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June 17, 2008
LL File No. 2008-01108

TO: The Honorable Brad Sherman, Chairman,
Subcommittee on Terrorism, Nonproliferation and Trade
Committee on Foreign Affairs
U.S. House of Representatives

Attention: Don MacDonald

FROM: Clare Feikert
Senior Foreign Law Specialist

SUBJECT: Human Genetic Engineering

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In response to your June 5, 2008 request, please find attached reports on Australia, Canada, France, Germany, Israel, New Zealand, Russia, the United Kingdom, International Organizations, and the European Union and a brief comparative analysis of these reports.

If you have any questions concerning this issue, please call me at (202) 707-5262 or email me at cfei@loc.gov. It has been my pleasure to assist you, and I hope that this information will be helpful.

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Attachments

2008-01108

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# REGULATION OF HUMAN GENETIC TECHNOLOGY

# COMPARATIVE ANALYSIS

*Executive Summary*

*The countries of this study have taken either a regulatory approach to human genetic engineering or have prohibited it completely. The various approaches to this issue demonstrate the complex moral, ethical, and social dilemmas that have presented themselves to governments. Various international groups have put forth a number of principles in the form of declarations and resolutions but there has yet to be a binding multilateral treaty on this issue, reflecting the difficulty in negotiating such an instrument.*

## Introduction

The following comparative analysis is based on the Law Library of Congress Reports for Australia, Canada, France, Germany, Israel, New Zealand, Russia, the United Kingdom, International Organizations, and the European Union. All the countries involved in this report have laws governing the use of embryos that take into account the unique cultural and religious identities of the countries. All the countries of the report have expressed concern over the moral and ethical dilemmas that are imposed by the use of human embryos in research and consider that the embryo has special significance, demonstrated either by prohibiting its use in research and genetic related testing completely, or through stringent regulations. There have been a large number of efforts at the international level, in the form of declarations, reports, and resolutions, to regulate the use of human embryos and genetic engineering, and to prevent cloning for reproductive purposes. The European Union has produced a number of Directives that regulate genetic issues amongst its Member States.

The following table shows whether the countries of the report permit pre-implantation genetic diagnosis (PGD), inheritable genetic modification (IGM), cloning, and stem cell research.

| Country | PGD | IGM | Cloning | Stem Cell Research |
|---|---|---|---|---|
| Australia | Yes | No | Yes – non-reproductive | Yes |
| Canada | Yes | No | No | Yes |
| France | Yes | No | No | Yes |
| Germany | Yes – limited to pre-fertilization | No | No | Limited to certain imported stem cell lines |
| Israel | Yes | Yes – non-reproductive | Yes – non-reproductive | Yes |

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# REPORT FOR CONGRESS

**June 2008**

Directorate of Legal Research
LL File No. 2008-01108

# REGULATION OF HUMAN GENETIC TECHNOLOGY

*Australia, Canada, France, Germany, Israel, New Zealand, Russia, the United Kingdom, International Organizations, and the European Union, plus a brief comparative analysis of these reports.*

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| | | | | |
|---|---|---|---|---|
| New Zealand | Yes | No | Yes – non-reproductive | Yes |
| Russia | Yes | No | Yes – non-reproductive | Yes |
| UK | Yes | No | Yes - non-reproductive | Yes |

**The Use of Human Embryos in Research**

Australia, Canada, Israel, New Zealand, Russia, and the UK, have taken a pragmatic approach to the use of human embryos in research and permit it, within the limits of their legislation. All these countries recognize that the embryo has a special status and have drafted laws to take this into account, permitting the use of embryos but restricting the time period in which they can be used. Australia, Canada, New Zealand, Russia, and the UK require that a license be obtained from the countries regulatory body before embryos can be used, to ensure that embryos are only used when absolutely necessary and that their use is according to the purposes of the law. These countries all have general public support of this type of research being undertaken on human embryos.

Russia has not altered its laws on this issue for the past seven years. France and Germany have restrictive regimes regarding the use of embryos. Germany currently has a law that provides legal protection to embryos, from the moment the cell nuclei fuse, and also provides embryo status to "any totipotent cell that has been taken from an embryo and that is capable of partition and of developing into an individual." Given that the embryo is protected, Germany thus has a restrictive policy on human genetic engineering and does not permit any form of cloning or inheritable genetic modification, and only allows limited pre-implantation genetic diagnosis on unfertilized ovum. It only permits stem cell research on specific imported stem cell lines. France has a general rule that prohibits research on embryos; however, it excludes from this rule research on embryos and embryonic stem cells if this results in major therapeutic benefits and there is no alternative method of research available, and in such cases allows for a trial of five years, after which time the Parliament will review the law.

