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Steering Committee on Bioethics (CDBI)

Report of the 26th Meeting

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The Steering Committee on Bioethics (CDBI) met at the Palais de l'Europe, in Strasbourg between the 16th and 19th March 2004.

The main item on the Agenda was the **Draft Recommendation of the Committee of Ministers to member states concerning the protection of the human rights and dignity of persons with mental disorder.** This Recommendation aims to further the protection of the dignity, human rights and fundamental freedoms of persons with mental disorder, in particular those who are subject to involuntary placement or involuntary treatment.

Work on this matter had began in 1996 when the Committee of Ministers established a Working Party under the authority of the Steering Committee on Bioethics in order to draw up guidelines to be included in a new legal instrument of the Council of Europe. In January 2000 the Working Party issued, with the authorisation of the Steering Committee on Bioethics, a "White Paper" for the purposes of public consultation with a view of drawing up the proposed guidelines. The response of the consultation supported the need to include all the fifteen elements, identified in the "White Paper" and to the further refinement of the principles to be reflected within each element. After the Working Party agreed on the principles, it was codified into the format of a draft Recommendation of the Committee of Ministers of the Council of Europe.

The draft recommendation was examined by the Steering Committee on Bioethics at its meeting in December 2003. Following further examination and in depth discussions, the draft recommendation was adopted on the 18th March. The seven chapters of this draft Recommendation cover: the object and scope; the general provisions; involuntary placement, and involuntary treatment, placement of persons not able to consent in the absence of objection; specific situations; involvement of the criminal justice system; and quality assurance and monitoring. Since a number of concerns exist in this field this Recommendation could be a major advance.

The **Draft Explanatory Report** which accompanies the Draft Recommendation was also discussed concurrently. This report provides information to clarify the object and purpose of the Recommendation and to make the scope of its provisions more comprehensible. The Draft Recommendation accompanied by the Draft Explanatory Report will now be passed to the Committee of Ministers.

Draft Protocol on Human Genetics (First part: applications for health purposes)

An interesting and enlightening discussion centred on three main issues concerning applications of genetics for human purposes identified by working party. These were:

- genetic tests directly sold to the public;
- genetic tests on persons not able to consent without direct benefit for the person concerned but for the benefit of family members; and
- genetic research and gene therapy.

Research on Stored Human Biological Materials

The introductory note by the chairperson of the working group specified situations in which biological materials were removed from persons and then stored. The ensuing debate centered on two main issues. These were whether the scope of the draft Protocol on Biomedical Research should include biobanks; and the specific aspects of consent.

The draft protocol on human genetics; and research on stored human biological materials will be the main items on the agenda of next meeting to be held in October.

Invitation to the European Group on Ethics in Science and New Technologies (EGE)

The Bioethics Consultative Committee (BCC) was invited to meet Professor Goran Hermerén, the chairman of the European Group on Ethics (EGE), in Brussels on 19th April 2004. This was one of a series of meetings with representatives of the National Ethics groups of accession countries to the European Union, aimed at finding out which structures are in place and how they are organised as well as to establish the level of ethical debate in the country. Ultimately the objective is to obtain a closer collaboration with and between the national committees.

The EGE is an independent multidisciplinary body which advises the European Commission on the ethical aspects of science and biotechnology, with respect to the preparation and implementation of Community legislation and policies. The European Parliament and the Council may direct the Commission's attention to specific issues that require study.

Malta was represented by the BCC and by the newly instituted Research Ethics Committee of the University of Malta, represented by the chair, Fr. Paul Pace. Also present were Dr Rena Petridou, chair of the Cyprus National Bioethics Committee and Dr. Jerzy Umiastowski, chair of the Medical Ethics Committee of the Polish Medical Board.

The meeting was structured such that we described our committee's background, composition and function. The main interest was in how effective the committees were and whether there were areas where the EGE could be of assistance. It was felt that national committees should be multidisciplinary. At present in Poland, legislative procedures are still underway to establish a multidisciplinary National Bioethics Committee.

The discussion included the official, and particularly, the legal backing to the committees. It is worth noting that while the BCC is only a consultative body, the Cyprus National Bioethics Committee was established by law to monitor, analyze and evaluate bioethical issues related to research and biotechnology in scientific and medical fields. However we share similar problems in the lack of administrative support, leading to difficulties in dissemination of issues and opinions.

We outlined some of the issues that the BCC has dealt with over the years and mentioned in particular the topics covered in seminars, open to the public, the proceedings of which have all been published. However, dissemination of information in Malta remains mainly among healthcare professionals, and the BCC has little influence eon public debate although individual members of the BCC have been active in promoting bioethical issues in the media.

One way of promoting ethical issues is to invest in the teaching of ethics in scientific institutions and medical schools. Prof. Hermerén, Professor of Medical Ethics, Faculty of Medicine, Lund University, Sweden, explained that this is best achieved by a formally structured curriculum, spread throughout the course.

