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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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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

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.

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AUSTRALIA

REGULATION OF HUMAN GENETIC TECHNOLOGY

Executive Summary

Australia seeks to have a nationally consistent approach to the regulation of genetically modified organisms and research involving human embryos and human cloning. Consistency is achieved via a combination of Commonwealth legislation and complementary or mirror legislation in each state. “Dealings” (that is, use, including the release, import, or manufacture) of genetically modified organisms is regulated and prohibited, unless falling within a category that is permitted on the basis of being a minimal risk, necessary for an emergency, or permitted under license and subject to license conditions. In general, human cloning is banned although it is possible (under license) to conduct limited human cloning for the purpose of making embryonic stem cells. Human embryos that are excess to requirements for assisted reproductive techniques (e.g., in-vitro fertilization, or fertilization in an artificial environment) may, with the consent of persons involved, be used for the purposes of research. Embryos may not be created purely for the purposes of research. Embryonic-based research is closely regulated and a license is required for use of embryos (other than excepted uses such as storage or use by an accredited assisted reproductive technology center).

I. Australia’s Legal System

The Commonwealth of Australia (“Australia”) is a federated constitutional monarchy with power divided between the federal government¹ and the states.

Sections 51 and 52 of the Australian Constitution² primarily define the areas for which the federal government may enact legislation. Generally these areas are taxation, defense, external affairs, trade, and immigration. States may make laws over any area (other than imposing duties of customs and excise, or raising defense forces) without the consent of the Commonwealth Parliament; however, such laws will be invalid where they conflict with a Commonwealth law. Therefore, in practice, states may make laws concerning any areas not falling within §§ 51 and 52 of the Australian Constitution. General areas of state law include education, health, roads, and criminal law.

In addition to the six states,³ there are ten Australian territories (seven governed by the Commonwealth⁴ and three that are self-governing, including the Australian Capital Territory, Norfolk Island, and the Northern Territory). Section 122 of the Australian Constitution authorizes the Federal

¹ Also referred to as the Australian government or Commonwealth government.

² Enacted via the Commonwealth of Australia Constitution Act 1900 (IMP).

³ New South Wales (NSW), Victoria (Vic), South Australia (SA), Tasmania (Tas), Western Australia (WA), and Queensland (Qld).

⁴ Ashmore and Cartier Islands, Australian Antarctic Territory, Christmas Island, Cocos (Keeling) Islands, Coral Sea Islands, Jervis Bay Territory, and the Territory of Heard Island and McDonald Islands. Generally these territories are sparsely populated.

Parliament to make laws in relation to the territories; thus the Federal Parliament may make laws on any subject that will be applicable within the territories. The Federal Parliament has conferred self-government on three territories, however, meaning that a range of government matters (including the making of laws) is handled by a locally elected parliament.⁵

II. Australia's Community Attitude and Policy Position Toward Biotechnology

A 2007 report on the Australian community's attitude towards biotechnology found that, since 2005, there was a general increase in support for the use of biotechnology in health and medicine, including an increase in support for "the use of stem cells, using gene technology to produce medicines and using gene technology in human transplants."⁶ Further, the report found that public perception focused on the ultimate goal (i.e., whether or not humanitarian objectives existed) rather than on the precise technique, and that support for the use of biotechnology in health and science was bolstered as the result of the perceived "low risk of potential negative consequences due to laboratory containment of technologies at the experimental stage, and the perception of strict regulation of medical research and medicines and of high compliance with these regulations."⁷

In 2005 the then Minister for Ageing (Hon. Julie Bishop, MP), appointed a six-member committee (the Lockhart Review Committee) to conduct independent reviews of the Research Involving Human Embryos Act 2002 (Cth) and the Prohibition of Human Cloning Act 2002 (Cth).⁸ The committee developed fifty-four recommendations, many of which were incorporated into the legislation, including, amending the definition of human embryo to avoid impeding "research on culture and maturation of immature eggs (called "in vitro maturation of oocytes," or IVM), storage of frozen eggs, various aspects of IVF [in vitro fertilization], and gamete (egg and sperm) development[,] while maintaining a community reluctance to have mature embryos used in research."⁹ The committee's reports were tabled in both Houses of Parliament and presented to the Council of Australian Governments on December 19, 2005.

In 2000 the Australian federal government launched the National Biotechnology Strategy¹⁰ with the intention of providing a framework for the development of Australian biotechnology and the strategic funding of biotechnology initiatives, including, Biotechnology Australia,¹¹ and the Australian Stem Cell

⁵ The Australian Capital Territory (ACT), the Northern Territory (NT), and Norfolk Island.

⁶ EUREKA STRATEGIC RESEARCH, BIOTECHNOLOGY AUSTRALIA: COMMUNITY ATTITUDES TO BIOTECHNOLOGY REPORT ON HEALTH AND MEDICAL APPLICATIONS (2007), available at <http://www.biotechnology.gov.au/assets/documents/bainternet/Eurekahealthandmedical200720070801081830%2Epdf> (last visited June 9, 2008).

⁷ *Id.*

⁸ See the Lockhart Review Committee Web site, at <http://www.lockhartreview.com.au/reports.html> (last visited June 11, 2008). Review was conducted in accordance with the Prohibition of Human Cloning Act 2002 (Cth) § 25(3) and the Research Involving Human Embryos Act 2002 (Cth) § 47(3).

⁹ Australian Government, Legislation Review: *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*, Reports XV (Canberra, Dec. 2005), available at <http://www.lockhartreview.com.au/files/Legislation%20Review%20Reports%20Full%20Doc-19Dec05.pdf> (last visited June 11, 2008).

¹⁰ See COMMONWEALTH OF AUSTRALIA, AUSTRALIAN BIOTECHNOLOGY: A NATIONAL STRATEGY (2000), available at http://www.biotechnology.gov.au/assets/documents/bainternet/BA%5F_Biotech%5Fstrategy20050520161600%2Epdf (last visited June 9, 2008).

¹¹ Established in 1999, Biotechnology Australia works with partner government departments and is responsible for managing the National Biotechnology Strategy and community awareness of biotechnology. See Biotechnology Australia's Web site, <http://www.biotechnology.gov.au/index.cfm> (last visited June 9, 2008).

Centre.¹² This strategy also provided funding for the Biotechnology Innovation Fund.¹³

III. Regulation of Genetically Modified Organisms

To implement a nationally consistent approach to the regulation of gene technology, Australia has implemented complementary legislation at the federal and state levels. The Federal Parliament does not have sufficient constitutional power to regulate all aspects of genetically modified organisms.¹⁴

Currently Australia has a co-operative national program that consists of:

- An inter-governmental agreement (Gene Technology Agreement 2001), which established the Gene Technology Ministerial Council;
- Commonwealth legislation (Gene Technology Act 2000 (Cth), Gene Technology Regulations 2001 (Cth)) and corresponding legislation enacted by each state and territory;¹⁵
- Advisory committees and officers, including the:

Gene Technology Ministerial Council

Consisting of parliamentary representatives, this committee is tasked with, among other things, issuing principles and policy to govern the activities of the Gene Technology Regulator and with implementation and operation of national legislation and policy regulating gene technology¹⁶;

Gene Technology Ethics and Community Consultative Committee

Consisting of twelve members (at least one of whom is a member of the Gene Technology Technical Advisory Committee and one of whom is a member of the Australian Health Ethics Committee¹⁷) with skills and experience in relevant areas,¹⁸ this

¹² Established in 2003, the Australian Stem Cell Centre is a collaborative effort involving nine leading Australian research institutes and universities for the purpose of developing therapeutic products to treat injury and disease. See the Australian Stem Cell Centre's Web site, <http://www.nsc.edu.au/default.aspx> (last visited June 9, 2008).

¹³ The Fund provided competitive financial grants to assist companies to demonstrate proof-of-concept between initial research and commercialization. Funding was moved to the Commercial Ready program (the Commercial Ready program ceased in 2008).

¹⁴ Areas that may be regulated by the Federal Parliament include: quarantine (§ 51(ix) of the Constitution), regulation of the Federal government departments and authorities, trading, financial and foreign corporations (§ 51(xx)), and interstate or international trade and commerce (§ 51(i)). However, the Federal Parliament does not have power to regulate state government bodies or research and use by individuals or partnerships, which fall outside of the quarantine power. See BILLS DIGEST NO. 11 2000-01, GENE TECHNOLOGY BILL 2000 (Dep't of the Parliamentary Library, Aug. 2000), available at <http://www.aph.gov.au/library/pubs/bd/2000-01/01BD011.htm#Contact> (last visited June 6, 2008).

¹⁵ Corresponding state legislation includes the Gene Technology (New South Wales) Act 2003 (NSW), Gene Technology Act 2001 (Vic), Gene Technology Act 2001 (SA), Gene Technology Act 2006 (WA), Gene Technology Act 2001 (Tas), and the Gene Technology Act 2001 (Qld). Generally, these pieces of legislation mirror the Commonwealth legislation.

¹⁶ In accordance with § 21(1) of the Gene Technology Act 2000 (Cth), the Gene Technology Ministerial Council has issued the Gene Technology (Recognition of Designated Areas) Principle 2003. This principle recognizes areas designated under State and Territory law as being designated for the purpose of preserving the identity of genetically modified and/or non-genetically modified crops for marketing purposes. Gene Technology (Recognition of Designated Areas) Principle 2003 (Commonwealth Gov't Special Gazette No. S340 Sept. 5, 2003), available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtrdap03-exp.htm> (last visited June 6, 2008). The Gene Technology Regulator may not consider or issue a license that is inconsistent with the Principle. Gene Technology Act 2000 (Cth) § 43(2)(e).

¹⁷ Refers to the Australian Health Ethics Committee (AHEC) established under the National Health and Medical

committee provides advice to the Gene Technology Ministerial Council and Gene Technology Regulator on ethical issues, community consultation issues, and other matters of policy and procedure;¹⁹

Gene Technology Technical Advisory Committee

Consisting of twenty members with skills and experience in relevant areas²⁰ (at least one of whom must be a lay person and one of whom must be a member of the Gene Technology Ethics and Community Consultative Committee, but neither of whom are required to have skills and experience in the relevant area), this committee provides scientific and technical advice to the Gene Technology Ministerial Council and the Gene Technology Regulator, as requested; and

- *Gene Technology Regulator*

The primary functions of the Gene Technology Regulator, an independent statutory officer appointed under the Gene Technology Act 2000 (Cth), include: licensing uses of genetically modified organisms in accordance with legislation; developing and drafting policy (under the direction of the Gene Technology Ministerial Council); providing advice on technical and procedural issues surrounding genetically modified organisms to the Australian government and the Gene Technology Ministerial Council; promoting harmonization of risk assessments relating to genetically modified organisms; and acting as an international liaison.²¹

The purpose of the Gene Technology Act 2000 (Cth) is the protection of human health and safety and the protection of the environment via the identification and management of risks posed by genetically modified organisms. Risks are managed by regulating the use or “dealings” that may be made with genetically modified organisms.²²

Thus the Gene Technology Act 2000 (Cth) prohibits any “dealing” (e.g., import, manufacture,

Research Council [NHMRC] Act 1992 (Cth). For further information on the AHEC, see NHMRC’s Web site, <http://www.nhmrc.gov.au/ethics/human/ahec/> (last visited June 10, 2008).

¹⁸ Relevant areas are: “(a) community consultation; (b) risk communication; (c) the impact of gene technology on the community; (d) issues relevant to businesses developing or using biotechnology; (e) issues relevant to gene technology research; (f) issues relevant to local government; (g) issues of concern to consumers; (h) law; (i) religious practices; (j) human health; (k) animal health and welfare; (l) primary production; (m) ethics; (n) environmental issues; [and] (o) issues specified by the regulations for the purposes of this paragraph.” Gene Technology Act 2000 (Cth) § 108(3).

¹⁹ *Id.* §§ 106-112.

²⁰ Relevant areas are: “(a) molecular biology; (b) ecology; (c) plant, microbial, animal or human genetics; (d) virology; (e) entomology; (f) agricultural or aquacultural systems; (g) biosafety engineering; (h) public health; (i) occupational health and safety; (j) risk assessment; (k) clinical medicine; (l) biochemistry; (m) pharmacology; (n) plant or animal pathology; (o) botany; (p) microbiology; (q) animal biology; (r) immunology; (s) toxicology; [and] (t) an area specified by the regulations for the purposes of this paragraph.” *Id.* § 100(5).

²¹ *Id.* § 27. For further information, see the Office of the Gene Technology Regulator’s Web site, <http://www.octr.gov.au/about/index.htm#regulator> (last visited June 9, 2008).

²² A genetically modified organism is defined as: “(a) an organism that has been modified by gene technology; or (b) an organism that has inherited particular traits from an organism (*the initial organism*), being traits that occurred in the initial organism because of gene technology; or (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms; but does not include: (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.” *Id.* § 10.

research, etc.) with any genetically modified organism unless the dealing is:

1. licensed by the Gene Technology Regulator (such license may be either for contained use or for intentional release into the environment);
2. considered a Notifiable Low Risk Dealing or an Exempt Dealing (generally contained usage that has been established to be a minimal risk) or an Emergency Dealing; or
3. on the Genetically Modified Organism (GMO) Register of the Gene Technology Regulator and therefore permitted.²³

The Office of the Gene Technology Regulator maintains a publicly available comprehensive record of all genetically modified organisms by the Gene Technology Regulator and of all genetically modified products approved by other product regulators.²⁴

Licenses

Any person may apply in writing to the Gene Technology Regulator for a license authorizing specified dealings with one or more genetically modified organisms by either the applicant or other persons.²⁵ The application must specify if the dealing includes the intentional release of the genetically modified organism into the environment.²⁶ The proposed dealings may be for all dealings with a specified organism, a specified class of dealings with a specified organism or class of organisms, or one or more specified dealings with a specified organism or class of organisms.²⁷ Where an organism has inadvertently come into the possession of any person, that person may make an application for a license to dispose of the organism.²⁸

Notifiable Low Risk Dealings, Exempt Dealings, and Emergency Dealings

Notifiable Low Risk Dealings are dealings that do not involve the intentional release of the genetically modified organism into the environment and are further defined by regulations and detailed within the Genetically Modified Organism (GMO) Regulator.²⁹ Conditions applicable to the dealing may be specified in the regulations and may include requirements that the dealing be undertaken by a certain class of persons, that the Gene Technology Registrar be notified of the dealing, that the dealing be

²³ A copy of the dealing is available online, at <http://www.ogtr.gov.au/gmorec/register.htm> (last visited June 13, 2008).

²⁴ *See id.*

²⁵ Gene Technology Act 2000 (Cth) §§ 40(1), (2), (6).

²⁶ *Id.* § 40(3).

²⁷ *Id.* § 40(4).

²⁸ *Id.* § 40A.

²⁹ Gene Technology Regulations 2001 (Cth). For an example, *see*, Determination That Dealings With Genetically Modified Carnation Lines Be Included On the GMO Register, Reg. 001/2004 (Australian Dep't of Health & Ageing, Office of the Gene Technology Regulator Nov. 27, 2006), available at [http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/2CB66A4E1CD45EA0CA25723300779291/\\$file/AttachmentI_LegislativeInstrument_forComLawlodgement.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/2CB66A4E1CD45EA0CA25723300779291/$file/AttachmentI_LegislativeInstrument_forComLawlodgement.pdf) (official source) (last visited June 13, 2008), which is a dealing for commercial release of color modified carnations, including the propagation, growth, and distribution of both genetically modified plants and cut flowers Australia-wide. The dealing had previously been authorized under a license but is now part of the Genetically Modified Organisms Register.

supervised by the Institutional Biosafety Committee of Notifiable Low Risk Dealings³⁰ and that the dealing only occur in facilities with specified containment levels.³¹

Exempt Dealings are dealings specified in the regulations to the Gene Technology Act 2000 (Cth) to be exempt dealings.³² The Gene Technology Regulator may review exempt dealings and recommend to the Gene Technology Ministerial Council that the regulations be amended.³³

Emergency Dealings permit the Minister³⁴ (by legislative instrument—an Emergency Dealing Determination) to specify dealings for a genetically modified organism in instances where there is an actual or imminent threat, such as, “a threat from the outbreak of a plant, animal or human disease; a threat from a particular plant or animal, such as a pest or an alien invasive species; [or] a threat from an industrial spillage.”³⁵

The Minister may make the Emergency Dealing Determination only after consulting with the states and receiving advice from senior public servants³⁶ regarding the threat and whether the proposed dealing would address the threat, and advice from the Gene Technology Regulator regarding whether the proposed dealing is able to be managed to protect humans and the environment.³⁷ An Emergency Dealing may be in relation to all dealings with an organism or with a specified class of organisms, a specified class of dealings with an organism or with a specified class of organisms, or one or more specified dealings with an organism or with a specified class of organisms.³⁸ An Emergency Dealing Determination is valid for a maximum of six months and may (if specified within the dealing) cease earlier or be revoked.³⁹

To date, several Emergency Dealing Determinations have been made to allow importation, transportation and other dealings with genetically modified organisms.⁴⁰ The Gene Technology

³⁰ The Institutional Biosafety Committee of Notifiable Low Risk Dealings is a committee established as an Institutional Biosafety Committee in accordance with written guidelines issued by the Gene Technology Regulator. Gene Technology Act 2000 (Cth) § 10.

³¹ *Id.* § 75(2).

³² *Id.* § 32(3); Gene Technology Regulations 2001 (Cth).

³³ Gene Technology Act 2000 (Cth) §§ 141, 143(3).

³⁴ The relevant Minister would be the Commonwealth Minister for Health and Ageing.

³⁵ Gene Technology Act 2000 (Cth) §§ 72B(3).

³⁶ That is, the Commonwealth Chief Medical Officer, the Commonwealth Chief Veterinary Officer, or the Commonwealth Chief Plant Protection Officer (or other person prescribed by the regulations). *Id.* § 72B(2).

³⁷ *Id.* § 72B(2).

³⁸ *Id.* § 72B(4).

³⁹ *Id.* § 72C.

⁴⁰ These include: Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007 (Cth), which provided for the dealings with Influenza A/equi-2/Kentucky/94[H3N8] recombinant Canarypox virus (vCP1529) and Influenza A/equi-2/Newmarket/2/93[H3N8] recombinant Canarypox virus (vCP1533) (contained in the vaccines PROTEQFLU, PROTEQFLU TE and RECOMBITEK FLU EQUINE INFLUENZA VIRUS vaccines (ceased)), available from the Australian Government ComLaw Web site, at [http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/CA75039BCA1E2559CA25735B0020192A/\\$file/1962007LL.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/CA75039BCA1E2559CA25735B0020192A/$file/1962007LL.pdf) (last visited June 6, 2008) (official source); and Gene Technology (Equine Influenza Vaccine) Emergency Dealing Extension Determination 2008, which permitted the continued use of the Equine Influenza virus vaccine (expires Sept. 19, 2008), available from the Australian Government ComLaw Website, at <http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/all/bytitle/782CCA33335F04A8CA25740C001668FA?OpenDocument> (last visited June 6, 2008) (official source).

Ministerial Council has released guidelines on the emergency provisions of the Gene Technology Act 2000 (Cth).⁴¹

Products that are derived from genetically modified organisms but that are not themselves genetically modified organisms are not regulated by the Gene Technology Act 2000 (Cth).⁴² For example, human tissue and cell extracts for therapeutic purposes achieved via chemical, pharmacological, or metabolic actions that are able to be “batch released” are likely to be regulated as medicines, while human derived tissue and cell products produced via a deliberate alteration of the cell or tissue that are not regulated as medicines are likely to be regulated as “therapeutic devices.”⁴³

The Australian government is currently working to introduce a national regulatory framework for human tissues and emerging biological therapies, and to amend the Therapeutic Goods Act 1989 (Cth) to accommodate therapeutic goods from viable human tissues.⁴⁴

IV. Regulation of Human Cloning and Research Involving Human Embryos

General

For constitutional reasons, issues surrounding human cloning and research involving human embryos is regulated by both Commonwealth and state legislation. Generally such state legislation is either complementary to or a mirror of the Commonwealth legislation and is supported by guidelines issued by the National Health and Medical Research Council (NHMRC).⁴⁵

The primary (Commonwealth) legislation is the Prohibition of Human Cloning for Reproduction Act 2002 (Cth) and the Research Involving Human Embryos Act 2002 (Cth).⁴⁶ The NHMRC is responsible for monitoring compliance with these Acts.⁴⁷

⁴¹ Guidelines for Emergency Response Under the Gene Technology Act 2000 (Cth) and the Gene Technology Agreement (Gene Technology Ministerial Council 2007), available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/gtmc-emergency+response+guidelines> (last visited June 6, 2008).

⁴² Such products may, however, be regulated by other legislation and regulatory agencies, such as the Therapeutic Goods Act 1989 (Cth), Therapeutic Goods Administration, Food Standards Australia New Zealand, and the Australian Pesticides and Veterinary Medicines Authority.

⁴³ Therapeutic Goods Act 1989 (Cth) § 41BD(3). See Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2004 (Dep’t of Health & Ageing, Therapeutic Goods Administration Apr. 21, 2004), available at <http://www.tga.gov.au/legis/tgdev0401.htm> (last visited June 13, 2008).

⁴⁴ See Proposed Regulatory Framework for Tissues and Emerging Biological Therapies (Dep’t of Health & Ageing, Therapeutic Goods Administration Feb. 27, 2004), available at <http://www.tga.gov.au/bt/prtisreg.htm> (last visited June 13, 2008).

⁴⁵ See NHMRC, “Commonwealth and State Legislation,” <http://www.nhmrc.gov.au/embryos/information/legislation/index.htm> (last visited June 11, 2008).

⁴⁶ Mirror legislation is in force in some States and Territories, e.g., the Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (NSW); Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003 (Qld); Infertility Treatment Act 1995 (Vic); Prohibition of Human Cloning Act 2003 (SA), Research Involving Human Embryos Act 2003 (SA); Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (Tas), Human Embryonic Research Regulation Act 2003 (Tas); Human embryo (Research) Act 2004 (ACT); and the Human Embryo (Research) Act 2004 (ACT). Other jurisdictions prohibit cloning; for example, in Western Australia, under the Human Reproductive Technology Act 1991 (WA), it is an offense to permit any procedure to be carried out directed at: human cloning, the obtaining of an embryo by means of embryo flushing, or the production of a chimera. Human Reproductive Technology Act 1991 (WA) § 7(1)(d).

⁴⁷ For information on compliance, see Australian Gov’t, Nat. Health & Medical Research Council, Booklet 4: Monitoring Compliance with the *Research Involving Human Embryos Act 2002* and the *Prohibition of Human Cloning Act 2002* (2006), available at <http://www.nhmrc.gov.au/publications/synopses/files/number4.pdf> (last visited June 13, 2008).

Human cloning

The Prohibition of Human Cloning for Reproduction Act 2002 (Cth) provides for some practices to be completely prohibited and for some to be permitted only under license. In accordance with § 9 of the Act, human cloning is banned within Australia. Beginning June 12, 2007, however, researchers have been able to apply for licenses to conduct human cloning to make embryonic stem cells.⁴⁸

Prohibited practices and practices prohibited other than under a license are offenses.⁴⁹ Offenses with a maximum penalty of fifteen years imprisonment include:

- Placing a human embryo clone in the human body or the body of an animal;
- Importing or exporting a human embryo clone;
- Creating a human embryo for a purpose other than achieving pregnancy in a woman;
- Creating or developing a human embryo by fertilization that contains genetic material provided by more than two persons;
- Developing a human embryo outside the body of a woman for more than fourteen days (excluding any period when the development is suspended);
- Intentional heritable alterations to a genome;
- Collecting a viable human embryo from the body of a woman with the intention of collecting a viable human embryo;
- Creating a chimeric embryo;⁵⁰
- Developing a hybrid embryo for more than fourteen days (excluding any period of suspended development);
- Placing of an embryo in an animal or in a human body other than in the female reproductive tract or an animal embryo within a human;
- Importing, exporting or placing a “prohibited embryo”⁵¹ (i.e., genetically one created other than by fertilization of a human egg by human sperm, created other than with the intention of pregnancy, or with genetic material of more than two persons);
- Commercial trading in human eggs, human sperm or human embryos; or
- Creating a human embryo other than by fertilization, or developing such an embryo other than under license.