**Pre-implantation Genetic Diagnosis**

PGD is permitted in Australia, Canada, France, Israel, New Zealand, and the UK. Australia, France, New Zealand, and the UK restrict the use of PGD to the diagnosis of certain disorders and do not permit the use of PGD for the purposes of sex selection. Germany has a very restrictive regime in place on the use of PGD, and only permits its use on unfertilized eggs. Israel does not have any laws in place that regulate the practice of PGD, and its use is regulated on a case-by-case basis for medical reasons by hospital committees. Israel allows the use of PGD for the purposes of sex selection in extremely limited circumstances, which extends to family balancing. The use must be approved by a State Committee and currently that Committee has only approved the use of PGD for sex selection in one instance, for "humanitarian purposes."

## Inheritable Genetic Modification

All the countries involved in the study do not permit the use of IGM for reproductive purposes, with many considering that this is contrary to human dignity. The majority restrict the

use of IGM in research. The UK is tentatively moving towards permitting the use of IGM in research, through a bill currently before the House of Commons.

**Cloning**

All countries in this study prohibit human cloning for reproductive purposes. Australia, Israel, New Zealand, and the UK permit cloning for therapeutic purposes.Russia's ban on cloning provides a mechanism to cancel the ban if new knowledge and changes in moral, social, and ethical rules occur.

The United Nations General Assembly has adopted a declaration on human cloning that calls upon its member states to prohibit all forms of human cloning. Currently, all the countries involved in this study expressly prohibit cloning for reproductive purposes. All the countries but Russia, which does not have any provisions regulating the punishment for illegal activities relating to genetic engineering, subject individuals that violate this law to a range of criminal penalties, from imprisonment for up to ten years to fines. The United Nations Educational, Scientific and Cultural Organization (UNESCO) unanimously adopted the Universal Declaration on the Human Genome and Human Rights in 1997. This is a non-binding instrument, but UNESCO is encouraging states to follow its principles, notably that reproductive cloning of humans should not be permitted, but the Declaration acknowledges that freedom of research in this area is "necessary for the progress of knowledge."

The European Union's Charter of Fundamental Rights of the Union expressly prohibits the cloning of human beings. In addition to this, the European Parliament adopted a resolution in 2000, which stated that therapeutic cloning is contrary to public policy. Despite this resolution, some countries in the EU permit therapeutic cloning.

**Import/Export Issues**

The countries involved in the study have various measures regarding the import and export of human embryos that are cumulatively fairly restrictive and clearly intended to prevent the export or import of embryos to bypass national laws. France requires that the import or export of embryonic or fetal tissue cells be authorized by a government agency, and the authorization is only granted if the tissues and cells have been obtained in compliance with the principles of the French Civil Code. An additional condition for the export of tissues and cells is that any research project involving these materials must involve a French research body. Russia prohibits the export of cloned embryos across its state borders. The UK permits the export of embryos and stem cells, provided they are sent to a licensed facility that is either within the EU and licensed in accordance with EU directives, or in accordance with the laws of the country the embryo or stem cells are being exported to. Embryos or stem cells may not be exported "if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre."

Australia prohibits the import or export of human embryo clones and human embryos for commercial trade purposes, and the import and export of human embryos is further regulated at the state level. New Zealand prohibits the import or export of in vitro embryos that are formed contrary to the laws of the country or those over fourteen days in development.

## Concluding Remarks

The legislative regime involving the many aspects of human genetic engineering varies from country to country depending upon a number of factors, both cultural and religious, as well as the prevailing social views of the status of the embryo. The combination of these factors and the country's resulting decision as to whether the benefits accorded to society through the use of embryos in research or reproductive technology overrides the costs has had an impact on the legislative measures that are in place.

Prepared by Clare Feikert
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June 2008

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# LAW LIBRARY OF CONGRESS

# REGULATION OF HUMAN GENETIC TECHNOLOGY

# INTERNATIONAL ORGANIZATIONS

*Executive Summary*

*The United Nations Educational, Scientific and Cultural Organization (UNESCO) has adopted a number of declarations and guidelines on the human genome and genetic data, placing principles for genetic technology in a human rights framework. One of these documents, the Universal Declaration on the Human Genome and Human Rights, has been endorsed by the United Nations General Assembly. The UN has also adopted a declaration on human cloning. It should be noted that these documents are not in the form of binding treaties or agreements. The World Health Organization has also issued resolutions and reports on aspects of genetic technology.*

