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Appendix E
Overview of International Human Embryonic Stem Cell Laws

Countries around the world have responded to the ethical problems raised by embryonic stem cell research in a number of ways. Some governments have passed laws prohibiting all research on human embryos, while others have explicitly endorsed and funded ES cell research. Many countries, like the United States, regulate the research through restrictions on government funding, while others license researchers to ensure compliance with the national policy. Here we describe the stem cell policies of several countries and international bodies, both to offer some perspective on the American policy and to indicate some of the policy options that other nations have pursued.

Australia. The laws in Australia relating to human embryonic stem cell research have undergone significant changes over the past decade. In 2002, the Australian Parliament passed the Prohibition of Human Cloning for Reproduction Act, which banned all kinds of human cloning, regardless of the purpose, and also banned all *in vitro* conception for purposes other than "achiev[ing] pregnancy in a particular woman."[1] Parliament also passed the Research Involving Human Embryos Act, which allowed for research on "excess ART embryos" if licensed by the National Health and Medical Research Council (NHMRC).

The cloning ban was loosened with the passage in 2006 of the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act.[2] The act retained the ban on so-called reproductive cloning, but it allowed SCNT for research purposes, so long as the cloned embryo did not grow beyond fourteen days.[3] Such research is permitted pursuant to the issuance of licenses by the NHMRC.[4] Human-animal hybrid embryos are permitted under the same licensing and similar growth restrictions, while the creation of chimeric embryos is altogether prohibited. (A "hybrid," in Australian law, is an embryo created by combining gametes or genetic material from two different species. A chimeric embryo is "a human embryo into which a cell, or any component part of a cell, of an animal has been introduced.")

Canada. Canadian regulations on human ES cell research are contained in the Updated Guidelines for Human Pluripotent Stem Cell Research,[5] which went into effect in June 2010 and which supersede earlier Guidelines from 2007. The new Guidelines apply to any research involving human pluripotent stem cells that is funded by any of the country's three central science-funding agencies—the Canadian Institutes of Health Research (CIHR), the National Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council. The Guidelines apply both to the derivation of ES cells from embryos, and to research carried out on established ES cell lines. Also in place is the 2004 Act Respecting Assisted Human Reproduction and Related Research, which was intended to regulate the derivation of ES cells from embryos, though it does not affect pre-existing human ES cell lines.

The guiding principles of current Canadian ES cell research regulations are that: (1) research should have potential health benefits for Canadians; (2) there should be free and informed consent based on full disclosure of all relevant information; (3) there should be respect for privacy and confidentiality; (4) there should be no payment or financial incentives for donating tissues or embryos for stem cell research; (5) there should be no creation of embryos for research purposes; and (6) there should be respect for "individual and community notions of human dignity and physical, spiritual, and cultural integrity."[6] To those ends, stem cell research proposals seeking funding from any of the three Canadian science agencies for established ES cell lines (either created in Canada or imported) must seek approval from the CIHR's Stem Cell Oversight Committee as well as from a local Research Ethics Board.

In order to minimize the need to create new embryonic stem cell lines, the CIHR established a national registry that would make human embryonic stem cell lines derived using government funding available to researchers. By making these cell lines available, the CIHR hopes to encourage researchers to use stem cell lines that have already been derived, rather than relying on donated embryos to create new stem cell lines. The Guidelines also expressly prohibit a number of research practices. Among the prohibited practices are creating human embryos specifically to derive ES cell lines, creating human embryos through SCNT to derive ES cell lines, combining pluripotent human or non-human stem cells with a human embryo, grafting pluripotent human or non-human stem cells to a human fetus, combining pluripotent human stem cells with a non-human embryo, and grafting human pluripotent stem cells to a non-human fetus (although grafting human pluripotent cells to newborn

or adult animals is permitted, provided that the animals are not allowed to breed).

