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Draft additional protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes

Committee Opinion[1]
Committee on Legal Affairs and Human Rights
Rapporteur: Mr Holger HAIBACH, Germany

A. Conclusions of the committee

1. The Committee on Legal Affairs and Human Rights congratulates the Rapporteur of the Committee on Culture, Science and Education, Mr Wolfgang Wodarg, on his excellent draft opinion.

2. The Committee on Legal Affairs and Human Rights supports most of the proposed amendments of the Committee on Culture, Science and Education, but has a number of reservations about the justification or need for some of them.

3. It particularly regrets that fewer than half of the Council of Europe's member states have so far ratified the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereafter referred to as "the Convention on Human Rights and Biomedicine" ETS No. 164).

B. Proposed amendment to the draft opinion of the Committee on Culture, Science and Education

Amendment A

Delete sub-paragraph 8.1 ("in Article 2.1, add the word 'only' after the words 'which are';").

C. Explanatory memorandum, by Mr Holger Haibach

1. The rapporteur refers to Mr Wodarg's explanatory memorandum, which describes the background to the draft Additional Protocol to the Convention on Human Rights and Biomedicine on Genetic Testing for Health Purposes. Mr Wodarg also sets out the main principles of the draft additional protocol.

2. So far, fewer than half of the Council of Europe's member states have ratified the Convention on Human Rights and Biomedicine.[2]The rapporteur considers this extremely regrettable given the importance of the subject matter and urges member states that have not yet done so to sign and/or ratify the convention as soon as possible.

1. See Doc. 11466.

3. He agrees with the rapporteur of the Committee on Culture, Science and Education that the draft additional protocol offers balanced and appropriate protection for those who take part in genetic testing, as well as legal safeguards that have hitherto not existed. It will be the first legally binding international instrument in this field.

4. The rapporteur notes that what might be termed a "thematic" approach has been adopted. In this way several additional protocols to the Convention on Human Rights and Biomedicine on various themes have already been adopted.[3]The latest draft additional protocol supplements existing protection by tackling a new topic, that of genetic testing for health purposes.

5. Clearly, other areas need to be covered to offer the widest possible protection and to respond to scientific progress in the biomedical field, which by its nature is constantly evolving. The rapporteur particularly wishes to encourage current work on the use of genetic testing for insurance purposes.

6. Turning to the proposed amendments of the Committee on Culture, Science and Education, the rapporteur fully supports the proposals in paragraphs 8.4, 8.5 and 8.6 of the draft opinion.

7. However, he wishes to comment on the other proposed amendments.

8. He has a number of reservations about the one in paragraph 8.1 of the draft opinion presented by the Committee on Culture, Science and Education, which reads: "in Article 2.1, add the word 'only' after the words 'which are'".

9. He is concerned that as currently worded the proposed amendment could be misinterpreted and thus be incompatible with the protocol's intentions.

10. The draft additional protocol must always be read in parallel with the Convention on Human Rights and Biomedicine, whose provisions are still applicable. Yet, Article 12 of the convention specifically bans predictive tests that are not performed for health purposes or for scientific research linked to health purposes. Far from filling a gap, therefore, adding the word "only" introduces an element of redundancy.

11. Moreover, the addition of "only" in paragraph 2 presents another risk, since the provisions of the protocol would only apply to tests performed for medical purposes, and not to those with dual medical and research purposes. The rapporteur considers that this aspect could cause problems.

12. He also notes that Article 2.1 defines the scope of the additional protocol and is very concerned that adding the word "only" could be interpreted as a prohibition, which is not appropriate in the scope.

13. The rapporteur cannot therefore support the proposed amendment of the Committee on Culture, Science and Education to Article 2.1 of the draft additional protocol.

14. He also wishes to comment on the proposed amendment in paragraph 8.3 of the draft opinion presented by the Committee on Culture, Science and Education, which reads: "in Article 7.1, add at the end the words 'of appropriately qualified physicians'".

15. The rapporteur considers that the proposed addition is already covered by Article 5 of the draft additional protocol. Article 5.*c* calls for measures to ensure that "persons providing genetic services" – a category that certainly includes physicians offering individualised medical supervision – "have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards".

16. It therefore seems unnecessary to repeat in Article 7.1 of the draft additional protocol that persons offering such supervision must have appropriate qualifications.

17. The rapporteur thinks that it might be more appropriate to change the proposed amendment to a clarification in the section of the explanatory report of the draft additional protocol dealing with Article 7.

18. Finally, the rapporteur wishes to return to the notion of clinical utility in Article 6 of the draft additional protocol. Clinical utility is a well-developed concept in genetics literature and the authors of the draft additional protocol have paid very close attention to the established terminology. They have drawn on a number of

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2. As Mr Wodarg states in paragraph 2 of the explanatory memorandum: "The Bioethics Convention was opened for signature in April 1997 and entered into force in December 1999. Altogether 34 member states have signed the convention and 21 have ratified (see appendix). There are 13 sig- natures still not followed by ratification (of which 8 are more than 10 years old), and 13 other member states have not yet signed", Doc. 11466.

3. The additional protocols on the Prohibition of Cloning Human Beings (ETS No. 168, 1998), Transplantation of Organs and Tissues of Human Origin (ETS No. 186, 2002), and Biomedical Research (ETS No. 195, 2005).

sources, such as the Organisation for Economic Co-operation and Development (OECD) guidelines for quality assurance in molecular genetic testing,[4] expert advice and the recommendations of the European Society of Human Genetics.

19. The notion of clinical utility has two dimensions, in that it is concerned not just with the state of the individual patients but also with the clinical potential of the test results themselves, in terms of both prevention and treatment. However, the notion of medical indication, which the Committee on Culture, Science and Education wishes to add to Article 6 of the draft additional protocol (see its proposed amendment in paragraph 8.2 of the draft opinion), only concerns the individual dimension and is already covered by the concept of clinical utility. Paragraph 58 of the explanatory report on Article 6 of the draft additional protocol also includes the notion of medical indication in the criteria for determining clinical utility.

20. The rapporteur therefore concludes that the proposed amendment in paragraph 8.2 of the draft opinion presented by the Committee on Culture, Science and Education, which reads "in Article 6, add the words 'and medical indication' after the words 'clinical utility'", serves no purpose.

Reporting committee: Committee on Culture, Science and Education.

Committee for opinion: Committee on Legal Affairs and Human Rights.

Reference to committee: Doc. 11440 and Reference No. 3376 of 1 October 2007.

Opinion approved by the committee on 22 January 2008. See 8th Sitting, 24 January 2008 (adoption of the draft opinion, as amended); and Opinion No. 267.

4. See www.oecd.org/dataoecd/43/6/38839788.pdf.