## United Nations

The Universal Declaration on the Human Genome and Human Rights (UDHGHR), which was adopted by UNESCO by unanimous acclamation on November 11, 1997, was endorsed by the UN General Assembly on December 9, 1998.[1] It states that "The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity."[2] In stressing the right to human dignity, the UDHGHR further states, "The human genome in its natural state shall not give rise to financial gains."[3] It describes the rights of the persons concerned in genetic research, including the right to privacy and to give consent to all procedures,[4] and declares clearly that reproductive cloning of human beings "shall not be permitted."[5] However, it also affirms the freedom of research, describing it as "necessary for the progress of knowledge."[6]

The UDHGHR has sections on promotion of its principles and on implementation. They provide that States should take steps to promote and implement UDHGHR principles though education.[7] The UDHGHR also refers to the International Bioethics Committee of UNESCO, calling on it to organize appropriate consultations and make recommendations to follow-up on the UDHGHR concerning "identification of practices that could be contrary to human dignity, such as germ-line interventions."[8]

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[1] Text available from the UNESCO Web site in many languages, http://portal.unesco.org/shs/en/ev.php-URL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited June 9, 2008).

[2] *Id.*, art. 1.

[3] *Id.*, art. 4.

[4] *Id.*, arts. 5-9.

[5] *Id.*, art. 11.

[6] *Id.*, art. 12, para. b.

[7] *Id.*, arts. 20-24.

[8] *Id.*, art. 24.

A key aspect of the UDHGHR is that it is not a legally binding instrument, in the way that a multilateral convention would be. It has therefore been described as one of "just the first steps towards the elaboration of an international biomedical law … ."[9]

The UN General Assembly has also adopted a declaration on human cloning.[10] It calls for Member States to:

- adopt all measures needed to protect human life in the application of life sciences;
- prohibit all forms of human cloning;
- adopt measures needed to prohibit the application of genetic engineering techniques that may be contrary to human dignity;
- take measures to prevent the exploitation of women in the application of life sciences;
- adopt and promptly implement legislation to bring these principles into effect; and
- in the financing of medical research, take into account pressing global issues such as HIV/AIDS, tuberculosis, and malaria, all of which have a particular impact in developing countries.

## UNESCO

The International Declaration on Human Genetic Data (DHGD) of October 16, 2003, was adopted unanimously at UNESCO's 32nd General Conference.[11] It was based on the UDHGHR and on prior UNESCO resolutions and is designed to ensure the, "Respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data[12] and of the biological samples from which they are derived ... ." In addition, the DHGD states that any such handling of human biological samples must be consistent with the international law of human rights and that the provisions of the Declaration apply in all cases except in the investigation, detection, and prosecution of criminal offenses and in testing for parentage. In those two situations, domestic law that is consistent with the international law of human rights applies.[13]

The DHGD also is written as a declaration, not a treaty, so it repeatedly uses terms like "every effort should be made to ensure that" and "it is ethically imperative that," which underline the fact that it is not a binding, international agreement, but a rather a set of standards.[14]

The DHGD outlines the purposes for which human genetic and proteomic data may be collected, processed, used, and stored. They are:

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[9] Roberto Andorno, *Biomedicine and International Human Rights Law: In Search of a Global Consensus*, BULLETIN OF THE WORLD HEALTH ORGANIZATION 959-963 (2002). The author is a member of the UNESCO International Bioethics Committee.

[10] United Nations Declaration on Human Cloning, A.RES.59/280, Mar. 8, 2005, *available at* http://daccessdds.un.org/doc/UNDOC/GEN/N04/493/06/PDF/N0449306.pdf?OpenElement.

[11] UNESCO Web site, http://portal.unesco.org/shs/en/ev.php-URL_ID=1882&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited June 6, 2008).

[12] Human proteomic data is defined in article 2 of the DHGD as "information pertaining to an individual's proteins including their expression, modification and interaction."

[13] DHGD, art. 1.

[14] *See, e.g.*, *id.*, arts. 6 & 7.

