

CRS Report for Congress

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Human Cloning

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Summary

On November 25, 2001, a Massachusetts company, Advanced Cell Technology (ACT), announced that they had created the world's first cloned human embryos. The cloned embryos survived only for a few hours. ACT has indicated that it intends to use such embryos to derive stem cells in producing new therapies for diseases like diabetes and Parkinson's disease. The ACT announcement has highlighted the ethical and social concerns associated with cloning human embryos. On July 31, 2001, the House passed **H.R. 2505**, the Human Cloning Prohibition Act of 2001, by a vote of 265-162. The bill would ban the process of human cloning as well as the importation of any product derived from an embryo created via cloning. The provisions mean that cloning could not be used for reproductive purposes or for research on therapeutic purposes, which has implications for stem cell research. This report will be updated as needed.

Background

The term cloning is used by scientists to describe many different processes that involve making copies of biological material, such as a gene, a cell, a plant or an animal. The cloning of genes, for example, has led to new treatments developed by the biotechnology industry for diseases such as diabetes and hemophilia. In the context of this report, a human embryo produced via cloning involves the process called somatic¹ cell nuclear transfer (SCNT). In SCNT, the nucleus of an egg is removed and replaced by the nucleus from a mature body cell, such as a skin cell. In cloning, the embryo is created without sexual reproduction.

Concern over the possibility of producing a human clone increased with the announcement on February 24, 1997, that scientists in Scotland had used SCNT in 1996 to produce the first cloned adult mammal, Dolly, the sheep. Scientists at the Roslin Institute in Edinburgh removed the nucleus from a sheep egg and replaced it with the nucleus of a mammary gland cell from an adult sheep. The resulting embryo was then transferred to the uterus of a surrogate sheep. A total of 277 such embryos were

¹ A somatic cell is a body cell, as opposed to a germ cell, which is an egg or sperm cell.

transferred, but only one lamb was born.² Analyses of Dolly's genetic material confirmed that she was derived from the adult lamb's mammary cell. Proponents maintain that cloning could be used for a number of significant agriculture applications, including the improvement of livestock.

On November 25, 2001, Advanced Cell Technology (ACT) announced that it had created the world's first human embryos produced via cloning; the results were published the following day in an electronic journal.³ ACT used two techniques to produce human embryos — SCNT and a second process called parthenogenesis. ACT researchers obtained eggs from seven women, ages 24 to 32, who were paid \$3000 to \$5000. In the SCNT approach, scientists removed the nucleus from 19 eggs and replaced it with a nucleus from another adult cell. For 11 of the eggs, the nucleus came from a skin cell, for the remaining eight eggs, from cells which cling to the egg and are called cumulus cells. None of the eggs that received a skin cell nucleus divided; seven of the eggs with the cumulus cell nucleus began to divide. Two embryos divided into four cells each, and one embryo divided into six cells before division stopped. In parthenogenesis, an egg cell is treated with chemicals causing it to divide without being fertilized by a sperm. ACT exposed 22 human eggs to the chemicals. After 5 days, six eggs had matured into a larger mass of cells before division stopped. None of the embryos developed by ACT through cloning divided sufficiently to produce stem cells.

The stated goal of ACT's work is not to produce cloned human baby (which requires implantation of the cloned embryo into a woman's uterus), but human embryonic stem cells.⁴ Other research groups have derived stem cells from mice and cattle using SCNT. ACT intends to derive stem cells from human embryos to develop new therapies for diseases such as diabetes and Parkinson's disease. Stem cells transplanted into a patient would treat disease or injury by replacing damaged tissue. If the cell nucleus used in SCNT is from the patient, the stem cells would be genetically identical to the patient, recognized by the patient's immune system, and avoid any tissue rejection problems that could occur in other stem cell therapeutic approaches. Because of this, many scientists believe the SCNT technique may provide the best hope of eventually treating patients using stem cells for tissue transplantation. A California biotechnology company, Geron Corporation, is also working on stem cells created via SCNT.⁵

Ethical and Social Issues

The possibility of using cloning technology not just for therapeutic purposes but also for reproducing human beings raises profound moral and ethical questions. In response to the creation of Dolly and concerns about the potential application of cloning humans,

² Wilmut, I., et al. Viable Offspring Derived From Fetal and Adult Mammalian Cells. *Nature*, v. 385, February 27, 1997. p. 810-813.

