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Report for Congress

Human Cloning

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Human Cloning

Summary

On December 27, 2002, a representative of Clonaid announced the overseas birth of the first cloned human to a 31-year old American woman. Although the company said genetic tests would show that the baby is a clone of the birth mother, tests results have not been released. Claims of a second birth of a cloned baby to a Dutch couple on January 3, 2003 have also not been proven. These announcements are likely to rekindle debate in the 108th Congress on the moral and ethical implications of human cloning as the disclosure by Advanced Cell Technology (ACT) did in the 107th Congress. In November 2001 ACT announced the creation of the first cloned human embryos (which survived only for a few hours). ACT intended to use the embryos to derive stem cells to produce therapies for diseases like diabetes and Parkinson's disease.

President Bush announced in August 2001 that for the first time federal funds will be used to support research on human embryonic stem cells, but funding will be limited to "existing stem cell lines." Federal funds will not be used for the cloning of human embryos for any purpose, including stem cell research. The President's Council on Bioethics was established in November 2001 to consider all of the medical and ethical ramifications of biomedical innovation. In July 2002 the Council released its report on human cloning which unanimously recommended a ban on reproductive cloning and, by a vote of 10 to 7, a 4-year moratorium on cloning for medical research purposes.

In January 2002, the National Academies released its report entitled *Scientific and Medical Aspects of Human Reproductive Cloning*. The panel recommended that the U.S. ban human reproductive cloning that is aimed at creating a child. It suggested the ban should be legally enforceable and carry substantial penalties rather than rely simply on voluntary actions. The panel noted that the ban should be reconsidered within 5 years, but only if compelling new data on safety and efficacy are presented and a national dialogue on the social and ethical issues suggests that a review is warranted. However, the panel concluded that research using cloning procedures to produce stem cells should be permitted because of the considerable potential for developing new therapies and advancing biomedical knowledge.

The House passed H.R. 534 (Weldon), the Human Cloning Prohibition Act of 2003, on February 27, 2003. H.R. 534 would ban the process of human cloning as well as the importation of any product derived from an embryo created via cloning. Cloning could not be used for reproductive purposes or for research on therapeutic purposes, which has implications for stem cell research. The House defeated a substitute amendment, H.Amdt. 5, that would have banned *only* human reproductive cloning; the ban would have sunset after 10 years. H.Amdt 5 is similar to H.R. 801 (Greenwood). Supporters of H.R. 534 argue that a partial ban on human cloning, such as H.R. 801, would be impossible to enforce. Critics of H.R. 534 argue that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. In the Senate, S. 234 (Brownback)would ban reproductive cloning and research on therapeutic cloning; S. 303 (Hatch) would ban only reproductive cloning. This report will be updated as needed.

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Human Cloning

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 somatic[1] 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 transferred, but only one lamb was born.[2] Analyses of Dolly's genetic material confirmed that she was derived from the sheep mammary cell. Dolly was euthanized on February 14, 2003, after developing a lung infection. Although some claim that her somewhat early death at 6 years was related to being a clone, scientists at the Roslin Institute believe her ailment may be due to the fact that she was raised indoors (for security reasons) rather than as a pastured sheep, which can live to 11 or 12 years of age.[3]

Although scientists have been successful in using SCNT to produce other animals (such as a cat, goat, cow, pig and mouse), the efficiency of the procedure is still very low and frequently results in abnormal development. Proponents maintain that one day cloning may be very useful for a number of agriculture applications, including the improvement of livestock.

Clonaid. On December 27, 2002, a representative of Clonaid announced the birth of the first cloned human, a seven pound baby girl nicknamed Eve. The baby was born at 11:55 AM on December 26, 2002, at an undisclosed location outside the United States. Although the company offered no proof of its claim, Dr. Brigette

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

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

[3] Kolata, G. First Mammal Clone Dies; Dolly Made Science History. The New York Times, February 15, 2003, p. A4.