- diagnosis and health care (including screening and predictive testing);
- medical and other scientific research;
- forensic medicine and civil, criminal, and other legal proceedings; and
- any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights (UDHGHR) and international human rights law in general.[15]

The DHGD proposes that the data be collected, processed, used, and stored on the basis of "transparent and ethically acceptable procedures. States should endeavor to involve society at large in the decision-making process ... in particular in the case of population-based genetic studies." It envisions that independent, multidisciplinary, and pluralist ethics committees should be created that would be consulted regarding the establishment of standards, regulations, and guidelines for work in the field. Informed consent of the person whose data is handled should be obtained on the basis of clear, balanced, adequate, and appropriate information, including details about the purpose for the collection of the data and how the data will be stored and used.[17] In addition, the declaration calls for every effort to be made to ensure that the data are not used to discriminate in a way that infringes on human rights.[18]

The DHGD also contains provisions calling for accuracy and security in the processing of human biological data; for States to regulate the cross-border flow of such data to foster international cooperation, together with adequate protection of the data and samples; and for sharing the benefits of the research.[19] The articles on promotion and implementation of the declaration suggest that countries take either legislative or administrative measures to give effect to the DHGD principles and enter into agreements with each other to enable developing countries to build their capacities to participate in research in the field. In addition, the DHGD suggests that States develop ethics education and training for researchers as well as the public at large.[20] The UNESCO International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee are directed to contribute to the implementation of the DHGD by collaborating in monitoring and evaluating that implementation. The two committees also should formulate proposals to further the effectiveness of the Declaration and make recommendations to UNESCO on the matter.[21]

The IBC issued a report in 2003 on Pre-Implantation Genetic Diagnosis and Germ-Line Intervention[22] At that time, correction of specific genetic abnormalities in germ cells or early stage embryos (i.e., germ-line intervention) had not yet been carried out. The report concluded, in part, that "[b]ecause of the many technical problems and uncertainties about possible harmful effects on future generations, germ-line intervention has been strongly discouraged or legally banned [in domestic legislation]."[23] The IBC declined to make a general statement on pre-implantation genetic diagnosis,

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[15] *Id.*, art. 5.

[16] *Id.*, art. 6.

[17] *Id.*

[18] *Id.*, art. 7.

[19] *Id.*, arts. 15-19.

[20] *Id.*, art. 23-24.

[21] *Id.*, art. 25.

[22] SHS-EST/02/CIB-9/2 (rev. 3.), Apr. 24, 2003, *available at* http://unesdoc.unesco.org/images/0013/001302/130248e.pdf.

[23] *Id.*, section VII, "Conclusions."

citing the "different ethical views about the value of human prenatal life." Instead it recommended a review of national level protocols and the process of information and consent of the couples involved.[24]

The report does recommend that such pre-implantation diagnosis be limited to situations where it is indicated for medical reasons, not for selection based on gender alone. It goes on to call unethical selecting and implanting embryos with a similar genetic disease or condition to that of one of the parents, testing for normal physical and mental characteristics, and analysis of the embryo to see if it is fit as a donor of blood stem cells after birth to save the life of a sibling. The latter is considered acceptable only if the embryo is also tested for the disease that affects the sibling. The fact that there is no match should not be considered grounds for not selecting a healthy embryo.[25]

In 2004, based in part on reports received from various nations under the DHGD, UNESCO issued a statement on genetic privacy and non-discrimination.[26] In the statement, nations were urged to ensure that no one be subjected to discrimination based on genetic information, that those undergoing genetic testing be assured of privacy, and that "prior, free, informed and express" consent be given for any use or storage of human genetic data. This resolution calls on nations to promote standards for these protections.[27] Through this resolution, UNESCO is asking countries to undertake to write the specific standards and procedures that will be applied domestically, as well as deciding to continue considering the ethical, legal, medical, employment, insurance, and other implications of genetic privacy and non-discrimination issues.[28]

### World Health Organization (WHO)

The World Health Assembly issued a resolution in 1997 discussing human reproductive cloning,[29] calling it "ethically unacceptable and contrary to human dignity and integrity." The Assembly re-affirmed that position in a resolution of the 51st Assembly meeting in 1998.[30] That resolution also urged Member States to continue debate on the issue and take steps to prohibit reproductive cloning.[31] The Director-General of the WHO was asked to establish a group of experts to clarify concepts and develop guidelines on the use of cloning for non-reproductive purposes; to monitor the implications of the use of cloning for human health; to ensure that Member States are informed of developments, so that they can make decisions about national regulatory frameworks; and to report on actions taken to future meetings of the Assembly.[32]

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[24] *Id.*

[25] *Id.*

[26] Resolution 2004/9, from the 46th plenary meeting, July 21, 2004, *available at* http://www.unesco.ru/files/docs/shs/ecosoc_eng.pdf.

[27] *Id.*, paras. 3-4.

[28] *Id.*, paras. 6 & 9.

[29] Cloning in Human Reproduction, Resolution WHA 50.37, May 14, 1997, described on the WHO Web site at http://www.who.int/genomics/publications/governance/wha/wha049/en/index.html.