Offenses with a maximum penalty of ten years imprisonment include:

- Creating or developing a human embryo containing genetic material provided by more than two persons other than under license;
- Using precursor cells from a human embryo or a human fetus to create a human embryo, or

⁴⁸ Prohibition of Human Cloning for Reproduction Act 2002 (Cth) § 23A.

⁴⁹ *Id.* §§ 9, 10, 12 – 23B.

⁵⁰ That is, a human embryo into which a cell, or any component part of a cell, of an animal has been introduced, or as declared by the regulations to be a chimeric embryo. Prohibition of Human Cloning for Reproduction Act 2002 (Cth) § 8.

⁵¹ A prohibited embryo is defined as: “(a) a human embryo created by a process other than the fertilisation of a human egg by human sperm; or (b) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman; or (c) a human embryo that contains genetic material provided by more than 2 persons; or (d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended; or (e) a human embryo created using precursor cells taken from a human embryo or a human fetus; or (f) a human embryo that contains a human cell (within the meaning of section 15) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or (g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or (h) a chimeric embryo or a hybrid embryo.” *Id.* § 20(4).

- developing such an embryo without a license, or with recklessness as to whether or not the activity is permitted by license; or
- Creating a hybrid embryo without authorization by license.

Human embryos

The Research Involving Human Embryos Act 2002 (Cth) provides a regulatory framework for the use of excess “assisted reproductive technology” embryos, and, establishes the National Health and Medical Council Licensing Committee.⁵² All uses (other than exempt uses) of excess embryos require a license issued by the NHMRC Licensing Committee.⁵³ Exempt uses include: storage; removal from storage or transportation; observation; allowing the excess embryo to succumb; use by an accredited assisted reproductive technology center (where the embryo is not biologically suitable for implantation); use by an accredited assisted reproductive technology center as part of a diagnostic investigation (in connection with the woman for whom the embryo was created); or use that is otherwise prescribed by regulation.⁵⁴

The following offenses are prescribed by law and carry a maximum penalty of five years imprisonment:

- Use of an excess ART embryo –intentionally use an excess assisted reproductive technology embryo (unless under license or the use is an ‘exempt use’);⁵⁵
- Use of other embryos - intentionally use (other than under license) an embryos that is created:
 1. other than via fertilization of a human egg by a human sperm;
 2. to contain genetic material provided by more than two persons (other than the fertilization of a human egg by a human sperm);
 3. using precursor cells taken from a human embryo or a human fetus;
 4. as a hybrid embryo;⁵⁶
- Certain activities involving use of human eggs - undertake research or training involving the fertilization of a human egg by a human sperm (up to, but not including, the first mitotic division), outside the body of a woman for the purposes of research or training in assisted

⁵² The functions of the National Health and Medical Council Licensing Committee are to perform functions in relation to licenses under Division 4, that is, review and authorize licenses for:

...use of excess embryos; creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos; creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos; creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos; research and training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in assisted reproductive technology; creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and use of such embryos up to, but not including, the first mitotic division, if: the creation or use is for the purposes of testing sperm quality; and the creation or use will occur in an accredited assisted reproductive technology centre. And perform functions in relation to databases under Division 5 (that is maintain a publicly accessible database with information about each license and licensee).

Research Involving Human Embryos Act 2002 (Cth) §§ 14, 21, 29.

⁵³ *Id.* §§ 10-12. For further information, see NHMRC, *Applying for a Licence under the Research Involving Human Embryos Act 2002*, <http://www.nhmrc.gov.au/publications/synopses/number2syn.htm> (last visited June 13, 2008).

⁵⁴ Research Involving Human Embryos Act 2002 (Cth) § 10(2).

⁵⁵ *Id.* § 10(1).

⁵⁶ *Id.* § 10A.

- reproductive technology (other than under license);⁵⁷
- Use of an embryo that is not an excess ART embryo - use an embryo (that is not an excess assisted reproductive technology embryo) outside the body of a woman (other than for the purposes of assisted reproductive technology by an accredited assisted reproductive technology center);⁵⁸ or
- Breach of a license condition - intentionally or recklessly breach a license condition.⁵⁹

A license may only be issued where the NHMRC Licensing Committee is satisfied that the activity or project proposed has been assessed and approved by the Human Research and Ethics Committee, in accordance with the NHMRC's NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH (hereinafter, NATIONAL STATEMENT ON ETHICAL CONDUCT),⁶⁰ and, that the applicant has complied with all statutory requirements, such as obtaining proper consent.⁶¹ Further in deciding whether or not to issue the license the Committee must have regard to specified matters including restricting the number of embryos to that necessary to achieve the research goal.⁶²

There is no legislative regulation of research using derived human stem cells (that is, the license granted by the NHMRC Licensing Committee covers use of excess embryos not subsequent research on stem cells).⁶³ However all research use of human stem cell lines must comply with relevant NHMRC guidelines,⁶⁴ including the NATIONAL STATEMENT ON ETHICAL CONDUCT⁶⁵ and require prior approval from a Human Research and Ethics Committee that is constituted in accordance with, and acting in

⁵⁷ *Id* § 10B.

⁵⁸ *Id* § 11.

⁵⁹ *Id* § 12

⁶⁰ Research Involving Human Embryos Act 2002 (Cth) § 21(3)(c). The committee must not issue the license unless it is satisfied of the following: "(a) that appropriate protocols are in place: (i) to enable proper consent to be obtained before an excess ART [assisted reproductive technology] embryo or human egg is used, or other embryo is created or used under the licence (see paragraph 24(1)(a)); and (ii) to enable compliance with any restrictions on such consent; (b) if the use of an excess ART [assisted reproductive technology] embryo proposed in the application may damage or destroy the embryo—that appropriate protocols are in place to enable compliance with the condition that such use is authorised only in respect of an embryo created before 5 April 2002 (see subsection 24(3)); (c) that the activity or project proposed in the application has been assessed and approved by a HREC [Human Research and Ethics Committee] that is constituted in accordance with, and acting in compliance with, the NHMRC NATIONAL STATEMENT ON ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS (1999), as in force from time to time." NHMRC, NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH (2007), *available at* http://www.nhmrc.gov.au/publications/2007_humans/contents.htm (last visited June 13, 2008).

⁶¹ Research Involving Human Embryos Act 2002 (Cth) § 21(3)(a).

⁶² Specifically the committee must have regard to: "(a) restricting the number of excess ART [assisted reproductive technology] embryos, other embryos or human eggs, to that likely to be necessary to achieve the goals of the activity or project proposed in the application; (b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART [assisted reproductive technology] embryos or human eggs, or the creation or use of other embryos, proposed in the application, which could not reasonably be achieved by other means; (c) any relevant guidelines, or relevant parts of guidelines, issued by the CEO of the NHMRC [National Health and Medical Research Council] under the NHMRC Act 1992 and prescribed by the regulations for the purposes of this paragraph; (d) the HREC [Human Research Ethics Committee] assessment of the application mentioned in paragraph (3)(c); (e) such additional matters (if any) as are prescribed by the regulations." Research Involving Human Embryos Act 2002 (Cth) § 21(4).

⁶³ See NMRC, *Information on Stem Cell Research, Research using Human Stem Cells*, <http://www.nhmrc.gov.au/ethics/human/issues/stemcell.htm> (last visited June 11, 2008).

⁶⁴ Guidelines are made under the NHMRC Act 1992 (Cth).

⁶⁵ *Supra* note 51.

compliance with, the NATIONAL STATEMENT ON ETHICAL CONDUCT.⁶⁶

The NHMRC has issued guidelines governing assisted reproductive technology, which include procedures for obtaining consent from couples who seek to declare their embryos excess and available for research purposes.⁶⁷

Embryos Used in Australia

As of March 31, 2007, 329 excess embryos had been used in licensed research in Australia. The NHMRC Embryo Research Licensing Committee had issued nine licenses authorizing the use of up to 1,915 excess embryos, four of which authorized the use of up to 550 excess embryos for the derivation of human embryonic stem cells (of which 197 had been used).⁶⁸

V. Regulation of Genetic Screening, Pre-implantation Genetic Diagnosis and Resulting Information

Information resulting from genetic testing is protected via the Privacy Act 1988 (Cth).⁶⁹ The Privacy Act 1988 (Cth) establishes standards regarding the collection, storage, and release of personal information and health information.⁷⁰ Information held by public hospitals are also subject to the laws of the state or territory in which the hospital resides. Generally, genetic information may not be released without the consent of the individual involved.⁷¹ The NHMRC has issued guidelines regarding the privacy of persons involved in medical research⁷² and the establishment of a genetic register.⁷³

The NHMRC ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY IN CLINICAL PRACTICE AND RESEARCH (hereinafter, ART GUIDELINES) state that: “pending further community discussion, sex selection (by whatever means) must not be undertaken except to reduce the

⁶⁶ See *supra* note 57.

⁶⁷ See NHMRC, ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY IN CLINICAL PRACTICE AND RESEARCH (ART guidelines) (June 2007), available at <http://www.nhmrc.gov.au/publications/synopses/files/e78.pdf> (last visited June 9, 2008).

⁶⁸ In accordance with the Research Involving Human Embryos Act 2002 (Cth) § 29, the NHMRC must maintain a public database containing information in relation to each license authorizing the use of excess embryos. The database is available at <http://www.nhmrc.gov.au/embryos/monitor/database/index.htm> (last visited June 9, 2008).

⁶⁹ For further information, see BIOTECHNOLOGY AUSTRALIA, BIOTECHNOLOGY FACT SHEET NO. 20: GENETIC TESTING AND PRIVACY (Nov. 2004), available at <http://www.biotechnology.gov.au/index.cfm?event=object.showContent&objectID=D3040B21-BCD6-81AC-1DDED9681B30EBE7> (last visited June 13, 2008).

⁷⁰ See NATIONAL PRIVACY COMMISSIONER, MY HEALTH MY PRIVACY MY CHOICE: A CONSUMER'S GUIDE TO PRIVACY AND HEALTH INFORMATION, available at <http://www.privacy.gov.au/publications/chib.pdf> (last visited June 13, 2008).

⁷¹ Privacy Act 1988 (Cth), Schedule 3, Principle 2 – Use and Disclosure, reproduced in OFFICE OF THE PRIVACY COMMISSIONER, PRIVATE SECTOR INFORMATION SHEET 1A – NATIONAL PRIVACY PRINCIPLES (Feb. 2008), available at <http://www.privacy.gov.au/publications/npps01.pdf> (last visited June 13, 2008).

⁷² NHMRC, GUIDELINES UNDER SECTION 95 OF THE PRIVACY ACT 1988 (March 2000), available at <http://www.nhmrc.gov.au/publications/synopses/files/e26.pdf> (last visited June 9, 2008); NHMRC, GUIDELINES APPROVED UNDER SECTION 95A OF THE PRIVACY ACT 1988 (Dec. 2001), available at <http://www.nhmrc.gov.au/publications/synopses/files/e43.pdf> (last visited June 13, 2008). Compliance with these guidelines is required by the National Privacy Principles established by the Privacy Act 1988 (Cth).

⁷³ See NHMRC, GUIDELINES FOR GENETIC REGISTERS AND ASSOCIATED GENETIC MATERIAL (1999), available at <http://www.nhmrc.gov.au/publications/synopses/files/e14.pdf> (last visited June 9, 2008).

risk of transmission of a serious genetic condition[,]”⁷⁴ and that preimplantation genetic diagnosis (PGD) must not be used for “prevention of conditions that do not seriously harm the person to be born; selection of the sex of an embryo except to reduce the risk of transmission of a serious genetic condition; or selection in favour of a genetic defect or disability in the person to be born.”⁷⁵

Generally, NHMRC guidelines are not mandatory; however, if specified as a license conditions or within legislation, they may have the force of law. Thus, in accordance with the Research into Human Embryos Act 2002 (Cth) §21(3)(c), the NHMRC Licensing Committee must not issue a license unless the proposed activity has been approved by a Human Research Ethics Committee acting in accordance with the NATIONAL STATEMENT FOR RESEARCH INVOLVING HUMAN GAMETES OR EMBRYOS, and this statement requires such research to be governed by any assisted reproductive technology guidelines. In this way, researchers must comply with the NHMRC’s ART GUIDELINES.⁷⁶

The NHMRC has released a report that examined case studies involving ethical dilemmas arising from human research, including gene therapy.⁷⁷

VI. Import and Export of Genetic Technology

The Australian Quarantine Inspection Service (AQIS) regulates the importation into Australia of all plant, animal, or biological material that may pose a risk to quarantine or pose a risk of disease. AQIS imposes import conditions on all human tissue and cell lines.⁷⁸ All imported products containing viable genetically modified organisms must declare this presence on the import permits and indicate the relevant authorization under the Gene Technology Act 2000 (Cth).⁷⁹

It is an offense to import or export to or from Australia a “prohibited embryo” or a human embryo clone or to trade commercially in human embryos within Australia.⁸⁰ The import of human embryos may also be regulated at the state level; for example, in accordance with the Infertility Treatment Act 1995 (Victoria), the import or export of gametes or embryos into or out of Victoria is prohibited unless undertaken with the written approval of the Infertility Treatment Authority. However it is permitted (with

⁷⁴ *Supra* note 62, ¶11.1, available at <http://www.nhmrc.gov.au/publications/synopses/files/e78.pdf> (last visited June 13, 2008).

⁷⁵ *Id.* ¶12.

⁷⁶ *Supra* note 62. Background information is available in NHMRC, ETHICAL ASPECTS OF HUMAN GENETIC TESTING: AN INFORMATION PAPER (2000), available at <http://www.nhmrc.gov.au/publications/synopses/files/e39.pdf> (last visited June 13, 2008). See also AUSTRALIAN LAW REFORM COMMISSION, ESSENTIALLY YOURS: THE PROTECTION OF HUMAN GENETIC INFORMATION IN AUSTRALIA (ALRC 96, 2003), available at <http://www.austlii.edu.au/au/other/alcrc/publications/reports/96/> (last visited June 13, 2008).

⁷⁷ NHMRC, CHALLENGING ETHICAL ISSUES IN CONTEMPORARY RESEARCH ON HUMAN BEINGS, Case Study H (Dec. 2006), available at <http://www.nhmrc.gov.au/publications/synopses/files/e73.pdf> (last visited June 13, 2008).

⁷⁸ See Import Conditions, Human Antibodies and Cell Lines: Therapeutic Use (Australian Quarantine & Inspection Serv., Dep’t of Agric., Fisheries & Forestry, June 2008), available at http://www.aqis.gov.au/icon32/asp/ex_casecontent.asp?intNodeId=8096615&intCommodityId=17017&Types=none&WhichQuery=Go+to+full+text&intSearch=1&LogSessionID=0 (last visited June 13, 2008).

⁷⁹ Quarantine Act 1908 (Cth); Imported Food Control Act 1992 (Cth). See Office of the Gene Technology Registrar, *Importation Requirements for GMOs*, <http://www.ogtr.gov.au/moncomp/imports.htm> (last visited June 13, 2008).

⁸⁰ Prohibition of Human Cloning for Reproduction Act 2002 (Cth) §§10, 20, 21.

appropriate export and import permission) to import to or export from Australia human embryonic stem cell lines that have been derived from human embryos using practices consistent with those applicable in Australia.⁸¹

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⁸¹ Prohibition of Human Cloning for Reproduction Act 2002 (Cth) § 23C; Customs (Prohibited Exports) Regulations 1958 (Cth) r.8.

LAW LIBRARY OF CONGRESS
REGULATION OF HUMAN GENETIC TECHNOLOGY
CANADA

Executive Summary

Since 2004, Canada has had legislation that prohibits some genetic technologies and places controls on cloning and other assisted reproduction activities. Offenses under the relevant act are punishable with stiff fines and fairly lengthy periods of imprisonment. Canada does not have legislation respecting research on stem cells that have already been derived. However, the Canadian Institutes of Health Research have developed guidelines for the federal funding of such research that follows the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.

I. Background

In 2004, the Parliament of Canada enacted the Assisted Human Reproduction Act [hereinafter referred to as “the AHR”].¹ The Government of Canada had been attempting to establish legislative and regulatory controls over the field ever since the Royal Commission on New Reproductive Technologies was created in 1989. That Royal Commission released its report entitled *Proceed With Care* in 1993,² and in 1995, the Minister of Health announced an interim voluntary moratorium on human cloning and on paying surrogate mothers. Three government bills were subsequently introduced in the House of Commons for the purpose of generally implementing the Royal Commission’s recommendations, but none of these bills were passed prior to the conclusion of the legislative session in which they received first reading. The AHR was thus the first Canadian law to establish a legal framework for regulating its field of concern. Prior to its passage, but after the release of *Proceed With Care*, the field had been again studied by the House of Commons Standing Committee on Health. The AHR follows the Royal Commission’s and the Standing Committee’s recommendation that Canada prohibit certain activities considered to be contrary to human dignity and societal values and regulate other activities considered to be open to abuse.³

II. The Guiding Principles

Section 2 of the AHR establishes seven guiding principles. These principles were derived from government-commissioned studies and are as follows:

1. The health and well-being of children born through the application of assisted reproductive technologies must be given priority in all decisions respecting their use.
2. The benefits of technology can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity, and rights in its usage.
3. Women are more significantly affected by AHR than men and their health must be protected.

¹ 2004 S.C. c. 2 (official source), also available at http://lois.justice.gc.ca/en/showdoc/cs/A-13.4/20080612/en?command=home&caller=SI&search_type=all&shorttitle=assisted%20reproduction&day=12&month=6&year=2008&search_domain=cs&showall=L&statuteyear=all&lengthannual=50&length=50&noCookie (unofficial source).

² Canada, Royal Commission on New Reproductive Technologies, *PROCEED WITH CARE: FINAL REPORT OF THE ROYAL COMMISSION ON NEW REPRODUCTIVE TECHNOLOGIES* (1993).

³ Library of Parliament, *Legisinfo: Bill C-6: Assisted Human Reproduction Act*, 2004, at 3.

4. The principle of free and informed consent must be followed.
5. Persons seeking assisted reproduction procedures must not be discriminated against on the basis of sexual orientation or marital status.
6. Trade in reproductive capabilities and exploitation of children must be prohibited.
7. Human individuality and diversity must be preserved and protected.⁴

These principles are not addressed separately, but are incorporated in the legislation.

III. Prohibited Activities

Following the statement of principles, the AHR sets out a series of prohibitions. Section 5(1) of this statute deals mostly with cloning and contains provisions prohibiting:

- reproductive and therapeutic human cloning;
- creating an *in vitro* embryo for any purpose other than creating a human being or improving assisted reproduction procedures;
- creating an embryo from a cell or part of a cell for the purpose of creating a human being;
- maintaining an embryo outside the body of a female more than fourteen days after its development following fertilization;
- performing any procedure on an embryo for the purpose of sex selection except to prevent, diagnose, or treat a sex-linked disorder or disease;
- altering the genome of a cell of a human being or *in vitro* embryo in a manner that the alteration is capable of being transmitted to descendants;
- transplanting a sperm, ovum, embryo, or fetus of a non-human life form into a human being;
- use of any human reproductive material or an *in vitro* embryo that is or was transplanted into a non-human life form;
- creating a chimera; (This term is defined to mean an embryo into which a cell of any non-human life form has been introduced or that contains the cells of more than one embryo.)
- creating a hybrid for the purpose of reproduction.⁵

Subsequent subsections of section 5 prohibit the offering or advertising of anything prohibited by the above provisions or offering to pay for a prohibited activity.

Section 6 of the AHR addresses the use of surrogates. This section prohibits the payment of compensation to surrogate mothers, as well as offering to pay or advertise for surrogate mothers.⁶ Additionally, section 6 prohibits persons from acting as intermediaries for surrogate mothers and from counseling or inducing a woman under the age of twenty-one to become a surrogate mother. However, the AHR does not generally prohibit women from becoming surrogate mothers or affect the validity of otherwise lawful agreements under provincial law.

Section 7 of the AHR prohibits the purchase, offering to purchase, or advertising for purchase of sperm or ova from a donor or person acting on behalf of a donor. Section 8 prohibits the removal of reproductive material from a deceased donor without the written consent of that person. Finally, section 9 of the AHR prohibits the obtaining of sperm or ovum from anyone under the age of eighteen, except for the purpose of creating a person that will be raised by the donor.⁷

⁴ 2004 S.C. c. 2, s. 2.

⁵ *Id.*, S. 5.

⁶ *Id.*, S. 6.

⁷ *Id.*, Ss. 7-9.

IV. Penalties

The Constitution Act, 1867 gives the Parliament of Canada exclusive jurisdiction to create criminal laws for the country,⁸ and Parliament's jurisdiction to enact the AHR is at least partially based upon this power. The AHR contains maximum, but not minimum, sentences and fines. A person convicted of violating any of the provisions of sections 5 to 9 of the Act is liable to imprisonment for up to ten years and a fine of up to Can\$500,000, (approximately US\$486,000), if he or she is indicted. However, prosecutors have the discretion to have an accused person tried in summary proceedings. A person tried summarily is liable to imprisonment for up to four years and a fine of up to Can\$250,000 (approximately US\$243,000).⁹

V. Controlled Activities

Sections 10-12 of the AHR require the following activities to be carried out under a license in accordance with government regulations:

- altering, manipulating, or treating any reproductive material to create an embryo;
- altering, manipulating, treating, or making use of an *in vitro* embryo;
- acquiring, storing, transferring, destroying, importing, or exporting sperm or ova for the purpose of creating an embryo;
- combining any part of the human genome with any part of the genome of another species; and
- reimbursing expenditures incurred by donors of sperm or ova or surrogate mothers. However, the AHR does allow surrogate mothers to be reimbursed for loss of income from work if continuing to work might pose a threat to their health.

Any person who contravenes any of the above provisions or any other part of the AHR, excluding the more serious offenses classified as prohibited activities, is liable to imprisonment for up to five years and a fine of Can\$250,000, (approximately US\$243,000), if tried by way of an indictment and two years imprisonment and a fine of up to Can\$100,000 (approximately US\$97,100), if tried in summary proceedings.¹⁰

VI. Privacy and Access to Information

The AHR sets out extensive rules respecting the obtaining, collection, and reporting of personal health information. Licensees are required to collect health reporting information before accepting a donation or performing a controlled activity. Licensees must inform persons of the requirements respecting the retention, use, provision, and destruction of human reproductive material, as well as obtaining the written consent of patients to reproductive services. Licensees are generally prohibited from disclosing personal health information except to the Assisted Human Reproductive Agency of Canada. This agency was created to monitor the activities of licensees, and it is also prohibited from releasing personal health information except for the purposes of enforcing the AHR and for certain specific purposes. For example, the Agency is required to disclose to any two individuals the nature of their relationship if they believe they are genetically related to one another. The agency is also required to disclose donor-identifying information to a physician, where there is a health or safety risk to a person

⁸ Constitution Act, 1867, R.S.C. No. 5 (Appendix 1985 (official source)).

⁹ 2004 S.C. c. 2, s. 60.

¹⁰ *Id.*, s. 61.

who was conceived by a AHR procedure. The agency can disclose non-identifying information for research or statistical purposes.¹¹

VII. Transfers of Technology

The AHR does not establish special rules for transfers of technology outside of the country. The rules that apply within Canada also apply to activities that have an international dimension. Thus, both prohibited and controlled activities are regulated in cases in which AHR procedures are either initiated in or performed in part in Canada.

VIII. Stem Cell Research

The AHR does not apply to research using human embryonic stem cell lines that have already been derived. The rules for federal funding of such research were set out by the Canadian Institutes of Health Research in the *Updated Guidelines for Human Pluripotent Stem Cell Research* of June 29, 2007.¹² These updated guidelines are based on principles established in the Tri-Council Policy Statement on the ethical standards governing research on human tissues, biological fluids, embryos, and fetuses. The guidelines provide that no funding will be granted without the prior review and approval of the Stem Cell Oversight Committee. Under the guidelines, funding for research on embryos that were originally created for reproductive purposes may be authorized. The types of research that do not conform to the guidelines are:

- research involving the creation of human embryos specifically to derive stem cell lines of a pluripotent nature;
- cloning and parthenogenesis for the purpose of developing embryonic stem cells or cell lines;
- research involving the directed donation of stem cell lines, unless the research involves autologous donation;
- research in which human or non-human cells that are likely to be pluripotent are grafted to a human fetus; and
- research in which human cells that are likely to be pluripotent are grafted to a non-human fetus.

