



Opinion 198 (1996)¹

Convention on Human Rights and Biomedicine

Parliamentary Assembly

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 fetuses, 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 wording 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:

6.1. 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.";

6.2. 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.";

6.3. 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.";

1. 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).



- 6.4. 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.";
- 6.5. 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.";
- 6.6. 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.";
- 6.7. 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.";
- 6.8. 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.";
- 6.9. 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.";
- 6.10. 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.";
- 6.11. 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;
- 6.12. 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.