Chile. In 2006, Chile's government enacted a law that "has as its purpose the protection of human life from the moment of conception, its physical and psychic integrity, as well as its diversity and genetic identity with regard to biomedical research and its clinical applications."[7] The law goes on to state that "the cloning of human beings is prohibited, regardless of the purpose sought and the technique used."[8] It also notes, with regard to ES cell research, that "the cultivation of lines or organs will only proceed with the goals of therapeutic diagnosis or scientific research. In no case is it permitted to destroy human embryos in order to obtain their stem cells, which give rise to the aforementioned lines and organs."[9]

China. Chinese ES cell research is governed by the 2003 Ethical Guiding Principles on Human Embryonic Stem Cell Research, the enforcement of which is entrusted to the Ministry of Science and Technology (MOST) and the Ministry of Health.[10] The Guiding Principles are relatively vague, however, and they lack strong mechanisms for enforcement.[11] MOST funding committees bear the responsibility for ensuring that proposed projects comply with the rules stipulated in the Guiding Principles, although these rules do not apply to the minority of research funded by sources other than MOST.[12]

The Guiding Principles specifically allow for ES cells to be derived from "spare" IVF embryos, from embryos created using voluntarily donated gametes or gametes left over from IVF procedures, from fetal cells derived from spontaneous or induced abortion, and from embryos created by SCNT. They also permit research on existing or imported ES cells. Such research is subject to basic requirements of informed consent (as to the "expected aim of the experiment as well as the potential consequences and risks") and to prohibitions on the buying and selling of gametes, fertilized eggs, embryos, and fetal tissues. The growing of embryos *in vitro* beyond fourteen days is also prohibited. Institutions performing research on ES cells must establish an ethics committee consisting of experts in biology, medicine, law, and sociology.

Denmark. The Danish government allows for ES cell research that destroys embryos only in the case of "spare" IVF embryos and only until fourteen days after fertilization. Denmark banned all cloning in 1992 with its Act on a Scientific Ethical Committee System and the Handling

of Biomedical Research Projects. In 1997, regulation concerning research on fertilized ova and germ cells intended for reproduction was transferred to the Act on Medically Assisted Procreation in Connection with Medical Treatment, Diagnosis, and Research.[13] That 1997 law was in turn amended in 2003 to permit research using spare IVF embryos, noting, "Research on fertilized ova and stem cells intended for reproduction is furthermore allowed, if research has the aim to get knowledge, which can improve treatment concerning human diseases."[14]

European Union. Since 1984, the European Union has provided funding for scientific research through a series of "framework programs for research and technological development."[15] From 2002 to 2006, under the Sixth Framework Program, the EU provided funding for research using embryonic stem cells, although it did not finance the actual act of destroying the embryos to derive the stem cells.[16] In 2006, ministers of science from the EU met to discuss the funding policies for the Seventh Framework Program, and upheld their previous stance.[17] Also funded as part of the Sixth Framework Program was a human ES cell registry, which began operations in April 2007 in order to make efficient use of pre-existing ES cell lines.[18] More recently, a legal battle over whether stem cell techniques can be patented may alter the research landscape, as the removal of the legal protections provided by the patent system might greatly dampen incentives for stem cell research in the EU.[19]

While the EU has demonstrated a willingness to provide funding for human ES cell research, the patentability of ES cells and their applications has proven more contentious. On October 18, 2011, the European Court of Justice ruled that German stem cell scientist Oliver Brüstle's patent on neural precursor cells derived from human ES cells violated Article 6 of the European Biopatent Directive, which specifies that "uses of human embryos for industrial or commercial purposes" cannot be patented.[20] (Since the central legal question in the EU case was whether Brüstle's research—and by extension, ES cell research generally—can be considered "uses of human embryos," it bears similarities to the *Sherley v. Sebelius* lawsuit in the United States, described in Appendix D.)

France. French legislation on ES cell research dates back to a 1994 bioethics law that prohibited the creation of embryos for research as well as experimentation on embryos.[21] That law was changed in 2004, with the passage of a law on Research on the Embryo and Embryonic Cells (Law No. 2004-800).[22] The law prohibits the creation of embryos *in*

vitro or through SCNT for the purposes of research, commerce, industry, or therapy.[23] The law also technically forbids "research on the human embryo," but this prohibition comes with various qualifications. For example, if the couple whose genetic material made an embryo wishes to donate it for this purpose, "research can be authorized on the embryo and embryonic cells when they are likely to allow great therapeutic progress."[24] Such research, however, must be authorized by France's Agency of Biomedicine.