Researchers who make stem cell lines available to other academics are required to ensure that they are anonymized.¹³

IX. Concluding Remarks

Canada's AHR prohibits cloning and a number of related activities such as sex-selection. This statute does not apply to research involving human stem cell research. This field is generally governed by the Updated Guidelines adopted by the Canadian Institutes of Health Research in 2007.

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¹¹ *Id.*, S. 18.

¹² Canadian Institutes of Health, *Updated Guidelines for Human Pluripotent Stem Cell Research*, June 29, 2007, available at <http://www.cihr-irsc.gc.ca/e/34460.html>.

¹³ *Id.*, S. 8.

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REGULATION OF HUMAN GENETIC TECHNOLOGY

FRANCE

Executive Summary

The 2004 Bioethics Law prohibits reproductive cloning, which constitutes a crime against the human species. It also prohibits therapeutic cloning. Pre-implantation genetic diagnosis is strictly regulated. Research on human embryos and embryonic stem cells is, as a general rule, prohibited, with a special dispensation for a five-year period for unused embryos conceived in vitro in medically assisted procreation programs and on stem cell lines from abroad created under the same conditions. The Law created a new agency, the Biomedicine Agency. Among other tasks, it ensures that research on human embryos is carried out ethically, with a high level of transparency. No part of the human body, at any stage in its formation and development, can constitute a patentable invention. Only an invention that is a technical application of a function of an element of the human body may be protected by a patent.

I. Introduction

France adopted its first Bioethics laws in 1994. The laws set out principles including the primacy of the human person; respect for the human being from the beginning of life; inalienability of the human body, its elements, and products; and respect for the integrity of the human species.¹ None of these laws referred specifically to cloning, but in light of the principles they set out, they have been interpreted as forbidding all possibility of human cloning. These Laws were later amended to take into account new scientific developments, and a new Bioethics Law based on the same principles was promulgated on August 6, 2004, after three years of parliamentary debates. The length of the parliamentary debates showed the difficult ethical issues at stake and highlighted the need to find “a balance point between the protection of the fundamental rights of a person and not impeding research.”² The 2004 Law is scheduled to be revised in 2009.³

II. Prohibition Cloning; Inheritable Genetic Modification

The 2004 Law specifically prohibits reproductive cloning and any modification to genetic traits with the purpose of modifying the descent of a person, also referred to as “inheritable genetic modification.” The main provision reads as follow:⁴

No one is permitted to violate the integrity of the human species.
Any eugenic practice with a view to organizing a selection of persons is prohibited.
Any intervention for the purpose of causing the birth of a child genetically identical to another person alive or dead is prohibited.

¹ CODE CIVIL, arts. 16 & 16-1 (Daloz 2008) (unofficial source widely used by attorneys and judges).

² La Documentation Française, La loi de Bioéthique de 2004, <http://www.ladocumentationfrancaise.fr/dossiers/bioethique/loi-bioethique-2004.shtml> (unofficial source, last visited June 11, 2008).

³ *Id.*

⁴ CODE CIVIL, art. 16-4 (Daloz 2008).

Without prejudice to research for the prevention and treatment of genetic diseases, no modification can be made to genetic traits with the purpose of modifying the descent of a person. [Translation by author of this report]

The general prohibition on reproductive cloning is reiterated in the Code of Public Health.⁵ Violation of any of the prohibitions listed above is punishable by thirty years of imprisonment and a €7,500,000 fine (about US\$11.6 million). The penalties are increased to life imprisonment and a €7,500,000 fine when the offenses are committed by an organized gang.⁶

In vitro conception of human embryos or creation of a human embryo by way of cloning for research,⁷ commercial, or industrial purposes is prohibited.⁸ In addition, creation of a human embryo by way of cloning for therapeutic use is also prohibited.⁹ In prohibiting therapeutic cloning, Parliament did not follow the opinion of a majority of the members of the National Consultative Ethics Committee for Health and Life (CCNE).

The CCNE is an independent authority whose primary mission is to render opinions on ethical issues raised by progress in the fields of biology, medicine, and health. In its opinion on the preliminary draft revision of the 1994 Bioethics Laws, the CCNE noted that therapeutic cloning raised extremely difficult ethical issues. On one hand, the Committee considers that “society has a duty to encourage therapeutic progress and to hasten improvements in the prevention and treatment of diseases” and that therapeutic cloning offers “ambitious therapeutic possibilities.” On the other hand, it noted that “it is a transgression of the rules regarding the respect owed to the embryo because of its unique nature and is a step forward in its reification.” A majority of the Committee’s members favored therapeutic cloning under strict conditions.¹⁰

Violation of the prohibitions on therapeutic cloning or on the creation of a human embryo for research, commercial, or industrial purposes is punishable by seven years of imprisonment and a €100,000 fine.¹¹ Additional criminal offenses include:

- agreeing to the extraction of cells or gametes with a view to causing the birth of a child genetically identical to another person living or deceased. This offense is punishable by ten years of imprisonment and a fine of €150,000;¹²
- inciting another person, whether by gifts, promises, threats, orders, or abuse of authority, to agree to the extraction of cells or gametes with a view to causing the birth of a child genetically identical to another person living or deceased. This offense is punishable by three years of imprisonment and a €45,000 fine;¹³ and

⁵ CODE DE LA SANTE PUBLIQUE, art. L 2151-1 (Daloz 2007).

⁶ CODE PÉNAL, arts. 214-1 to 214-4 (Daloz 2008).

⁷ CODE DE LA SANTE PUBLIQUE, art. L 2151-2 (Daloz 2007).

⁸ *Id.*, art. L 2151-3

⁹ *Id.*, art. L 2151-4.

¹⁰ Comité Consultatif National d’Ethique, *Avis 67 sur l’avant projet de révision des lois de bioéthique*, Jan,18, 2001, available at <http://www.ccne-ethique.fr/docs/fr/avis067.pdf>.

¹¹ CODE PENAL, arts. 511-17, 511-18 & 511-18-1 (Daloz 2008).

¹² *Id.*, art. 511-1.

¹³ *Id.*, art. 511-1-2.

- the same penalties apply to propaganda or advertising, in whatever form, in favor of eugenic practices or reproductive cloning.¹⁴

III. Research on Human Embryos and Embryonic Stem Cells

The Bioethics Law of August 6, 2004, prohibits research on embryos. However, it provides that, as an exception to the general rule and for an experimental period of five years, “research may be authorized on embryos and embryonic stem cells when such research may result in major therapeutic benefits and on the condition that there is no other alternative method of research available and with comparable effectiveness.”¹⁵ This provision is in line with the opinion of the CCNE, which is “in favor of opening up limited and regulated research possibilities on spare embryos.” The CCNE was concerned about “the risk of ethical misuse which could result from the reification of the human embryo, that is to say to consider it as a thing and no longer as a potential human being” if research was opened without strict regulation.

An implementing decree setting forth the conditions applicable to the research was published eighteen months later.¹⁶ It enables French scientists to work on stem cell lines derived domestically from unused embryos conceived in vitro in medically assisted procreation programs and on stem cell lines from abroad created under the same conditions. During a five-year period, starting from the date of publication of the decree, researchers may use embryos from couples undergoing in vitro fertilization. They include:

1. spare embryos no longer required for fertility treatments. The couple must give written consent for the donation of the embryo for research purposes and cannot receive any remuneration. There is a three-month reflection period, and consent must be reaffirmed at the end of the period;
2. embryos in a condition unsuitable for re-implantation or storage for a future pregnancy; and
3. embryos carrying an abnormality for which there was pre-implantation screening.¹⁷

Authorization from the couple is also mandatory in the last two situations.

The Biomedicine Agency authorizes and supervises the research. This new public agency, under the supervision of the Ministry of Health, was created by the 2004 Law and operates in four key areas of human medicine and biology: assisted reproductive technologies; prenatal and genetic diagnosis; embryo and stem cell research and procurement; and transplant of organs, tissues, and cells. One of the Agency’s missions is to ensure that research on human embryos and on the cells derived from them is carried out ethically and with a high level of transparency, in strict accordance with the Bioethics Law.

Stringent criminal penalties apply to those violating the procedures set forth for embryos or embryonic cell research. Performing research on an embryo without authorization or without conforming to the protocols set forth by the Biomedicine Agency is punishable by seven years of imprisonment and a €100,000 fine.¹⁸ Unauthorized research on embryonic stem cells is punishable by two years of imprisonment and a €30,000 fine.¹⁹

IV. Pre-implantation Genetic Diagnosis

¹⁴ *Id.*

¹⁵ CODE DE LA SANTE PUBLIQUE, art. L 2151-5 (Daloz 2007).

¹⁶ Decree 2006-121, Feb. 6, 2006, regarding embryo research and on embryonic cells, and modifying the Code of Public Health, JOURNAL OFFICIEL, [France’s official gazette] Feb. 7, 2006, at 1974.

¹⁷ CODE DE LA SANTE PUBLIQUE, arts L 2151-1 to L 2151-8 (Daloz 2007).

¹⁸ CODE PÉNAL, art. 511-19 (Daloz 2008).

¹⁹ *Id.*

Pre-implantation genetic diagnosis (PGD) may only be carried under strict conditions and in exceptional circumstances.²⁰ A couple seeking PGD must have a high probability of giving birth to a genetically affected child, and the genetic defect must be of a particular severity and recognized as incurable at the time of the diagnosis. The genetic defect must be fully characterized in one of the parents or one of the immediate ascendants, and only the previously identified defect may be investigated. The parents must give their written consent for the PGD.²¹ It can only be carried out in a licensed center monitored by the Biomedicine Agency.²²

Exceptionally, PGD performed on cells taken from an *in vitro* embryo may also be carried for experimental purposes to attempt to cure a child who has an incurable genetic illness using the birth of a sibling not affected by the disease. In France, these children are sometimes referred to as “double hope babies” or “medicine babies.” The following conditions must be met:²³

The couple has given birth to a child having a genetic defect that will result in the death of the child in the first years of his/her life, which is incurable at the time of the diagnosis;
 The life prognosis of the child may be improved, in a conclusive way, by the implementation in him/her of a treatment that will not infringe upon the integrity of the body of the child born from the transfer of the embryo *in utero*, in conformity with article 16-3 of the Civil Code; [art 16-3 states that there may be no invasion of the integrity of the human body except in case of medical necessity or exceptionally in the therapeutic interests of others];
 The only diagnostic purposes are to research the genetic illness and the means to prevent it or to treat it and to implement the treatment referred to above. [Translation by author of this report.]

Violation of the provisions regarding pre-implantation genetic diagnosis is punishable by two years of imprisonment and a €30,000 fine.²⁴

V. DNA Identification and Collection

The study of a person’s DNA may only be undertaken for medical reasons or scientific research. A written, informed consent of the individual concerned is mandatory. The consent may be revoked at any time.²⁵ The identification of a person through a DNA profile may be ordered during a criminal investigation by a judge. It also may be undertaken for medical reasons and scientific research or to identify a soldier who has died in combat. In civil cases, this identification may only be sought in order to implement a judge’s investigation in cases including the establishment of paternity or for obtaining or canceling financial support. Prior and express consent must be secured from the person concerned. If a person did not expressly consent while alive, the identification by means of a DNA profile cannot take place after his/her death.²⁶ Violation of any of the above provisions is punishable by one year of imprisonment and a €15,000 fine.²⁷

In 1998, France established a national DNA database for the identification of sexual offenders, but gradually added other type of offenders. It now includes the following offenses: crimes against humanity, voluntary manslaughter, torture, barbaric acts, violence, terrorism, offenses against persons and property, drug trafficking, procuring, and money laundering. It contains DNA of convicted criminals and

²⁰ CODE DE LA SANTE PUBLIQUE, art. L 2131-4 (Daloz 2007).

²¹ *Id.*

²² *Id.*, art. L 2131-4-2.

²³ *Id.*, art. L 2131-4-1.

²⁴ CODE PÉNAL, art. 511 21 (Daloz 2008).

²⁵ CODE CIVIL, art. 16-10 4 (Daloz 2008) & CODE DE LA SANTE PUBLIQUE, art. L.1131-1 (Daloz 2007).

²⁶ CODE CIVIL, art. 16-11 (Daloz 2008).

²⁷ CODE PENAL, arts. 226-25 to 226-30 (Daloz 2008).

suspects and DNA collected at crime scenes.²⁸ The database is supervised by a judge and is only available to the national police and *gendarmerie*.

Genetic data are treated in the same way as other medical data in terms of confidentiality. They are protected by the general right to respect for one's private life as stated in the Civil Code²⁹ and by medical confidentiality. If the data collected are processed by a computer, the stringent legal requirements concerning personal data processing contained in Law 78-17 of January 1978, on Data Processing, Data Files, and Individual Liberties, as amended, apply.³⁰

VI. Importation and Exportation of Embryonic or Fetal Tissues or Cells

Importation and exportation of embryonic or fetal tissues or cells must be authorized by the Biomedicine Agency. The authorization may only be granted if the tissues and cells have been obtained in conformity with the fundamental principles set forth in the Civil Code (consent of the couple, absence of remuneration, etc). In addition, the exportation authorization is conditioned upon the participation of a French research body in the international research program.³¹ The Biomedicine Agency is also in charge of accrediting storage facilities for embryonic stem cells. Throughout the authorization period, the Agency carries out checks to ensure quality and safety.³²

Importation or exportation without authorization is punishable by two years of imprisonment and a €30,000 fine.

VI. Patentability of Biotechnical Inventions Relating to Certain Elements of the Human Body

The Code of Intellectual Property provides that “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.”³³ The basis for this prohibition is established by the Civil Code, which provides “the human body, its elements, and its products cannot be the object of any right of patrimony, and Conventions with a view to confer rights of patrimony to the human body, its elements, or its products are null and void.”³⁴ In several of its opinions, the CCNE has stated that the principle of not making commercial use of the human body is one of the cornerstones of bioethics laws and that the Civil Code provisions are “one of the main instruments to combat the risk of the human body being made into an instrument.”³⁵

The Code of Intellectual Property further states that “only an invention constituting the technical application of a function of an element of the human body may be protected by a patent.”³⁶ It specifies that the following cannot be patented: processes for cloning of human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and total or partial sequences of a gene as such. It also contains a general provision stating that

²⁸ CODE DE PROCÉDURE PÉNALE, arts 706-54 to 706-56-1 (Daloz 2008).

²⁹ CODE CIVIL, art. 9 (Daloz 2008).

³⁰ Included in the CODE PENAL (Daloz 2008) at 676.

³¹ CODE DE LA SANTE PUBLIQUE, art. L 2151-6 (Daloz 2007).

³² *Id.*, art. L 2151-7.

³³ CODE DE LA PROPRIETE INTELLECTUELLE, art. L 611-18. (Daloz 2007).

³⁴ CODE CIVIL, arts. 16-1 & 16-5 (Daloz 2008).

³⁵ Comité Consultatif National d’Ethique, *Avis 64 sur l’avant projet de loi portant transposition de la Directive 98/44/CE*, June 8, 2001, <http://www.ccne-ethique.fr/docs/fr/avis064.pdf> (last visited June 12, 2008).

³⁶ CODE DE LA PROPRIETE INTELLECTUELLE, art. L 611-18 (Daloz 2008).

inventions whose commercial exploitation is contrary to the dignity of the human beings, public order, or morality are not patentable.³⁷

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³⁷ *Id.*, art. L 611-17.

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REGULATION OF HUMAN GENETIC TECHNOLOGY
GERMANY

Executive Summary

Germany has very restrictive legislation on human genetic engineering that prohibits reproductive and therapeutic cloning, inheritable genetic modifications, and pre-implantation genetic diagnosis except for polar body diagnosis. Stem cell research must observe these prohibitions and is only permitted on certain imported stem cell lines. The German legislation is rooted in the constitutional guarantee of human rights.

I. Introduction

Germany has a very restrictive policy on human genetic engineering that may have developed in reaction to the eugenics policy of the Third Reich, when the “unfit” were sterilized or killed and those with the genetic make-up of the “master race” were encouraged to breed.¹ In 1949, Germany adopted a new Federal Constitution that guarantees human dignity as the most essential of human rights,² and this guarantee applies to the embryo and the fetus, thereby limiting human reproductive technology and genetic research in many ways.³

In 1990, Germany enacted an Embryo Protection Act⁴ that is based on the premise that constitutionally protected life exists as soon as a human egg cell is fertilized. According to the Act, fertilized human egg cells that are capable of development are deemed to be embryos as soon as the cell nuclei fuse. Moreover, the Act also affords embryo status to any totipotent cell that has been taken from an embryo and that is capable of partition and of developing into an individual⁵

On the basis of these definitions, German law prohibits much human genetic research or engineering that is permitted in other countries.⁶ Thus, cloning is prohibited and pre-implantation genetic diagnosis is at least severely restricted. In keeping with its philosophy, the Act also limits reproductive techniques to those producing outcomes foreseen by nature. Inheritable gene modification is specifically prohibited not only for embryos and fetuses, but for human beings at any stage of life. The Act provides stringent criminal penalties for violations.⁷

¹ A. Campbell, *Ethos and Economics, Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany, and Japan*, 31 AMERICAN JOURNAL OF LAW AND MEDICINE 47 (2005).

² Grundgesetz für die Bundesrepublik Deutschland [GG], May 23, 1949, BUNDESGESETZBLATT [BGBl, official law gazette of the Federal Republic of Germany] 1.

³ H. DREIER, 1 GRUNDGESETZ KOMMENTAR 173 (München, 2004).

⁴ Embryonenschutzgesetz [ESchG], Dec. 13, 1990, BGBl I at 2746, as amended by Gesetz, Oct. 23, 2001, BGBl I at 2702. A translation into English is available at the official Web site http://www.bmj.bund.de/enid/Publications/Embryo_Protection_Act_19u.html (last visited June 16, 2008).

⁵ ESchG, § 8

⁶ Max Planck Institut für ausländisches und internationales Strafrecht, *Rechtliche Regelung zur Fortpflanzungsmedizin in europäischen Ländern*, 2003, available at http://www.cueno.de/medr/show_all.asp.

⁷ The Embryo Protection Act was enacted as a criminal law because in 1990 the Federation lacked legislative power over matters relating to human reproduction and genetic research. In 1994, the Constitution was amended to grant these powers to the Federation [Gesetz, Oct. 27, 1994, BGBl I at 3146, art. 1 no. 6, introducing GG art. 74 ¶ 1 no. 26].

The strictures of the Embryo Protection Act originally prevented German scientists from working with stem cells, yet upon the urging of the scientific community, a compromise was reached that allowed the importation of certain stem cell lines that had been harvested before January 2002,⁸ and this cut-off date is about to be changed to 2007 (*see below*, “Stem Cell Research”). The stem cell issue shows that opinions are divided on the merits of genetic research and therapeutic cloning.

Different views also prevail on issues relating to genetic testing for non-medical purposes, and these have until now prevented the enactment of comprehensive legislation to regulate this growing field, even though there appears to be consensus that legislation is needed to forestall abuses.⁹

Internationally, the German positions also have shown certain ambivalence. Germany is not a member of the European Bioethics Convention,¹⁰ because Germany views the provisions of the Convention as not being protective enough.¹¹ In adherence to the same philosophy, Germany, together with France, proposed to the United Nations that an international convention against reproductive and therapeutic human cloning be prepared,¹² an effort that ultimately led to the United Nations Declaration on Human Cloning that was adopted by the General Assembly in 2005.¹³ In 2003, however, Germany changed its position and communicated to the United Nations that therapeutic (research) cloning should be permitted. It was alleged that this German position was intended to further the cause of changing German domestic legislation to make it less restrictive for German scientists.¹⁴

II. Cloning

Reproductive cloning is prohibited by section 6 of the Embryo Protection Act, which makes subject to a criminal penalty “anyone who causes artificially a human embryo to develop with the same genetic information as another embryo, fetus, human being or deceased person,” or who transfers such an embryo into a woman.

Therapeutic cloning is prohibited by section 2 of the Act, which penalizes any interference with an embryo that does not serve the purpose of its preservation. In addition, cloning methods that would involve the creation of hybrids or chimeras are also prohibited, because the creation of such organisms is prohibited by section 7 of the Act, and cloning through the transfer of a nucleus may also violate the prohibition of germ line alteration.¹⁵

Whereas Germans generally agree with the prohibition of reproductive cloning, opinions are divided on the desirability of prohibiting all therapeutic cloning. Many Germans find that cloning for

⁸ Gesetz zur Sicherstellung des Embryonenschutzgesetzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen [StZG], Jun. 28, 2002, The German text is available at the official Web site http://209.85.215.104/search?q=cache:3_RYAVvh8TQJ:www.bmbf.de/pub/stammzellgesetz.pdf+Stammzellengesetz&hl=de&ct=clnk&cd=6&gl=us&lr=lang_de.

⁹ E. Richter-Kuhlmann, *Gendiagnostikgesetz*, DEUTSCHES ÄRZTEBLATT 101 (2004).

¹⁰ Council of Europe Convention for the Protection of Human Rights and the Dignity of Human Beings with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, EUROPEAN TREATY SERIES No. 164, at the official Web site <http://conventions.coe.int/treaty/en/treaties/html/164.htm> (last visited June 16, 2008).

¹¹ *Unterzeichnung der Europäischen Bioethik-Konvention wäre derzeit falsch*, DIE WELT, July 5, 2005, at 31, from LEXIS/NEXIS, News Library, wse Zeitung file.

¹² Campbell, *supra* note 1, at 63.

¹³ United Nations Declaration on Human Cloning, adopted by the General Assembly, Mar. 8, 2005, A/RES/59/280, available at <http://www.brad.ac.uk/acad/sbtwc/gateway/HEALTH/Cloning.htm>.

¹⁴ Campbell, *supra* note 1, at 63.

¹⁵ ESchG, § 5. For a detailed analysis of the legal aspects of cloning *see* Nationaler Ethikrat, *Klonen zu Fortpflanzungszwecken* (Berlin, 2004), available at the official Web site <http://www.ethikrat.org/stellungnahmen/stellungnahmen.html>.

research purposes should be allowed within limits, because it may lead to therapeutic breakthroughs. Moreover, it is argued that the rigid protection of the embryo or the totipotent cell is not consistent with the German law relating to abortion.¹⁶ Abortion is permissible to a large extent, if certain procedures are observed.¹⁷

III. Stem Cell Research

Research on stem cells from human embryos is currently permissible only on imported stem cell lines that originate from stem cells harvested before January 1, 2002, from embryos created for in vitro fertilization and for which no pecuniary compensation had been granted. This is provided in the Stem Cell Act of 2002¹⁸ that tried to reach a compromise between the prohibitions of the Embryo Protection Act and the interests of German scientists. A change in the Act that would extend the harvesting deadline to 2007 appears to be imminent, as both houses of the legislature passed an amending act by May 23, 2008, which is now awaiting the Federal President's signature.¹⁹

The Embryo Protection Act intended to disallow stem cell research by prohibiting the harvesting of stem cells from embryos. The Act provides that embryos may only be created to impregnate the woman from whom the egg originated and that no more embryos may be created than would be necessary for this purpose.²⁰ Even the use of "leftover" embryos is prohibited, because this would violate article 2 of the Act by improperly using the embryo, and in fact, destroying it. Moreover, totipotent cells are deemed to be embryos, thus enjoying the same protections. For these reasons, German embryos cannot be used for the harvesting of stem cells.

The Stem Cell Act was enacted in June 2002 to give German researchers an opportunity to research in this field, and the extension of the harvesting deadline to 2007 was deemed necessary to provide for a new supply of stem cell lines. The decision to extend the deadline was reached after an extensive debate in Parliament that showed how divided Germans are on this issue.²¹

The Stem Cell Act, however, does not free the scientists from the limitations of the Embryo Protection Act. To ensure compliance with the law, research projects must obtain a license from the designated authority, currently the Robert Koch Institute,²² and, to review the ethical aspects of research applications, an Ethics Commission has been created that consist of biologists, physicians, ethicists, and theologians.²³ Licenses will be granted only for research projects that serve goals of ethically high standing and that are limited to basic and therapeutic research for which human stem cell research is indispensable.²⁴

Restrictions for stem cell research may arise from the Embryo Protection Act's definition of the embryo, according to which the protective purposes of the Act apply not only to any fertilized egg cell but

¹⁶ E. Hilgendorf, *Therapie muss erlaubt sein*, FRANKFURTER ALLGEMEINE ZEITUNG, Feb. 13, 2003, at 42.