³ Cibelli, J.B., et al. Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development. *Journal of Regenerative Medicine*, v. 2, November 26, 2001. p. 25-31.

⁴ For more information about stem cells, please see CRS Report RL31015, *Stem Cell Research*, by Judith A. Johnson.

⁵ Weiss, R. Embryo Work Raises Spector of Human Harvesting. *Washington Post*, June 14, 1999. p. A01.

on February 24, 1997, President Clinton asked the National Bioethics Advisory Commission⁶ (NBAC) to review the ethical and legal issues associated with the use of cloning technology; NBAC reported its findings and recommendations on June 9, 1997.⁷ NBAC recommended a continuation of the moratorium on the use of federal funding in the support of any attempt to create a child by SCNT, and an immediate request to all non-federally funded investigators to comply voluntarily with the intent of the federal moratorium. NBAC also recommended that federal legislation be enacted, with a 3- to 5-year sunset clause, to prohibit anyone from attempting to create a child through the use of SCNT in a research or clinical setting. The NBAC found it morally unacceptable to attempt to clone humans for the purpose of human reproduction because scientific data from animal experiments indicate the method is not safe for mother or baby.⁸ In addition to concerns about physical safety, the NBAC report pointed out that SCNT raises issues about the individuality, autonomy, objectification and kinship of the resulting children.

Cloning, if used for human reproduction, may affect society's perception of what it means to be a human being. Uncertainties over a cloned individual's personal uniqueness or freedom to create their own identity may haunt him or her. Relatives or friends could have specific expectations regarding the cloned individual's talents and abilities. Others may ill treat or discriminate against a cloned individual. Some worry that cloning would lead to diminished respect for human life in general, and for cloned individuals in particular, since the cloned person might simply be replaced with another clone. Others point out, however, that this altered perception does not occur today with identical twins, who are naturally produced clones. Cloning human embryos also raises difficult questions about the rights of parents to control their own embryos and other issues concerning reproductive rights and privacy. Some observers believe that it would be ethical to clone human embryos to help infertile couples conceive.

Human Embryo Research: Policy, Regulations, Guidelines

Currently no U.S. laws or regulations would prohibit all cloning research. However, federal funding of *any* type of research involving human embryos, starting with *in vitro* fertilization (IVF) then later cloning and stem cells, has been blocked by various policy

⁶ NBAC was established by Presidential Executive Order 12975 on October 3, 1995, to provide guidance to federal agencies on the ethical conduct of current and future human biological and behavioral research. A September 16, 1999 executive order extended the NBAC charter until October 2001. NBAC has been replaced by the President's Council on Bioethics, which was described by the Bush Administration in its August 9, 2001 policy decision on human embryonic stem cell research.

⁷ National Bioethics Advisory Commission. *Cloning Human Beings*. June 1997.

⁸ On January 7, 1998, a Chicago scientist, Dr. Richard Seed, announced his intention to clone a human being. In response, bills were introduced in Congress that would have banned human cloning indefinitely or imposed a moratorium. The legislation was opposed by a number of medical organizations, the biotechnology industry and distinguished scientists and was not enacted. Others expressing an interest in reproductive cloning include: (1) Clonaid, a company directed by chemist Brigitte Boisselier and formed by the Raelians, a group that believes humans are descendants of extraterrestrials and that cloning can allow humans to become immortal; and, (2) Panos Zavos, of the University of Kentucky, and Severino Antinori, director of a fertility clinic in Rome, who are working together to help infertile couples have children via cloning.