Boisselier, Managing Director of Clonaid, stated that genetic tests would show that the baby is the clone of the 31 year old American woman who is the birth mother. To date tests have not been performed; the company claims that the parents fear the test results could lead to legal actions and loss of custody of the child.[4]

Dr. Boisselier stated that as of December 27, 2002, four other women were pregnant with clones created by Clonaid scientists, and two of the women were carrying clones of children who have died. On January 4, 2003, the company announced the birth of a second cloned baby to a Dutch couple. The baby was born on January 3, 2003; no additional information or evidence was provided by Clonaid. The company plans to implant cloned embryos in 20 additional women in January 2003. Clonaid was founded in 1997 by the leader of the Raelians, an international sect of 55,000 people in 84 countries, which claims that life on Earth was created via genetic engineering by a human extraterrestrial race.[5]

The Food and Drug Administration (FDA) is investigating the company's actions; the agency would consider any human cloning activity to be illegal if performed in the United States.[6] In April 2001 FDA investigated a Clonaid laboratory in Nitro, West Virginia; the laboratory closed shortly thereafter.[7]

Advanced Cell Technology. On November 25, 2001, Advanced Cell Technology (ACT) of Massachusetts 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.[8] 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, which occur at the blastocyst stage in 1-week-old embryos.

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[4] Chang, K. Scientist in Clone Tests Says Hoax is Possible. *The New York Times*, January 7, 2003, p. A12.

[5] For further information, see: [http://www.clonaid.com] and [http://www.rael.org].

[6] Greenhouse, L. FDA Exploring Human Cloning Claim. *The New York Times*, December 30, 2002, p.

[7] Kolata, G. and K. Chang. For Clonaid, a Trail of Unproven Claims. *The New York Times*, January 1, 2003, p. A13.

[8] 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.

The stated goal of ACT's work is not to produce a cloned human baby (which requires implantation of the cloned embryo into a woman's uterus), but human embryonic stem cells.[9] 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. Some scientists believe that stem cells transplanted into a patient could 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, has also explored creating stem cells via SCNT.[10]

Dr. Richard Seed, Dr. Panos Zavos, Dr. Severino Antinori. Within a year of the Dolly announcement, concerns over human cloning were heightened when Dr. Richard Seed, a Chicago scientist, announced on January 7, 1998, his intention to clone a human being. In response, bills were introduced in the 105th 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 many scientists and was not enacted. Others who have expressed an interest in reproductive cloning include Dr. Panos Zavos, of the University of Kentucky, and Dr. Severino Antinori, director of a fertility clinic in Rome. At one time, Dr. Zavos and Dr. Antinori were working together to help infertile couples have children via cloning. In April 2002, there were unconfirmed reports in the media that Dr. Antinori had implanted cloned human embryos in women. Dr. Antinori claimed there were 3 such pregnancies of 6 to 9 weeks duration, 2 in Russia and 1 in an Islamic state. His claim was disputed by his former partner Dr. Zavos.

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, on February 24, 1997, President Clinton asked the National Bioethics Advisory Commission[11] (NBAC) to review the ethical and legal issues associated with the use of cloning technology; NBAC reported its findings and

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

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

[11] 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. The President's remarks on embryonic stem cell research are available at:
[http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html].

recommendations on June 9, 1997.[12] 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. 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 allowed for human reproduction, could 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 one's own identity may haunt him or her. Relatives or friends could have specific expectations regarding the cloned individual's talents and abilities. Others might 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. Lastly, the possibility of human cloning is offensive to the religious and other deeply held beliefs of many people.

Brief History of Federal Policy Involving Human Embryo Research

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 decisions dating back 25 years.

Ethics Advisory Board. 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.[13] The EAB released its report on May 4, 1979, which found that IVF research was acceptable

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[12] National Bioethics Advisory Commission. *Cloning Human Beings*. June 1997.

[13] 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).

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 (45 CFR 46) 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 National Institutes of Health (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.

NIH Human Embryo Research Panel. In response, the 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.[14] 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 cloning[15] 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 to 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.

Dickey Amendment. NIH plans to develop guidelines on embryo research were halted on 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, often referred to as the Dickey amendment, has been attached to the Labor, HHS and Education

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

[15] 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.

Appropriations Acts for FY1997 through FY2002.[16] For FY2003, the provision is found in Section 510 of Division G in H.J.Res. 2, which is the Labor, HHS and Education division of the Omnibus FY2003 appropriation bill. It prohibits HHS from using FY2003 appropriated funds for:

> (1) the creation of a human embryo or embryos for research purposes; or,
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> (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.

Bush Administration Policy Regarding Human Embryo Research

On August 9, 2001 President Bush announced that for the first time federal funds will be used to support research on human embryonic stem cells, but funding will be limited to "existing stem cell lines." In the speech, President Bush stated that he strongly opposes human cloning. Although not mentioned specifically in the August 9 speech, a fact sheet on the White House website states that federal funds will not be used for "the cloning of human embryos for any purpose."[17] In his speech, President Bush announced his intention to name a President's council, chaired by Dr. Leon Kass of the University of Chicago, "to consider all of the medical and ethical ramifications of biomedical innovation." The President's Council on Bioethics, was established for a period of up to 2 years by Executive

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[16] 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; FY2001, P.L. 106-554; and FY2002, P.L. 107-116.

