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Ethics Committees: the European Convention on Human Rights and Biomedicine, and ethical review of biomedical research

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The main goal of the article is to present a comprehensive analysis of one of the most important documents in the field of bioethics – the European Convention on Human Rights and Biomedicine – emphasizing the regulations related to biomedical research.

Method: Utilising a comparative legal analysis, the most important documents on bioethical issues drafted by the Council of Europe and their application in the field of biomedical research and human genetics are presented and elucidated.

Results: The Council of Europe is an intergovernmental organisation with a pan-European vocation, which fosters political, legal and cultural cooperation between its 46 members – European pluralistic democracies. The most tangible results of intergovernmental cooperation in the Council are European conventions drawn up as a contract between signatory states. The Council of Europe has drawn up more than 150 multilateral conventions, including the European Convention on Human Rights. Five additional Protocols have been proposed to supplement the Convention. The most recent additional Protocol to be completed and opened for signature is that on Biomedical Research. Article 4 of the Convention requires that any intervention in the field of health, including research, must be carried out in accordance with the relevant professional obligations and standards. The Convention also stipulates additionally that research on a person may only be undertaken if certain conditions are met. Particular attention is being paid in the Council of Europe to the fulfilment of the requirement for multidisciplinary review of the ethical acceptability of biomedical research. The Convention pays specific attention to the protection of persons not able to consent to research and of embryos *in vitro*. Chapter IV (Human genome) is relevant to research specifically in the genetic field.

Conclusions: The Convention acknowledges the importance of the interests of society and science, which come immediately after those of the individual. But by protecting human rights and dignity in the context of the new biomedical technologies, the Convention helps to provide assurance that the positive implications of such activities will be appreciated and supported while threatening developments which alarm the people of Europe and the rest of the world are not allowed to blacken the image of biomedical research.

Key words: biomedical research, biomedicine, European Convention on Human Rights and Biomedicine, Council of Europe, ethics committee, human rights

INTRODUCTION

The European Convention on Human Rights and Biomedicine (1) will be discussed in this article. In addition, the article addresses the additional Protocols to the Convention, including the one on Biomedical Research (2).

The Convention is a legally binding instrument which must be implemented in those states that sign and ratify it. It sets out minimum standards in the field of biomedicine, and the additional Protocol on Biomedical Research does the same in that specific field.

The Convention on Human Rights and Biomedicine is the first international agreement on the new biome-

dical technologies. Its full title is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. It was opened for signature on 4 April 1997 in Oviedo, Spain, and 32 countries have signed to date and 19 have ratified. The Convention is in force in those states, including Lithuania. It is expected that many more states will be signing the Convention in the near future. The preparation of the Convention was an initiative of the Council of Europe.

METHOD

Utilising a comparative legal analysis, the most important documents on bioethical issues drafted by the Council of Europe and their application in the field of biomedical research and human genetics are presented and elucidated in this article.

RESULTS

Set up in 1949, the Council of Europe is an intergovernmental organisation with a pan-European vocation which fosters political, legal and cultural cooperation between its 46 members European pluralistic democracies. It is quite distinct from the 25-nation European Union, though all of the EU member countries are also members of the Council of Europe. The aims of the Council of Europe, as specified by its Statute, are to protect human rights and strengthen pluralist democracy, to enhance European cultural identity and seek out solutions to the major problems of our time such as the bioethical problems addressed by the Convention on Human Rights and Biomedicine.

The Council of Europe operates through two principal bodies, the Committee of Ministers, its decision-making body, and the Parliamentary Assembly, its deliberative body. The Secretariat General serves these bodies and is headed by Secretary General elected for five years. The most tangible results of intergovernmental cooperation in the Council are European conventions drawn up as a contract between signatory states. Each state accepts a number of obligations in return for acceptance of the same obligations by the other states. The Council of Europe has drawn up more than 150 multilateral conventions, including the European Convention on Human Rights.

The Ad hoc Committee of Experts on Bioethics (CAHBI) was set up under the direct authority of the Committee of Ministers in 1985, and in 1992 became the Steering Committee on Bioethics (CDBI). The CDBI is responsible for the intergovernmental activities of the Council of Europe in the field of bioethics. These activities have led to the adoption of Recommendations of the Committee of Ministers in the field of bioethics on subjects such as genetic engineering, medical research on human beings, genetic testing, and on the use of human embryos and foetuses in scientific research; and to the preparation of the Convention, which was adopted by the Committee of Ministers on 19 November 1996.