[30] Ethical, Scientific and Social Implications of Cloning in Human Health, Resolution WHA 51.10, May 16, 1998, *available at* http://www.who.int/ethics/en/WHA51_10.pdf

[31] *Id.*, para. 2.

[32] *Id.*, para. 3.

The WHO has published a number of reports on issues related to human genetic technology, such as *Review of Ethical Issues in Medical Genetics*,[33] and several reports on *Cloning in Human Health*.[34] The WHO maintains a database of regulations from various nations and reports on policy matters related to genetic technology.[35]

## Concluding Remarks

A number of resolutions, reports, and declarations have been adopted by international bodies that discuss human genetic technology, data, and techniques such as cloning. They seek to insure human dignity through the application of a human rights framework to developing policies in the field. The documents are not binding agreements, but rather general statements of principles that encourage nations to adopt legislation to protect human rights through privacy and consent procedures, and through a ban on human reproductive cloning.

Prepared by Constance A. Johnson
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June 2008

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[33] D.C. WERTZ, J.C. FLETCHER, & K. BERG, REVIEW OF ETHICAL ISSUES IN MEDICAL GENETICS (2003), *available at* http://www.who.int/genomics/publications/en/ethical_issuesin_medgenetics%20report.pdf.

[34] *See, e.g.*, WHO, FIFTY-SECOND WORLD HEALTH ASSEMBLY, CLONING IN HUMAN HEALTH: REPORT BY THE SECRETARIAT (Apr. 1, 1999), *available at* http://www.who.int/ethics/en/A52_12.pdf; *and* WHO, FIFTY-THIRD WORLD HEALTH ASSEMBLY, CLONING IN HUMAN HEALTH: REPORT BY THE DIRECTOR-GENERAL (May 10, 2000), *available at* http://www.who.int/ethics/en/A53_15.pdf.

[35] WHO, http://www.who.int/genomics/elsi/regulatory_data/topic/testing/en/ (last visited June 6, 2008).

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# REGULATION OF HUMAN GENETIC TECHNOLOGY

# EUROPEAN UNION

*Executive Summary*

*In the area of science and biotechnology, the European Union (EU) is legally bound to respect human rights and freedoms for its citizens. Such obligations arise from the Treaties establishing the EU and also from the Charter of Fundamental Rights. The Charter explicitly prohibits human cloning. Furthermore, EU legislation on biotechnical inventions stipulates as unpatentable processes for cloning of human beings and uses of human embryos for industrial or commercial purposes.*

*Processing of genetic data, which falls within the definition of personal data, is subject to the EU's strict rules on privacy and personal data protection, established in 1995.*

*Under the Seventh Framework Program on Research and Technological Development for the period of 2007-2013, any research proposal, in addition to the technical standards, must undergo an ethical review. Otherwise, such proposals do not qualify for EU funds.*

## I. Introduction

The European Union is founded on respect for human rights and fundamental freedoms, which also form part of the legal traditions of its Member States. The Treaties establishing the European Community/European Union, including the Lisbon Treaty which is in the process of ratification by EU Members, contain language to the effect that the Union guarantees the rights and freedoms of its citizens.

Advances in the area of sciences, genomics, and biotechnology have generated extensive debates within the European institutions and other EU bodies. Central to these discussions at the EU level are the right to dignity and integrity of human beings and the right to confidentiality of personal data. These are deemed to be core human rights which must be respected and balanced against other issues, such as freedom of research and science and advancement of medicine for the betterment of mankind.

In general, ethical issues fall within the purview of the Member States, under the subsidiarity principle. However, the EU's approach in adopting legislation on ethical questions in the area of genetics is to include specific reference to its legal obligation to respect human rights and observe ethical standards. For instance, under the Seventh Framework Program for Research for the period of 2007-2013, approved in 2006, research projects, to be eligible for EU funds must undergo an ethical review in addition to the technical evaluation.

At the European Union level, ethical questions arising from new developments in science and technologies are examined by the European Group on Ethics in Science and New Technologies (EGE). Its task is to draft opinions for the European Commission in connection with the legislative drafting and implementation of Community legislation.[1] The European Parliament has also established its own

[1] The European Group on Ethics in Science and New Technologies (EGE) is an independent, multidisciplinary, group that plays an advisory role to the European Commission, Web site updated June 13, 2008, *available at* http://ec.europa.eu/european_group_ethics/index_en.htm.

committees. Moreover, the 1995 Directive on Personal Data established a Working Party, which advises the European Commission on issues and impeding legislation that may have an adverse impact on EU rules on privacy and personal data protection.

