater consensus, and she urged that that be taken up again in January next.

Mr VALKENIERS (*Belgium*) suggested that the Assembly attempt to achieve broad consensus as his country often had to do. The matter had not had sufficient consideration and the Steering Committee on Bioethics had not yet reached sufficiently detailed conclusions. He urged that the discussion on the final decision be taken up in January.

Mr PEREIRA MARQUES (*Portugal*) described the debate as one step in a long process, and he hoped it would be a decisive one in order that, once the approval of the Committee of Ministers had been gained, the convention could be ratified by member states. He did not think that the long period of consideration given to the subject was surprising; it was a complex issue. There was general agreement on the need to defend human rights and dignities and it was important to strike the right balance. He reminded the Assembly that the first country in Europe to establish a law on ethics and medical research had been the German Weimar Republic. What happened thereafter was common knowledge. It was, therefore, important that politicians, as well as scientific experts, were considering the matter. He was concerned that some old sinister problems, such as racial discrimination, were being re-advanced. The right criteria should be established in order to ensure that the risks involved did not outweigh the benefits and yet at the same time did not slow down the pace of medical research. Biotechnology should not be subject to the whims of market caprice where the criminal trade in organs has caused great concern.

THE PRESIDENT.- The last speaker on the list is Mr Van Der Maelen.

Mr VAN DER MAELEN (*Belgium*), who opposed the adoption of the convention, said there was a lack of clarity in the situation, and certain principles embodied in it were objectionable. Article 36 was also objected to.

Some amendments had called for a ban on intervention in the human germ cell line as this could affect not just an individual, but also the descendants. However, scientific confusion made it difficult to decide this matter. He recommended that the Assembly refrain from immediate adoption of the convention in the light of limited scientific knowledge on certain topics. Furthermore, Article 36 did not deal with member states on an equal footing.

(Mrs Fischer, President of the Assembly, took the Chair in place of Mr Bársony.)

THE PRESIDENT.- Thank you. That concludes the list of speakers. We shall conclude our discussion on human rights and biomedicine and vote on the subject this afternoon.

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE
1996 ORDINARY SESSION

(Fourth part)

excerpt from the OFFICIAL REPORT
Thirty-first sitting

Thursday 26 September 1996 at 3 pm

Mr Bársony, Vice-President of the Assembly, took the Chair at 3.02 pm.

...

THE PRESIDENT.- The first item of business this afternoon is the resumed debate on human rights and biomedicine. The list of speakers was concluded this morning and we now come to the replies of the rapporteurs.

I call Mr Schwimmer, rapporteur, for an opinion on behalf of the Committee on Legal Affairs and Human Rights. Mr Schwimmer, you have two minutes.

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*) said that the debate had demonstrated how seriously the Assembly took this issue. He wished to address one point in particular on which he had not tabled an amendment, namely interventions and research on human beings incapable of giving their consent. The draft convention specified five conditions that had to be met before research on such people could be undertaken: that there was no suitable alternative; that the risks were proportionate to the potential benefits; that the research had been approved on the basis of an independent evaluation of its merits; that the people undergoing research had been informed of their rights and legal safeguards; and that they had either given consent or, in the case of those unable to give consent, that their legally appointed guardians had consented in writing on their behalf.

The additional provisions for those incapable of giving consent should be entirely adequate to ensure their protection and he hoped the draft convention could be approved on that basis.

THE PRESIDENT.- Thank you, Mr Schwimmer.

In the absence of Mr Daniel, I give the Floor to Mr Plattner. You have seven minutes, Mr Plattner. If the chairman of the committee wishes to speak, you must share the seven minutes with him.

Mr PLATTNER (*Switzerland*) (*Rapporteur of the Social, Health and Family Affairs Committee*).- Permit me, colleagues, to speak German on this occasion. I have a few things to say to my German colleagues, I apologise to the interpreters.

(The speaker continued in German.)

He wished to clarify three points that had arisen in the debate. The first had been raised by Mr Lenzer, who had questioned the applicability of the restrictions contained in Article 26. However, that article made clear that these restrictions did not apply to Articles 16 - 20. While these rules were not as precise as those that would be appropriate in national legislation they were sufficient for a framework convention. He suggested that Mr Lenzer had misread the text. The second point had been raised by Mr Probst, who had argued that the rules in the convention should only be valid in conjunction with national legislation, but this was precisely what the convention itself stated. The third point concerned Article 17 and an apparent confusion between "persons" and "human beings". This, however, was a problem that had arisen in the translation from English to French and the English text was entirely clear on this point.