It is up to the countries signing and ratifying the Convention to give effect to its provisions in their national legislation. This process is followed up by the Secretariat and the CDBI at the Council of Europe. Assistance is provided to signatories to adapt their institutions and legislation to the requirements of the Convention.

Five additional Protocols have been proposed to supplement the Convention. The Protocols are designed to address the ethical and legal issues raised by present or future scientific advances through the further development, in specific fields, of the principles contained in the Convention. The most recent additional Protocol to be completed and opened for signature is that on Biomedical Research.

The completed additional Protocols have all been drafted by working parties made up of high level experts nominated by Council of Europe member States with the assistance of the Secretariat of the Council of Europe (the Bioethics Department in the Directorate of Legal Affairs). The high level experts take into account the views of non-governmental and professional organisations active in the respective fields in the preparation of the Protocols. This is done through consultations with such organisations between meetings and through consultations with European-wide bodies arranged in Strasbourg during the meetings of the working parties. The working parties also consult with other regional and international bodies working with related issues.

The working parties meet at least twice a year in Strasbourg and between meetings consult with their own governments and with other national delegations not represented in the particular working party. The progress of work on the Protocols is reviewed at least twice a year by the CDBI plenary. Protocols may be signed by states which have signed the Convention, and may be ratified once the Convention has been ratified in that state.

The Convention gives precedence to the human being over the sole interest of science or society. The aim of the Convention is to protect human rights and dignity, and all of its articles must be interpreted in this light. The main focus of the Convention in regard to biomedical research is specifically this human rights aspect, unlike other legal instruments in the field which may concentrate, for example, to a large extent on the economic and public health aspects of making new medicines available more quickly. The interests of society and science are not neglected, however, and come immediately after those of the individual. On this basis, it establishes that consent is obligatory for any medical treatment or research and recognises the right of all individuals to have access to information concerning their health. The text also sets out safeguards protecting anyone, of any age, who is unable to give consent.

The term “Human Rights” as used in the title and text of the Convention refers to the principles found in the European Convention for the Protection of Human

Rights and Fundamental Freedoms of 4 November 1950, which guarantees the protection of such rights. The Convention on Human Rights and Biomedicine not only shares the same underlying approach, many ethical principles and legal concepts, but also elaborates on some of the principles found in that Convention.

Additionally, Preamble to the Convention acknowledges the fundamental nature of the principles of human rights enshrined in the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social, and Cultural Rights, the Convention on the Rights of the Child, the European Social Charter, and, in a more specific instrument, the European Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. This Convention builds on the principles embodied in these instruments to ensure the protection of human rights in the context of the recent advances in biology and medicine.

Cooperation between the Council of Europe and the European Union in the field of biomedical research is invaluable as the membership of the Council stretches beyond the EU member States.

Requirements for research to be undertaken on persons in the fields of biology and medicine are set out in the Convention in the Chapter on Scientific Research specifically and in other chapters. The Convention and its additional Protocol on Biomedical Research apply to all biomedical research undertaken on human beings. The fundamental principle for research involving human beings, as in the rest of the Convention, is the free, informed, express, specific, and documented consent of the person(s) taking part.

DISCUSSION

Article 4 (Professional standards) of the Convention requires that any intervention in the health field, including research, must be carried out in accordance with the relevant professional obligations and standards. The term "intervention" is used here in a broad sense covering all medical activities directed at human beings for preventive care, diagnosis, treatment, rehabilitation, or research. The Article covers both written and unwritten rules.

The Convention also stipulates additionally (in Article 16) that research on a person may only be undertaken if all the following conditions are met:

i. if there is no alternative of comparable effectiveness to research on humans;

ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

iii. the research has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability.

iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Particular attention is being paid in the Council of Europe to the fulfilment of the requirement for multidisciplinary review of the ethical acceptability of biomedical research. First of all, this is being done through a more detailed examination of the subject of ethical review and ethics committees in the additional Protocol on Biomedical Research. This will serve to harmonise the principles of ethical review of research involving human beings in Europe. Additionally, the Council is undertaking a program of cooperation in 1997–2005 with its member countries in Central and Eastern Europe, called the Demo droit Ethical review of Biomedical Research Activity (DEBRA) consisting of multilateral and bilateral meetings, and informative materials on best practice in this field in Europe. This activity was also supported by the European Commission and Norway.