¹⁷ Schwangeren- und Familienhilfe Änderungsgesetz, Sep. 21, 1995, BGBl I at 1050.

¹⁸ StZG, *supra* note 8.

¹⁹ *Mehr Spielraum bei Stammzellenforschung*, STUTTARTER NACHRICHTEN, May 24, 2008, at 2, from LEXIS/NEXIS, News Library, Zeitng file.

²⁰ ESchG, § 1 provides that for *in vitro* fertilization, no more than three egg cells may be fertilized for one treatment cycle and that no more than no more than three embryos may be transferred into a woman within a treatment cycle.

²¹ Deutscher Bundestag, *Experten uneins über Stammzellenforschung*, Mar. 19, 2008, available at the official Web site http://www.bundestag.de/aktuell/archiv/2008/19706134_kw10_stammzellen/index.html.

²² The Robert Koch Institute, at the official Web site <http://www.rki.de/> (last visited June 16, 2008), is the German agency for disease control and related matters.

²³ StZG, §§ 6-9.

²⁴ StZG, § 5.

also to any totipotent cell that is capable of development.²⁵ The prohibitions on cloning²⁶ and on creating hybrids and chimeras are also relevant. The latter are prohibited by section 7 of the Act which prohibits:

- the uniting of embryos with different genetic material to a cell conglomerate using at least one human embryo;
- the joining of a human embryo with a cell that contains genetic information different from the embryo and the further development of such an organism: and,
- the fertilization of a human egg cell with the sperm of an animal or the fertilization of an animal's egg cell with the sperm of a man, to generate an embryo capable of development.

An alternation of germ line cells, however, is not generally prohibited in stem cell research, because the Act's prohibition of such alterations does not apply to cells that will not be transferred to an embryo, fetus, or human being, and that will not lead to the origination of a germ cell.²⁷

The German government informs Parliament and the public biannually of the stem cell research that has been carried out in Germany. The latest report was published in January 2007.²⁸ It covers the period 2003 through 2005, and it reveals that fourteen research permits have been granted in those two years and these dealt primarily with basic research for the long-term goal of developing diagnostic, preventive, or therapeutic procedures. Until now, Germany has been hampered in its stem cell research not only by legal restrictions, but also by the alleged deficiency of the stem cell lines from before 2002.²⁹

IV. “Designer Babies”, DNA Banking, and Pre-Implementation Genetic Diagnosis

The Embryo Protection Act places a few hurdles in the path of “designer babies.” The Act does not permit selection of the sex of the child in assisted reproduction.³⁰ The Act also prohibits pre-implantation or pre-natal germ line modification,³¹ and it restricts pre-implementation genetic diagnosis [PGD] to polar body diagnosis, which only examines the maternal contribution to the genetic makeup of the child.³² Sperm banks are not prohibited; in fact sperm banks exist in Germany and offer their services to the public.³³ The use of the sperm of a dead donor is however prohibited, as is the use of sperm or an egg cell without the consent of the donor.³⁴

To prevent parents from determining the sex of their child in assisted reproduction, the Act prohibits the determination of the sex of the embryo through the selection of a sperm according to its sex chromosome for in vitro fertilization, except when the attending physician selects the sex of the sperm to avoid Duchenne muscular dystrophy or a similar serious illness.³⁵

²⁵ ESchG, § 8. See also *supra* notes 6 & 7 and accompanying text.

²⁶ ESchG, §§ 2 & 6.

²⁷ ESchG, § 5, ¶ 2. See also M. BREWE, EMBRYONENSCHUTZ UND STAMMZELLENGESETZ 34 (Berlin, 2006).

²⁸ DEUTSCHER BUNDESTAG, *Unterrichtung*, DEUTSCHER BUNDESTAG DRUCKSACHE [BT] 16/4050.

²⁹ *Deutscher Bundestag lockert Gesetz zur Stammzellforschung*, EURO NEWS – DEUTSCHE VERSION, Apr. 11, 2008, from LEXIS/NEXIS, News Library, Zeitng File.

³⁰ ESchG, § 3.

³¹ ESchG, § 5.

³² K. Ven et al, *Polar Body Diagnosis – A Step in the Right Direction?* DEUTSCHES ÄRZTEBLATT 190 (2008), available at <http://www.aerzteblatt.de/int/article.asp?id=59402>.

³³ See Fertility Center Hamburg, <http://www.fertility-center-hh.de/suche/suchergebnis.php> (last visited June 14, 2008).

³⁴ ESchG, § 4.

³⁵ ESchG § 3.

Currently available PGD methods that examine the fertilized egg cell are generally considered to be irreconcilable with the German Embryo Protection Act,³⁶ because they either lead to the destruction of a totipotent cell or they are fraught with risks if testing is carried out at the Blastocyst stage, when the cells are no longer totipotent. This has led to an extensive debate in Germany, with arguments ranging from the undesirability of eugenic selections to the desirability of prenatal genetic diagnosis to avoid the implantation of an embryo with genes carrying a serious disease that later-on could lead to the testing of the fetus and an abortion.³⁷

Polar body diagnosis, a new diagnostic method for indirect genetic analysis, is permissible because it occurs on the egg cell, before fertilization. In Germany, polar body diagnosis is performed primarily to improve the chance of implantation of the embryo in older women. It is performed less frequently to detect monogenic disorders.³⁸

VI. Genetic Testing Disclosure and Confidentiality of DNA Information

Unlike its neighbors Austria³⁹ and Switzerland,⁴⁰ Germany does not as yet have an Act on Genetic Testing.⁴¹ A draft for such a law was introduced in Parliament in November 2006 by the caucus of the Green Party.⁴² The draft was discussed extensively in committee hearings in which experts, interest groups, and associations were heard, all with different points of view.⁴³ This draft, however, did not become law. Instead, the governing coalition parties agreed on the salient points of a draft for a genetics testing act that the executive branch of government will submit to Parliament.⁴⁴ Such a draft should have a good chance of becoming enacted.

The draft being developed by the Executive Branch is expected to provide that genetic testing may be carried out only under the auspices of a physician and that a physician must advise the patient before a prognostic test is carried out. Individuals should retain their right not to know about predilections for disease. There is concern, in particular, about testing for incurable diseases that develop later in life, such as Huntington's Chorea. The decision on whether someone wants to know about that should be deliberated carefully, with the help of a physician.⁴⁵

³⁶ Ven, *supra* note 32.

³⁷ A. Schräer, *Blickpunkt Präimplantationsdiagnostik*, (Nov. 2007), available at <http://www.drze.de/themen/blickpunkt/pid>.

³⁸ Ven, *supra* note 32.

³⁹ Austria covers human genetic testing in its Genetic Engineering Act: Gentechnikgesetz, BUNDESGESETZBLATT [official law gazette of Austria] No. 510/94, as amended by Bundesgesetz, BUNDESGESETZBLATT I No. 127/200.

⁴⁰ Bundesgesetz über genetische Untersuchungen beim Menschen, Oct. 8, 2004, Systematische Sammlung des Bundesrechts [official codification of Swiss Federal Law], No. 810.12, at the official Web site http://www.admin.ch/ch/d/sr/c810_12.html. See also I. Filges and M. Morris, *Das Schweizer Bundesgesetz über genetische Untersuchungen beim Menschen*, MEDGEN 18 (2007), available at http://www.medgenetik.de/2006/2006_3_226_GUMG_Schweiz.pdf?PHPSESSID=6fec6bd671049d4571c8e869a8929557.

⁴¹ The only legal provisions that have been enacted so far relate to paternity testing. The Act for the Establishment of Paternity Without a Proceeding to Contest Paternity [Gesetz zur Klärung der Vaterschaft, Mar. 28, 2008, BUNDESGESETZBLATT I at 441], makes it easier for presumptive fathers to have paternity testing done in a legally binding form. Until now, such tests frequently have been carried out surreptitiously, and these have not been admitted by the courts. See M. Wellenhofer, *Das neue Gesetz* 61 NEUE JURISTISCHE WOCHENSCHRIFT 1185 (2008).

⁴² Entwurf eines Gesetzes über genetische Untersuchungen beim Menschen, Nov. 3, 2006, BT 16/3233.

⁴³ Deutscher Bundestag, *Gesetz zur Gendiagnostik bleibt umstritten. Öffentliche Anhörung des Ausschusses für Gesundheit*, Nov. 7, 2007, available at the official Web site http://www.bundestag.de/aktuell/archiv/2007/gendiagnostik_kw45/index.html.

⁴⁴ Antwort der Bundesregierung, Mar. 11, 2008, BT 16/8483.

⁴⁵ N. Silbermann, *Die Macht der Gene*, DIE WELT, Apr. 19, 2008, from LEXIS/NEXIS, News Library, Zeitung file.

The draft also is expected to prevent employers and insurers from requiring genetic testing, to the extent that this does not conflict with European Union law. Currently, the German insurers are bound by a gentleman's agreement to forego predictive genetic testing, and this agreement is expected to be effective until 2011.⁴⁶ The draft also prohibits prenatal genetic tests that serve exclusively to determine the sex of the fetus.⁴⁷

It appears that Germans cannot be prevented by law from having genetic tests performed abroad, through the use of the Internet, yet German experts advise against such tests, because they do not include a consultation with a physician. Genetic testing, however, is used in Germany to the extent that it is medically indicated, and such tests are being paid for by the health insurers.⁴⁸

VII. Inheritable Genetic Modification

Section 5 of the Embryo Protection Act prohibits the artificial alteration of a human germ line cell and the use of a human germ cell with artificially altered information for fertilization. These prohibitions apply to the germ lines of embryos and fetuses as well as to human beings at any stage of life. An exception from these broad provisions exists for experiments with cells that are not used for human reproduction. In addition, the Act permits inoculation and therapeutic uses of radiation, chemotherapy, or other treatments, as long as they do not intend to alter the germ line cells, even though they may have that effect.

In the public discussion of the possible use of inheritable genetic modification to prevent certain hereditary diseases, the opponents of such techniques point out that the currently available procedures are risky and not reliable.⁴⁹ Moreover, warnings have been issued of the permanent, irreversible, and unpredictable effects that these alterations would have on the human genome.⁵⁰

VIII. Restriction of Technology Transfers

Germany has no legislation that would specifically restrict the transfer of technologies relating to human genetic engineering. Given the restrictions faced by German scientists in this field, it could be assumed that other countries would have more advanced technologies to offer. It is not certain whether German restrictions of technology transfers might arise from the supervision of stem cell research by authorities and ethics councils (*see above*, "Stem Cell Research"). It appears that currently the supervisory regime of the Stem Cell Act does not apply to any exports of stem cells.⁵¹

IX. Conclusion

Germany has one of the most restrictive laws in the world on human genetic engineering. Although it is possible that the German stance may soften on issues such as pre-implantation genetic diagnosis or therapeutic cloning, it appears more than likely that Germany will continue to apply a high

⁴⁶ Richter-Kuhlmann, *supra* note 9.

⁴⁷ Silbermann, *supra* note 45.

⁴⁸ Richter-Kuhlmann, *supra* note 9.

⁴⁹ Evangelisch-Lutherische Kirche in Bayern, *Gentechnik am Menschen*, http://www.bayern-evangelisch.de/web/engagiert_leben_gentechnik_stufenmodell.php#stufe4-7 (last visited June 14, 2008)

⁵⁰ Alexander Kekulé, *Menschenrecht auf Erbgut*, 46 DER SPIEGEL 206 (Nov. 12, 2001), available at <http://wissen.spiegel.de/wissen/dokument/dokument.html?id=20660240&top=SPIEGEL>.

⁵¹ Brewe, *supra* note 27, at 143.

human rights standard to human reproductive and genetic issues and that Germany will not permit reproductive cloning or inheritable gene modification.

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ISRAEL

REGULATION OF HUMAN GENETIC TECHNOLOGY

Executive Summary

Israel maintains a policy of encouraging medical research involving genetic engineering for therapeutic purposes. While generally prohibiting human reproductive cloning and germ line gene therapy for the purpose of creating a human, it provides a procedure for authorizing limited genetic intervention in cases where human dignity is not harmed, and under conditions and recommendations of the appropriate committee. The law further permits the use of pre-implementation genetic diagnosis (PGD) for medical purposes while heavily restricting the use of this method in fetal sex selection. Holders of DNA data, including DNA banks, are under an obligation to preserve confidentiality regarding the identity of their donors. The law restricts the transfer of DNA samples and/or information regarding such samples outside of Israel.

I. Introduction and Background

Israel pays great attention to fertility and birth. The significance and the centrality of the right to parenthood were recognized by the Supreme Court in a 1996 decision centering on the right of a wife to inseminate a surrogate with her eggs, fertilized by her husband prior to the couple's separation and his objection.¹

Israeli law permits surrogacy motherhood procedures under conditions enumerated by law.² The use of genetic engineering for medical research, disease prevention and treatment is generally permitted. Accordingly, although reproductive cloning is expressly prohibited, therapeutic cloning is permitted, subject to certain conditions specified by law and directives issued by the Ministry of Health.³ Like therapeutic cloning, pre-implementation genetic diagnosis (PGD) is also permitted to prevent the birth of babies afflicted with severe chronic diseases. In rare cases PGD is permitted for sex selection.

Certain medical procedures related to fertility and births are fully covered by Israel's public health system. Accordingly, some prenatal genetic testing and in-vitro fertilization (IVF) treatments are fully covered. PGD for patients undergoing IDF due to infertility who are carriers of genetic diseases or chromosome abnormality are also covered.⁴ Other genetic tests are partially covered by Israel's health funds.⁵

The Ministry of Health is charged with implementation of the law with regard to genetic

¹ Special Hearing 2401/95 Nachmani v. Nachmani, 50(4) PISKE DIN [Decisions of the Supreme Court] 661 (1996), available in Hebrew in the Nevo Legal Database, at <http://www.nevo.co.il/> (by subscription) (last visited June 13, 2008).

² Surrogacy Pregnancy Agreements (Approval of an Agreement and the Status of a Newborn) 5766-1996, SEFER HA-HUKIM [Book of Laws, Official Gazette, hereafter S.H.] 5756 No. 1577 p. 176 (March 17, 1996), available at <http://www.nevo.co.il/>.

³ DINA TSADOK, THE PROHIBITION OF GENETIC INTERVENTION LAW (The Knesset Center for Research and Information Nov. 20, 2005), available in Hebrew on the Knesset Official Web site, at <http://www.knesset.gov.il> (last visited June 14, 2008).

⁴ Public Health Decree (Amendment of the 2nd addendum to the law), 5768-2008, §1(5), Kovetz hatakanot [subsidiary Legislation, hereafter KT] No. 6643 p. 419 (January 29, 2008); available at <http://www.nevo.co.il/>.

⁵ Israeli residents subscribe to health funds that enjoy public subsidies for distributing health services.

engineering. The Ministry has recognized the conflicting interests between the “basic right of a person for freedom and the right to select what is best for him, when technological methods enable this” and the interests in maintaining a moral and ethical society that opposes medical procedures for non-medical goals, prevention of gender based discrimination, and maintaining the demographic balance.⁶

The preservation of genetic information and its transfer are subject to strict statutory requirements of confidentiality. The transfer of DNA samples and/or information regarding such samples from a DNA bank outside of Israel requires pre-authorization by the Superior Committee for Medical Experiments in Humans and depends on concealing identification of DNA samples while preserving the identification code in Israel.

II. Genetic Engineering & Related Technologies

A. General Prohibition

Genetic engineering in humans is regulated by the Prohibition of Genetic Intervention Law (Human Reproductive Cloning and Genetic Change in Reproductive Cells), 5759-1999,⁷ as amended.⁸

The original law was enacted in 1999 for a period of five years to allow for a public debate of the moral, legal, social and scientific implications of genetic intervention on human dignity. In January 2004 the Knesset (Parliament) Committee for Science and Technology conducted hearings for examination of the need to extend the law and its amendment. Following these hearings the law was extended for an additional five years subject to several changes.

The law states the following as its objective:

[t]o prevent cloning for the purpose of human reproduction by determining that certain types of genetic intervention in humans shall not be carried out in consideration of the moral, legal, social and scientific aspects of the prohibited types of intervention, and their implications on human dignity, and for the purpose of examining the policy regarding the said types of intervention in light of these aspects, and in consideration of freedom of scientific research for the advancement of medicine.⁹

The law generally prohibits both human reproductive cloning as well as germ line gene therapy for the purpose of creating a human.¹⁰ The law defines human reproductive cloning as any of the following:

- (1) The creation of a human fetus by transferring a stem cell from a body cell into an egg or into a fertilized egg from which the stem was removed (in this law--cloned embryo) in order to create a human identical from a genetic chromosome aspect to another human or an embryo, live or dead;
- (2) Insertion of a cloned embryo into the uterus or the body of a woman or into a uterus or another body[.]¹¹

⁶ Directive No. 21/05 for Fetal Sex Selection by PGD Testing (State of Israel, Ministry of Health, National Committee for Fetal Sex Selection by PDG testing, May 9, 2005), available at <http://www.health.gov.il/pages/printer.asp?pageid=3634&parentid=10&catid=6&maincat=1> (last visited June 10, 2008).

⁷ Sefer Ha-Hukim [Book of Laws, Official Gazette, hereafter S.H.] 5759 Issue no. 1697 p. 47.

⁸ Prohibition of Genetic Intervention (Human Reproductive Cloning and Genetic and Genetic Change in Reproductive Cells), (Amendment), 5764-2004, S.H. 5764 Issue no. 1934 p. 340 (hereafter the 2004 Amendment), available at http://www.knesset.gov.il/privatelaw/plaw_display.asp?LawTp=2. For up-to-date text, see <http://www.nevo.co.il>.

⁹ The 2004 Amendment §1 (as translated by the author, R.L.).

¹⁰ *Id.* §3.

¹¹ *Id.* §2.

Although the law currently does not expressly distinguish between reproductive cloning and therapeutic cloning, it expressly prohibits the former but not the latter.¹² The lack of prohibition on therapeutic cloning is said to reflect the policy of Israel's Superior Helsinki Committee¹³ in support of the advancement of research for treating patients inflicted with chronic diseases.¹⁴

This approach may reflect the Jewish perception of “human status” and medical treatments. In accordance with the Jewish viewpoint, the “human status” of the embryo is not established upon conception but rather is acquired gradually. Thus, the embryo transforms into a “cohesive” human only at the end of the first forty days of the pregnancy.¹⁵ Therefore the embryo's status outside of the womb is similar to that of reproduction cells—an egg and semen: although they should not be wasted in vain, it is permitted to use them for medical reasons. Additionally, *Pikuach Nefesh* (the saving of a life)¹⁶ supersedes numerous laws. This commandment provides a justification for creating embryos by cloning for medical objectives.¹⁷

The support for research leading to treatment of diseases is further expressed in the 2004 amendment that states that the examination of moral, legal, social, and scientific aspects of genetic intervention will be conducted “in consideration of freedom of scientific research for the advancement of medicine.”

The performance of an unauthorized human reproductive cloning or germ line gene therapy for the purpose of creating a human in violation of the law is punishable by four months imprisonment or a fine.¹⁸ The prohibition is in effect until March 1, 2009.¹⁹

B. Exceptions

The Minister of Health may, if (s)he finds that a deviation from the general prohibition does not harm human dignity, upon a recommendation of the Consulting Committee²⁰ and under conditions to be specified by the Minister, permit by subsidiary legislation the carrying out of certain types of genetic intervention that are otherwise prohibited. The utilization of such technologies requires pre-authorization.²¹

The Consulting Committee is defined as the Superior Helsinki Committee and is tasked with keeping up to date with the advancement of medicine, science, biotechnology, bioethics and law in the area of genetic experiments in humans in Israel and abroad. The Consulting Committee should submit a

¹² *Id.* §2-3; *see also* DINA TSADOK, *supra* note 3.

¹³ For information on the authorities and duties of the Committee, *see* discussion below.

¹⁴ A letter by the Committee dated Nov. 12, 2003, *cited in* SHARON PAZ, CLONING STEM CELLS FOR PURPOSES OF RESEARCH AND MEDICINE, n. 15 at 4 (The Knesset Center for Research and Information Mar. 23, 2004), *available at* <http://www.knesset.gov.il> (in Hebrew).

¹⁵ *Id.* at 3.

¹⁶ Translated by author, R.L.

¹⁷ SHARON PAZ, *supra* note 14, at 3.

¹⁸ Prohibition of Genetic Intervention Law (Human Reproductive Cloning and Genetic Change in Reproductive Cells), 5759-1999 §6, Sefer Ha-Hukim [Book of Laws, Official Gazette, hereafter S.H.] 5759 Issue no. 1697 p. 47, as amended.

¹⁹ *Id.* §8.

²⁰ The Consulting Committee is defined as the Superior Helsinki Committee and is appointed in accordance with the Public Health (Medical Experiments in Humans) Regulations, 5741-1980, Kovetz hatakanot [subsidiary Legislation, hereafter KT] 5741 No. 4198 p. 292 (December 11, 1980), as amended, *available at* <http://www.nevo.co.il/>.

²¹ Prohibition of Genetic Intervention Law §5.

yearly report of its activities to the Minister of Health and to the Knesset Committee of Science and Technology. The Consulting Committee also advises the Minister of Health on the issue of genetic experiments in humans and on the prohibitions regarding human reproductive cloning and germ line gene therapy.²²

C. Procedure

The Prohibition of Genetic Intervention Regulations (Human Reproductive Cloning and Genetic Change in Reproductive Cells) (Authorities of the Consulting Committee) 5766-2006²³ regulate the procedures for obtaining pre-authorization for approval of requests to deviate from the general prohibition on utilizing these techniques.

The regulations require any person who applied to the Consulting Committee for a permit to conduct a genetic medical experiment in humans, to provide the Committee, upon its request, information regarding the experiment, its procedure, and its results. The information will be provided within 30 days from the receipt of the Committee's request and will be transmitted as a computer file in accordance with the Committee's instructions.²⁴

The Consulting Committee may not disclose or include in its report any information it has received in the course of fulfilling its duties, including information received in connection with a request to conduct genetic experiments in a human, that constitutes a trade or professional secret or one of economic value, the publication of which may cause real harm to its value or to any professional, business, or economic interest.²⁵

The regulations provide the Consulting Committee with inspection, review and enforcement authorities. The Committee, thus, may request any person who conducts a medical experiment in humans that is suspected of being in violation of the law to display a permit, and may enter and inspect premises, documents, and equipment suspected of being used for unlawful genetic experimentation.²⁶ The Committee is further authorized to report violations of the law to the General Manager of the Ministry of Health and to recommend the voiding of permits. The voiding of a permit requires the Manager to provide a hearing for the affected person.²⁷

III. Pre-implementation Genetic Diagnosis (PGD)

Although practiced in Israel for several years, the use of PGD has not been regulated by statutory law. The technique has been generally approved for use in individual cases by hospital committees based on medical reasons. In PGD "a single cell is removed mechanically or with lasers from an eight-cell blastomere produced by IVF. After testing the pre-embryos for genetic diseases, only healthy ones are implanted in the woman's uterus."²⁸

²² *Id.* §4.

²³ KT 5766 No. 6452 p. 318 (January 10, 2006), available at <http://www.nevo.co.il/>.

²⁴ Prohibition of Genetic Intervention Law §2.

²⁵ *Id.* §3.

²⁶ *Id.* §4.

²⁷ *Id.* §5.

²⁸ *Boy or Girl? You Choose! [Israel]*, JERUSALEM POST, May 18, 2005, available at <http://www.geneticsandsociety.org/article.php?id=1641&&printsafe=1> (last visited June 14, 2008).