## II. General Principles Governing Genetic Engineering and Genetic Data

The Lisbon Treaty, which is in the process of ratification by the EU Members, reiterates language contained in earlier documents concerning the rights and freedoms of European citizens. Two key provisions must be stated:

- the Union recognizes the rights, freedoms, and principles as established in the Charter of Fundamental Rights of the European Union; and
- fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union's law.

The Charter of Fundamental Rights of the European Union stipulates that in the field of medicine and biology, the following must be respected:

- the free and informed consent of the person concerned;
- the prohibition of eugenic practices, especially those which aim at the selection of persons;
- the prohibition on making the human body and its parts a source of financial profit;
- the prohibition of the reproductive cloning of human beings.[2]

The Charter also prohibits discrimination based on genetic features.[3]

## III. Genetic Issues Regulated by the European Union

### Human Cloning

Article II-3, paragraph 2(d) of the Charter of Fundamental Rights of the Union, which was proclaimed in Nice in 2000, explicitly prohibits the reproductive cloning of human beings. In 2000, the European Parliament adopted a resolution on Human Cloning which stated that "therapeutic cloning" which involves the creation of human embryos exclusively for research purposes raises "a profound ethical dilemma" and is against the public policy. It urged the Member States to enact binding legislation banning human cloning and to adopt criminal penalties for any violators.[4]

### Patents

Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions[5] in general prohibits the patentability of inventions in cases where their commercial exploitation would be contrary to public order or morality. The basic provisions of the

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[2] Art. 3 of the Charter of Fundamental Rights of the European Union, 2000, OFFICIAL JOURNAL [OJ] C 364 9.

[3] *Id.*, art. 21.

[4] European Parliament Resolution on Human Cloning, adopted / Sept. 7, 2000, *available at* http://www.europarl.europa.eu/omk/omnsapir.so/pv2?PRG=CALDOC&TPV=PROV&FILE=000907&TXTLST=1&POS=1&SDOCTA=8&Type_Doc=FIRST&LANGUE=EN. See also previous resolutions: 1989 on the Ethical and Legal Problems of Genetic Engineering, 1993 on the Cloning of the Human Embryo, 1997 on Cloning, 1998 on Human Cloning.

[5] 1998 OJ L 213 13.

Directive have been incorporated by the European Patent Convention through a decision of the Administrative Council of the European Patent organization in 1999.[6]

The Directive provides that the human body cannot be subject to a patentable invention. The key language is as follows: "[the] human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."[7] It also stipulates that "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[8]

Recital 41 of the Directive defines "cloning" as "any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being."[9] Pursuant to Article 6, the following are unpatentable:

- processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes; and
- processes to modify the genetic identity of animals which are likely to cause suffering without any substantial benefit either to animal or to humans.10

In spite of the objectives of the Directive to harmonize patent legislation among the EU Members and at the same time clarify which elements are subject to patent and which are not, application and implementation of its provisions by EU Members proved to be cumbersome. Even though the implementation deadline was set for 2000, by 2003, few EU Members had implemented it, forcing the European Commission to institute legal proceedings against the Members. By 2004, most of the old EU Members had implemented the Directive.[11] As of January 2007, all twenty-seven EU Members had transposed the directive into their national legislation.[12]

The Directive was challenged before the European Court of Justice in 1998. The Court upheld the provisions of the Directive related to non-patentability of the human body. It added that the Directive affords sufficient protection to the rights of human dignity and integrity, since it forbids patenting of the human body or of the discovery of elements of the human body. The issue arose due to legal action instituted by Netherlands, which requested that the Court of Justice annul the Directive. In its arguments, Netherlands, supported by Italy and Norway, claimed *inter alia* that neither plants, nor animals, nor human biological materials should be patentable and that the Directive in allowing the grant of patents for isolated parts of the human body, "undermines the inalienable nature of living human matter which is a component of the fundamental right to human dignity and integrity."[13]

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[6] See Report from the Commission to the European Parliament and the Council, Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering, 7 COM(2002) 545 final.

[7] Directive 98/44/EC, art. 5, para. 1.

[8] *Id.*, art. 5, para. 2.

[9] Id.

[10] *Id.*, art. 4.

[11] For an analysis of this Directive and other issues related to patents in genetic testing, *see* Sirpa Soini, et. al., *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues,* 16 Eur. J. Hum.Genetics 10 (2008).

[12] *State of Play of the Implementation of Directive 98/44/EC,* Jan. 15, 2007, *available at* http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf.