decisions dating back 25 years. Following the birth of the first IVF baby, Louise Brown, in July 1978, the Ethics Advisory Board (EAB) was tasked with considering the scientific, ethical, legal, and social issues surrounding human IVF.⁹ The EAB released its report on May 4, 1979, which found that IVF research was acceptable from an ethical standpoint and could be supported with federal funds. The EAB's recommendations were never adopted by HHS, the EAB was dissolved in 1980, and no other EAB was ever chartered. Because federal regulations that govern human subject research stipulated that, at the time, federally supported research involving human IVF must be reviewed by an EAB, a so-called "de facto moratorium" on human IVF research resulted. Other types of embryo research ensuing from the development and use of IVF, such as cloning and stem cells, were therefore also blocked. The de facto moratorium was lifted with the enactment of the NIH Revitalization Act of 1993 (P.L. 103-43, Section 121(c)) which nullified the regulatory provision (45 CFR 46.204(d)) requiring EAB review of IVF proposals.

In response, the National Institutes of Health (NIH) established the Human Embryo Research Panel to assess the moral and ethical issues raised by this research and develop recommendations for NIH review and conduct of human embryo research. The NIH Panel released a report providing guidelines and recommendations on human embryo research in September 1994. It recommended that some areas of human embryo research be considered for federal funding, including SCNT, stem cells and (under certain limited conditions) embryos created solely for the purpose of research.¹⁰ The NIH Panel also identified areas of human embryo research it considered to be unacceptable, or to warrant additional review. It determined that certain types of cloning¹¹ without transfer to the uterus warranted additional review before the Panel could recommend whether the research should be federally funded. However, the Panel concluded that federal funding for such cloning techniques followed by transfer to the uterus should be unacceptable into the foreseeable future. The Panel's report was unanimously accepted by the NIH Advisory Committee to the Director (ACD) on December 2, 1994.

After the ACD meeting on December 2, 1994, President Clinton directed NIH not to allocate resources to "support the creation of human embryos for research purposes." The President's directive did not apply to research involving so-called "spare" embryos, those that sometimes remain from clinical IVF procedures performed to assist infertile couples become parents. Nor did it apply to human parthenotes, eggs that begin development through artificial activation, not through fertilization. Following the Clinton December 2, 1994 directive to NIH, the agency proceeded with plans to develop guidelines to support research using spare embryos. However, these plans were halted on

⁹ The EAB was created in 1978 by the Department of Health Education and Welfare (HEW), the forerunner of the Department of Health and Human Services (HHS). The EAB was formed at the recommendation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission operated from 1974 to 1978 and issued 10 reports, many of which formed the basis of federal regulations for research involving human subjects (45 CFR 46).

¹⁰ National Institutes of Health. *Report of the Human Embryo Research Panel*, September 27, 1994.

¹¹ These were **blastomere separation**, where a two- to eight-cell embryo is treated causing the cells (blastomeres) to separate; and, **blastocyst division**, in which an embryo at the more advanced blastocyst stage is split into two.

January 26, 1996, with the enactment of P.L. 104-99 which contained a rider that affected FY1996 funding for NIH. The rider prohibited HHS from using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. This same rider has been attached to the Labor, HHS and Education Appropriations Acts for FY1997 through FY2001.¹² Current language, Section 510 of the FY2001 Labor, HHS and Education Appropriations Act, included in the Consolidated Appropriations Act, 2001 (P.L. 106-554), prohibits HHS from using FY2001 appropriated funds for:

- (1) the creation of a human embryo or embryos for research purposes; or,
- (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). For purposes of this section, the term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 ... that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells.

One month after the Dolly announcement, on March 4, 1997, President Clinton sent a memorandum to the heads of all executive departments and agencies making it “absolutely clear that no federal funds will be used for human cloning.” This action extended the congressional ban beyond HHS to all federally supported research. Clinton also urged the private sector to adopt a voluntary ban on the cloning of human beings. The *NIH Guidelines on Stem Cell Research*, published by the Clinton Administration in August 2000, would not have funded research in which: human stem cells are used for reproductive cloning of a human; human stem cells are *derived* using SCNT; or, human stem cells that were derived using SCNT are *utilized* in a research project. The August 9, 2001 Bush Administration policy decision on stem cell research stated that federal funds will not be used for the cloning of human embryos for any purpose.