No such confusion arose between the words "person" and "human being" in English.

He reproached the German delegation for saying that they needed another three months for consideration. No member of the delegation had submitted a motion to this effect and so there was no possibility of voting on this matter.

If the convention were killed off today he thought it would be dead forever and that would lead to anarchy in biomedicine in Europe.

Mr ROSETA (*Portugal*) said that the Council of Europe should carry on thinking about human rights and biomedicine but only after today's vote. Of course there were some areas which needed strengthening, and he was confident that the draft protected the weakest elements of the population. Some of the criticisms he heard today had not taken account of amendments already made. His committee's basic criterion had been to safeguard essential principles; that was the aim of all politicians.

The Convention on Human Rights had not been complete initially but had been modified over the years. Not adopting the convention today would represent a defeat of politicians by scientists. He said that the Council of Ministers must go along with the decision of the Assembly, not groups of experts, because the Assembly had a mandate to represent the people of Europe. He hoped that adoption would end once and for all the to-ing and fro-ing of the convention between the Assembly and the Council of Ministers.

Mr BÜHLER (*Germany*) on a point of order, said that he was not well versed in procedure but he wished to point out that on Monday he had asked that the debate be postponed.

THE PRESIDENT.- Come to the point of order please, Mr Bühler. After the closing speeches of the rapporteurs, there is no way that you can make a further speech. However, if you have a point of order you can raise it.

Mr BÜHLER.- I will do that, Mr President.

(The speaker continued in German.)

He moved that the report be returned to the Committee on Science and Technology to consider over the next three months the objections raised today.

THE PRESIDENT.- Thank you, Mr Bühler. You have four minutes to speak in favour of the motion because under Rule 33 (2) the motion now takes precedence over the main question. You therefore have four minutes to explain your position if you so wish.

Mr BÜHLER (*Germany*) said that he would not need four minutes. All contributors to the debate had spoken with passion and genuine commitment. Although it remained clear that there were points in the report that needed refinement he recognised that many improvements had already been built in. His fear was that if the Assembly followed its conscience today it might settle the matter without discussing many vital issues. He did not want to see the Council of Europe accused of this when the subject was taken up in national parliaments.

He thought that it was unreasonable to ask members to vote on such a substantial report when they had only received one of the major documents on Monday. He nevertheless respected the work done by the committee and rapporteur.

THE PRESIDENT.- Thank you, Mr Bühler. Before I call the next speaker I must remind members that in the debate on the motion only the proposer, Mr Bühler, one speaker against the motion and the rapporteur or chairman concerned have the right to speak - Rule 33 (3) - and the Assembly votes on the motion by sitting and standing - Rule 33 (4). I ask members and substitutes to ensure that they are in the right seats.

I call Mr Martínez to speak against the motion.

Mr MARTÍNEZ (*Spain*) thanked Mr Bühler for recognising that there had been many improvements to the document. He was pleased that the motion to postpone consideration had been presented before discussion on the amendments had commenced. He nevertheless hoped that the Assembly would proceed to vote on the amendments and then on the revised text in order to reassure the general public that the Assembly had taken positive steps on this matter. Postponing the debate until January would serve no purpose, and he wondered whether that would result in further opposition, more amendments and subsequent change. In his view the

opposition of the German delegates was more a matter of theology than anything else. It would be impossible for member states to legislate on the issue without the basis of a Council of Europe opinion. He asked the Assembly to vote on the amendments and the text.

THE PRESIDENT.- Thank you, Mr Martínez. I call the chairman of the committee to give its opinion.

Mr PLATTNER (*Switzerland*) (*Chairman of the Committee on Science and Technology*).- The committee has no opinion on the matter since it has not debated it. In a way, I am glad that the Assembly must now take a decision and that the matter is taken out of my hands. The Assembly, in its wisdom, will do the right thing. Everything that can be said about the matter has been said and I leave it at that.

THE PRESIDENT.- The Assembly will now vote by sitting and standing. Members of the Assembly must now move to their correct seats and non-members must leave.

Sir Anthony DURANT (*United Kingdom*).- On a point of order, Mr President. Substitutes are entitled to remain in the seat of the member for whom they are substituting, are they not?