[17] The White House Fact Sheet on embryonic stem cell research is available at: [http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html].

Order 13237 on November 28, 2001. The White House announced the other 17 members of the council on January 16, 2002.

The first meeting of the President's Council on Bioethics was held on January 17-18, 2002, in Washington, D.C.[18] Dr. Kass announced that the first topic to be addressed by the Council would be human cloning. At the Council's second meeting, the terminology of cloning was discussed in order to reach a consensus on the terms used to describe the two types of cloning: reproductive vs. therapeutic or research cloning. All Council members voted in opposition to reproductive cloning; however, they could not come to an agreement on articulating the precise nature of their objection, whether solely on safety grounds or which of the various moral objections were most important. On the issue of therapeutic cloning, what the Council prefers to call research cloning, the Council also could not come to agreement. Dr. Kass proposed that the Council's final report should reflect both the arguments supporting cloning for the purpose of medical treatment and those against. He asserted that the report should also provide the soundest arguments for each position and indicate how many Council members supported each viewpoint.

The third meeting of the Council was held on April 25 and 26, 2002. The Council heard presentations on the scientific and therapeutic promise of embryonic stem cells from John Gearhart of Johns Hopkins University and the potential of adult stem cells from Catherine Verfaillie of the University of Minnesota. In an informal vote, about half of the 18 members of the Council voiced their support for the therapeutic use of human cloning. The May 2002 meeting was cancelled.

At the June 20, 2002, meeting, nine Council members voted to support cloning for medical research purposes, without a moratorium, provided a regulatory mechanism was established.[19] Because one member of the Council had not attended the meetings and was not voting, the vote seemed to be 9 to 8 in favor of research cloning. However, draft versions of the Council report sent to Council members on June 28, 2002, indicated that two of the group of nine members had changed their votes in favor of a moratorium. Both made it clear that they have no ethical problem with cloning for biomedical research, but felt that a moratorium would provide time for additional discussion.[20] The changed vote took many Council members by surprise, and some on the Council believe that the moratorium option, as opposed to a ban, was thrown in at the last minute and did not receive adequate discussion. In addition, some on the Council believe that the widely reported final vote of 10 to 7 in favor of a moratorium does not accurately reflect the fact "that the majority of the council has no problem with the ethics of biomedical cloning."[21] The final report, *Human Cloning and Human Dignity: An Ethical Inquiry*, was released at the July 11, 2002, meeting of the Council.

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[18] A transcript of the first meeting and papers developed by staff for discussion during the meeting can be found at [http://www.bioethics.gov].

[19] Hall, S.S. President's Bioethics Council Delivers, *Science*, v. 297, July 19, 2002, p. 322-324.

[20] Ibid., p. 324.

[21] Ibid., p. 322.

In March 2001, the FDA 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.[22] FDA stated 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.[23] They find little evidence to support FDA's position that cloned human embryos are "drugs." However, the biotechnology industry and the American Society for 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.[24]

On January 18, 2002, the National Academies released its report entitled *Scientific and Medical Aspects of Human Reproductive Cloning*.[25] The panel recommended that the U.S. ban human reproductive cloning that is aimed at creating a child. Based on the results of animal cloning experiments, the panel was concerned for the safety of both the woman and the fetus and judged the procedure to be too dangerous for use in humans at the present time. It recommended that the ban should be legally enforceable and carry substantial penalties rather than be based simply on voluntary actions. The panel stated that the ban should be reconsidered within 5 years, but only if compelling new data on safety and efficacy are presented and a national dialogue on the social and ethical issues suggests that a review is warranted. However, the panel concluded that research using SCNT to produce stem cells should be permitted because of the considerable potential for developing new therapies and advancing biomedical knowledge. This position is in agreement with a previous National Academies' report entitled *Stem Cells and the Future of Regenerative Medicine* which was released on September 11, 2001.[26]

Legislation

On February 27, 2003, the House passed H.R. 534 (Weldon), the Human Cloning Prohibition Act of 2003 by a vote of 241-155. H.R. 534 amends Title 18 of the United States Code and would ban the process of human cloning as well as the importation of any product derived from an embryo created via cloning. Under this measure, cloning could not be used for reproductive purposes or for research on therapeutic purposes, which would have implications for stem cell research. H.R.

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[22] The FDA position statement and letters to the research community are available at [http://www.fda.gov/cber/genetherapy/clone.htm].

