Germline Intervention Policy
(United States and International)

The international community has expressed deep concern over the prospect of human inheritable genetic modifications. The Council of Europe's *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* specifically addresses germline manipulation.[1] Article 13 offers that human genome interventions and interventions aiming to modify the human genome "may only be undertaken for preventative, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."[2] Furthermore, it provides that medically assisted procreation techniques shall not be used to select a future child's sex, except where a serious hereditary sex-related disease can be avoided by sex selection.[3] The World Health Organization (WHO) at its fifty-first World Health Assembly reaffirmed that "germ-cell therapy, where there is an intention or possibility of altering the genes passed on to the next generation, should not be permitted in the foreseeable future."[4]

The Center for Genetics and Society reported that as of November 2003, 14% of countries have taken steps to ban inheritable genetic modification.[5] The United States currently does not have any federal legislation to prohibit inheritable genetic modifications in human beings. However, state legislation prohibiting or limiting embryo research may be applicable to the technologies of inheritable genetic modifications. Existing American state laws banning embryo research, dating back in some states to the mid-1970s, could potentially be used to prohibit certain species-altering technologies at the experimental stage.[6] Eleven states have laws regulating research and/or experimentation on conceptuses, embryos, fetuses or unborn children that use broad enough language to apply to early embryos.[7] Eight of the eleven states prohibit some form of research on some product of conception, referred to in the statutes as a conceptus,[8] embryo,[9] fetus[10] or unborn child.[11] These bans, however, would cease to apply if the techniques used were no longer considered research, but standard practice.

At least eight of the state laws banning embryo research are sufficiently general that they might be struck down as unconstitutionally vague.[12] The concept of a statute being "void for vagueness" is grounded in the Due Process Clause of the Fourteenth Amendment to the United States Constitution, which guarantees individuals fair notice that their conduct is prohibited by law. Individuals must be afforded a reasonable opportunity to discern whether their conduct is proscribed by the legislation in order to be able to decide whether or not to comply with the law. Where criminal laws are implicated, as would be the case with state legislation relating to human embryo research, the U.S. Supreme Court has held that the statute must define offenses with "sufficient definiteness" and "in a manner that does not encourage arbitrary and discriminatory enforcement."[13] With respect to the existing state legislation banning embryo research, many could be attacked due to potentially indefinite and/or arbitrary language contained within the statutes, such as "scientific experimentation,"[14]

"experimentation,"[15] and "research."[16]

Attempts to insert genes into embryos would be prohibited under the state embryo research laws if undertaken strictly to gain scientific knowledge. If the genes were added in an attempt to provide a "treatment" or "cure" to a particular embryo that was intended to go to term, however, it would likely be permissible in most states. The Maine statute may serve to ban all experimental germline manipulations, because it prohibits "any form of experimentation."[17] But several of the other embryo research bans explicitly allow procedures for the purpose of providing a health benefit to the fetus or embryo, and therefore might not prohibit germline intervention.[18] In some states, the embryo research bans might forbid the use of evolving or insufficiently-tested therapies if such therapies were not necessary to the preservation of the life of the fetus.

However, these laws or related laws generally require the protection and preservation of viable fetuses. Therefore, it seems unlikely that the embryo research laws in these states would be invoked to enforce the withholding of gene therapy as a form of treatment if doctors argued that the procedure held out some actual promise of a health benefit to the prospective child.

The New Hampshire and Louisiana laws have unique variations. New Hampshire's law might ban creating a child with inheritable alterations because it prohibits the transfer of any embryo donated for research to a uterus.[19] Louisiana's law has the opposite effect, prohibiting farming or culturing embryos solely for research purposes,[20] but apparently allowing research as long as the embryo is implanted.

While there are no federal or state laws directly dealing with inheritable genetic modifications, the Recombinant DNA Advisory Committee (RAC), under the auspices of the National Institutes of Health, has developed a set of federal guidelines that address the manipulation of genetic material through the use of recombinant DNA techniques.[21] Under the powers granted to them by the federal government, RAC examines clinical trials that involve the transfer of recombinant DNA to humans. All human gene therapy trials funded by the NIH, either directly or indirectly, must be approved and registered with the RAC.

Outside of the United States, many foreign countries have approached species-altering procedures with caution, some having instituted moratoria in order to consider the wide-ranging impacts of the technologies and the wealth of issues involved in species-altering procedures.[22] Other countries have already determined that such technologies are inimical to human values and human dignity.[23]

Many of the international bans on inheritable or germline interventions are general enough to include a vast range of technologies. These laws reflect a profound understanding of the need to avoid attempts to engineer a "better" race, as occurred in the Nazi era. German law understandably forbids germline intervention.[24] Victoria, Australia, in its Infertility Treatment Act of 1995, has comprehensive language

prohibiting germline genetic alterations.[25] The law prohibits altering the genetic constitution of either immature egg cells[26] or fertilized egg cells.[27] A Western Australia law prohibits the alteration of the genetic structure of either an egg in the process of fertilization or an embryo.[28]

In Norway, a 1994 law provides that the "human genome may only be altered by means of somatic gene therapy for the purpose of treating serious disease or preventing serious disease from occurring," and prohibits germline manipulation entirely.[29] Sweden prohibits research that attempts to modify the embryo.[30] France, too, prohibits such interventions.[31] Canada bans any alteration of a human cell or in vitro embryo that is capable of being transmitted to descendants[32] and Costa Rica bans any manipulation or alteration of an embryo's genetic code.[33]

Various international declarations and laws already oppose inheritable genetic interventions, either directly or indirectly, yet these existing legal documents have shortcomings. Some are mere moratoria. Some are limited in the types of species-altering technologies they ban, covering only cloning and not inheritable genetic interventions, or applying only to cloning via a limited range of techniques.