A. Utilizing PGD for Medical Reasons

In February 2008 the *Jerusalem Post* reported that the Hadassah University Medical Center in Jerusalem's Ein Kerem was successful in making a “[b]reakthrough in-vitro fertilization plus pre-implantation genetic diagnosis (PGD) of fraternal twins. ... [The success] offers hope to many defective-gene carrier couples around the world of having children free of their mutation.”²⁹ The *Jerusalem Post* further stated:

[a] 38-year-old Jerusalemite whose cells carry defective BRCA2 genes is apparently the first woman in the world in an advanced state of pregnancy with fetuses that were screened for the mutation as three-day-old embryos and selected for implantation when shown to be healthy... A very Orthodox woman who covers her hair with a wig, Esther and her husband consulted with numerous rabbis here and abroad. The rabbis unanimously approved the procedure after saying that embryos only a few days old and swimming in a Petri dish are not considered human life but only cells, and that producing disease-free babies with a healthy future was not only permitted but preferred in her situation.³⁰

In 2007 the *Jerusalem Post* reported that “[t]he Jerusalem's *Shaare Zedek* Medical Center is apparently the first in the world to produce by PGD and in-vitro fertilization (IVF) a normal baby to a dwarf mother suffering from the genetic disease *achondroplasia* ...”³¹ An earlier case reported by the *Haaretz* Newspaper in 2005 involves the use of PGD in selecting healthy embryos for a woman who herself as well as three of her siblings were born with *myotonic dystrophy*. The procedures were conducted at *Shaare Zedek* hospital.³²

B. Utilizing PGD in Fetal Sex Selection

In May 2005 the Ministry of Health published a directive for fetal sex selection by PGD testing.³³ The directive was issued in accordance with the recommendations of the Joint Committee of the Israel National Academy for Science Bio-ethics Committee and the Ministry of Health Helsinki Committee for Genetic Experiments in Humans. The Joint Committee recommended prohibiting fetal sex selection by PGD not for medical reasons, except for rare cases and under extremely limited circumstances. The Directive specifies the guiding rules for approval of sex selection PGD s testing for both medical and non-medical reasons.

According to the Directive, fetal sex selection not for medical reasons is generally prohibited except for the following rare situations and subject to written pre-authorization issued by a State Committee appointed by the Ministry of Health for this purpose. Pre-authorization may be granted if all the following conditions are met:

1. There is a real and substantial danger for causing significant harm to the emotional health of one or both parents or of the expected child, if the requested procedure will not be performed;

²⁹ Judy Siegel-Itzkovich, *Hadassah Breaks chain of BRCA Mutation*, JERUSALEM POST ONLINE EDITION, Feb. 25, 2008, <http://www.jpost.com/servlet/Satellite?pagename=JPost%2FJPArticle%2FShowFull&cid=1203847457014> (last visited June 14, 2008).

³⁰ *Id.*

³¹ Judy Siegel-Itzkovich, *World's first: Israeli dwarf Helped to have Normal-Sized Baby*, JERUSALEM POST ONLINE EDITION, July 17, 2007, <http://www.jpost.com/servlet/Satellite?cid=1184613675936&pagename=JPost%2FJPArticle%2FPrinter> (last visited June 14, 2008).

³² Tamara Traubman & Ran Reznick, *A Case of Almost Eugenics*, HAARETZ.COM ONLINE, Aug. 11, 2005, <http://www.haaretz.com/hasen/pages/ShArt.jhtml?itemNo=611189>.

³³ *Supra* note 6.

2. In very rare cases and for special reasons to be noted, where the requestors already have together at least four children of the same sex, and do not have children of the other sex;
3. The designated parents received genetic consultation and were informed of the details of the procedure, its chances and risks, as well as ethical considerations, including the status and destiny of embryos of the sex that was not selected for pregnancy; the parents consented in writing for the procedure, as well as for implementing IVF;
4. The parents were informed that if the healthy embryos were not of the desired sex, no additional permission would be granted for another IVF cycle before the healthy embryos were used for reproduction;
5. After consideration of all professional and ethical aspects the committee was convinced that there was a serious justification for fetal sex selection in the appropriate case.

Among its considerations the State Committee should evaluate:³⁴

1. Whether the prospective parents require IVF for medical reasons unconnected to the issue of fetal sex selection;
2. The level of risk and burden to the woman if the IVF procedure is done not for a medical reason, but merely for fetal sex selection;
3. Whether the embryos will undergo genetic testing for a medical reason, independent of the subject of fetal sex selection;
4. The family and social status of the requesters, including their age.

The State Committee is composed by the General Manager of the Ministry of Health. The Committee should include at least seven members: a clinical psychologist, an expert in the field of medical ethics or bio-ethics, a social worker, a lawyer, a doctor specializing in medical genetics, a doctor expert in gynecology and obstetrics, and a religious leader (according to the faith of the requesters).³⁵

The following are entitled to file requests with the Committee: married couples; persons who live together as married (proven by a written agreement), and single women.³⁶ So far the Committee approved fetal sex selection by PGD testing only in one case. The approval was said to be granted for humanitarian reasons.³⁷ The only known such case involves a *haredi* (Jewish ultra-orthodox) couple in which the husband was infertile. The wife underwent IVF with donor sperm, but since he was a *kohen* (of the priestly tribe), the couple wanted only a girl and not a boy, who would eventually be expected to recite the Priestly Blessing in the synagogue, as the “son” of a *kohen*, but be forbidden to do so and thus “found out.” This non-medical application for PGD was approved by the ministry’s legal adviser, Mira Huebner, as an exception for humanitarian reasons.”³⁸

³⁴ Prohibition of Genetic Intervention Law §2.3

³⁵ *Id.* §3.

³⁶ *Id.* §3.2

³⁷ *Id.*

³⁸ *Supra* note 28.

An October 2006 report of the Knesset Center for Research and Information was provided to a joint meeting of the Knesset Committees of Science and Technology, Labor, Welfare and Health. The report states that the ministry of Health and the ministry of Justice were conducting joint hearings on the topic of fetal sex selection, but that no draft bill had been adopted.³⁹

C. Guidelines for Preimplantation [sic] Genetic Diagnosis (PGD)⁴⁰

On December 20, 2006, the Ministry of Health issued Guidelines for Preimplantation [sic] Genetic Diagnosis (PGD).⁴¹ These guidelines deal exclusively with the technical aspects of PGD. As stated, hearings on the ethical, social, philosophical and medical implications of PGD were reported to have been conducted by the Joint Knesset Committee in 2006. A search for the Joint Committee's protocols did not result in identification of its conclusions.

The introduction to the Guidelines suggests that PGD can be divided into two main categories: (1) PGD to couples who are carriers of monogenic genetic diseases; and (2) couples where one of them is a carrier of a balanced translocation and who are at high risk for giving birth to an affected child. According to the introduction, "there is an agreement regarding the efficiency and the justification in performing PGD in these couples."⁴² To be recognized by the Ministry of Health in Israel, laboratories that conduct exams by utilizing PDG must follow the guidelines.⁴³

IV. DNA Banking /Disclosure & Confidentiality

Genetic Information Law, 5761-2000,⁴⁴ as amended,⁴⁵ entered into force on December 25, 2001. The law is designed to regulate the provision of genetic consultation, the conduct of genetic testing and the protection of privacy in connection with identifiable genetic information while advancing medical treatment and research.⁴⁶

The law provides that the preservation of DNA samples and the results of the genetic testing conducted on it should be made in accordance with rules issued by the General Manager of the Ministry of Health or his/her designee and subject to the following: (1) identifying information will not be removed from identifiable DNA taken for the purpose of medical treatment; (2) In the absence of a written consent by the tested person, identifying information will be removed from a DNA sample taken for the purpose of research.⁴⁷

A. Establishment of DNA Bank and Preservation of Data

In accordance with the authorization provided by the law, the Ministry of Health issued the Directives of the Superior Committee for Medical Experiments in Humans for the Establishment and Use

³⁹ SARA TSVAVNER, FETAL SEX SELECTION (The Knesset Center for Research and Information Oct. 26, 2006), available at www.knesset.gov.il.

⁴⁰ Ministry of Health, *Guidelines for Preimplantation [sic] Genetic Diagnosis (PGD)*, <http://www.health.gov.il/search/default.asp> (official Web site; last visited June 11, 2008).

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.* §2.

⁴⁴ S.H. 5761 Issue No. 1766 p. 62 (Dec. 25, 2000).

⁴⁵ Full up-to-date text is available online, <http://www.nevo.co.il>.

⁴⁶ The Genetic Information Law, 5761-2000, §1.

⁴⁷ *Id.* §15.

of Genetic Testing Samples (hereafter the Directives).⁴⁸ The directives are based on rules used by the Committee, as well as on relevant legislation including the Genetic Information Law, 5761-2000,⁴⁹ as amended,⁵⁰ the Privacy Protection Law, 5741-1981,⁵¹ and related regulations.

In accordance with the Regulations, the establishment of a DNA bank for medical or research purposes requires the submission of a detailed request to the Helsinki Committee for Genetic Experiments in Humans. The request should provide information on the purpose of establishing such a bank, the identity of the data bank possessor and its manager, the number of DNA samples planned to be included in the bank, their source, the method of their collection, reimbursement for the donors or the data collectors, the identifiability of the samples, conditions of their use, preservation and protection, methods of privacy protection, extent of use (in Israel or abroad) and information regarding financial sources for the establishment and operation of the bank.⁵² The submission of a request for the establishment of a DNA Bank does not exempt the requester from the requirement to submit a separate request for a permit to conduct genetic research in humans.⁵³

The establishment and maintenance of the DNA information bank depends on receipt of the Committee's approval and is subject to its conditions. The requestor must notify the Committee immediately of any change in the information based on which the permit was granted and on the significant or outstanding event related to the establishment of the bank.⁵⁴

B. Transfer of Samples from the Bank

The holder or manager of a DNA data bank should not transfer samples from the bank except for research purposes as approved by the Committee and subject to the conditions set in the permit issued to the bank. The receiver of samples from the bank will confirm in writing and by his/her signature information on the received samples and will further certify that the samples and the information derived from them will be protected and will not be transferred to a third party without written pre-authorization of the bank holder and the Committee.

C. Confidentiality/ Disclosure

The Genetic Information Law, 5761-2000,⁵⁵ as amended,⁵⁶ provides that holders of identifiable genetic information in a data bank are subject to the requirements of the Privacy Protection Law, 5741-1981,⁵⁷ as amended.⁵⁸ Such requirements include registration, public access to requests and privacy protection, among other.

⁴⁸ Directives of the Superior Committee for Medical Experiments in Humans for the Establishment and Use of Genetic Testing Samples, Ministry of Health Official Website at <http://www.health.gov.il/search/default.asp> (last visited June 11, 2008).

⁴⁹ S.H. 5761 Issue No. 1766 p. 62 (Dec. 25, 2000).

⁵⁰ Full up-to-date text is available at the Nevo legal Database at www.nevo.co.il.

⁵¹ S.H. 5741 Issue no. 1011 p. 128 (Mar. 11, 1981), as amended.

⁵² Directives of the Superior Committee for Medical Experiments in Humans for the Establishment and Use of Genetic Testing Samples, §2a, Ministry of Health Official Web site, at <http://www.health.gov.il/search/default.asp> (last visited June 11, 2008).

⁵³ *Id.* §2b.

⁵⁴ *Id.* §4.

⁵⁵ S.H. 5761 Issue No. 1766 p. 62 (Dec. 25, 2000).

⁵⁶ Full up-to-date text is available at <http://www.nevo.co.il> (last visited June 11, 2008).

⁵⁷ S.H. 5741 Issue no. 1011 p. 128 (Mar. 11, 1981).

⁵⁸ Full up-to-date text is available at <http://www.nevo.co.il> (last visited June 11, 2008).

Whoever received genetic information related to a person in the course of fulfilling his duties or work is under a duty of confidentiality and cannot use it, unless the person subject to the testing consented to disclosure.⁵⁹ The law further imposes a duty on a permit holder, a person responsible for the research, a caregiver, a manager of a genetic institute, a manager of a laboratory for genetic testing, and whoever participates in the research to use reasonable measures to guarantee that workers under their supervision will protect the confidentiality of information they receive in the course of fulfilling their work.⁶⁰

A permit holder, a person responsible for the research, a caregiver, a manager of a genetic institute, a manager of a laboratory for genetic testing, and whoever participates in the research are, however, allowed to transfer genetic information to another, in accordance with the rules specified by the Patients Rights Law, 5756-1996.⁶¹ Accordingly, such information may be transferred when the patient consented when the caregiver or the medical institution are under a legal duty to do so when the information is transferred to another for treatment of the patient when the patient did not receive the information to protect his mental or physical health and instead transferred to another per special permission when the information was transferred to the treating medical facility or its employee for the purpose of recording or reporting by law when the information is designed to be published in a scientific publication and for purpose of research as long as no identifiable details regarding the patient are disclosed.⁶²

Genetic information may be provided by a caregiver or one who provides genetic consulting to another caregiver or consultant unless the patient has expressed opposition to such, except where such opposition was overridden by an ethics committee established by the law and under conditions set by the committee.⁶³

The law provides that a holder of genetic information or a genetic data bank may transfer information in his possession for the purpose of legally authorized research, teaching, or publication in a scientific publication if the information does not identify the donor or if the donor consented to the disclosure in writing.

V. Technology Export Regulation

The transfer of DNA samples and/or information regarding such samples from a DNA bank outside of Israel is regulated by the Directives of the Superior Committee for Medical Experiments in Humans for the Establishment and Use of Genetic Testing Samples.⁶⁴ Accordingly such transfer requires pre-authorization of the Committee in accordance with its rules and the Privacy Protection Regulations (Transfer of Information to Foreign Data Bases). The receiver of such samples abroad must pre-confirm in writing that (s)he is bound to complying with the Committee's conditions and directions as well as the requirements detailed in the Privacy Protection Regulations.⁶⁵

According to the Directives, DNA samples will not be transferred abroad when they include identifying information of the donors. Identifiable samples will be transferred only if necessary for

⁵⁹ The Genetic Information Law, 5761-2000, §18(a)

⁶⁰ *Id.* §18(b).

⁶¹ S.H. 5756 Issue No. 1591 p. 327 (May 12, 1996).

⁶² *Id.* §20.

⁶³ *Id.*

⁶⁴ Directives of the Superior Committee for Medical Experiments in Humans for the Establishment and Use of Genetic Testing Samples, Ministry of Health Official Web site, at <http://www.health.gov.il/search/default.asp> (last visited June 11, 2008).

⁶⁵ *Id.* §8(a) & (b).

authorized research and when the identifying information is codified without providing the code, so that connecting the identifying information to the samples can only be done in Israel.⁶⁶

VI. Conclusion

Israel's policies regarding genetic engineering support the advancement of research for therapeutic purposes. This approach seems to reflect an interest in the development of science as well as the traditional Jewish respect for life and health.

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⁶⁶ *Id.* §8(c)

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NEW ZEALAND
REGULATION OF HUMAN GENETIC TECHNOLOGY

Executive Summary

New Zealand has sought to regulate the use of genetically modified organisms and to regulate the use of gene technology in relation to humans. Under the Hazardous Substances and New Organisms Act 1996, all “new organisms” (including a genetically modified organism) may not be imported, developed or released other than with approval. Approval will be refused for any organism that fails to meet the “minimum standards,” for example, by having “any significant adverse effect to New Zealand’s inherent genetic diversity.” Other organisms may be imported, developed, or released but may be subject to conditions, including containment. Human cloning and research involving human embryos is primarily regulated by the Human Assisted Reproductive Technology Act 2004, which establishes a regime where activities are either: “established procedures” (and therefore permitted), “prohibited actions,” or “permitted with the approval of the Ethics Committee.” It is possible for the government to initiate a moratorium on specified activities for the purposes of developing advice or guidelines, during which it is prohibited (unless approved by the Ethics Committee) to undertake activities that are the subject of the moratorium. Gene therapy and the administration of nucleic acids are regulated under the Medicines Act 1981; in accordance with that Act any “medicine” administered for the sole purpose of obtaining clinical and scientific information must have prior approval. Preimplantation genetic diagnosis is permitted but only for limited reasons and not for social reasons or solely for the purpose of sex selection.

I. Legal System of New Zealand

New Zealand is a Constitutional¹ monarchy with a single house of parliament (the House of Representatives); the other house (Legislative Council) was abolished in 1951. Parliament consists of one hundred and twenty Members of Parliament, elected for three year terms.²

II. Community Attitude Towards Stem Cell Research and Biotechnology

A 2006 report on New Zealand’s community attitude toward embryonic stem cell research concluded that there was general support³ within the community for the concept of stem cell research due

¹ New Zealand’s constitution is not contained in a single document but rather is found within the Constitution Act 1986, the New Zealand Bill of Rights Act 1990, the Electoral Act 1993, the Treaty of Waitangi, the Standing Orders of the House of Representatives, and other constitutional conventions.

² For further information, see the Ministry of Justice Web site, http://www.justice.govt.nz/pubs/other/pamphlets/2001/legal_system.html (last visited June 13, 2008).

³ Some respondents were reported to eschew stem cell research for ethical reasons or believing it to be inconsistent with *whakapapa*— the principle governing Maori culture.

to the potential benefits to human health, although there was some concern at the need to destroy an embryo to obtain stem cells. Of those who supported embryonic stem cell research, most preferred donor embryos created specifically for research and for the stem cells to be sourced from New Zealand.⁴

In addition a 2006 study exploring community perceptions of reproductive technology established that for human embryo research to be acceptable to the community, it is imperative that:

1. Embryos are obtained only from fully informed, consenting adults.
2. There are tight controls ensuring the overall medical, scientific and ethical integrity of the research.
3. Research on embryos is only related to research that is of undoubted benefit to society.
4. The research will not produce a human being or any other type of complete, living organism.⁵

III. Regulation of Genetically Modified Organisms

The primary legislation regulating genetically modified organisms are the Hazardous Substances and New Organisms Act 1996 and the Biosecurity Act 1993.

The purpose of the Hazardous Substances and New Organisms Act 1996 is “...to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.”⁶ The Act is applicable to all “new organisms”⁷—that is, any genetically modified organism or new animal, plant or organism entering New Zealand for the first time—and hazardous substances (any explosive, flammable or toxic substances).⁸

⁴ TOI TE TAIAO BIOETHICS COUNCIL, ATTITUDES TO EMBRYONIC STEM CELL RESEARCH IN NEW ZEALAND (Feb. 2006), available at <http://www.bioethics.org.nz/publications/stem-cells-attitudes-feb06/stem-cells-attitudes-feb06.html> (last visited June 11, 2008).

⁵ TNS, HUMAN EMBRYO RESEARCH QUALITATIVE RESEARCH REPORT PREPARED FOR THE BIOETHICS COUNCIL 3 (Oct. 2006), available at <http://www.bioethics.org.nz/publications/human-embryos-qualitative-research-oct06/human-embryos-qualitative-research-oct06.pdf> (last visited June 11, 2008).

⁶ Hazardous Substances and New Organisms Act 1996 § 4.

⁷ A “new organism” is defined in Hazardous Substances and New Organisms Act 1996 § 2A as being:

[(1)...] (a) An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:

(b) An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:

(c) An organism for which a containment approval has been given under this Act:

(ca) an organism for which a conditional release approval has been given:

(cb) a qualifying organism approved for release with controls:

(d) A genetically modified organism:

(e) An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

(2) An organism is not a new organism if—

(a) the organism is not a genetically modified organism and—

(i) an approval is granted under section 38 to release an organism of the same taxonomic classification; or

The Environmental Risk Management Authority (ERMA), an independent government agency established under the Hazardous Substances and New Organisms Act 1996, has responsibility for regulating research, development, importation, use (including release) of genetically modified organisms.⁹ The ERMA is authorized to establish conditions for how and when substances (including genetically modified organisms) are used—that is how they are contained, labeled, stored, used, transported or disposed of during their life span. The ERMA may also, on application from any person, determine if an organism is a “new organism.”¹⁰

In accordance with the Hazardous Substances and New Organisms Act 1996 new organisms may not be imported, developed or released other than with approval granted in accordance with the Act.¹¹ In relation to new organisms, “approval” may be for the purposes of:

- importation for release or release from containment of any new organism;
- conditional release to import for release or release from containment a new organism;
- importation for release or to release from containment a qualifying organism; or
- importation of any new organism into containment, field testing any new organism in containment, or developing any new organism in containment.¹²

(ii) the organism is a qualifying organism and an approval has been granted under section 38I to release an organism of the same taxonomic classification without controls; or

(iii) an organism of the same taxonomic classification has been prescribed as not a new organism; or

(b) the organism is a genetically modified organism and—

(i) an approval is granted under section 38 to release an organism of the same taxonomic classification with the same genetic modification; or

(ii) the organism is a qualifying organism and an approval has been granted under section 38I to release an organism of the same taxonomic classification with the same genetic modification without controls; or

(iii) an organism of the same taxonomic classification with the same genetic modification has been prescribed as not a new organism; or

(c) the new organism was deemed to be a new organism under section 255 and other organisms of the same taxonomic classification were lawfully present in New Zealand before the commencement of that section and in a place that was not registered as a circus or zoo under the Zoological Gardens Regulations 1977.

(2A) A new organism does not cease to be a new organism because—

(a) it is subject to a conditional release approval; or

(b) it is a qualifying organism approved for release with controls; or

(c) it is an incidentally imported new organism.

(3) Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.

(4) Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.

⁸ Hazardous Substances and New Organisms Act 1996 §§ 2, 4.

⁹ *Id.* §§ 11, 14-24. See also the ERMA Web site, <http://www.ermanz.govt.nz/> (last visited June 13, 2008).

¹⁰ Hazardous Substances and New Organisms Act 1996 § 26.

¹¹ *Id.* § 34(1).

¹² *Id.* §§ 25(1)(b), 34-45B.

Approval is not required for “the importation of an incidentally imported new organism, if it is imported in or on goods lawfully imported under the Biosecurity Act 1993, or, the movement or use of those goods, together with any new organisms incidentally imported while they remain in or on those goods, after their importation.”¹³ Further, the restriction on importation of an organism does not extend to the “biological material of the organism that cannot, without human intervention, be used to reproduce the organism.”¹⁴ No approval, however, may be given to import, develop, field test or release those new organisms that are prohibited by being specified within the Hazardous Substances and New Organisms Act 1996.¹⁵

Thus, prior to any importation or release from containment, or any conditional import or release from containment, an application (in the approved format) must be made to the ERMA for approval.¹⁶ The application must contain specified information including details of any adverse effects on the environment, any previous approval and the potential use of the organism.¹⁷

All organisms must meet minimum standards for approval.¹⁸ The ERMA must refuse the application if the organism does not meet these standards, that is, the organism is likely to cause any significant displacement of any native species within its natural habitat, a significant deterioration of natural habitats, or have a significant adverse effect on human health and safety or New Zealand’s inherent genetic diversity.¹⁹ Further, the organism must not cause “disease, be parasitic, or become a vector for human, animal, or plant disease” (unless that is the specific purpose of the organism).²⁰

When considering an application for approval to import or to release from containment, or for approval to import or release a new organism with controls (or for release from containment an organism previously approved for importation with controls), the ERMA must consider:²¹

- Whether the organism meets the minimum standards (and, in the case of a new organism with controls, what controls will be placed on the organism, how effective these controls will be, and the ease with which the organism could be recovered or eradicated should it form a self-sustaining population); and

¹³ *Id.* § 25(1A).

¹⁴ *Id.* § 25(5).

¹⁵ *Id.* § 25(2), Schedule 2. Prohibited organisms are currently various kinds of animals and plants.

¹⁶ *Id.* §§ 34, 38A.

¹⁷ In accordance with Hazardous Substances and New Organisms Act 1996 §§ 34(2), 38A(2), any application must contain:

(a) Any information prescribed; and (b) Information on all occasions where the organism has been considered by the government of any prescribed state or country or by any prescribed organisation and the results of such consideration; and (c) The identification of the organism; and (d) Any likely inseparable organisms; and (e) All the possible adverse effects of the organism on the environment; and (f) The affinities of the organism with other organisms in New Zealand; and (g) The potential use for the organism.” An application for a conditional release approval must also include information on “the controls that the applicant proposes the organism would be subject to on its release.

Id. § 38A(2)(h).

¹⁸ *Id.* § 36.

¹⁹ *Id.* §§ 36(a)-(d).

²⁰ *Id.* § 36(e).

²¹ *Id.* § 38.