The Convention pays specific attention to the protection of persons not able to consent to research and of embryos *in vitro*. Article 17 deals with protection of persons not able to consent to research and sets out that research on a person not able to consent to research may only be undertaken if:

- the conditions just mentioned from Article 16, which are applicable to all research, are fulfilled;
- the persons to undergo research have been informed of their rights and the safeguards prescribed by law for their protection;
- the results of the research have the potential to produce real and direct benefit to his or her health;
- research of comparable effectiveness cannot be carried out on individuals capable of giving consent;
- the necessary authorisation provided for under Article 6 (of the Convention) has been given specifically and in writing; and
- the person concerned does not object.

Article 6 (Protection of persons not able to consent) of the Convention sets out the manner in which consent may be obtained for a minor or an adult who does not have the capacity to consent to an intervention. It requires that the individual concerned take part in the authorisation procedure as much as possible. In the case of minors, it provides that the opinion of the minor will be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity. The authorisation may be withdrawn at any time in the best interests of the individual concerned. It is important to note in the case of parents that they have responsibility for a child, not power over a child. This means that the parent must always act in the interests of the child and must ensure that the de-

cisions taken further the well-being and health of the child.

Article 17 also provides, exceptionally and under the protective conditions prescribed by law, that research which does not have the potential to produce results of direct benefit to the health of a person not able to consent to research may be carried out if stringent conditions are fulfilled. To the aforementioned requirements for research on persons not able to consent, it adds that the research has the aim of contributing, through significant improvement to the scientific understanding of the individual's condition, disease, or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition. Finally, the research must entail only minimal risk and minimal burden for the individual concerned.

Article 18 states that where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo and stipulates that the creation of human embryos for research purposes is prohibited. This does not mean that research on supernumerary embryos created for fertilisation purposes is prohibited by this Article.

Chapter IV (Human genome) is relevant to research specifically in the genetic field. This Chapter seeks to prevent the use of genetic tests for purposes which may be selective or discriminatory. Article 11 establishes the principle that any form of discrimination against an individual because of his or her genetic heritage is prohibited. This expands the protections of Article 14 of the European Convention on Human Rights, which states that the enjoyment of the rights and freedoms set forth in the Convention must be secured without discrimination on the basis of sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status, to include genetic heritage.

Article 12 states that tests which are predictive of genetic diseases or which serve to identify the person being tested as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to additional genetic counselling. Thus research utilising such tests should be undertaken in the context of developing medical treatment and enhancing the possibility to prevent disease.

Article 13 states that interventions which seek to modify the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes and only if the aim is not to introduce any modification in the genome of any descendants. The Explanatory Report explains that medical research intending to genetically modify spermatozoa or ova which are not for procreation is only possible *in vitro* with an appropriate ethical or regulatory approval. Provisions regarding genetic research will be developed further primarily in the additional Protocol on Human Genetics, but also, in a more general sense, including ethical review of research, in the additional Protocol on Biomedical Research.

Article 21 prohibits financial gain from the human body and its parts. This issue is further addressed in the context of biomedical research in the additional Protocol on Biomedical Research.

While there is no possibility for recourse to the European Court of Human Rights at this time in regard to individual cases connected to the Convention, Article 29 of the Convention provides that the European Court of Human Rights may give advisory opinions concerning interpretation of the Convention at the request of the Government of a Party or the CDBI (with membership restricted to the Parties to the Convention for this question). Additionally, it requires any Party to furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention if so requested by the Secretary General of the Council of Europe.

CONCLUSIONS

The Convention acknowledges the importance of the interests of society and science, they come immediately after those of the individual. But by protecting human rights and dignity in the context of the new biomedical technologies, the Convention helps to provide assurance that the positive implications of such activities will be appreciated and supported while threatening developments which alarm the people of Europe and the rest of the world are not allowed to blacken the image of biomedical research. The Council of Europe stresses the need for international cooperation in this field to extend the same protections for the individual in this field beyond its member states in Europe, and Article 29 of the additional Protocol concerning Biomedical Research is an evidence of the Council's efforts in this direction.

In conclusion, the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine and its additional Protocols serve to encourage scientific research in biology and medicine as long as the human dignity and fundamental rights and freedoms of the individual are safeguarded.

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