While the 2004 law represented a compromise between the interests of medical research and the duty to protect embryonic life, members of the French left and socialist movements have sought to liberalize France's embryo research laws, particularly as they relate to SCNT.[25] In early 2011, the French Parliament considered whether to renew the 2004 law, or to ease the extant restrictions on ES cell research. On July 7, 2011, the French Parliament renewed the law on embryo research, maintaining the country's 2004 compromise on embryonic stem cell research.[26]

Germany. Germany strictly regulates ES cell research. The Stem Cell Act of 2002 "ban[s], as a matter of principle, the importation and utilization of embryonic stem cells," and prevents the derivation of stem cells from embryos in Germany.[27] The Act makes exceptions, however, for the importation of ES cell lines derived before January 1, 2002, provided that these lines were derived from "spare" IVF embryos rather than embryos created for the purpose of research. Research on authorized ES cell lines must serve "eminent research aims" for which the value of other experimental techniques have been exhausted.[28] In 2008, German lawmakers voted to extend the January 1, 2002 cutoff date to May 1, 2007 to keep German scientists internationally competitive.[29] Lawmakers also limited the scope of the Act by eliminating provisions that made it a criminal offence for German scientists to use ES cells in other countries.[30]

The Act is enforced by the Central Ethics Commission on Stem Cell Research, an agency created by the Ministry of Health and consisting of nine experts from the fields of biology, ethics, medicine, and theology. The Commission is charged with evaluating research applications to ensure that they comply with the Act.[31] Unlike many ethical research guidelines in other countries, this legislation contains fairly harsh penal provisions: the importation of stem cells without approval, or "deliberately giving false information" to gain approval, can be punished with fines or up to three years in prison.[32]

Iceland. While Iceland's first regulations, issued in 1997, were a straightforward ban on most embryo research,[33] legislative changes in 2008 considerably liberalized the country's embryonic stem cell policy. Icelandic law now permits licensed researchers to derive stem cell lines from spare IVF embryos, subject to approval from a Bioethics Committee.[34] Licensed researchers may also perform SCNT using donated egg cells and genetic material, if it is "deemed impossible to achieve the same results or acquire the same knowledge by the use of stem-cell lines made using excess embryos or by other means."[35] Reproductive cloning using SCNT is prohibited, however, and the embryos created through SCNT may not be grown for more than fourteen days.[36]

India. The Indian Department of Biotechnology, together with the Indian Council of Medical Research, drafted the nation's stem cell policy in 2007, the Guidelines for Stem Cell Research and Therapy.[37] The Guidelines call for the establishment of a national body for the review of stem cell research proposals, the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). This committee was established only recently, with the twelve-member group being formed by the government in March 2011.[38] Institutions conducting stem cell research are also required to establish their own committees for reviewing stem cell research proposals. Scientists conducting research on stem cells must be registered with the NAC-SCRT, and the creation of new stem cell lines must be approved by both the local and national review committees.

The Guidelines divide research on human stem cells into three areas: permissible, restricted, and prohibited. Permissible research includes *in vitro* studies on previously established cell lines from any cell type (including ES cells), *in vivo* studies in animals with established cell lines from any type of stem cells (including ES cells), the establishment of new ES cell lines from "spare" IVF embryos, and clinical trials with minimally manipulated cells. The Guidelines restrict the creation of human embryos by IVF or SCNT for the purpose of deriving an ES cell line: If researchers seek to create ES cell lines specifically for research purposes, they must provide explicit justification for the procedure, establishing that the creation of the embryo is essential for their research. The Guidelines also restrict clinical trials using cells that have undergone major manipulations such as genetic alteration (which would seem to include many iPS cells and ANT-derived stem cells). And the Guidelines restrict various forms of chimera research, such as the introduction of human ES cells into embryonic animals. The Guidelines prohibit germ-line engineering and

human cloning for reproductive purposes, the growing of embryos *in vitro* for longer than fourteen days, transferring SCNT embryos into a uterus, and the breeding of animals that have received human ES cells.