THE PRESIDENT.- Substitutes may remain in the seat of the member for whom they are substituting.

(A vote was taken by sitting and standing.)

The motion is rejected.

THE PRESIDENT.- The Committee on Science and Technology has presented a draft opinion, to which 15 amendments and one sub-amendment have been tabled. They will be taken in the order in which they appear in the notice paper: 1, 2, 15, 3 and sub-amendment 1, 4, 9, 5, 10, 13, 6, 12, 11, 14, 7 and 8. If Amendment No. 10 is agreed, 13 falls; if Amendment No. 6 is agreed, 12 falls; and if Amendment No. 11 is agreed, Amendment No. 14 falls. I ask those speaking on the amendments to take no longer than two minutes.

We come to Amendment No. 1, proposed by Mr Schwimmer on behalf of the Committee on Legal Affairs and Human Rights, which is,

In the draft opinion, at the beginning of paragraph 6, insert a new sub-paragraph worded as follows:

"amend Article 1 (Purpose and object) of the draft convention by inserting a second sentence as follows:

'The parties to this convention shall take all legislative and administrative actions necessary to give effect to and carry out the provisions of this convention within their own territories!'"

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*).- This amendment takes account of the demand strongly expressed by many speakers for legislative and administrative measures and actions in member countries that sign and ratify the convention in the future.

THE PRESIDENT.- Does anyone wish to speak against the amendment?

What is the opinion of the committee?

Mr ROSETA (*Portugal*) (*on behalf of the Committee on Science and Technology*) spoke in favour of the amendment.

THE PRESIDENT.- I will put Amendment No. 1 to the vote.

Amendment No. 1 is adopted.

We come to Amendment No. 2, proposed by Mr Schwimmer on behalf the Committee on Legal Affairs and Human Rights, which is,

In the draft opinion, at the beginning of paragraph 6, insert a new sub-paragraph worded as follows:

"modify Article 2 (Primacy of the human being) of the draft convention as follows:

`The interests and welfare of the human being shall prevail over the sole interest of society *or* science!'"

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*).- A key question is whose interests and welfare shall prevail. It is clear that the interests and the welfare of the human being should take priority over the sole interests of either society or science.

THE PRESIDENT.- Does anyone wish to speak against?

Mr ABOUT (*France*) said that the word `or' in the amendment should be replaced by `and'.

THE PRESIDENT.- What is the opinion of the committee?

Mr PLATTNER (*Switzerland*) (*Rapporteur of the Committee on Science and Technology*).- There are in Boolean logic two ways of expressing "or" - the exclusive or inclusive way. In this amendment, the term is meant inclusively, which means either/or.

THE PRESIDENT.- I will put Amendment No. 2 to the vote.

Amendment No. 2 is adopted.

We come to Amendment No. 15, proposed by Mr Figel, which is,

In the draft opinion, paragraph 6, add a new sub-paragraph worded as follows:

"amend Article 4 (Professional standards) of the draft convention by inserting a second sentence as follows:

`But persons working in the field of health and biomedical research shall have the right to exercise conscientious objection to any such interventions!'"

I call Mr Figel to support the amendment.

Mr FIGEL (*Slovakia*).- The amendment will improve Article 4, which states: "Any intervention in the health field, including research, must be carried out in accordance with professional obligations and standards." There is no harm in repetition, particularly for people who have conscientious objections. Clarification is important for member states that wish to create legislation in health research. I am glad that my colleagues in other political groups feel able to support the amendment.

THE PRESIDENT.- Does anyone wish to speak against?

What is the opinion of the committee?

Mr ROSETA (*Portugal*) said that the committee was in favour of the amendment.

THE PRESIDENT.- I shall now put the amendment to a vote by a show of hands.

Amendment No. 15 is adopted.

We now come to Amendment No. 3, to which a sub-amendment is proposed. Amendment No. 3, proposed by Mr Schwimmer, Rapporteur of the Committee on Legal Affairs and Human Rights, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amend Article 12 (Predictive genetic tests) of the draft convention by adding the two following sub-paragraphs:

2. Results of genetic tests may only be communicated where they serve to determine a person's descent or as evidence in official procedure to try a criminal offence.

3. Even where the person concerned has consented or is bound by contract, the results of predictive genetic tests shall be used strictly in accordance with paragraphs 1 and 2 above."