The Food and Drug Administration (FDA) has sent letters to the research community stating that the creation of a human being using cloning is subject to FDA regulation under the Public Health Service Act and the Food, Drug and Cosmetic Act.¹³ FDA claims that such research could only occur when an investigational new drug application (IND) is in effect. Some legal scholars believe that there is no legal basis for the regulation of cloning by FDA.¹⁴ They find little evidence to support FDA’s position that cloned human embryos are “drugs.” However, the biotechnology industry and the American Society for

¹² The original rider, introduced by Representative Jay Dickey, is in Section 128 of P.L. 104-99; it affected NIH funding for FY1996 contained in P.L. 104-91. For subsequent fiscal years, the rider is found in Title V, General Provisions, of the Labor, HHS and Education Appropriations Acts in the following public laws: FY1997, P.L. 104-208; FY1998, P.L. 105-78; FY1999, P.L. 105-277; FY2000, P.L. 106-113; and FY2001, P.L. 106-554.

¹³ The FDA position and letter are available at [<http://www.fda.gov/cber/genetherapy/clone.htm>].

¹⁴ Weiss, R. Legal Barriers to Human Cloning May Not Hold Up. *Washington Post*, May 23, 2001. p. A1.

Reproductive Medicine believe FDA has the authority to regulate cloning and legislation is unnecessary because FDA regulation is preferred to any new action by Congress.¹⁵

Legislation

On July 19, 2001, the House Judiciary Subcommittee on Crime approved **H.R. 2505** (Weldon) by voice vote. The bill would ban the process of human cloning as well as the importation of any product derived from an embryo created via cloning. The provisions mean that cloning could not be used for reproductive purposes or for research on therapeutic purposes, which has implications for stem cell research. The bill includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than \$1 million. A companion bill, **S. 790** (Brownback), was introduced in the Senate.

H.R. 2608 (Greenwood), introduced on July 24, 2001, would ban *only* human reproductive cloning; the ban would sunset after 10 years. It has the same criminal and civil penalties as **H.R. 2505** when cloning is used “with the intent to initiate a pregnancy.” On July 24, 2001, the House Judiciary Committee approved **H.R. 2505** by a vote of 18 to 11 and defeated a substitute that was identical to the Greenwood bill by a vote of 11 to 19. The Bush Administration announced its support for **H.R. 2505** on July 24, 2001.

On July 31, 2001, the House passed **H.R. 2505** by a vote of 265-162. Prior to the vote on **H.R. 2505**, the House defeated a substitute amendment, **H. Amdt. 285**, which is identical to **H.R. 2608**, by a vote of 178 to 249. During debate, supporters of **H.R. 2505** argued that a partial ban on human cloning, such as **H.R. 2608**, would be impossible to enforce. Critics of **H.R. 2505** argued that SCNT creates a “clump of cells” rather than an embryo, and that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. On December 3, 2001, the Senate considered an amendment that would have imposed a 6-month moratorium on all human cloning research; an attempt to attach the amendment to a separate bill failed.

Some legal scholars believe a ban on human cloning may be unconstitutional because it would infringe upon the right to make reproductive decisions which is “protected under the constitutional right to privacy and the constitutional right to liberty.”¹⁶ Other scholars do not believe that noncoital, asexual reproduction, such as cloning, would be considered a fundamental right by the Supreme Court. However, in decisions involving IVF, which is noncoital but not asexual because both parents are required, the justices have suggested that reproduction by IVF is a fundamental right, but the issue is unresolved.¹⁷ A ban on human cloning research raises other constitutional issues: scientists’ right to personal liberty and free speech. In the opinion of some legal scholars, any government limits on the use of cloning in scientific inquiry or human reproduction would have to be “narrowly tailored to further a compelling state interest.”¹⁸

¹⁵ Ibid.

¹⁶ Andrews, L. B. Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning. *Harvard Journal of Law and Technology*, summer 1998. p. 643-680.

¹⁷ Weiss, Legal Barriers to Human Cloning May Not Hold Up, p. A1.

¹⁸ Andrews, Is There a Right to Clone?, p. 667.