Some of the existing laws have also been outpaced by technology and do not comprehensively ban all forms of inheritable interventions. Others are ambiguous as to what they cover. In some cases, potentially relevant laws were adopted more than two decades ago to deal with a different set of technologies and concerns; it is unclear whether their expansive prohibitions will be applied to the newer technologies of human cloning and germline interventions. Moreover, many of the existing declarations and laws do not include sanctions.

The Council for Responsible Genetics (CRG) has issued a statement entitled *Position Paper on Human Germline Manipulation* that strongly opposes the use of germline modification in humans.[34] Specifically, the CRG "unequivocally oppose(s) germline modification" and "calls for a permanent ban on germline gene modification" on the basis that:

(1) Germline modification is not needed in order to save the lives, or alleviate the suffering, of existing people. Its target population are 'prospective people' who have not even been conceived.
(2) The cultural impact of treating humans as biologically perfectible artifacts would be entirely negative. People who fall short of some technically achievable ideal would be seen as 'damaged goods', while the standards for what is genetically desirable will be those of the society's economically and politically dominant groups. This will only increase prejudices and discrimination in a society where too many such prejudices exist.
(3) There is no way to be accountable to those in future generations who are harmed or stigmatized by wrongful or unsuccessful germline modifications of their ancestors.[35]

The Biotechnology Industry Organization (BIO), made up of commercial trade organizations across the U.S. and numerous other countries, also specifically addresses germline intervention in its *Bioethics Statement of Principles*.[36] The BIO principles provide that members will not alter the genes of human sperm or

eggs to treat genetic disorders until the medical, ethical and social issues have been discussed and clarified.[37]

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[1] Council of Europe European Treaties ETS No. 164, "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," April 4, 1997, available at: http://conventions.coe.int/treaty/en/Treaties/Html/164.htm, last visited April 23, 2004.

[2] Council of Europe European Treaties ETS No. 164, "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," April 4, 1997, available at: http://conventions.coe.int/treaty/en/Treaties/Html/164.htm, last visited April 23, 2004.

[3] Council of Europe European Treaties ETS No. 164, "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," April 4, 1997, available at: http://conventions.coe.int/treaty/en/Treaties/Html/164.htm, last visited April 23, 2004.

[4] World Health Organization, Fifty –First World Health Assembly, April 8, 1998, available at: http://www.who.int/gb/ebwha/pdf_files/WHA51/eaba1.pdf, last visited May 25, 2004.

[5] Center for Genetics and Society, "National Policies Governing New Technologies of Human Genetic Modification: A Preliminary Survey," available at: http://www.genetics-and-society.org/policies/survey.html, last visited May 24, 2004.

[6] Yet despite the risks, only nine states—Arkansas, California, Iowa, Michigan, New Jersey, North Dakota, Rhode Island, South Dakota, and Virginia—have passed legislation that prohibits human reproductive cloning. Ark. Code § 20-16-1001 et seq.; Cal. Health & Safety Code Ann. § 24185; Iowa Gen. Laws § 707B; Mich. Comp. Laws Ann. § 750.430a; N.J. Stat. § 2C:11A-1; N.D. Cent. Code § 12.1-39-01 et seq.; R.I. Gen. Laws § 23-16.4; S.D. 2004 SB 184; Va. Code Ann. §§ 32.1-162.21, 162.22. In addition, Missouri prohibits the use of any state funds to bring about the birth of a child via cloning techniques. Mo. Ann. Stat. § 1.217. Louisiana also had a reproductive cloning ban that expired July 1, 2003. La. Rev. Stat. 40:1299.36.2. The U.S. House of Representatives in both July 2001 and February 2003 voted to ban human cloning. *See* The Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Congress and The Human Cloning Prohibition Act of 2003, H.R. 534, 108th Congress.

[7] Fla. Stat. Ann. § 390.0111(6); La. Rev. Stat. Ann. § 9:121-129; Me. Rev. Stat. Ann. tit. 22, § 1593; Mass. Gen. Laws Ann. ch. 112, § 12J West; Mich. Comp. Laws Ann. § 333.2685-.2692; Minn. Stat. § 145.421 (2001); N.D. Cent. Code § 14-02.2-01; N.H. Rev. Stat. Ann. § 168-B:15; 18 Pa. Cons. Stat. § 3216; R.I. Gen. Laws § 11-54-1. A South Dakota law bans research that destroys an embryo, when such research has not been undertaken to preserve the life and health of the particular embryo. S.D. Codified Laws § 34-14-18.