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*) said that the most important point of the amendment was to ensure that the results of genetic tests could not be passed on to a third party when the person concerned was contractually obliged to consent.

THE PRESIDENT.- We will now consider the sub-amendment, which is also proposed by Mr Schwimmer on behalf of the Committee on Legal Affairs and Human Rights, which is,

In the amendment, leave out after "In the draft opinion", the words "after paragraph 6.i, insert a new sub-paragraph worded as follows:

amend Article 12 (Predictive genetic tests) of the draft convention by adding the two following sub-paragraphs:

2. Results of genetic tests may only be communicated where they serve to determine a person's descent or as evidence in official procedure to try a criminal offence'."

and insert the words "add at the end of sub-paragraph 6.i".

I call Mr Plattner to support the sub-amendment.

Mr PLATTNER (*Switzerland*) (*Rapporteur of the Committee on Science and Technology*).- The compromise compromises a second and third paragraph added to Article 12. The second paragraph is precisely the same text that appears in the opinion of the Committee on Science and Technology. The third paragraph represents the second part of the amendment proposed by the Committee on Legal Affairs and Human Rights. That way genetic tests may only be undertaken in the health and health-related fields. The results of such tests may only be used in the health and health-related fields, with the exception of considerations of public security, crime prevention and the rights of other citizens under Article 26. As that exception might be considered too broad, the third paragraph will restrict it so that even if a person has consented or made a contract to give data away, it still can only be used in the health and health-related fields - not for commercial purposes, the insurance business or other reasons. The sub-amendment closes all the loopholes.

THE PRESIDENT.- Does anyone wish to speak against the amendment or sub-amendment?

What is the opinion of the committee?

Mr ROSETA (*Portugal*) (*on behalf of the Committee on Science and Technology*) said that the sub-amendment improved the safeguard provisions.

THE PRESIDENT.- I will first put the sub-amendment to the vote.

The sub-amendment is adopted.

I will now put Amendment No. 3, as amended, to the vote.

Amendment No. 3, as amended, is adopted.

We now come to Amendment No. 4, proposed by Mr Schwimmer, Rapporteur of the Committee on Legal Affairs and Human Rights, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"replace Article 13 (Intervention on the human genome) of the draft Convention by the following text:

`An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes. Intervention in the human germ cell line shall be neither an aim nor an accepted secondary effect'."

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (*Austria*)(*Rapporteur of the Committee on Legal Affairs and Human Rights*) said that there were reservations about intervention in human germ cell line. The convention said that intervention may be admitted despite the effects on descendants. It should be permissible to use radiotherapy for curative purposes.

THE PRESIDENT.- Does anyone wish to speak against the amendment?

Mr OLRICH (*Iceland*).- Radiotherapy treatment in the case of cancer of the testicles is an intervention that affects the human germ cell line. The acceptance of this amendment would, I believe, mean that the radiotherapy treatment of patients suffering from cancer is prohibited. I am convinced that that is not the Assembly's intention.

THE PRESIDENT.- What is the committee's opinion of the amendment?

Mr PLATTNER (*Switzerland*).- The committee has decided that this is one of the few amendments that it is not ready to accept. The reasoning is as follows. The first reason is the more technical one. Using the words "germ cell line" instead of the much more precise "genome of the descendants" - as the draft convention proposes - is inappropriate. Not only would research on sperm and ovaries be prohibited, but also testicles, ovaries and other parts of the germ cell line would go into the convention as the objects needing protection. However, the object that needs protection is the genome of the descendants: the children and their descendants.

I am unhappy that the words have been changed. The Steering Committee discussed at length the exact change of words and it finally arrived at the almost unanimous conclusion that the "genome of the descendants" was the appropriate wording.

Secondly, as was mentioned by Mr Schwimmer out of intellectual honesty, and by the previous speaker, if we say that life-saving interventions that have the additional accepted medical side effect of impairing the ability to father or mother healthy children must not be carried out, we are doing something that the committee believes is unethical. It is also against the Hippocratic oath: we cannot forbid a doctor to heal a patient if he is aware of the method of achieving that end. This would be the case with cancer of the testicles and the ovaries and cancer in the abdominal region generally.

While I understand what the Committee on Legal Affairs and Human Rights wants, the wording is not useful. It is too restrictive and the amendment should be rejected. The committee shares my opinion.