This was a useful first contact with the EGE, which suggested three possible ways of assistance: provision of literature, including not only the opinions of the EGE but also of other recognized bodies within the various countries; invited visits by members of the EGE to Malta to assist with any problems; and invitation of the national committees to Brussels, to attend the proceedings on a given topic, particularly where both countries are working on the same issues.

Bridget Ellul

Cloning milestones since Dolly the sheep

Some of the landmark moments since 1997, when British scientists unveiled the first successful mammal clone.

1997: Dolly the sheep and the big breakthrough - the first successful mammal clone from an ordinary adult cell.

1997 to 2000: Scientists at various institutes cloned various species of animal - as other scientists claimed to be working towards the first human clone.

1998: American Dr Richard Seed said he was ready to begin experiments on cloning a human being within the next three months.

January 2001: Controversial Italian doctor Severino Antinori announced plans to clone human babies for infertile couples at his fertility clinic in Rome.

April 2001: Dr Antinori reportedly said that a woman he was treating was pregnant with a cloned embryo. It was later denied.

July 2002: Authorities in South Korea investigated a company's claim that it had implanted a cloned human embryo in a South Korean woman.

November 2002: Dr Antinori announced that the first human baby clone would be born in January 2003.

December 2002: Clonaid, founded by the Raelian sect, claimed the first human clone was born, sparking surprise and condemnation. It has never provided DNA proof of its cloning claims.

February 2003: Dolly the sheep is put down after a veterinary examination showed she had a progressive lung disease.

July 2003: The first UK research licence of its kind permitting a technique that creates embryonic stem cells from human eggs was granted to the scientists who cloned Dolly the sheep in Edinburgh. This is therapeutic, not reproductive, cloning.

September 2003: Dr Panos Zavos claims to have created the world's first cloned human embryo. He announced plans to implant the human embryo in a surrogate mother later in the year.

October 2003: Scientists in China claimed they had created twins which effectively had two "genetic mothers" and one father, but the experiment did not create any live babies. One expert called the experiment "proof of principle" for human cloning, but others disagreed. The work was not aimed at producing genetic copies of humans.

January 2004: Dr Zavos announces a 35-year-old woman is hoping to give birth to the world's first cloned baby.

February 2004: South Korean scientists clone 30 human embryos and develop them over several days to a stage where special cells known as embryonic stem cells could be extracted. The researchers hope to obtain cells that could one day be used to treat disease.

Three parents for toddler: Victory for sperm donor

A land-mark court decision has given a sperm donor rights to shared guardianship over a 2-year old child born after sperm donation. Judge Sarah Fleming of the Auckland Family Court (New Zealand) awarded the donor shared guardianship as well as access of up to seven days a month.

This is a precedent-setting decision, and involves recognition of sperm donors as legal parents of resulting offspring.

It has been accepted standards of sperm donation procedures that both donor and recipient are kept unaware of each others identity, precisely to remove the possibility of claims arising from either donor or child. More recently, legislation in a number of countries has been updated, giving the child the right to find out the identity of the sperm donor i.e. his or her biological father. This, however, is the first case where a donor has won right relating to offspring.

Such a decision has marked ethical as well as legal and social implications. While the catholic tradition has always been against sperm donation by a third party, such a practice is considered ethical by most clinics in Europe. It has always been subject to strict regulation relating to confidentiality. When such regulations are flouted, as in this particular case where a lesbian couple approached their friend to donate sperm, all confidentiality is lost, and personal considerations become significant and confounding factors.

Notes:

The BCC participated last December in the second meeting of the National Ethics Committees (NECs) of the EU member states. The subject that was covered at this meeting dealt mostly with the ethical, legal and social implications of nanotechnology. Nanotechnology is the scientific technology which deals with matter at a very small scale, the atomic scale; one billionth of a meter or one thousandth of a micron, that is 10^{-9}m, hence nanotechnology. As in all biotechnological engineering, this science holds much promise, but has to be ethically regulated as it may be abused. The EU has invited the BCC to attend its third meeting in Dublin in June 2004.

The BCC will be organising its Annual Seminar on Human Stem Cell Research at St. James' Cavalier on Friday the 29th October 2004, from 7.15pm to 10.00pm. in the Music Room. Foreign and local speakers will be in attendance. There will be no charge levied for the event and it will be open to the public. The event will be held under the auspices of the Minister for Health Dr. Louis Deguara MP.

The Parliamentary Assembly of the Council of Europe, has just approved the third protocol to the Oviedo Convention on Bioethics dealing with biomedical research and that means that it is in the final phases of being adopted. The other two established protocols deal with the cloning of human beings and the transplantation of human organs. The Maltese Government has not yet signed the main Convention thereby making it possible to acceed to the protocols. However it has signified its intention to do so in the immediate future with the inclusion of some important safeguard qualifications. The BCC has written to the authorities concerned signalling its agreement of our accession to this important Convention with respect to Bioethics.

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