Italy. Along with Germany, Italy has some of the strictest laws in Western Europe regulating human ES cell research. Law 40, which came into effect on March 10, 2004, regulated both embryo research and IVF (Italy had no regulations in place on IVF prior to this law) and banned research on human embryos, including the use of embryos for deriving ES cell lines.[39] In addition, the law limited the number of embryos that could be created during IVF procedures to three, and required that all embryos created by IVF be implanted in the recipient mother—which prevents any supply of "spare" embryos and thus precludes any demand to use them for ES cell research. The creation of human embryos for research purposes is also prohibited. Italian law on embryonic research includes serious penal provisions for forbidden experimentation on embryos, including jail time ranging from ten to twenty years for reproductive cloning.[40]

Japan. In September 2001, the Japanese government issued its Guidelines for Derivation and Utilization of Human Embryonic Stem Cells,[41] which outline the regulations that the Ministry of Education, Culture, Sports, Science, and Technology is responsible for implementing and enforcing. While the Guidelines were theoretically permissive with respect to many ethically controversial stem cell sources, structural regulations regarding the approval and practice of embryo research reportedly encumbered ES cell research.[42] A number of these regulations were relaxed in 2009 by the Council for Science and Technology Policy, a cabinet office chaired by the prime minister and composed of cabinet members, academics, and industrial leaders, following recommendations from its subcommittee, the Expert Panel of Bioethics.[43]

Under the revised Guidelines, ES cells can be derived only from "spare" IVF embryos, and only if the embryos are younger than fourteen days (not counting time spent frozen), were donated with informed consent, and were donated without financial compensation beyond "necessary costs."[44] The Guidelines ban reproductive cloning, but research-oriented SCNT is permitted, although regulatory delays in the approval process have retarded the development of human SCNT research.[45] Prominent Japanese stem cell researcher Norio Nakatsuji has described the relaxation of the rules as ranging "from absurd to excessively strict" and as

"irrational," since researchers seeking to derive new human ES cell lines must go through a two-stage approval process by both an Institutional Review Board and the Ministry, institutions must have the content of their bioethics and technical training courses approved by the Ministry, and word-for-word minutes of local board meetings on approval for work with existing lines must be sent to the Ministry.[46]

Lithuania. Lithuania's human ES cell laws are remarkably strict. The relevant legislation is the Law on Ethics of Biomedical Research, first enacted in 2000 and amended in 2004, which states: "Human embryos may be subjects only of clinical observations (non-invas[ive] investigations). Other clinical investigations involving human embryos and their creation for purposes of biomedical research shall be prohibited. Human embryos may be subjected to such biomedical research where the medical risks for the embryo are not disproportionate to the potential benefits."[47] Likewise, the law states that the "cloning of a human being shall be prohibited."

The Netherlands. In the Netherlands, the Embryos Law of 2002[48] regulates human ES cell research and bans both human reproductive cloning and the creation of hybrids and chimeras.[49] The law makes a distinction between cloning for reproductive purposes and research-oriented SCNT, instituting a five-year moratorium on SCNT.[50] The creation of human embryos for research purposes is illegal under the law.[51] A 2007 reevaluation of the policy by the Dutch cabinet ended with the existing policy being left in place for the foreseeable future.[52]

Norway. In 2003, the Storting, Norway's parliament, passed the fairly restrictive Act Relating to the Application of Biotechnology in Human Medicine.[53] Chapter 3 of the Act states, "It is prohibited to carry out research on fertilized eggs, human embryos, and cell lines derived from fertilized eggs or human embryos."[54] It is also prohibited "to create human embryos by cloning" and to conduct research on cell lines derived from cloned human embryos.[55]

Poland. Poland's Medical Profession Act of 1996 states that "conceived children"—a term that encompasses human embryos—"cannot participate in research experiments."[56] Because this law antedates both the news about Dolly the cloned sheep (1997) and the isolation of human embryonic stem cells (1998), it explicitly mentions neither human cloning nor stem

cell research, but it is nonetheless understood to ban both cloning and the creation of ES cell lines. In 2006, as the European Union was debating whether to fund human ES cell research (see "European Union," above), the Sejm, the lower house of the Polish parliament, passed a resolution declaring that human ES cell research is "inconsistent with Polish law," in that it violates the article in Poland's constitution ensuring "the legal protection of the life of every human being."[57] The resolution went on to state that experimentation on human embryos would violate the Polish penal code and medical ethics code.[58]