[8] Minn. Stat. Ann. § 145.421.

[9] Mich. Comp. Laws Ann. § 333.2685.

[10] Fla. Stat. Ann. § 390.0111(6); Me. Rev. Stat. Ann. tit. 22, § 1593; Mass. Gen. Laws Ann. ch. 112, § 12J; Mich. Comp. Laws Ann. § 333.2685-.2692; N.D. Cent. Code § 14-02.2-01; R.I. Gen. Laws § 11-54-1.

[11] 18 Pa. Cons. Stat. § 3216.

[12] Four states' fetal research bans—those of Arizona, Illinois, Louisiana, and Utah—have already been struck down on those grounds. Forbes v. Napolitano, 236 F.3d 1009 (9th Cir. 2000); Margaret S. v. Edwards, 794 F.2d 994, 998-99 (5th Cir. 1996); Jane L. v. Bangerter, 61 F.3d 1493, 1499-1502 (10th Cir. 1995); Lifchez v. Hartigan, 735 F. Supp. 1361, 1363-66 (N.D. Ill. 1990).

[13] Kolnder v. Lawson, 461 U.S. 352, 357, 103 S. Ct. 1855, 75 L. Ed. 2d 903 (1983).

[14] *See, e.g.,* Me. Rev. Stat. Ann. tit. 22, § 1593.

[15] *See, e.g.*, Fla. Stat. Ann. § 390.0111(6); Mass. Gen. Laws Ann. ch. 112, § 12J; Mich. Comp. Laws Ann. § 333.2692; N.D. Cent. Code § 14-02.2-01.

[16] *See, e.g.,* Mich. Comp. Laws Ann. § 333.2692.

[17] Me. Rev. Stat. Ann. tit. 22, § 1593.

[18] *See, e.g.*, Fla. Stat. Ann. § 390.0111(6); Mass. Gen. Laws Ann. ch. 112, § 12J; Mich. Comp. Laws Ann. § 333.2685-.2692; Minn. Stat. § 145.421; N.D. Cent. Code § 14-02.2-01; 18 Pa. Cons. Stat. § 3216; R.I. Gen. Laws § 11-54-1.

[19] N.H. Rev. Stat. Ann. § 168-B:15(II).

[20] La. Rev. Stat. Ann. § 9:122.

[21] Recombinant DNA Advisory Committee, "NIH Guidelines for Research Involving DNA Molecules," available at: http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf, last visited June 18, 2004.

[22] *See* Ania Lichtarowicz, "Scientist Warns on Human Cloning," BBC News (Dec. 21, 2001) available at: http://news.bbc.co.uk/1/hi/world/europe/1719195.stm, last visited April 23, 2004 (noting that Spain and Belgium are still considering different types of legislation for adoption).

[23] "Britain to Ban Human Cloning," CNN.com (April 19, 2001), available at: http://news.bbc.co.uk/1/hi/health/1285151.stm, last visited April 23, 2004. *See also* Human Reproductive Cloning Act 2001, U.K. Stat. 2001, ch. 23, Enactment Clause (Eng.) (stating that the law "prohibit[s] the placing in a woman of a human embryo which has been created otherwise than by fertilisation").

[24] Federal Embryo Protection Law, 1990 (Eng.).

[25] Victoria Infertility Treatment Act, 1995.

[26] Federal Embryo Protection Law, 1990 (Eng.), at Part 5, § 39(1).

[27] Federal Embryo Protection Law, 1990 (Eng.), at Part 5, § 39(2).

[28] Human Reproductive Technology, 1991, § 7(1)(j) (Australia).

[29] The Act Relating to the Application of Biotechnology in Medicine, August 1994, ch. 7.

[30] Law No. 115 of March 14, 1991, Act Concerning Measures for the Purposes of Research or Treatment in Connection with Fertilized Human Oocytes (1993).

[31] Law No. 94-654 of July 29, 1994, on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis.

[32] An Act Respecting Assisted Human Reproduction and Related Research (Bill C-6), Ottawa, March 29, 2004, available at: http://www.hc-sc.gc.ca/English/pdf/protection/ahr/C-6_4_RA.pdf, last visited May 24, 2004.

[33] Decree No. 24029-S: A Regulation on Assisted Reproduction, Feb. 3, 1995.

[34] *See* Council for Responsible Genetics, "Position Paper on Human Germline Manipulation," available at: http://www.gene-watch.org/programs/cloning/germline-position.html, last visited April 23, 2004.

[35] *See* Council for Responsible Genetics, "Position Paper on Human Germline Manipulation," available at: http://www.gene-watch.org/programs/cloning/germline-position.html, last visited April 23, 2004.

[36] Biotechnology Industry Organization (BIO), "Bioethics Statement of Principles," available at: http://www.bio.org/bioethics/principles.asp, last visited May 24, 2004
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[37] Biotechnology Industry Organization (BIO), "Bioethics Statement of Principles," at Principle Seven, available at: http://www.bio.org/bioethics/principles.asp, last visited May 24, 2004.