- With regards to all effects of the organism and the required matters,²² if the “positive effects of the organism outweigh the adverse effects of the organism and any inseparable organism.”²³

Where the application is for importation or release with controls, the ERMA must also give consideration to whether there is sufficient information to assess the adverse effects of the organism.²⁴ The ERMA may decline an application if: the organism fails to meet the minimum standards; or after considering all effects of the organisms and the required matters “the adverse effects of the organism and any inseparable organism outweigh the positive effects;” or there is insufficient information for the ERMA to assess the adverse implications of the organism.²⁵

The ERMA may impose any controls on a conditional release approval, including limits as to the extent and purpose for which the organism may be used, monitoring, auditing and reporting obligations, and training and knowledge prerequisites for any person dealing with the organism.²⁶ These controls may be reviewed on the basis of the ERMA’s own initiative, on application by the user of the organism, or by request of any person with enforcement powers under the Hazardous Substances and New Organisms Act 1996.²⁷

Generally, approvals will expire after five years and there is an obligation to notify the ERMA once the organism has been released.²⁸ Upon expiration of a conditional release approval, the organism that is the subject of the approval must be destroyed.²⁹

Any food,³⁰ medicine or agricultural product that contains a genetically modified organism will also be subject to the Food Act 1981, the Medicines Act 1981, or the Agricultural Compounds and Veterinary Medicines Act 1997 (respectively) with regards to the safety, quality and efficiency of the products. However, the application of these Acts will not negate the requirements for approval under the Hazardous Substances and New Organisms Act 1996.

IV. Regulation of Human Cloning and Research Involving Human Embryos

Human cloning and research involving human embryos is regulated by the Human Assisted Reproductive Technology Act 2004 and the Hazardous Substances and New Organisms Act 1996.

A purpose of the Human Assisted Reproductive Technology Act 2004 is: “to secure the benefits of assisted reproductive procedures, established procedures, and human reproductive research for

²² *Id.* § 37. The additional matters to be consider by virtue of § 37 are the ability of the organism to establish an undesirable self-sustaining population, and the ease with which it could be eradicated if it was to do so.

²³ *Id.* §§ 38(1)(a)(ii); 38(1)(c).

²⁴ *Id.* § 38C.

²⁵ *Id.* § 38(1)(b).

²⁶ *Id.* § 38D.

²⁷ *Id.* § 38G (these reviews are subject to some limitations).

²⁸ *Id.* §§ 38E, 38H.

²⁹ *Id.* § 38F.

³⁰ Food products containing genetically modified substances must also comply with the AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE, Standard 1.5.2.

individuals and for society in general by taking appropriate measures for the protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research.”³¹

To regulate assisted reproductive technology, the Human Assisted Reproductive Technology Act 2004 establishes a regime where activities are either: “established procedures” (and therefore not subject to the Act), “prohibited actions,” or “procedures permitted with the approval of the Ethics Committee.” The Ethics Committee is established under the Human Assisted Reproductive Technology Act 2004,³² and must have one or more one or more members with expertise in assisted reproductive procedures and one or more members with expertise in human reproductive research.³³ The primary functions of the Ethics Committee are “to consider and determine applications for approvals for the performance of assisted reproductive procedures or the conduct of human reproductive research” and to “keep under review any approvals previously given and, without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals.”³⁴

The Ethics Committee may only approve activities in accordance with guidelines and advice from the Advisory Committee.³⁵ The Advisory Committee is established under the Human Assisted Reproductive Technology Act 2004³⁶ and must consist of between eight and twelve members with one or more members having expertise in assisted reproductive procedures, human reproductive research, ethics, and the relevant law.³⁷ Further, there must be one or more Maori members with expertise in Maori customary values and practice and the ability to articulate issues from a Maori perspective, one or more members with the ability to articulate issues from a consumer perspective, and one or more members with ability to articulate the interests of children by virtue of holding the office of Children’s Commissioner (or

³¹ Human Assisted Reproductive Technology Act 2004 § 3(a). The underlying principles that must guide “all persons exercising powers or performing functions” under the Act are:

- (a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure;
- (b) the human health, safety, and dignity of present and future generations should be preserved and promoted;
- (c) while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the use of these procedures;
- (d) no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent;
- (e) donor offspring should be made aware of their genetic origins and be able to access information about those origins;
- (f) the needs, values, and beliefs of Maori should be considered and treated with respect;
- (g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

Human Assisted Reproductive Technology Act 2004 § 4.

³² *Id.* §§ 27, 32. See also the Ethics Committee on Assisted Reproductive Technology’s (ECART’s) Web site, <http://www.ecart.health.govt.nz/> (last visited June 13, 2008).

³³ Human Assisted Reproductive Technology Act 2004 § 27(3)(b).

³⁴ *Id.* § 28(1).

³⁵ *Id.* § 29.

³⁶ *Id.* §§ 27, 32; see also the ECART Web site, <http://www.ecart.health.govt.nz/>.

³⁷ *Id.* §§ 34(4)(a)-(c).

be a representative or employee of the person who holds that office).³⁸ In addition, at least half of the members must be “laypersons.”³⁹

The primary functions of the Advisory Committee are to issue guidelines and advice to the Ethics Committee and to provide the Minister with advice regarding reproductive procedure or human reproductive research.⁴⁰

Established Procedures

“Established procedures” are those assisted reproductive procedures that are declared to be established in accordance with the Human Assisted Reproductive Technology Act 2004.⁴¹ Established procedures do not require individual ethics approval.⁴²

To date the following have been declared established procedures⁴³ (although some versions of these procedures have been declared not to be established procedures):⁴⁴

- Artificial insemination
- Assisted hatching
- Blastocyst culture
- Collection of eggs for purposes of donation
- Collection of sperm for purposes of donation
- Egg cryopreservation
- Embryo cryopreservation
- Gamete intrafallopian transfer (GIFT)
- Intracytoplasmic sperm injection (ICSI)
- In vitro fertilisation (IVF)
- Ovarian tissue cryopreservation
- Pre-implantation genetic diagnosis (PGD)

³⁸ *Id* §§ 34(4)(d)-(g), (5).

³⁹ *Id* §§ 34(6), (7).

⁴⁰ *Id* § 35.

⁴¹ *Id* § 6.

⁴² *Id* § 5. Individual ethics approval is not required because an established procedure does not fall within the definition of assisted reproductive procedure.

⁴³ Human Assisted Reproductive Technology Order 2005, June 2005, *available at* <http://rangi.knowledge-basket.co.nz/regs/regs/text/2005/2005181.txt> (last visited June 12, 2008). The Minister of Health may be advised by the Advisory Committee that certain procedures should be declared (via an Order in Council) to be established procedures. Human Assisted Reproductive Technology Act 2004 § 6.

⁴⁴ These procedures are: Use of donated eggs or donated sperm (other than from a family member); Use of ovarian tissue or eggs that have previously undergone cryopreservation; collection of immature eggs or the use of eggs that have been matured by in vitro maturation; Use of sperm from a deceased person (without prior consent); Use of pre-implantation genetic diagnosis (for purposes other than the prevention or treatment of a genetic disorder or disease). Human Assisted Reproductive Technology Order 2005, June 2005, part 2.

- Sperm cryopreservation.

Prohibited Actions and Offenses

Prohibited actions include:⁴⁵

- For reproductive purposes artificially form: a cloned embryo (excluding splitting an embryo that has been formed by the fusion of gametes) or a hybrid embryo;
- Implant into a human a: cloned embryo; an animal gamete or embryo; or a hybrid embryo;
- Implant into an animal: a human gamete or human embryo or a hybrid embryo;
- Implant into a human being a genetically modified gamete, human embryo, or hybrid embryo;
- Implant into a human gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus; and
- Import or export to or from New Zealand or possessions (without reasonable excuse) an in vitro gamete, an in vitro embryo, an in vitro foetus, or an in vitro being formed through a prohibited practice.

The maximum penalty for an offense involving a prohibited practice is imprisonment of up to five years and/or a fine of up to \$200,000 NZD (about US\$150,600).⁴⁶

It is also an offense to import, export, cause further development (outside the human body, or in the case of a hybrid embryo any further development), possess; or use for the purposes of assisted reproductive technology, an embryo that is over fourteen days in development (or in the case of a hybrid embryo the day on which the primitive streak appears (if earlier than fourteen days)).⁴⁷ The maximum penalty for these offenses is imprisonment for a term not exceeding two years and/or a fine not exceeding \$100,000 NZD (about US\$75,300).⁴⁸ Providers or persons responsible for an activity approved by an ethics committee must take practical steps to ensure an offense is not committed.⁴⁹ The penalty for failure to take such steps is a fine of up to \$50,000 NZD (about US \$37,650).⁵⁰

Other offenses include: storage of an embryo for longer than ten years, other than with the approval of an ethics committee; selecting the sex of an embryo (including an procedure to influence the sex of an embryo) for the purposes of reproduction, other than to avoid genetic conditions; obtaining a gamete from a person less than sixteen years of age; commercial supply of embryos or gametes; or

⁴⁵ Human Assisted Reproductive Technology Act 2004 § 8, Schedule 1.

⁴⁶ *Id.* § 8(4). Currency equivalencies are based on the June 16, 2008, exchange rate.

⁴⁷ *Id.* § 9.

⁴⁸ *Id.* § 9(5).

⁴⁹ *Id.* § 9(3).

⁵⁰ *Id.* § 9(6).

advertising for any of these activities.⁵¹ Surrogacy arrangements per se are not illegal but may not be commercial in nature and are unenforceable.⁵²

Procedures Requiring Ethics Committee Approval

It is an offense (maximum penalty of a fine of \$50,000 NZD (about US\$37,650)) to perform an “assisted reproductive procedure”⁵³ or to conduct “human reproductive research”⁵⁴ without the prior written approval of the Ethics Committee.⁵⁵ Any such activity approved by the Ethics Committee must be performed in accordance with any conditions imposed by the Ethics Committee or any other applicable regulations in force.⁵⁶

Approval from the Ethics Committee is obtained via written application (in approved form) detailing the activity for which approval is sought, the purpose of the activity and the person nominated as responsible for the activity.⁵⁷ Approval may only be granted where the activity is consistent with advice or guidelines from the Advisory Committee.⁵⁸ If the activity is not addressed in existing guidelines or advice, the Ethics Committee must decline the application and refer the application to the Advisory Committee,⁵⁹ potentially resulting in a regulatory gap should emerging technology not be regulated by the Human Assisted Reproductive Technology Act 2004 on the basis of being neither a prohibited practice nor the subject of advice or guidelines issued by the Advisory Committee.⁶⁰ The Ethics Committee must report all approvals granted to the Advisory Committee.⁶¹

The Ethics Committee may impose (and subsequently change) any conditions upon its approval, including limitations as to the duration of the approval or limitations as to the class of persons on whom

⁵¹ *Id.* §§ 10-13, 15.

⁵² *Id.* § 14.

⁵³ An assisted reproductive procedure is defined as:

- a) means a procedure performed for the purpose of assisting human reproduction that involves—
- (i) the creation of an in vitro human embryo; or
 - (ii) the storage, manipulation, or use of an in vitro human gamete or an in vitro human embryo; or
 - (iii) the use of cells derived from an in vitro human embryo; or
 - (iv) the implantation into a human being of human gametes or human embryos; but
- (b) does not include an established procedure.

Human Assisted Reproductive Technology Act 2004 § 5.

⁵⁴ Human reproductive research is defined as: “research that uses or creates a human gamete, a human embryo, or a hybrid embryo.” *Id.* § 5.

⁵⁵ *Id.* § 16.

⁵⁶ *Id.* § 17.

⁵⁷ *Id.* § 18.

⁵⁸ *Id.* § 19(2).

⁵⁹ *Id.* § 19(2).

⁶⁰ See ALISON DOUGLASS, REPORT ON THE REGULATORY FRAMEWORK GOVERNING ASSISTED REPRODUCTIVE TECHNOLOGIES IN NEW ZEALAND 3 (Ministry of Health, Aug. 2006), available at [http://www.acart.health.govt.nz/moh.nsf/pagescm/1097/\\$File/regulatory-framework-report-aug06.doc](http://www.acart.health.govt.nz/moh.nsf/pagescm/1097/$File/regulatory-framework-report-aug06.doc) (last visited June 13, 2008).

⁶¹ Human Assisted Reproductive Technology Act 2004 § 30.

the reproductive activity may be performed.⁶² The Ethics Committee must impose reporting requirements on the recipient of any approval.⁶³ Any approval by the Ethics Committee may be subsequently revoked, in which case the person approved as being responsible for the activity must ensure that the activity ceases and that there is compliance with any directions from the Ethics Committee.⁶⁴

Moratorium on Activities

Where the government believes it is necessary for the Advisory Committee to develop advice or guidelines, the government may declare a particular kind of assisted reproductive technology or human reproductive research to be subject to a moratorium for a period of up to eighteen months (with one eighteen month extension).⁶⁵ During this moratorium the Ethics Committee may not consider applications for activity that is subject to the moratorium⁶⁶ and it is an offense to perform any procedure or research that is subject to the moratorium (unless acting under prior approval of the Ethics Committee).⁶⁷

Guidelines and Advices

To date the Advisory Committee has provided advice on a range of areas including cloning for non-reproductive purposes and genetic modification of gametes and embryos.⁶⁸

Research Using Embryonic Stem Cells

Research on embryos is not prohibited per se under the Human Assisted Reproductive Technology Act 2004 but is limited to embryos less than fourteen days old.⁶⁹

While the creation and use of embryos to produce embryonic stem cells falls under the Human Assisted Reproductive Technology Act 2004, subsequent use of embryonic stem cells and stem cell lines for research or therapy does not.⁷⁰ However such use of embryonic stem cells would fall under the Ministry of Health's Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research.⁷¹ Those guidelines require, among other things, that:

⁶² *Id.* § 21.

⁶³ *Id.* § 19(5).

⁶⁴ *Id.* §§ 22-23.

⁶⁵ *Id.* § 24.

⁶⁶ *Id.* § 25.

⁶⁷ *Id.* § 26.

⁶⁸ Guidelines include: Guidelines on Surrogacy Arrangements involving Providers of Fertility Services (Nov. 2007); Guidelines on donations of Eggs or Sperm between Certain Family Members (Nov. 2007); Embryo Donation for Reproductive Purposes (Aug. 2005); Guidelines on Preimplantation Genetic Diagnosis (Mar. 2005); Guidelines on the Use, Storage and Disposal of Sperm from a Deceased Man (Feb. 2000), available at <http://www.acart.health.govt.nz/moh.nsf/indexcm/acart-resources-guidelines> (last visited June 12, 2008).

⁶⁹ Human Assisted Reproductive Technology Act § 9.

⁷⁰ Embryo is defined to include: "includes a zygote and a cell or a group of cells that has the capacity to develop into an individual; but does not include stem cells derived from an embryo." Human Assisted Reproductive Technology Act § 5.

⁷¹ MINISTRY OF HEALTH, GUIDELINES FOR USING CELLS FROM ESTABLISHED HUMAN EMBRYONIC STEM CELL LINES FOR RESEARCH (Sept. 2006), available from the New Zealand Health and Disability Ethics Committee Web site, at

- Research must be approved by an ethics committee (generally the Health and Disability Ethics Committee established under the New Zealand Public Health and Disability Act 2000) prior to commencement of research and prior to the importation of any cell line into New Zealand;
- Research involving genetic modification must be reviewed and approved by the Environmental Risk Management Authority;
- Research involving human embryonic stem cell lines must comply with all applicable standards of ethical research in New Zealand;
- Embryos must have been created for the purpose of fertility treatment and no longer be required for that purpose;
- Persons whose gametes were used to create embryos must have given free and informed consent to the use of their embryos to derive stem cells; and
- Any imported cell lines were obtained and exported in accordance with the laws of the originating country.⁷²

V. Regulation of Genetic Screening and Resulting Information

Both the Privacy Act 1993 and the Health Information Privacy Code 1994 (developed under the Privacy Act and granted the force of law) impose rules on agencies within the health sector that collect or use personal or health information. The definition of health information within the Health Information Privacy Code 1994 includes such things as medical history, donations of body parts or bodily substance, and information collected during or in the course of providing any health service.⁷³

Generally, personal and health information may only be collected and disclosed with the consent of the person involved.⁷⁴ Health information may be collected for research purposes with the consent of the individual concerned or from sources other than the individual concerned provided approval is granted by an ethics committee and the published form of the material will not identify the individual concerned.⁷⁵

The Guidelines on Preimplantation Genetic Diagnosis provide that all applications for preimplantation genetic diagnosis for Human Leucocyte Antigen tissue typing must be submitted to the Ethics Committee for approval.⁷⁶ Those types of preimplantation genetic disorder diagnosis (e.g., for familial single gene disorders or familial sex link disorders or familial chromosomal disorder) that are

[http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6779/\\$File/guidelines-stem-cell-use.pdf](http://www.ethicscommittees.health.govt.nz/moh.nsf/pagescm/6779/$File/guidelines-stem-cell-use.pdf) (last visited June 13, 2008).

⁷² *Id.*

⁷³ Health Information Privacy Code 1994 § 4(1). Copies of the Code are available from the Privacy Commissioner's Web site, at <http://www.privacy.org.nz/assets/Files/38197000.pdf> (last visited June 13, 2008).

⁷⁴ Privacy Act 1993 § 6; Health Information Privacy Code 1994 § 5.

⁷⁵ Health Information Privacy Code 1994 § 5, Rule 2(2)(g)(3).

⁷⁶ NATIONAL ETHICS COMMITTEE ON ASSISTED HUMAN REPRODUCTION, GUIDELINES ON PREIMPLANTATION GENETIC DIAGNOSIS (Mar. 2005), available on the Advisory Committee on Reproductive Technology's Web site, at [http://www.acart.health.govt.nz/moh.nsf/pagescm/30/\\$File/pgd.pdf](http://www.acart.health.govt.nz/moh.nsf/pagescm/30/$File/pgd.pdf) (last visited June 13, 2008).

considered established procedures do not require prior approval.⁷⁷ However, preimplantation genetic diagnosis may not be used for “social reasons, including sex selection; to alter the genetic constitution of an embryo; to select embryos with a genetic impairment seen in a parent,” or any other reason than for those listed as established procedures.⁷⁸

VI. Regulation of Gene Therapy

Gene therapy and the administration of nucleic acids are regulated under the Medicines Act 1981. In accordance with that Act, if any “medicine” is administered for the sole purpose of obtaining clinical and scientific information then the administrator must seek prior approval for its use.⁷⁹ Approval must be sought from the Director-General of Health on the recommendation of the Health Research Council of New Zealand. In the area of gene therapy the Health and Research Council is advised by the Gene Technology Advisory Committee.⁸⁰

Applications for approval are made to the Ministry of Health in the prescribed format and accompanied by an application fee, which may be waived by the Ministry of Health.⁸¹ The Health and Research Council may provide guidelines regarding specific technology and where these are relevant the proposed activity must comply with the guidelines.⁸² The application will be reviewed within thirty days and advice given to the Director General of Health.⁸³

⁷⁷ NATIONAL ETHICS COMMITTEE ON ASSISTED HUMAN REPRODUCTION, GUIDELINES ON PREIMPLANTATION GENETIC DIAGNOSIS, March 2005 ¶ 1.

⁷⁸ *Id.* ¶ 8.

⁷⁹ Medicines Act 1981 § 30(1).

⁸⁰ The terms of reference for the Gene Technology Advisory Committee, for purposes of the Medicines Act 1981 § 30, include:

Proposals for clinical trials which include the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated microorganisms, viruses or cells into human subjects for the purpose of gene therapy or cell marking. Proposals for clinical trials in which the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory), or genetically manipulated microorganisms, viruses or cells is designed to stimulate an immune response against the subject’s own cells, as in the treatment of certain cancers. Proposals for clinical trials in which nucleic acids either from or within cells from animal species are transferred into humans for the purpose of disease treatment i.e. xenotransplantation. Proposals for clinical trials in which human nucleic acids have been introduced into the genome of an animal species, including genetically manipulated microorganisms, for the purpose of developing products to be used for either disease prevention or treatment in human subjects. Proposals for clinical trials involving vaccines in which nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated microorganisms, viruses or cells have been introduced to stimulate an immune response to antigenic determinants of an infectious agent.

For a copy of the Terms of Reference, see Health Research Council of New Zealand’s Web site, http://www.hrc.govt.nz/root/pages_regulatory/GTAC_Terms_of_Reference.html (last visited June 13, 2008).

⁸¹ HEALTH RESEARCH COUNCIL, GENE TECHNOLOGY ADVISORY COMMITTEE, PROCESS AND GUIDELINES FOR APPLICATION FOR APPROVAL OF PROPOSALS INVOLVING ADMINISTRATION OF GENE PRODUCTS TO HUMAN SUBJECTS IN NEW ZEALAND 3 (Mar. 2008), available at http://www.hrc.govt.nz/assets/pdfs/publications/GTACProcess%20and%20Guidelines%202008%20_2.pdf (last visited June 13, 2008).

⁸² See, e.g., HEALTH RESEARCH COUNCIL OF NEW ZEALAND, GUIDELINES FOR PREPARATION OF APPLICATIONS INVOLVING CLINICAL TRIALS OF XENOTRANSPLANTATION IN NEW ZEALAND (Sept. 2007), available at <http://www.hrc.govt.nz/assets/pdfs/publications/Guidelines%20for%20Preparation%20of%20Applications%20Involving%20Clinical%20Trials%20of%20Xenotransplantation%20in%20NZ.pdf> (last visited June 13, 2008).

⁸³ HEALTH RESEARCH COUNCIL of New Zealand, GENE TECHNOLOGY ADVISORY COMMITTEE, PROCESS AND GUIDELINES FOR APPLICATION FOR APPROVAL OF PROPOSALS INVOLVING ADMINISTRATION OF GENE PRODUCTS TO HUMAN SUBJECTS IN NEW ZEALAND 3 (Mar. 2008).

VII. Import and Export of Cell Lines

Cell lines derived from human cells (but not embryos or gametes) are considered human tissue for the purposes of standards for collection or use of human tissue for non-therapeutic purposes and for the export and import of human tissue.⁸⁴ In accordance with sections 66 and 75 of the Human Tissue Act 2008, regulations may be issued prescribing standards in relation to the export and import of human tissue.

In accordance with the Guidelines for Using Cells from Established Human Embryonic Stem Cell Lines for Research, any imported stem cell lines must be obtained and exported in accordance with the laws of the originating country.⁸⁵ Additionally, it is an offense to import into or export from New Zealand an in vitro gamete, an in vitro embryo or an in vitro fetus, or an in vitro being formed through a “prohibited practice.”⁸⁶ Likewise, it is an offense to import or export an embryo that is over fourteen days in development (or, in the case of a hybrid embryo, the day on which the primitive streak appears if earlier than fourteen days).⁸⁷

VIII. Conclusion

New Zealand regulates gene technology by regulating the importation and release of genetically modified organisms, and by limiting the genetic technology use and research that may be undertaken. Regulation is implemented by categorization, with some activities and organisms being prohibited while others are permitted, and with a final category of activates and organisms being permitted but only through a licensing system.

In particular, there are limits on how embryos may be used in research. Embryos must be excess to those required for assisted reproductive technology and generally less than fourteen days developed. The research must be done under license and in accordance with promulgated ethical guidelines.

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⁸⁴ Human Tissue Act 2008 §§ 7, 47, 74 (collection or use of human tissue for non-therapeutic purposes) and §§ 66, 75 (export and import of human tissue).

⁸⁵ MINISTRY OF HEALTH, GUIDELINES FOR USING CELLS FROM ESTABLISHED HUMAN EMBRYONIC STEM CELL LINES FOR RESEARCH ¶ 11 (Sept. 2006).

⁸⁶ Human Assisted Reproductive Technology Act 2004 § 8(2).

⁸⁷ *Id.* § 9(2)(a).

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RUSSIAN FEDERATION

REGULATION OF HUMAN GENETIC TECHNOLOGY

Executive Summary

Russian legislation in the field of genetic engineering is underdeveloped. Two major laws regulate the field. One law prohibits human cloning and the transfer of cloned embryos across Russia's border, while the other establishes basic principles of licensing and safety monitoring over genetic engineering activities if they do not affect human body, tissues, or cells. All issues related to the development, use, or transfer of human genetic technologies are regulated by the Federal Health Protection Ministry. General policies of development and implementation of biotechnologies are formulated by a special interagency commission created under the Ministry of Science and Education. Because Russian legislation does not meet the requirements established by the European Convention on Human Rights and Biomedicine, Russia is not a signatory to this Convention. In addition, issues of bioethics are not regulated by Russian law.