THE PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

Amendment No. 4 is rejected.

We now come to Amendment No. 9, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amend Article 14 (Non-selection of sex) of the draft convention to read as follows:

`The use of techniques of medically assisted procreation shall not be permitted for the purpose of choosing a future child's sex.'"

I call Mrs Terborg to support the amendment.

Mrs TERBORG (*Germany*) said that the amendment sought changes to Article 14. Sex selection sounded harmless but as well as being used to prevent serious hereditary diseases it could be easily abused for unacceptable purposes.

The PRESIDENT.- Does anyone wish to speak against the amendment? No. What is the opinion of the committee?

Mr ROSETA (*Portugal*) (*on behalf of the Committee on Science and Technology*) said that the committee had already adopted this amendment. One of the categories of people who would be affected by this amendment were haemophiliacs, who would say they were glad to be alive even though they suffered from this condition. This was a sufficient reason to oppose sex selection.

THE PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

Amendment No. 9 is adopted.

We come now to Amendment No. 5, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amplify Article 16.iii (Protection of persons undergoing research) of the draft convention as follows:

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

I call Mr Schwimmer to support the amendment.

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*) said that this amendment reflected the views of many members of the Assembly. The convention already required research on people to be subject to an independent scientific assessment by a competent body. The amendment added that this body must be multidisciplinary and independent.

THE PRESIDENT.- Does anyone wish to speak against the amendment? No. What is the opinion of the committee?

Mr ROSETA (*Portugal*) (*on behalf of the Committee on Science and Technology*) said that the amendment improved the text and was unanimously supported by the committee.

THE PRESIDENT.- I now put the amendment to the vote by a show of hands.

Amendment No. 5 is adopted.

We now come to Amendment No. 10, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amend Article 17 (Protection of persons not able to consent to research) of the draft convention by deleting Paragraphs 1i, 1ii, 1iii, 1iv, 1v and Paragraph 2 and sub-paragraphs 2i and 2ii and amending Paragraph 1 to read as follows:

`Research on a person without the capacity to consent as stipulated in Article 5 is not permitted."

I call Mrs Terborg to support the amendment.

Mrs TERBORG (*Germany*) said that the conditions specified in Article 17 of the draft convention were questionable and that the distinction between those capable and those incapable of giving consent was open to abuse, given that it was possible chemically to induce a state in which someone was incapable of giving consent. For this reason the amendment proposed the deletion of those conditions.

The PRESIDENT.- Does anyone wish to speak against the amendment?

Mr ABOUT (*France*) said that from a scientific and parliamentary point of view, he regarded the amendment as unacceptable. Everyone, including those unable to give their consent, was equally entitled to whatever medical treatment would be to their benefit.

THE PRESIDENT.- What is the opinion of the committee?

Mr PLATTNER (*Switzerland*) (*Rapporteur of Committee on Science and Technology*).- The committee agrees with Mr About. The proposed article would lead to a complete ban on medical research carried out on those who are unable to give their consent - the mentally ill and children, for instance. Children cannot legally give such consent. People with Alzheimer's disease would also come into this category.

Imposing such a complete ban would be unethical; it would render impossible research into children's diseases such as leukaemia, or Alzheimer's, or Creutzfeldt-Jacob disease. Thanks to the progress of modern medical research done on children with leukaemia - patients who cannot by definition give their consent, children with the disease can often be healed of it. A boy in my neighbourhood was recently so healed. That is why I say that a ban would be unethical.

We do not want to condemn people with these diseases to remaining forever without a cure; hence we must allow research into their illnesses, even though it is by no means sure that they can profit personally. Research is generally much slower than the progress of a deadly illness.

By way of reassurance to those of you who are still sceptical, I might add that the draft convention so narrowly defines the possibilities for such research - by listing nine explicit conditions that must be simultaneously and strictly fulfilled - that not even the highly critical representative of the German Government on the Steering Committee voted against the article.

I strongly advise you to follow his advice, my advice and the advice of the committee and to reject the amendment.

THE PRESIDENT.- I shall now put the amendment to a vote by a show of hands.

Amendment No. 10 is rejected.

We now come to Amendment No. 13, proposed by Mr About, which is,

In the draft opinion, after paragraph 6.i, add a new sub-paragraph worded as follows:

"Amend Article 17, paragraph 1.ii of the draft convention to read:

`the results of the research have the potential to produce real and direct benefit to his or her health.'"