Singapore. While Singapore does not have specific legislation on stem cell research, the government has established a Bioethics Advisory Committee (BAC) that has promulgated recommendations on stem cell research and other areas of biomedical research in Singapore that are adhered to by the scientific community.[59] In 2002, the BAC issued a report containing recommendations on stem cell research. The report recommends that researchers should "wherever possible" draw on existing embryonic stem cell lines for research, rather than destroying embryos for research purposes.[60] However, deriving new stem cell lines from spare IVF embryos is permitted as "a suitable alternative source of ES cells."[61] Furthermore, the creation of embryos through SCNT to derive patient-specific ES cell lines should be permitted on a case-by-case basis,[62] although the report does note that future developments in cell reprogramming may make it "unnecessary to resort to using embryos as a source of stem cells."[63] The report recommends "a complete ban" on reproductive cloning.[64]

Further recommendations of the BAC on stem cell research include guidelines for obtaining informed consent from embryo and gamete donors, and prohibitions against the sale of embryos.[65] In 2010, the BAC released a report entitled "Human-Animal Combinations in Stem Cell Research"; it recommends permitting interspecies SCNT, which employs human genetic material and animal egg cells. The creation of human-animal chimeras by injecting human stem cells into animal embryos was also permitted for scientific research, with the caveat that these chimeras should not be allowed to breed.[66]

Slovakia. Slovakia has very strict laws on human ES cell research and human cloning. Slovakia's Law No. 277/1994 on health care forbids performing research on embryos that is not for their own benefit. According to the law, "Research without medical indication is not permitted on human embryos or fetuses."[67] The law also bans all cloning, stating, "Any

intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."[68] Anyone who violates the prohibition on human cloning is subject to penalties including a possible sentence of up to twelve years in prison.[69]

Slovenia. In Slovenia, the current policy relevant to stem cell research is found in the Law on Biomedically Assisted Fertilization, which was enacted in 2000.[70] In it, the use of embryos created for the purpose of assisted reproductive therapies is allowed for research, so long as they are not suitable for future reproductive purposes.[71] The law also forbids creation of embryos for research and cloning, and *in vitro* growth of human embryos past fourteen days.[72]

South Korea. The most recent South Korean legislation on human ES cell research is the Bioethics and Safety Act, which came into effect on December 6, 2008.[73] The Act prohibits human reproductive cloning and prohibits the production of embryos for non-reproductive purposes. Nonetheless, sources of human ES cells permitted under the act include SCNT, "for the purpose of conducting research aimed at curing rare or currently incurable diseases," and "spare" IVF embryos if they have exceeded a maximum storage period of five years or if researchers receive consent from their parents. Payment for gametes is prohibited as well, although oocyte donors may be reimbursed for costs associated with the procedure.

The 2008 law replaces the Bioethics and Biosafety Act of 2005,[74] which had been criticized for failing to protect not only human embryos, but embryo and egg donors as well.[75] The 2005 law was repealed in large part due to the scandals surrounding South Korean researcher Hwang Woo Suk. In papers published in *Science* in 2004 and 2005, Hwang claimed to have successfully cloned human embryos and derived stem cells from them.[76] These claims made him a national hero—until it was revealed early in 2006 that his results were fabricated and that he had pressured his female subordinates to donate oocytes for his research.[77] Hwang's high-profile fraud and brazen ethical lapses, which had slipped through the cracks of South Korea's biotechnology policy regime and caused a national embarrassment, prompted the 2008 legislation.

Spain. From 1988 until 2003, Spanish law only allowed for studies on "non-viable" embryos.[78] The law was modified in 2003 to permit research using "spare" IVF embryos.[79] In 2006, the government undertook a new

Law on Assisted Reproduction in order to allow for therapeutic options not possible under Laws 35/1988 and 45/2003.[80]

In 2007, the Congress of Deputies, the lower house of the Spanish legislature, approved a new Law on Biomedical Research that allows for research-oriented SCNT.[81] The relevant clause reads, "The use of whatever technique for obtaining human stem cells for therapeutic or research purposes is permitted, insofar as it does not entail the creation of a pre-embryo or an embryo exclusively for this purpose, in the terms defined through this law, including the activation of oocytes through nuclear transfer."[82] In effect, therapeutic cloning has been approved, while reproductive cloning is still banned.