I. Major Acts of Domestic Legislation

Russia does not pay special attention to issues of regulating the use of biotechnological products. It appears that no legislative acts on this issue were passed during the last seven years. Two federal laws and a few government resolutions regulate the issues related to the development, use, or transfer of human genetic technologies. On April 19, 2002, the Parliament of Russia adopted Federal Law No. 54-FZ, a Temporary Ban on the Cloning of a Human.¹ The Law, which entered into force on June 23, 2002, imposed a moratorium on human cloning and prohibited the transportation of cloned human embryos across the country's border. Russian legislators stated that this action was based on respect for the dignity of a human being, recognition of a human's value, the necessity to protect personal rights and freedoms, and insufficient knowledge of potential biological and social consequences of human cloning.

The Law provided for the possibility of canceling the ban on cloning, depending on obtaining new knowledge and the determination of moral, social, and ethical rules used in the cloning technology; however, no further decisions have been made since the adoption of this law in 2002. The moratorium on human cloning does not apply to the cloning of other organisms. The ban does not prohibit research into therapeutic cloning or the cloning of individual organs of the human body.

The major Russian legislative act on issues related to genetic engineering is the Federal Law on State Regulation in the Field of Genetic Engineering Activities. The law establishes major definitions for terms such as genetic engineering, genetic therapy, genetic diagnostics, genetic modification, and others. However, the conduct of genetic engineering and the application of genetic methods to the human body, tissues, or cells are not covered by this law. The law introduced state regulation of all activities related to genetic technologies and requires their mandatory licensing. According to amendments to this law dated June 28, 2000, all "genetic manipulations on the molecular and cellular levels for the purposes of genetic diagnostics and/or genetic therapy in regard to the human" must be licensed by federal authorities.² The

¹ ROSSIISKAIA GAZETA [official daily newspaper of the Russian Government, RG], May 23, 2002, at 4.

² SOBRANIE ZAKONODATELSTVA ROSSIISKOI FEDERATSII [Russian official gazette, SZ RF] 2000, No. 29, Item 3005.

law states that products and services made with the usage of genetic engineering methods shall meet the requirements of environmental safety, sanitation and pharmaceutical norms, and federal standards of the Russian Federation.

The use of biotechnologies for medical purposes and the application of biological objects as medicines are regulated in the same manner as the use of all other pharmaceuticals by the Federal Law on Medicines of June 12, 1998.³ In 1999, the government drafted the Bill on Legal Foundations of Biomedical Ethics and Guarantees of Its Implementation, but it was not approved by Parliament.

II. Implementing Documents

The Federal Ministry of Health Protection is charged with conducting government control over activities related to cloning. Government Regulation No. 1801 of December 25, 1997,⁴ provides for the development of clinical microbiological laboratories, which are allowed to conduct research on cloning. The Health Ministry of Russia insists on full control over clinics that conduct cell research. In May 2002, the Health Ministry promulgated a resolution to reduce the number of such clinics and to keep 16 research centers where cloning experiments were allowed. As the result of this resolution, a state-owned bank of stem cells was created in Moscow.

State registration of food products and their components received from genetically modified sources was introduced in June 1999, by Order No. 7 of the Chief Sanitary Physician of the Russian Federation. Government Regulation No. 120 of February 16, 2001, On State Registration of Genetically Modified Organisms, introduced the state registration of GMOs that are for the first time released into the environment, used in industry, or are being imported. Russian and foreign enterprises receive certificates of registration upon entry of a GMO into the state registry.

To coordinate the activities of different government agencies in the field of genetic engineering, an interagency commission was established in 2005. Its main task is to provide suggestions regarding the formation and implementation of state policies in the field of biotechnology and genetic engineering, and to secure coordinated activities of federal, state, scientific, educational, and other institutions. The commission includes representatives of all interested government agencies.⁵

Because of the existing inability to exercise total control over human genetic technologies, all works in this field were recognized as activities that cause an increased danger to human health by Russian Supreme Court Ruling No. 3 of April 28, 1994, on Judicial Practice In Regard to the Health Damage Compensation Cases.⁶ That ruling appears to be the only judicial ruling that reflects an approach toward human genetic technologies.

III. Non-Participation in International Conventions

Russia did not join the 1996 Convention on Human Rights and Biomedicine, mostly because of the incompatibility of domestic legislation with the Convention's requirements. Russian health care legislation does not provide for specific regulation of the medical use of human genetic technologies, and its criminal laws do not contain specific punishments for receiving financial profits from operations with

³ RG, June 25, 1998, at 2.

⁴ SZ RF 1998, No. 3, Item 211.

⁵ RG, June 14, 2005, at 7.

⁶ BULLETEN' VERKHOVNOGO SUDA ROSSIISKOI FEDERATSII [Russian Federation Supreme Court Bulletin] 1994, No. 6, at 12.

human genome, organs, tissues, or experiments with embryos, both of which are required by the Convention.

Several provisions of the Russian Fundamentals of Health Care Legislation of July 22, 1993, and the Federal Law on Transplantation of Human Organs and Tissues of December 22, 1992, correspond to the rules established by the Convention on Human Rights and Biomedicine, by establishing that human organs and tissues cannot be sold or purchased, and that activities aimed at selling or purchasing human organs, or advertisement of such activities, shall be prosecuted under the Criminal Code of the Russian Federation, but the existing Criminal Code does not include provisions that would punish these activities or other manipulations in the field of human genetic engineering.

The adoption of the Federal Law on a Temporary Ban on the Cloning of a Human, which provided for prosecution for all human cloning experiments in the country and for the transportation of cloned embryos across the border of the Russian Federation, was not followed by a relevant amendment to the Criminal Code. Despite the fact that the Law states that violators of this ban shall be prosecuted under Russian law, it is not clear what kind of legal liability would be imposed.

Presently, Russian specialists believe that article 120 of the Russian Criminal Code, which prosecutes the coercive removal of human organs and tissues for transplantation, needs to be amended.⁷ This is the only Criminal Code provision aimed at protecting an individual from the impact of illegally used biotechnologies and does not provide for punishment of illegal activities related to human genetic engineering.

Because Russia did not join the Convention, Russia did not sign the supplementary protocol to the Convention of the European Council on Bio-Ethics, which prohibits human cloning.

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⁷ See, e.g., Elena Karavaeva, Roman Kravtsov, *Biomeditsinskie Tehnologii: Voprosy Pravovogo Regulirovaniia I Otvetstvennosti* [Biomedical Technologies: Issues of Legal Regulation and Liability], 3 SIBIRSKII IURIDICHESKII VESTNIK (2005), available at www.law.edu.ru/doc/document.asp?docID=1229696

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REGULATION OF HUMAN GENETIC TECHNOLOGY
UNITED KINGDOM

Executive Summary

The United Kingdom has a large medical biotechnology sector and has encouraged the development of this sector through legislation that bestows a degree of flexibility on a regulator, the Human Embryology and Fertilisation Authority, which can approve the use of embryos for research and reproductive purposes, provided they meet one of the criteria in the legislation.

I. Introduction

The UK has a substantial medical biotechnology sector, second only to the United States, with approximately 450 biotechnology businesses in the UK that have a combined revenue of £2.63 billion (about US\$5.2 billion).¹ The UK has strived to create a legislative regime that provides stringent controls over the use of embryos, but that at the same times is flexible and competitive in encouraging research and development in the area.

II. Regulation of the Use of Human Embryos

Following the birth of the first baby created through the *in vitro* fertilization (IVF) process in 1978, in 1982, the government established the Warnock Committee² to review the ethical and social issues surrounding the use of human embryos in research and IVF treatment and to recommend legislation regulating the use of these embryos.³ After hearing evidence from various scientific, religious, and ethical bodies on the controversial issue of what status the human embryo should be accorded, the Committee recommended that “though the human embryo is entitled to some added measure of respect beyond that accorded to other animal subjects, that respect cannot be absolute, and may be weighed against the benefits arising from research.”⁴ As such, it determined that research on human embryos is morally justified in certain circumstances and made a number of recommendations⁵ that led to the enactment of the Human Fertilisation and Embryology Act 1990⁶ [hereinafter the 1990 Act], the first legislation in the United Kingdom to regulate scientific research of human embryos.

¹ Department for Business, Enterprise and Regulatory Reform, Medical Biotechnology Sector, <http://www.berr.gov.uk/sectors/biotech/biotechmedic/page10217.html> (last visited June 13, 2008).

² The terms of reference of the Warnock Committee were to “consider recent and potential developments in medicine and sciences related to human fertilization and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.” Department of Health & Social Security, REPORT OF THE COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY, 1984, Cmnd. 9314, *quoted in* Alex Sleator, *Stem Cell Research and Regulations under the Human Fertilisation and Embryology Act 1990 (Revised Edition)*, Dec. 2000, at 14, House of Commons Library Research Paper 00/93.

³ Sleator, *id.*

⁴ *Id.*

⁵ The government issued a consultation paper and White Paper detailing the government’s policy prior to enacting the 1990 Act: LEGISLATION OF HUMAN INFERTILITY SERVICES AND EMBRYO RESEARCH, 1986, Cm. 46; Department of Health and Social Security, HUMAN FERTILISATION AND EMBRYOLOGY: A FRAMEWORK FOR LEGISLATION, 1987, Cm. 259.

⁶ Human Fertilisation and Embryology Act 1990, c. 37, *available at* http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source).

The 1990 Act regulated the use of human embryos through prohibiting the creation, use, or storage of a human embryo or of gametes⁷ without a license issued by the Human Fertilisation and Embryology Authority (HFEA), a regulatory body established by the 1990 Act. The HFEA is accountable to Parliament and ensures that human embryos are used only for the purposes specified in the 1990 Act through a system of licensing.

After the decision to allow research on embryos, the next controversial issue that faced the government was what was the most ethically and socially acceptable period that embryos should be used in research. As a result of a recommendation from the Warnock Committee, the 1990 Act granted the HFEA the authority to issue licenses for research on embryos up to fourteen days old, or when the primitive streak⁸ appears, whichever occurs first.⁹

The 1990 Act further limits the use of human embryos by authorizing the purposes for which the HFEA can issue a license. These purposes are known as the statutory purposes and the use of human embryos are currently limited to:

- promoting advances in the treatment of infertility;
- increasing knowledge about the causes of congenital disease;
- increasing knowledge about the causes of miscarriages;
- developing more effective techniques of contraception;
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation;
- increasing knowledge about the development of embryos;
- increasing knowledge about serious diseases; or
- enabling any such knowledge to be applied in developing treatments for serious diseases.¹⁰

The HFEA is given some discretion in the granting of licenses to ensure that embryos are not arbitrarily used in research, as not only must the applicant meet one of the above purposes, but the HFEA also must be satisfied that the use of the embryo is necessary or desirable for that purpose.¹¹

If a person creates a human embryo without a license from the HFEA, they are guilty of an offense and are liable, upon indictment, to imprisonment for up to two years and/or a fine.¹²

To ensure that the 1990 Act maintains pace with scientific and technological developments, it includes a provision that allows for the expansion of the scope of research for which licenses can be granted through secondary legislation.¹³ The secondary legislation can be passed only to, “increase

⁷ *Id.* Section 1(1) defines an embryo as a “live human embryo where fertilization is complete, and references to an embryo include an egg in the process of fertilization, and, for this purpose, fertilization is not complete until the appearance of a two cell zygote,” and the term gametes refers to mature sexual reproductive cells.

⁸ The primitive streak is defined as “a collection of cells from which the human central nervous system develops.” House of Lords, REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, H.L. 83(1) (2001-2) at 5.

⁹ The Human Fertilisation and Embryology Act 1990, c. 37, available at http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source), §§ 3(3)(a) and 3(4). The 14-day period does not apply to any time that the embryo is kept in storage. Department of Health, CHIEF MEDICAL OFFICER’S EXPERT GROUP REPORT, STEM CELL RESEARCH: MEDICAL PROGRESS WITH RESPONSIBILITY, June 2000.

¹⁰ The Human Fertilisation and Embryology Act 1990, *id.*, c. 37, sch. 2, and *see further* Human Embryology and Fertilisation Authority, *Regulation of Research on Human Embryos*, 2007, available at http://www.hfea.gov.uk/docs/2006_Guidance_Notes_for_All_Research_Licence_Applications.pdf.

¹¹ The Human Fertilisation and Embryology Act 1990, *id.*, c. 37, sch. 2.

¹² *Id.*

¹³ Regulations refer to Statutory Instruments made by the Secretary of State. *Id.*, c. 37, § 45(4). This section further provides that if a statutory instrument contains regulations that have not been approved in draft form by a resolution of each

knowledge about the creation and development of embryos, or about disease, or [to] enable such knowledge to be applied.”¹⁴ It is not typical in the United Kingdom to allow the expansion of the scope of primary legislation through secondary legislation. In this case, to ensure that Parliamentary approval was obtained and that the secondary legislation on such a contentious issue was not quietly passed without debate, a draft must be placed before both the House of Lords and House of Commons and approved by a resolution in each House.¹⁵

Cloning

The UK currently permits therapeutic cloning, and the creation and use of clones are regulated by the HFEA, acting under the authority of the 1990 Act. While there is no distinction in the 1990 Act between embryos created by the replacement of the nucleus of an unfertilized egg with the nucleus of another cell (CNR) or fertilization, the government believes the HFEA is an appropriate mediation body to deal with ethical concerns over the use of embryos created by CNR as it grants licenses on a case-by-case basis, and must follow the statutory criteria.¹⁶

While the 1990 Act permitted the creation of embryos¹⁷ specifically for research,¹⁸ since its enactment,¹⁹ the introduction of regulations resulted in an “increase in demand for embryos created through ... CNR, also referred to as therapeutic cloning.”²⁰ This is because it is thought that stem cells derived from embryos created by CNR are therapeutically valuable as they are “genetically compatible with the person being treated, from whom the donor nucleus [originates].”²¹ This issue was examined by the Warnock Committee, which recommended, by a narrow margin, that embryos could be created solely for research as it considered that most needs could be met with embryos created for IVF treatment that are either not suitable for use or later not needed.²²

Because of the sensitivity of the issues raised, a House of Lords Select Committee on Stem Cell Research was established. After examining the evidence, it reiterated the view of the Warnock

House of Parliament, it is subject to annulment by a resolution of either House.

¹⁴ *Id.*, c. 37, sch. 2, ¶ 3(3).

¹⁵ For further reading on this subject, see ERSKINE MAY, ERSKINE MAY’S TREATISE ON THE LAW, PRIVILEGES, PROCEEDINGS AND USAGE OF PARLIAMENT 666-701 (Sir. William McKay et al. eds., 23d ed. 2004) & Joint Committee on Delegated Legislation, SECOND REPORT, 1972-2, H.L. 204; H.C. 468 ¶ 49, in which the government agreed to avoid the use of the positive resolution procedure under normal circumstances.

¹⁶ Department of Health, *supra* note 9, ¶ 1.6.

¹⁷ This currently occurs either through IVF or CNR, *id.*, ¶ 24.

¹⁸ Between the years 1991 and 1998, 763,509 embryos were created by IVF predominantly for infertility treatment. Out of that figure, 48,444 were given for use in research, 118 were created in the course of research, and 237,603 were not used for any purpose and destroyed; *id.* ¶ 3.5.

¹⁹ This currently prevents the United Kingdom from becoming a party to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, *opened for signature* Apr. 4, 1997, E.T.S. 164; 36 I.L.M. 821 (Jan. 1, 1999). Art. 18 prohibits the creation of human embryos for research.

²⁰ Department of Health, *supra* note 9.

²¹ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8. The idea for a Select Committee was put forward in the House of Lords during debates on the draft regulations. A peer of the House of Lords advocated that the regulations should be rejected until a Select Committee reviewed the issues. This view was not followed, and a Select Committee was appointed retrospectively to review the issues surrounding the regulations. See 621 PARL. DEB., H.L. (5th ser.) (2001) 15 available at http://www.parliament.the-stationery-office.co.uk/pa/ld200001/ldhansrd/vo010122/text/10122-04.htm#10122-04_head2.

²² Between Aug. 1, 1991 and Mar. 31, 2000, 53,497 surplus embryos were donated for research and 118 embryos were specifically created for research. Human Fertilisation and Embryology Authority, NINTH ANNUAL REPORT AND ACCOUNTS, 2000, in REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, at 25.

Committee and established a general rule that is followed by the HFEA that: “embryos should not be created specifically for research purposes unless there is a demonstrable and exceptional need which cannot be met by the use of surplus embryos.”²³

In August 2004, the first license to clone human embryos for therapeutic purposes was issued by the HFEA to scientists for research into treatments for diabetes and Parkinson’s and Alzheimer’s diseases.²⁴

Research License Applications

To obtain a license from the HFEA to conduct research on human embryos, the researcher must assemble a detailed application which is considered by the HFEA’s Research License Committee.²⁵ The purposes of the research must be considered scientifically valid and necessary for one of the statutory purposes, listed above under the heading *Regulation of the use of Human Embryos*.

The HFEA then obtains peer reviews concerning a number of issues, including the merits of the research project, its importance in the field, whether the use of embryos is justified, the length of the study, and whether the applicant’s qualifications are adequate.²⁶ When considering whether the use of embryos is justified, the HFEA considers whether the research can be undertaken in any other way, such as through the use of adult stem cells, and whether there are existing stem cell lines in the stem cell bank that are suitable.²⁷ Any research undertaken must also conform to the various research guidelines from professional and research bodies and from the Department of Health.²⁸ Once the application is reviewed, the HFEA must then inspect the site where the research is to occur

There was much concern that permitting therapeutic cloning would lead to reproductive or human cloning. Since the famous cloning of Dolly the sheep in 1996, the government has made clear its position that cloning individuals is ethically unacceptable.²⁹ After researching this issue, the House of Lords Select Committee on Stem Cell Research stated that:

Developing the CNR technique would in technical terms facilitate reproductive cloning. But the fact that a technique developed for a worthwhile purpose may be used for different, unacceptable purposes is not a conclusive argument for prohibiting ... [the HFEA] reinforced with specific statutory prohibitions provides sufficient protection against the development of CNR leading to reproductive cloning in the United Kingdom.³⁰

It was initially thought that embryos created by CNR would fall within the definition of an embryo within the 1990 Act. This was found not to be the case after a pro-life group sought, and was granted, a declaration that an embryo created by CNR was not within the definition of an embryo in the

²³ *Id.*

²⁴ Human Embryology and Fertilisation Authority, *HFEA Grants the First Therapeutic Cloning Licence for Research*, Aug. 11, 2004, available at <http://www.hfea.gov.uk/en/1048.html>.

²⁵ Human Embryology and Fertilisation Authority, *Regulation of Research on Human Embryos*, 2007, available at http://www.hfea.gov.uk/docs/2006_Guidance_Notes_for_All_Research_Licence_Applications.pdf.

²⁶ *Id.*

²⁷ *Code of Practice for the UK Stem Cell Bank*, version 3, Aug. 2006, available at <http://www.ukstemcellbank.org.uk/documents/Code%20of%20Practice%20for%20the%20Use%20of%20Human%20Stem%20Cell%20Lines.pdf>.

²⁸ The Polkinghorne Report, REVIEW OF GUIDANCE ON THE USE OF FETUSES AND FETAL MATERIAL, 1989, Cm. 762.

²⁹ Science and Technology Committee, THE CLONING OF ANIMALS FROM ADULT CELLS, GOVERNMENT RESPONSE TO THE FIFTH REPORT, 1997, Cm. 3815, ¶¶ 9 & 16.

³⁰ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, ¶¶ 5.14 and 5.24.

1990 Act, as it had not technically been fertilized.³¹ This decision was later overturned in the Court of Appeal, which held that the definition of an embryo should be given a purposive interpretation.³² Prior to the decision of the Court of Appeal, the government passed on an emergency basis the Human Reproductive Cloning Act 2001.³³ This Act contains one narrowly drafted clause to clarify the prohibited position of reproductive cloning and makes it a criminal offense punishable by up to ten years imprisonment upon conviction and/or an unlimited fine to “place in a woman a human embryo created otherwise than by fertilisation.”³⁴ The government continues to maintain that “in the absence of any obvious potential benefit to humanity that would be uniquely delivered by human reproductive cloning, we see no circumstances in which human reproductive cloning could be justified or allowed.”³⁵

Stem Cell Research

Legislation in the United Kingdom regulating stem cell research varies depending upon whether the stem cells are derived from embryos or adult tissue. Tissue can be obtained for research or treatment purposes from living adults, provided that their consent is obtained.³⁶ The use of human embryos in stem cell research is regulated by the 1990 Act, which prohibits the creation, use, or storage of a human embryo or of gametes³⁷ without a license issued by the HFEA. Once a license has been granted, the continued oversight of research projects is maintained by the requirement that reports be provided to the HFEA every six to twelve months, with a final report being produced at the end of the project detailing all results and conclusions.³⁸

After considerable debate in Parliament and a number of government and department reports³⁹ over the moral, ethical, and public policy implications of research on human embryos, the government decided that the purposes for which research on embryos could be undertaken should be extended to allow stem cell research. It was concluded that this could occur without unjustifiably extending the use of embryos under the 1990 Act.⁴⁰

In furtherance of the authority granted in the 1990 Act, the Human Fertilisation and Embryology (Research Purposes) Regulations 2001[hereinafter the Regulations] were introduced based on the recommendations and conclusions of various government and scientific studies. The Regulations

³¹ R v. Secretary of State for Health, *ex parte* Quintavalle (on behalf of Pro-Life Alliance) [2001] 4 All ER 1013 (Q.B.) (official source).

³² R v. Secretary of State for Health, *ex parte* Quintavalle (on behalf of Pro-Life Alliance) [2002] 2 All ER 625 (C.A.) (official source).

³³ Human Reproductive Cloning Act 2001, c. 23, available at http://www.opsi.gov.uk/acts/acts2001/pdf/ukpga_20010023_en.pdf (official source).

³⁴ *Id.*, § 1(1).

³⁵ Department of Health, Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, 2005, available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4119524.

³⁶ Alex Sleator, *supra* note 2, at 26.

³⁷ Human Fertilisation and Embryology Act 1990, c. 37, available at http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source).

³⁸ The Human Fertilisation and Embryology Authority, TWELFTH ANNUAL REPORT AND ACCOUNTS 2002/3, at 15.

³⁹ Department of Health, Department of Trade and Industry, Office of Science and Technology, CLONING ISSUES IN REPRODUCTION, SCIENCE AND MEDICINE, 1999, Cm. 4387; Department of Health, GOVERNMENT RESPONSE TO THE RECOMMENDATIONS MADE IN THE CHIEF MEDICAL OFFICER’S EXPERT GROUP REPORT “STEM CELL RESEARCH: MEDICAL PROGRESS WITH RESPONSIBILITY,” 2000, Cm. 4833, which responded to CHIEF MEDICAL OFFICER’S EXPERT GROUP REPORT, *supra* note 9, which was issued in response to Human Genetics Advisory Commission and Human Fertilisation and Embryology Authority, CLONING ISSUES IN REPRODUCTION, SCIENCE AND MEDICINE, 1998.

⁴⁰ CHIEF MEDICAL OFFICER’S EXPERT GROUP REPORT, *supra* note 9.

legalized stem cell research by extending the permitted purposes for research on embryos to include when it is necessary or desirable to increase knowledge into:

- the development of embryos;
- serious diseases; and
- treatments for serious diseases.⁴¹

Various reports rejected the argument that equivalent research could be conducted solely with adult stem cells and “were satisfied on the basis of the scientific evidence that as yet research on adult stem cells has not, as some claim, made research on embryonic stem cells unnecessary.”⁴² Successive government and scientific reports examining the issue echoed the reasoning of the Warnock Committee that was stated over fifteen years prior, and repeatedly noted that:

The great potential to relieve suffering and treat disease means that research [is] warranted across the whole range of possible sources of stem cells ... including embryos ... the potential benefit of discovering the mechanism for reprogramming adult cells and thereby providing compatible tissue for treatment justifies this transitional research involving the creation of embryos by cell nucleus replacement [CNR].⁴³

Upon the commencement of the Regulations, the legal status and regulation of human stem cells was uncertain, as once extracted from a human embryo, the stem cells are no longer considered to be an embryo and fall outside the scope of the HFEA.⁴⁴ In 2004, the Human Tissues Act was enacted, to govern the removal, storage, and use of human material, but this Act was not extended to established cell lines or to any human material created outside the human body.⁴⁵ The government stated the opinion that:

embryonic stem cell lines once established are not embryos and ... decided that research involving established stem cell lines does not need the same level of regulation to which embryo research is subject to by the HFEA. However, as the generation of embryonic stem cell lines involves the destruction of human embryos, oversight in form of [the] Steering Committee was recommended to ensure that research is conducted within an ethical framework that is transparent to the public and is keeping with HFEA Regulations. The oversight mechanisms governing research involving established embryonic stem cell lines and this Code of Practice are voluntary. However, they are a condition of the statutory regulation in the UK, and there is an expectation by Government that they are adhered to.⁴⁶

⁴¹ The Human Fertilisation and Embryology (Research Purposes) Regulations 2001, SI 2001/188 ¶ 2(2), available at <http://www.opsi.gov.uk/SI/si2001/20010188.htm> (official source).