Mr ABOUT (*France*) said that the amendment was designed to ensure that any research must have potential to produce real health benefits.

THE PRESIDENT.- Does anyone wish to speak against the amendment? What is the opinion of the committee?

Mr ROSETA (*Portugal*) (*on behalf of the Committee on Science and Technology*) was happy with the reinforcement offered by the amendment.

THE PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

Amendment No. 13 is adopted.

We now come to Amendment No. 6, proposed by Mr Schwimmer, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"replace Article 18 (Research on embryos in vitro) of the Draft Convention by the following text:

"The creation of human embryos for research purposes and the research on living human embryos is prohibited."

Mr SCHWIMMER (*Austria*) (*Rapporteur of the Committee on Legal Affairs and Human Rights*) said that embryos unable to survive could not be treated as research tools without first recognising their human rights. Research on living human embryos should be prohibited.

THE PRESIDENT.- Does anyone want to speak against the amendment?

Mr ABOUT (*France*) said that the amendment was based on sound principles but it was not sensible to ban research on embryos if the embryos themselves could benefit from it. This would certainly be the case in the future. He suggested that the wording of Amendment No. 12 was in a similar spirit but was better suited to the convention today.

THE PRESIDENT.- What is the opinion of the committee?

Mr PLATTNER (*Switzerland*).- Here we approach one of the core issues of the convention. We must argue but then decide according to our consciences. No one is right or wrong; people will decide according to their personal values.

Two amendments are relevant at this point; we are discussing the stricter one from the Committee on Legal Affairs and Human Rights. If we reject this one, the other one will come up for discussion shortly.

So why has the committee decided to prefer Mr Kaspereit's amendment to this one? This amendment would forbid any research on embryos, not just the creation of embryos for research purposes, as the draft convention would have it. That is too far reaching for many countries which already accept such research. Germany allows research provided it is for the benefit of the embryo. France allows research on condition that the embryo is not harmed. Spain allows research on non-viable embryos. That is the position that the Assembly accepted last year.

Many other countries accept research on embryos that were created for procreation but which were later deemed to be surplus because only one can be implanted. That is one reason why many countries are of different opinions.

Secondly, as research on embryos is such a difficult and controversial issue and as any small agreement, taking into account different opinions in different countries, takes years to achieve, the Steering Committee decided not to take a final stand but to leave the issue for a future protocol. The committee was under pressure to work speedily. Such a protocol will be in addition to the convention, which will take several years to elaborate. That is already clear. It was the Assembly's wish, as expressed in last year's debate, that such a protocol should be prepared.

The Steering Committee has already installed a working group to consider the matter. That group has been organising a four-day symposium on medically assisted procreation and the protection of the human embryo, which will take place in Strasbourg from 15 to 18 December. That will be a starting point on work on a protocol. Mr Schwimmer and myself have been invited to attend the symposium.

Thirdly, Amendment No. 12, which I propose to support, provides what might be described as a compromise solution while we await the future protocol. The amendment would replace the generality of the first paragraph with a somewhat stricter form of words.

The provisions of the draft convention with Mr Kaspereit's amendment, No. 12 offer the best foundation for agreement at a European level. The issue of embryo research is not yet ready for a detailed European convention and there must be further development. I advise the Assembly to adopt Amendment No. 12 and not No. 6 and to await the future protocol.

THE PRESIDENT.- Thank you, Mr Plattner. As you have said, if Amendment No. 6 is adopted, No. 12 falls.

I shall now put Amendment No. 6 to the vote by a show of hands...

Amendment No. 6 is rejected.

We now come to Amendment No. 12, proposed by Mr About or Mr Kaspereit, which is,

In the draft opinion, paragraph 6, insert after sub-paragraph i, a new sub-paragraph worded as follows:

"amend Article 18 (Research on embryos in vitro) of the draft convention as follows:

- research on embryos in vitro shall be permitted only in the interests of their development. It may, nevertheless, relate to the diagnosis of the most serious diseases."
- the creation of human embryos for research purposes is prohibited."

Mr ABOUT (*France*) said that his country allowed research on in vitro embryos only in the interest of the embryos themselves in their development towards becoming a child.

THE PRESIDENT.- Does anyone wish to speak against the amendment? It seems not.