[13] *See* Press Release No. 48/01, Judgment in Case C-377/98 *Netherlands v. Parliament and the Council* (Oct. 9, 2001), available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61998J0377:EN:HTML (last visited June 16, 2008).

Meanwhile, new developments in genetic engineering and application of the Directive generated new issues. The European Commission proceeded to clarify such issues in two reports: on the Development and Implication of Patent Law in the Field of Biotechnology and on Genetic Engineering, prepared in 2002 and 2005.[14]

The EGE, which is entrusted by the above Directive with the task of examining all ethical issues arising from biotechnology, prepared an opinion in 2002, on ethical aspects of patenting inventions involving human stem cells.[15] The EGE clarified that "only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application, fulfill the legal requirements of patentatiblity" can be patented. Regarding processes involving human stem cells, whatever their source, since there is no specific ethical obstacle and provided that they meet the other legal criteria for a patent, they can be patented.[16].

**Advanced Therapy Medications**

Regulation No. 1394/2007 on Advanced Therapy Medicinal Products[17] defines "advanced therapy medicinal product" to include the following;

- a gene therapy medicinal product;
- a somatic therapy medicinal product; and
- a tissue-engineered product.[18]

The Regulation establishes for the first time the term "engineered cell or tissue." A tissue-engineered product, which could include cells or tissues of human or animal origin, is a product that contains or consists of engineered cells or tissues and is administered to humans with the objective of regenerating, repairing, or replacing a human issue.[19] This Regulation also makes a general reference to the effect that it is in compliance with fundamental rights, the principles enunciated in the Charter of Fundamental Rights of the EU, and those embodied in international instruments adopted by the Council of Europe.[20]

**Privacy Concerns Related to Genetic Data**

In general, the EU has strict rules concerning privacy and personal data protection. Genetic data falls within the definition of article 2(a) of Directive 95/46/EC on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data.[21] Personal data is defined as "any information relating to an identifiable natural person (data subject); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural, or social identity."

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[14] See Report from the Commission to the Council and the European Parliament, Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering, COM(2005) 312 final.

[15] Ethical Aspects of Human Stem Cell Research and Use, Nov.14, 2000, *available at* http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf.

[16] *Id.*, at 15.

[17] 2007 O.J. L 324 121.

[18] *Id.*, art. 2, para. 1(a).

[19] *Id.*, art. 2, para. 1(b).

[20] *Id.*, Recital 8.

[21] 1995 O.J. L 281 31.

The Directive subjects certain categories of personal data which are extremely sensitive to stricter safeguards. Health data fall within this particular group. The EGE has deemed that since genetic data provide specific information on a person's health status, physical details. or even ethnic origin, they must be treated as sensitive data and should be subject to an increased level of protection.[22]

Consequently, genetic data are subject to the following standards:

- they can be processed only by health professionals subject to professional confidentiality and secrecy for the purpose of preventive medicine, care and treatment, or medical diagnosis;[23]
- genetic data can be collected for specific, explicit, and lawful purposes (finality principle) ;
- processing of genetic data must be adequate, relevant, and proportionate to the purpose for which the data were collected (proportionality principle); and
- the data subject has the right to receive information prior to any genetic testing performed and give explicit and informed consent.

On the issue as to whether genetic data belong to a specific individual or whether family members have the right to access such data, the EGE argued that genetic data can be considered "a shared information," since family members may claim that they have the right to know of tests that could have an impact on their own health.

Concerning the processing of genetic data in the area of employment, the Working Party has concluded that processing should be prohibited in principle and that authorization could be possible under very limited cases.[24] The expediency and legality of such processing were also assessed by the EGE. An opinion of that group adopted in July 2003 on Ethical Aspects of Genetic Testing in the Workplace stated that "there is, up to now, no proven evidence that the existing genetic tests have relevance and reliability in the context of employment. They still have uncertain predictive value."[25]

The Working Party also concluded that processing of genetic data for insurance purposes must be banned in principle and allowed under very limited cases prescribed by law, in order to avoid discrimination based on one's own genetic profile. A 2001 report issued by the European Parliament Committee on Human Genetics also urged that insurance companies must be prevented from requiring genetic testing.[26]

### Research and Development

Human embryonic stem cell research is a controversial topic among the EU Members, and their legislative measures reflect their diverging opinions and their different ethical, religious, social, and political beliefs. In a 2007 opinion, the EGE made clear that "the ethical dilemma regarding the moral status of the human embryo and its use in research still persists both within the EGE and the EU."[27] The opinion contained the Recommendations of the Ethical Review of the Human Embryonic Stem Cell

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[22] *Id. See* art. 29, Data Protection Working Party, *Working Document on Genetic Data,* Mar. 17, 2004, 12178/93/EN WP 91, *available at* http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2004/wp91_en.pdf. The Working Party was established under art. 29 of Directive 95/46/EC and functions as an independent advisory body to the European Commission on issues related to data protection and privacy.