⁴² Roger Highfield, *Lords Back Research on Cloned Embryo Stem Cells*, DAILY TELEGRAPH (London), Feb. 28, 2002, at 11.

⁴³ CHIEF MEDICAL OFFICER’S EXPERT GROUP REPORT, *supra* note 9, ¶¶ 25 and 28. The Expert Group lists the benefits of research involving CNR as:

understanding how adult cells can be reprogrammed; establishing the role of the egg in reprogramming an adult nucleus; discovering whether stem cells derived from embryos created by CNR differentiate in the same way and have the same potential as stem cells derived from embryos created from eggs and sperm; clarifying whether the stem cells from embryos created by CNR can produce tissue compatible with the donor of the nucleus; clarifying whether concepts developed in animal studies apply to humans, in particular the conditions required to achieve CNR in a human egg. *Id.* at 31.

⁴⁴ Code of Practice for the UK Stem Cell Bank, version 3, Aug. 2006, available at <http://www.ukstemcellbank.org.uk/documents/Code%20of%20Practice%20for%20the%20Use%20of%20Human%20Stem%20Cell%20Lines.pdf>. The HFEA initially looked at placing additional conditions in licenses issued for embryos to be used in stem cell research, but reasoned that if it did it would be acting beyond the powers granted to it in the 1990 Act. REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, at 470, referring to Department of Health, SUPPLEMENTARY MEMORANDUM (2) – OVERSIGHT OF STEM CELL RESEARCH – THE CASE FOR AND AGAINST REGULATION.

⁴⁵ *Code of Practice for the UK Stem Cell Bank, id.*

⁴⁶ *Id.*

In relation to the therapeutic use of stem cell, the House of Lords Select Committee concluded that sufficient controls already exist, most notably through the Medicines Control Agency (MCA), an executive agency of the Department of Health.⁴⁷ The MCA has stated that it is responsible for the regulation of

certain stem cell therapy products provided that they fall within the legal definition of a medicinal product ... [and that] there are situations where certain stem cell therapy products will fall within the definition of a medicinal product and will be regulated at clinical trials stages and at marketing authorization and beyond by the MCA.⁴⁸

Stem Cell Bank

The House of Lords recommended that a non-statutory Stem Cell Bank⁴⁹ should be established to provide oversight of the use of stem cell lines; ready access for scientists to stem cells with ensured purity and provenance from sources that operate ethically approved standards and to minimize the use of embryos by providing access to lines that are already in existence.⁵⁰

In response to this recommendation, the Medical Research Council launched the Stem Cell Bank in September 2002 in an independent national laboratory to avoid any conflicts of interest that might arise if it were, for example, housed in an academic laboratory.⁵¹ It is a condition of receiving a license by the HFEA for research on human embryos that a sample of every stem cell extracted from an embryo be placed in the Bank,⁵² and the deposit of foreign embryonic stem cells and UK somatic stem cells is encouraged.⁵³

The aim of the Bank is to regulate the use of stem cell lines and minimize the use of embryos in research by removing the need to generate new embryonic stem cell lines.⁵⁴ This is done by the Steering Committee, which “oversees on a voluntary basis the withdrawal and deposit of stem cell lines from the bank on a case by case basis.”⁵⁵ On the completion of an application that meets all relevant criteria, the stem cell lines in the Bank are available to researchers from industry and academia, both within the United Kingdom and from overseas. A recent government report noted that the self regulation of the use of embryonic stem cell lines through the stem cell bank is “currently appropriate and proportionate.”⁵⁶

⁴⁷ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, at 256, quoting a Memorandum by the Medicines Control Agency. The MCA is responsible for ensuring medicines meet appropriate standards of safety, quality, and efficacy prior to entry into the market in the United Kingdom.

⁴⁸ *Id.* at 256-57. The legal definition of medicinal product is governed by European Community law, which has been incorporated into the national law of the United Kingdom.

⁴⁹ The Stem Cell Bank “curates human adult and fetal somatic stem cell lines as well as human embryonic stem cell lines ... [as] it is not yet clear which stem cell source will prove most useful in terms of developing human therapies.” Code of Practice for the UK Stem Cell Bank, *supra* note 44.

⁵⁰ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, ¶ 8.29.

⁵¹ The Human Fertilisation and Embryology Authority, *supra* note 38, at 21. For further information about the Stem Cell Bank see The UK Stem Cell Bank, *Overview*, http://www.ukstemcellbank.org.uk/overview_new.html (last visited June 13, 2008).

⁵² Code of Practice for the UK Stem Cell Bank, *supra* note 44.

⁵³ UK Stem Cell Bank, *Depositing Stem Cells*, <http://www.ukstemcellbank.org.uk/depositing.html> (last visited June 13, 2008).

⁵⁴ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, ¶ 8.24.

⁵⁵ UK STEM CELL INITIATIVE, REPORT AND RECOMMENDATIONS, 2005, ¶ 5.3.1 available at <http://www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf>.

⁵⁶ *Id.*

Depositing Stem Cell Lines

When deciding on the procedure for depositing stem cell lines in the bank, the steering committee took into account the financial interests and interest in the intellectual property of the depositor, the often limited financial resources of academic institutions, and the need to make the use of the stem cell lines as accessible as possible. To cover these needs, the Code of Practice for the Use of Human Stem Cell Lines⁵⁷ established a regime whereby the depositor signs a Materials Deposition Agreement (MDA) with the Stem Cell Bank that allows the depositor to maintain a limited amount of control of the stem cell lines, as they can set out the terms of access to a Materials Use License (MUL), which must be negotiated and agreed upon before the Bank will release the stem cell line.⁵⁸ The MDA specifies a number of conditions that apply to both the depositor and those requesting the use of the stem cell lines, most notably:

- embryonic stem cell line samples may only be passed to those for whom the HFEA or Steering committee have been give notice;
- if the depositor is a company, they may have the first option of negotiating a license to any intellectual property arising from the use of a cell line by an academic group;
- if the depositor is an academic group, they may seek a share of the revenue of any product developed with their deposited stem cell lines; and
- the depositor is not permitted to impose any restrictions that could impede or prevent timely basic research or the development of therapies.⁵⁹

Applications for Using Stem Cells

The Stem Cell Bank steering committee has established a number of criteria that must be met before access to the stem cell lines will be granted. The application for access must be accompanied by all relevant licenses, accreditation from the relevant ethical and regulatory authorities in the United Kingdom, or the overseas equivalent.

Additional requirements must be met before embryonic stem cell lines can be accessed. The cell line must only be used for:

- research which increases the knowledge about the development of embryos or has the long term goal of helping to increase knowledge about serious disease and their treatment;
- basic research which underpins these aims; or
- the development of cell-based therapies for clinical trials in respect of serious human diseases.⁶⁰

Research in other countries on exported stem cells must comply with legislation in the UK, as well as the legislation of the country where the research is occurring, and comply with the Code of Practice.⁶¹ Users must also complete the standard Materials Access Agreement, an agreement between the user and the Stem Cell Bank, and the Materials Use License (MUL), an agreement between the user and the owner or depositor of the stem cell line.

⁵⁷ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, ¶ 8.24.

⁵⁸ *Id.*, annex 11.

⁵⁹ UK Stem Cell Bank, *Materials Deposit Agreement*, [http://www.ukstemcellbank.org.uk/documents/Materials%20Deposition%20Agreement%20\(MDA%20v5%2009-10-07\).pdf](http://www.ukstemcellbank.org.uk/documents/Materials%20Deposition%20Agreement%20(MDA%20v5%2009-10-07).pdf) (last visited June 13, 2008)

⁶⁰ Code of Practice for the UK Stem Cell Bank, *supra* note 44, ¶ 8.1.1.

⁶¹ *Id.*, ¶ 8.4.

Consent of the Embryo Donor

Due to the sensitive nature of the use of embryos for research and the fact that the embryo contains genetic information about the donor, the 1990 Act requires that consent be obtained from a donor of embryos or gametes.⁶² The 1990 Act specifies that a donor must have the opportunity to receive counseling about the implications of their use and be “provided with such relevant information as is proper.”⁶³

Donors of embryos and gametes must consent in writing to allow the use of their embryos for research and can specify the conditions under which embryos may be used.⁶⁴ Once an embryo has been used for research, written consent from the donor cannot be withdrawn.⁶⁵ The Code of Practice for the Use of Human Stem Cell Lines states that the embryo will be regarded to have been used for research “after it is under the control of the researchers and is being cultured/grown for use in research. If researchers generate stem cells or stem cell lines from the embryo,”⁶⁶ consent for the use of the stem cells or stem cell lines cannot be withdrawn.

Issues Surrounding Genetic Identity

The nature of science and technology surrounding stem cell research means that it is likely a person’s genetic identity can be reproduced indefinitely.⁶⁷ This has raised issues over what research the donors “informed” consent extends to regarding the stem cell lines, as the material donated in the future may be used for a different purpose than the for which one initially consented.⁶⁸ Due to the immortality of the stem cell lines, to prevent future legal conflicts the House of Lords Select Committee recommended that when consent is obtained from the donors, no restrictions are placed on the future use of embryos or gametes.⁶⁹

Research on embryonic stem cells will inevitably lead to the discovery of genetic information about the donors. To prevent inadvertent and unauthorized disclosure of this information it is coded so that researchers do not have access to details that will link the embryo to the donors’ personal information.⁷⁰ The Code of Practice for the Stem Cell Bank takes this into account and recommends that donors are informed that “no individual feedback will be given on tests performed by the UK Stem Cell Bank or research results of subsequent studies unless in the very unlikely event that the Stem Cell Steering Committee considers that the donor should be contacted in relation to confirmed test results of direct relevance to the donor’s or the donor’s family health or public health.”⁷¹

Patents

Concern has arisen among researchers as to what legal protection their research has under British

⁶² The HFEA considered issues surrounding genetic identity, such as confidentiality and the right to know about any diseases that may be discovered during research. It concluded that these issues were already adequately covered by current medical ethics. The Human Fertilisation and Embryology Authority, *supra* note 38, at 25.

⁶³ The Human Fertilisation and Embryology Act 1990, c. 37, sch. 3, ¶ 3, available at http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source).

⁶⁴ *Id.*, sch. 3, ¶ 2.

⁶⁵ *Id.*, sch. 3, ¶ 4.

⁶⁶ Code of Practice for the UK Stem Cell Bank, *supra* note 44, ¶ 10

⁶⁷ *Id.*, ¶ 8.32.

⁶⁸ REPORT FROM THE SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 8, ¶ 8.32.

⁶⁹ *Id.*, ¶ 8.33.

⁷⁰ Code of Practice for the UK Stem Cell Bank, *supra* note 44, ¶ 10.

⁷¹ *Id.*

patent law. While the Patents Act 1977 contains provisions on biotechnological inventions, it does not “directly address the patentability of human embryonic stem cells.”⁷² The United Kingdom’s Patent Office has issued a notice on the general practice that it intends to follow regarding the patentability of “stem cells which have been isolated from human embryos and processes involving these cells.”⁷³ It has noted that the guidelines are merely general practice and that each case will be decided on its own merits.

The Patents Office has stated that the Patents Act 1977 expressly excludes the patentability of:

- the process for obtaining stem cells from human embryos; and
- human totipotent cells as they are cells that have the “potential to develop into an entire human body.”⁷⁴

The Patent Office has stated that human embryonic pluripotent stem cells⁷⁵ can be patented as they “do not have the potential to develop into an entire human body.”⁷⁶ The Patent Office has further reasoned that:

Although there is some opposition in the United Kingdom to research involving embryonic stem cells, a number of reports from influential United Kingdom political, medical and scientific bodies in recent years have emphasized the enormous potential of stem cell research, including embryonic stem cell research, to deliver new treatments for a wide range of serious diseases. This indicates that on balance the commercial exploitation of inventions concerning human embryonic pluripotent stem cells would not be contrary to public policy or morality in the United Kingdom. Thus the Patent Office is ready to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability.⁷⁷

Pre-Implantation Genetic Diagnosis

Pre-implantation genetic diagnosis (PGD)⁷⁸ is permitted in the UK under the 1990 Act, which provides the HFEA with the authority to license treatment, including cases to “secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose.”⁷⁹ The HFEA reasons that an applicant is entitled:

to regard an embryo as unsuitable unless it is both free of abnormality and tissue compatible with [a sibling]. Without such testing, [the applicant] cannot make an informed choice as to whether she wants the embryo placed in her body or not. The authority considers it desirable for the purpose of providing [the applicant] with treatment services, ie IVF treatment, that she should be

⁷² The Patent Office, *Practice Notice: Inventions Involving Human Embryonic Stem Cells*, Apr. 2003, available at <http://www.patent.gov.uk/patent/notices/practice/stemcells.htm>. See Patents Act 1977, c. 37, sch. A2, ¶ 3, available at <http://www.statutelaw.gov.uk/legResults.aspx?LegType=All+Legislation&title=Patents+Act+&Year=1977&searchEnacted=0&extentMatchOnly=0&confersPower=0&blanketAmendment=0&TYPE=QS&NavFrom=0&activeTextDocId=1344006&PageNumber=1&SortAlpha=0> (unofficial source).

⁷³ *Id.*

⁷⁴ *Id.* sch. A2, ¶ 3. See also *Practice Notice: Inventions Involving Human Embryonic Stem Cells*, *supra* note 72.

⁷⁵ These cells arise from the division of totipotent cells.

⁷⁶ *Practice Notice: Inventions Involving Human Embryonic Stem Cells*, *supra* note 72.

⁷⁷ *Id.*

⁷⁸ PGD is defined by the HFEA as a “technique which involves the genetic testing of embryos created through IVF for deleterious, heritable genetic conditions which are known to be present in the family of those seeking treatment and from which the embryos are known to be at risk.” Human Fertilisation and Embryology Authority, *Pre-implantation Genetic Diagnosis*, <http://www.hfea.gov.uk/en/495.html> (last visited June 12, 2008).

⁷⁹ The Human Fertilisation and Embryology Act 1990, c. 37, sch. 1, available at http://www.opsi.gov.uk/acts/acts/1990/pdf/ukpga_19900037_en.pdf (official source).

able to make such a choice ... the Act does not require that PGD or HLA typing should constitute treatment services. They must be activities in the course of such services, ie in the course of providing IVF treatment.⁸⁰

Currently, PGD has been licensed by the HFEA for over fifty conditions, and its use is limited to screening out disorders, thus it is not permitting people to create “designer babies.”⁸¹ The decision to license a condition, and thus enable PGD, is made by a Licence Committee of the HFEA, which considers whether the treatment is lawful under the 1990 Act and determines that the decision to provide treatment is in accordance with the Code of Practice and HFEA policy.⁸²

For the practical use of HGD the HFEA’s Code of Practice notes that:

The use of PGD should be considered only where there is a significant risk of a serious genetic condition being present in the embryo. The perception of the level of risk by those seeking treatment is an important factor in the decision making process. The seriousness of the condition should be a matter for discussion between the people seeking treatment and the clinical team. In any particular situation the following factors should be considered when deciding the appropriateness of PGD:

- the view of the people seeking treatment of the condition to be avoided;
- their previous reproductive experience
- the likely degree of suffering associated with the condition;
- the availability of effective therapy, now and in the future;
- the speed of degeneration in progressive disorders;
- the extent of any intellectual impairment;
- the extent of social support available; and
- the family circumstances of the people seeking treatment.⁸³

The selection of the gender of any embryo for social purposes is explicitly prohibited by the HFEA’s Code of Practice,⁸⁴ however, the government has stated that it is seeking “wider public views on whether sex selection for family balancing purposes should be permitted.”⁸⁵

Pre-implantation Tissue Typing

Pre-implantation tissue typing, a technique that allows embryos to be selected to provide a matched tissue donation to an existing sibling, is currently permitted in the UK under the 1990 Act, under the same premise as PGD.⁸⁶

⁸⁰ *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (H.C), available at <http://www.publications.parliament.uk/pa/ld200405/ldjudgmt/jd050428/quint-1.htm> (official source).

⁸¹ The HFEA has provided a list of a number of the example conditions that they license the use of PGD for that is available at http://www.hfea.gov.uk/docs/PGD_list.pdf (last visited June 12, 2008). See further *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (H.C) available at <http://www.publications.parliament.uk/pa/ld200405/ldjudgmt/jd050428/quint-1.htm> (official source) as to the lawfulness of licensing this activity.

⁸² *Pre-implantation Genetic Diagnosis*, *supra* note 78.

⁸³ Human Fertilisation and Embryology Authority, *Code of Practice*, 2007, G.12.3.2 available at http://cop.hfea.gov.uk/cop/pdf/CodeOfPracticeVR_3.pdf.

⁸⁴ *Id.*, G.8.7.

⁸⁵ Department of Health, Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, 2005, ¶ 45, available at http://www.dh.gov.uk/en/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_5401577.

⁸⁶ The Human Fertilisation and Embryology Act 1990, c. 37, sch. 2, ¶ 1 available at http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source). See further *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (H.C). available at <http://www.publications.parliament.uk/pa/ld200405/ldjudgmt/jd050428/quint-1.htm> (official source).

In 2001, the HFEA produced an interim policy that allowed pre-implantation tissue typing, but only in combination with PGD.⁸⁷ This decision was challenged in the courts by a group claiming that the HFEA was acting *ultra vires* from the 1990 Act by licensing pre-implantation tissue typing.⁸⁸ The claim was initially successful, but the HFEA, joined by the Department of Health, was successful in an appeal at the court of appeal, with that decision later affirmed by the House of Lords, who ruled that the use of pre-implantation tissue typing fell under the remit of the 1990 Act and could thus be licensed by the HFEA.⁸⁹ PGD's legal status and acceptance was recently shown by the substantial defeat of a provision in the Human Fertilisation and Embryology Bill that would have banned this procedure.⁹⁰

In 2004, the HFEA reviewed its interim policy and issued a new policy, which now permits pre-implantation tissue typing

in cases in which there is a genuine need for potentially life-saving tissue and a likelihood of therapeutic benefit for an affected child. However, each application for the procedure will be considered on a case-by-case basis and the policy as a whole will be kept under review as new information and evidence continue to emerge.⁹¹

The Code of Practice contains a number of factors that are much more extensive than those used for PGD, which must be taken into account prior to the use of pre-implantation tissue typing.⁹²

Inheritable Genetic Modification

Inheritable genetic modification (also referred to in the UK as germline engineering or the genetic modification of embryos) is currently specifically prohibited.⁹³ However, the law contains a provision that allows the introduction of secondary legislation to specify circumstances under which the genetic structure of the cell of an embryo may be altered, thus enabling the prohibition to be removed.

The government has stated that the prohibition on genetic modification of human embryos less than fourteen days old should be removed for research purposes. It further recommended that “future legislation, while prohibiting the modification of chromosomal DNA for reproductive purposes, should provide for regulations to be made to relax this ban under tightly controlled circumstances if and when the technology is further advanced.”⁹⁴ These views have been submitted in the Human Fertilisation and Embryology Bill, which does not contain the prohibition on the genetic modification of embryos for research purposes. If the Bill is enacted as it is currently written, such modification will be permitted for embryos up to fourteen days old.⁹⁵ The genetic modification of embryos for reproductive purposes would

⁸⁷ Human Fertilisation and Embryology Authority, *Pre-implantation Tissue Typing*, <http://www.hfea.gov.uk/docs/PreimplantationReport.pdf> (last visited June 12, 2008).

⁸⁸ *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (H.C.), available at <http://www.publications.parliament.uk/pa/ld200405/ldjudgmt/jd050428/quint-1.htm> (official source).

⁸⁹ *Id.*

⁹⁰ *Id.*; see also 19 May 2008 PARL. DEB. (6th ser) H.C. 68.

⁹¹ *Pre-implantation Tissue Typing*, *supra* note 87.

⁹² *Code of Practice*, *supra* note 83, G.12.5.

⁹³ The Human Fertilisation and Embryology Act 1990, c. 37, sch. 2, ¶ 3(4) available at http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source), which provides that the HFEA shall not grant a “licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations.”

⁹⁴ HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE, HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW (2004-5), H.C. 7-1, 177, available at <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf>.

continue to be prohibited.

III. Regulation of the Transfer of Embryos and Stem Cells

The export of stem cells is permitted in the UK and the regime is discussed above under the heading “Stem Cell Bank.”

Embryos and gametes may be exported outside the UK, and this activity is regulated by the HFEA and through Directions issued under the 1990 Act.⁹⁶ There are two regimes in place, one for the export of embryos and gametes to countries within the European Economic Area (EEA) and one for those outside the EEA. Transfers to countries within the EEA can only be made to centers that have been “accredited, designated, authorised or licensed” by an EEA state in accordance with the EU’s Tissues and Cells Directives.⁹⁷ The following criteria must also be met:

- the person who provided the gametes (and in the case of an embryo, both persons that provided the gametes from which the embryo was created) have given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving center is situated;
- prior to giving consent, the person(s) must have been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country to which the gametes or embryos are to be exported as it is in the United Kingdom and have been given any further information which they may require;
- no money or other benefits shall be given or received in respect of the supply of the gametes or embryos, unless the money or benefit paid or received is in accordance with the Directions;
- the purpose of exporting the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical, or obstetric services for the purposes of assisting a woman to carry a child or to be stored for the purpose of such use in the future;
- the gametes or embryos must 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 center.⁹⁸

To export gametes or embryos outside the EEA or Gibraltar, in addition to the above criteria, the following criteria must be met:

- the receiving center must be accredited, designated, authorized, or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety;

⁹⁵ Human Fertilisation and Embryology Bill, Bill 70 (2007-8) available at <http://www.publications.parliament.uk/pa/cm200708/cmbills/070/08070.i-iv.html>.

⁹⁶ The Human Fertilisation and Embryology Act 1990, c. 37, § 24 available at http://www.opsi.gov.uk/acts/acts1990/pdf/ukpga_19900037_en.pdf (official source), which provides that “Directions may authorise any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or embryos outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions.”

⁹⁷ Council Directive 2004/23 2004 O.J. (L 102/48) (EC), available at http://europa.eu/eur-lex/pri/en/oj/dat/2004/l_102/l_10220040407en00480058.pdf (official source); Commission Directive 2006/17 2006 O.J. (L 38/40) (EC), available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_038/l_03820060209en00400052.pdf (official source) and Commission Directive 2006/86 2006 O.J. (L 294/32) (EC), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:294:0032:0050:EN:PDF> (official source). The EEA consists of the Member States of the EU and Iceland, Liechtenstein, Norway and Switzerland.

⁹⁸ Human Fertilisation and Embryology Authority, Directions Given under the Human Fertilisation and Embryology Act 1990: *Export of Gametes and Embryos to Gibraltar and the European Economic Area (EEA)*, available at <http://www.hfea.gov.uk/docs/D2008.2.pdf> (last visited June 13, 2008).

- the receiving center must have a quality management system in place which has been certified by an internationally recognized body; and
- the receiving centre must have a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa.⁹⁹

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⁹⁹ Human Fertilisation and Embryology Authority, *Directions Given under the Human Fertilisation and Embryology Act 1990: Export of Gametes and Embryos outside of Gibraltar and the European Economic Area (EEA)*, <http://www.hfea.gov.uk/docs/D2008.4.pdf> (last visited June 13, 2008).

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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 through 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

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 data¹² 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:

⁹ Roberto Andormo, *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.”¹⁶ 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 Intervention²² 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,

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

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.

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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 Inventions⁵ 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

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&SD OCTA=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

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 patentability” 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 Products¹⁷ 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.”

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

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_opinion_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/EC³³ and Directive 2006/17/EC.³⁴ With regard to imports of tissues and cells from third countries, article 9 of Directive 2004/23/EC requires Member States to take all necessary measures to ensure that such imports are undertaken by tissue

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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