The committee is in favour of the amendment.

I shall now put the amendment to the vote by a show of hands.

Amendment No. 12 is adopted.

We now come to Amendment No. 11, proposed by Mrs Terborg, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amend Article 20 (Protection of persons not able to consent to organ removal) of the draft convention as follows:

Delete Paragraphs 2.i, 2.iv and 2.v and Paragraph 2 of Article 20 to read as follows:

`No organ or tissue removal may be carried out on a person who does not have the capacity to consent unless the recipient is a brother or sister of the donor and

- i. a suitable donor who has the capacity to consent is not available,
- ii. the donation must have the potential to be life-saving for the recipient."

Mrs TERBORG (*Germany*) withdrew her amendment in favour of Amendment No. 14.

THE PRESIDENT.- The amendment is withdrawn.

We now come to Amendment No. 14, proposed by Mr About, which is,

In the draft opinion, after paragraph 6.i, add a new sub-paragraph worded as follows:

"amend Article 20, paragraph 2.iv, to read:

`the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the judicial authorities responsible for the protection of children"

Mr ABOUT (*France*) said that it would be dangerous if organs were allowed to be taken from persons who could not give their consent. For instance, there could be a conflict of interest in the case of a suggestion to transplant an organ from one child to another in the same family. There was a need for legal protection.

THE PRESIDENT.- Does anybody wish to speak against the amendment? It seems not.

What is the opinion of the committee?

Mr ROSETA (*Portugal*) said that the amendment improved the text.

THE PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

Amendment No. 14 is adopted.

We now come to Amendment No. 7, which is proposed by Mr Schwimmer, on behalf of the Committee on Legal Affairs and Human Rights, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amplify Article 26, paragraph 2 (Restrictions on the exercise of the rights) of the draft convention as follows:

"The restrictions contemplated in the preceding paragraph may not be places on Articles 11, 12, 13, 14, 16, 17, 20 and 21."

Mr SCHWIMMER (*Austria*).- Given the adoption of Amendment No. 3, as sub-amended, I withdraw Amendment No. 7.

THE PRESIDENT.- The amendment is withdrawn.

We now come to the last amendment, Amendment No. 8, proposed by Mr Schwimmer, on behalf of the Committee on Legal Affairs and Human Rights, which is,

In the draft opinion, after paragraph 6.i, insert a new sub-paragraph worded as follows:

"amend Article 32, paragraph 6 (Amendments to the convention) of the draft convention by amplifying it as follows:

"the committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The committee shall submit the text adopted by a two-third majority of the votes cast to the Committee of Ministers for approval. *The Committee of Ministers shall transmit the adopted text, before approval, to the Parliamentary Assembly, for opinion.* After its approval, this text shall be forwarded to the parties for ratification, acceptance or approval."

Mr SCHWIMMER (*Austria*) said that the amendment would provide appropriate flexibility for the future.

Mr ROSETA (*Portugal*) said that the committee accepted the amendment. He also reminded the Assembly that only two amendments had been rejected. He thanked everybody for their contributions, especially Mr Schwimmer and Mr About.

THE PRESIDENT.- I shall now put the amendment to the vote by a show of hands.

Amendment No. 8 is adopted.

All the amendments have been debate and decided upon. We shall now proceed to vote on the whole of the draft opinion contained in Doc. 7622 as amended.

The draft opinion contained in Doc. 7622, as amended, is adopted.

I call Mr Schloten to take the floor to explain his vote.

Mr SCHLOTEN (*Germany*) explained that he had voted against his own delegation's line because he supported some of the very good passages in the draft document. He fully understood his country's caution about abuse, given its history, but thought it would be wrong to overreact. The text, despite some failings, did provide good basic standards and was a positive step forward.

THE PRESIDENT.- Thank you, Mr Schloten.

PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE
1996 ORDINARY SESSION

OPINION N_198 (1996)³

*on 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*

1. The adoption on 7 June 1996 by the Steering Committee on Bioethics (CDBI) of a revised draft convention marked the culmination of many long years of work. In this connection, the Assembly draws particular attention to its Recommendations 934 (1982) on genetic engineering, 1046 (1986) and 1100 (1989) on the use of human embryos and foetuses, and 1160 (1991) on the preparation of a convention on bioethics, as well as its Opinion No. 184 (1995) on the first draft convention in which it recommended that the Committee of Ministers "review thoroughly" the draft text.
2. The new draft convention is more complete and better structured as a whole. The order in which its provisions are placed and the links between them are more logical than in the initial draft. The text has been more carefully worded, and the addition of new articles, for example, on organ transplantation, constitutes an improvement. On some points, such as the protection of embryos, the articles have been kept brief and are intended merely to provide the basis for future protocols.
3. The draft text is in tune with the thinking behind the Assembly's proposals, although the exact working of the individual amendments has not always been followed. A series of newly drafted provisions provides a satisfactory response to one of the Assembly's main concerns, namely the question of "consent" and, in particular, the protection of persons unable to give consent. At the same time, a further guarantee is enshrined in a new provision, based on the Assembly's amendments, concerning the role to be played by the European Court of Human Rights in interpreting the convention.
4. The Assembly believes that the new draft convention is a coherent and balanced text. It represents the maximum degree of European consensus that can be achieved at present. Once it has been adopted, the convention will serve as a universal benchmark and will encourage many states to comply with and go beyond the standards it lays down.
5. As with all texts based on compromise, it could, however, be improved in some areas. In the view of the Assembly, the draft convention provides no clear guidance on the question of the communication of results of genetic tests to third parties. This problem, which is likely to assume considerable social and economic importance in the years ahead, cannot be left unmentioned.
6. The Assembly therefore recommends that the Committee of Ministers :
 - i. amend Article 1 (Purpose and object of the draft convention) by inserting a second sentence as follows:

"The Parties to this convention shall take all legislative and administrative actions necessary to give effect to and carry out the provisions of this convention within their own territories.";
 - ii. modify Article 2 (Primacy of the human being) of the draft convention as follows:

"The interests and welfare of the human being shall prevail over the sole interest of society or science.";

³*Assembly debate* on 26 September 1996 (30th and 31st Sittings) (see Doc. 7622, report of the Committee on Science and Technology, rapporteur: Mr Plattner; Doc. 7664, opinion of the Social, Health and Family Affairs Committee, rapporteur: Mr Daniel; and Doc. 7654, opinion of the Committee on Legal Affairs and Human Rights, rapporteur: Mr Schwimmer). *Text adopted by the Assembly* on 26 September 1996 (30th and 31st Sittings).

iii. amend Article 4 (Professional standards) of the draft convention by inserting a second sentence as follows:

"But persons working in the field of health and biomedical research shall have the right to exercise conscientious objection to any such interventions.";

iv. amend Article 12 (Predictive genetic tests) of the draft convention by adding the following two new paragraphs:

"2. The communication of results of genetic testing outside the health field may be allowed only in accordance with the provisions of Article 26, paragraph 1, of this convention and in accordance with national legislation on data protection.

3. Even where the person concerned has consented or is bound by contract, the results of predictive genetic tests shall be used strictly in accordance with paragraphs 1 and 2 above.";

v. amend Article 14 (Non-selection of sex) of the draft convention to read as follows:

"The use of techniques of medically assisted procreation shall not be permitted for the purpose of choosing a future child's sex.";

vi. amplify Article 16.iii (Protection of persons undergoing research) of the draft convention as follows:

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

vii. amend Article 17, paragraph 1.ii, of the draft convention to read:

"the results of the research have the potential to produce real and direct benefit to his or her health";

viii. amend Article 18 (Research on embryos (*in vitro*) of the draft convention as follows:

"- research on embryos *in vitro* shall be permitted only in the interests of their development. It may, nevertheless, relate to the diagnosis of the most serious diseases;

ix. amend Article 20, paragraph 2.iv, of the draft convention, to read:

"The authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the judicial authorities responsible for the protection of children.";

x. amend Article 32, paragraph 6 (Amendments to the convention), of the draft convention by amplifying it as follows:

"The committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. The Committee of Ministers shall transmit the adopted text, before approval, to the Parliamentary Assembly for opinion. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.";

xi. adopt the amended draft convention without referring it back to the CDBI and open it for signature before the end of this year, as any further delay could jeopardise the innovative nature of the text as a model for national legislators;

xii. establish a timetable for the preparation of the draft protocols on organ transplantation, medical research and the protection of embryos, instruct the CDBI also to prepare a protocol on genetics, and transmit each draft protocol to the Assembly for opinion as soon as it has been finalised.