Switzerland. In Switzerland, the framework for human ES cell research and human cloning is laid forth in the 2003 Federal Act on Research Involving Embryonic Stem Cells (StRA). The law forbids numerous practices, among them efforts "to create an embryo for research purposes...[or] to derive stem cells from such an embryo, or to use such cells" in efforts "to create a clone, a chimera, or a hybrid."[83] At the same time, the law forbids the use of spare IVF embryos "for any purpose other than the derivation of embryonic stem cells."[84] After StRA survived a referendum challenge, the Swiss Federal Council, the government's executive branch, issued an ordinance in 2005 implementing the law, which sets forth licensing procedures for researchers seeking permission to derive human ES cells from IVF embryos. Research applications must include, among other standard descriptions, an explanation of "why equivalent insights could not also be gained in a different way, in particular through experiments involving animal embryos."[85]

United Kingdom. The U.K. has liberal regulations for human ES cell research. Permitted sources of ES cell lines under the 2008 Human Fertilization and Embryology Act (HFE Act) include unused IVF embryos, embryos created by IVF specifically for research purposes, embryos created by SCNT, "admixed embryos" including hybrids (created from human and animal gametes), "cytoplasmic hybrids" (created by SCNT using human nuclei and animal oocytes), transgenic human embryos (created by introducing animal DNA into a human cell), chimeric human embryos (created by introducing one or more animal cells into a human embryo), or any other embryos that contain both human and animal DNA, but in which animal DNA is not predominant.[86] Research on embryos that are over fourteen days old is prohibited.[87]

The Human Fertilization and Embryology Authority (HFEA) is responsible for enforcing the regulations of the HFE Act, and for licensing both IVF clinics and scientists carrying out research on human embryos. The HFEA will not grant a license for embryo research unless it is satisfied that the use of embryos is necessary for the research and that the research is relevant to the purposes specified by the HFE Act; these purposes include increasing knowledge about serious medical conditions, developing treatments for serious medical conditions, advancing the treatment of infertility, increasing knowledge about the causes of miscarriage, developing more effective contraception techniques, developing methods for detecting genetic or mitochondrial abnormalities in preimplantation embryos, and increasing knowledge of embryonic development.[88]

In addition, the HFEA requires licensees to deposit a sample of the cell lines they generate in the U.K. Stem Cell Bank.[89] Licensees must have approval from the Steering Committee for the U.K. Stem Cell Bank before conducting secondary research projects on human ES cells.[90]

United Nations. While the U.N. does not have a policy on human embryonic stem cell research *per se*, on March 8, 2005 the General Assembly approved a non-binding Declaration on Human Cloning which called on member states "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."[91] However, the official press release announcing the vote describes the Declaration as "a weak, non-binding political statement" that does not "reflect anything approaching consensus within the Assembly," and thus does not affect the stem cell research of any of its member nations."[92]

Notes

1. Australia, Parliament, *Prohibition of Human Cloning for Reproduction Act 2002*, no. 144, 2002, §12.1, http://www.comlaw.gov.au/Series/C2004A01081.

2. Australia, Parliament, *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*, no. 172, 2006, http://www.comlaw.gov.au/Details/C2006A00172.

3. *Prohibition of Human Cloning for Reproduction Act 2002*, §14.

4. *Research Involving Human Embryos Act 2002*, §20.

5. Canadian Institutes of Health Research (CIHR), *Updated Guidelines for Human Pluripotent Stem Cell Research*, 2010, http://www.cihr-irsc.gc.ca/e/42071.html.

6. CIHR, *Updated Guidelines for Human Pluripotent Stem Cell Research*, §4.

7. Chile, Congreso Nacional, *Sobre la investigacion cientifica en el ser humano, su genoma, y prohibe la clonacion humana*, September 22, 2006, no. 20.120, art. 1, Witherspoon Council staff translation, http://www.leychile.cl/Navegar?idNorma=253478 [Spanish].