[23] Directive, *id.*, art. 8.

[24] The Working Party, *Ethical Aspects of Genetic Testing in the Work Place,* July 28, 2003, *available at* http://ec.europa.eu/european_group_ethics/docs/avis18_en.pdf.

[25] *Id.,* at Opinion2.9.

[26] Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine, http://www.europarl.europa.eu/comparl/tempcom/genetics/intro_en.htm (last visited June 13, 2008).

[27] EGE opinion, July 12, 2007, *available at* http://ec.europa.eu/european_group_ethics/activities/docs/press_release_opnion_22_final_follow_up_en.pdf.

(hESC) EP7 Research Project stipulating the guidelines to be followed during the ethics review of any research proposals on human embryonic stem cells under the 7th Framework Program.[28]

The Seventh Framework Program of the European Community for Research, Technological Development and Demonstration covers the period 2007-2013.[29] Each research proposal that raises ethical questions is subject to at least two independent ethical reviews: a) in the Member States where the research will be carried out; and b) at the European Union level.

As a general basic requirement, the Seventh Framework program specifies that that all research activities undertaken under this program must follow fundamental principles, including those contained in the Charter of Fundamental Rights of the European Union, and must take into account the opinions of the European Group on Ethics in Science and New Technologies.

The following fields of research shall not be financed under the Seventh Program;

- research activity on human cloning for reproductive purposes;
- research activity intended to modify the genetic heritage of human beings which could make such changes inheritable;
- research activities intended to create human embryos for the purpose of research or for the purpose of stem cell procurement by means of somatic cell nuclear transfer.[30]

The following fields of research may be financed:

- research on human stem cells, both adult and embryonic, depending on the contents of the proposal. Applications to receive funding for research on human embryonic stem cells must include licensing and control measures that must be applied by the national authorities of the Member States;
- derivation of human embryonic stem cells, by institutions, organizations, and researchers that must be subject to strict licensing requirements.[31]

In July 2007, the EGE recommended that the following criteria must apply to hESC: a) human embryonic stem cell lines have to result from non-implanted IVF embryos; b) hESC lines banked in the European Registry should be used where possible; c) if alternatives to hESC with the same scientific potential as those derived from embryos are found in the future, their use has to be exploited; and d) donor's rights regarding informed consent, data protection, and free donation must be protected.[32]

Import and export of human tissues and cells, including fetal tissues and cells and adult and embryonic stem cells, are regulated by Directives 2004/23/EC[33] and Directive 2006/17/EC.[34] With regard to imports of tissues and cells from third countries, article 9 of Driective 2004/23/EC requires Member States to take all necessary measures to ensure that such imports are undertaken by tissue

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[28] Id.

[29] Decision No. 1982/2006/EC Concerning the Seventh Framework Program of the European Community for Research Technological Development and Demonstration Activities (2007-2013). 2006 O.J. L 412 1.

[30] *Id.*, art. 6: Ethical Principles of the Seventh Framework Program.

[31] *Id.*

[32] EGE, *supra* note 27

[33] Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells, 2004 O.J. L102 48.

[34] Directive 2006/17/EC Implementing Directive 2004/23/EC As Regards Certain Technical Requirements for the Donation, Procurement and Testing of Human Tissues and Cells, 2006 O.J. L38 40.

establishments which are "accredited, designated, authorized or licensed" as such and also to ensure that imported tissues and cells can be traced from the donor to the recipient and vice versa.

With regard to exports, Member States must ensure that exports to third countries comply with the provisions of the above directives. In addition, Members must ensure that the following additional requirements are met:

- Directive 2006/17/EC Implementing Directive 2004/23/EC As Regards Certain Technical Requirements for the Donation, Procurement and Testing of Human Tissues and Cells. in case of emergency, the import or export of certain tissues and cells may authorized directly by the competent authorities;
- direct distribution to the recipient of specified tissues and cells for immediate transplantation can be done with the agreement of the competent authority, provided that the supplier is accredited, designated, authorized or licensed for such activity; and
- import and export of tissues and cells refer to in a) and b) must meet the general quality and safety standards specified in the above directives.

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