8. *Ibid.*, art. 5.

9. *Ibid.*, art. 6.

10. People's Republic of China, Ministry of Science and Technology and the Ministry of Health, *Ethical Guiding Principles on Human Embryonic Stem Cell Research*, 2003, http://www.chinaphs.org/bioethics/regulations_&_laws.htm#_Toc113106142.

11. U.K. Stem Cell Initiative, "Global Positions in Stem Cell Research: China," http://www.advisorybodies.doh.gov.uk/uksci/global/china.htm.

12. *Ibid.*

13. Anne Lykkeskov, Project Leader, The Danish Council of Ethics, e-mail correspondence with the staff of the Witherspoon Council, September 9, 2011.

14. Denmark, *Folketinget, Act No. 460/97 on Medically Assisted Procreation in Connection with Medical Treatment, Diagnosis and Research* (1997, amended 2003), §25, unofficial translation.

15. European Commission Community Research and Development Information Services (CORDIS), "What is FP7?" http://cordis.europa.eu/fp7/faq_en.html.

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17. Council of the European Union, "Competitiveness (Internal Market, Industry and Research)," press release, July 24, 2006, http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/intm/90654.pdf, p. 7. See also CORDIS, "Stem Cell Compromise Allows Approval of FP7 by Council," press release, July 25, 2006, http://cordis.europa.eu/fetch?CALLER=FP7_NEWS&ACTION=D&QM_EN_RCN_A=26062.

18. European Human Embryonic Stem Cell Registry, "About hESCreg," http://www.hescreg.eu/index.php?id=14.

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20. "Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions," OJ L 213, 30.7.1998, §42, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:NOT.

21. France, Parlement, Act No. 94-654, Article L 152-8, http://www.genethique.org/carrefour_infos/textes_officiels/titres_textes/textes/loi_n94654.htm [French].

22. France, Parlement, Act No. 2004-800, http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441469.

23. France, Code of Public Health, Legislative Part, Part 2, Book 1, Title V, Article L2151, http://www.legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000006687452&idSectionTA=LEGISCTA000006171138&cidTexte=LEGITEXT000006072665 [French].

24. *Ibid.*, Article L2151-5.

25. Jean-Yves Nau, "Roger-Gérard Schwartzenberg veut autoriser les recherches sur le clonage thérapeutique," *Le Monde*, May 27, 2005, 10 [French].

26. Nicole Atwill, "France: New Bioethics Law," July 18, 2011, http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205402748_text; The text of the law is available, in French, at: http://www.loc.gov/lawweb/servlet/lloc_news?disp1_l205402748_France.

27. Germany, *Bundestag, Stem Cell Act of 2002* (Stammzellgesetz), Bundesgesetzblatt [Federal Law Gazette] 2002, Part I, no. 42, p. 2277, June 29, 2002, §1-1, http://www.bmbf.de/pubRD/stammzellgesetz.pdf [German], unofficial translation accessed at http://www.hinxtongroup.org/docs/Germany1.html [English].

28. Stammzellgesetz, §5.

29. Dorothee Bürkle, "Balancing Act: German Stem Cell Research," trans. Jonathan Uhlaner, Goethe Insitut, August 2008, http://www.goethe.de/wis/fut/fuw/ftm/en3610292.htm [English].

30. *Ibid.*

31. Stammzellgesetz, §8-1.

32. *Ibid.*, §13-1.

33. Iceland, The Ministry of Health and Social Security, *Regulation on Artificial Fertilization No. 568/1997*, art. 22, issued September 30, 1997, http://eng.velferdarraduneyti.is/legislation/regulations/nr/17686 [English].

34. Iceland, *Alþingi, Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research No 55/1996 (with amendments according to Act 65/2006, Act 27/2008 and Act 54/2008)*, art. 12, trans. Anna Yates, http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20092 [English, unofficial translation].

35. *Ibid.*, art. 13.

36. *Ibid.*, art. 13.

37. India, Department of Biotechnology and Indian Council of Medical Research, *Guidelines for Stem Cell Research and Therapy*, November 2007, http://www.icmr.nic.in/stem_cell/stem_cell_guidelines.pdf.

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