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

[24] Ibid.

[25] The National Academies are the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council. The report on human cloning is available at:
[http://www.nap.edu/catalog/10285.html?onpi_topnews_011802].

[26] The National Academies' report on stem cell research is available at:
[http://www.nap.edu/catalog/10195.html?onpi_topnews_091101].

534 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than $1 million.

H.R. 534 is essentially identical to the measure which passed the House in the 107th Congress (H.R. 2505). During floor debate on H.R. 534, an amendment, H.Amdt. 4 (Scott), was agreed to by voice vote. H.Amdt. 4 requires that the General Accounting Office (GAO), in consultation with the National Academy of Sciences, conduct a study on the impact of the cloning ban on medical technology and assess the need (if any) for modification of the cloning ban contained in the bill. A report to Congress with findings and recommendations would be required within 2 years of enactment. An amendment in the nature of a substitute, H.Amdt 5 (Greenwood), was not adopted by a vote of 174 to 231. The amendment would have prohibited human SCNT technology when used to initiate a pregnancy but allowed SCNT to be used in medical research. H.Amdt 5 is similar to H.R. 801 (Greenwood) (see below).

H.R. 534 was introduced on February 5, 2003, and reported (19-12 vote) by the House Judiciary Committee on February 12, 2003 (H.Rept. 108-18). During mark-up, four amendments were defeated by 12-19 or by voice vote. The amendments attempted to either limit the ban to 3 years, exempt the importation of medical treatments, exempt the use of cloning in research, or in the creation of additional stem cell lines. A fifth amendment that would add the GAO study was withdrawn when Chairman Sensenbrenner assured his support if it was added to the bill during floor debate.

A companion bill, S. 245 (Brownback), was introduced on January 29, 2003. It is similar to H.R. 534, except that: (1) it does not contain the ban on importation of products derived from therapeutic cloning; and (2) it amends Title 4 of the Public Health Service Act (42 U.S.C. 289 et seq.) instead of Title 18 of the United States Code. S. 245 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than $1 million. It requires the General Accounting Office to conduct a study to assess the need (if any) for any changes of the prohibition on cloning in light of new developments in medical technology, the need for SCNT to produce medical advances, current public attitudes and prevailing ethical views on the use of SCNT and potential legal implications of research in SCNT. The study is to be completed within 4 years of enactment. S. 245 has been referred to the Senate Health, Education, Labor, and Pensions Committee.

H.R. 801 (Greenwood), the Cloning Prohibition Act of 2003, was introduced on February 13, 2003. H.R. 801 would prohibit human reproductive cloning while allowing cloning for medical research purposes, including stem cell research. The bill includes a civil penalty of up to $10 million and a criminal penalty of up to 10 years in prison for those convicted of using SCNT for human reproductive purposes, or for importing the products of human cloning if the products would be used to initiate a pregnancy. The bill amends the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and requires that all researchers performing SCNT on human cells must register their research activity with the Secretary; such registration would most likely be submitted to the FDA.

H.R. 801 stipulates that all research involving human SCNT shall be conducted in accordance with Part 50 (Protection of Human Subjects) and Part 56 (Institutional

Review Boards) of Title 21 of the Code of Federal Regulations (CFR). Under the bill, individuals whose cells are used for such research (presumably the donor of the unfertilized egg and the donor of the somatic cell) would be considered human subjects for the purposes of Parts 50 and 56 of 21CFR. In addition to the requirements under Parts 50 and 56 of 21CFR, the human cell donors must sign an informed consent statement declaring that: (1) the cells are donated for research purposes; (2) the donor understands that Federal law regulates SCNT and use of SCNT to initiate a pregnancy is a criminal act; and, (3) the individual does not intend for the donated cells to be used to initiate a pregnancy. A sunset provision states that the prohibition would expire 10 years after enactment.

H.R. 801 requires the Secretary of HHS to request a study reviewing the current state of knowledge on: (1) the biological properties of stem cells obtained from embryos, fetal tissue, and adult tissue; (2) any biological differences of such stem cells and the consequences for research and medicine; and (3) the ability of stem cells to generate different types of tissue and their potential clinical uses. The study must be conducted by the Institute of Medicine or another appropriate public or nonprofit private entity.

S. 303 (Hatch), the Human Cloning Ban and Stem Cell Research Protection Act of 2003, was introduced on February 5, 2003. Although S. 303 would amend Title 18 of the United States Code while H.R. 801 would amend Title 21, both bills have the same intent: human reproductive cloning would be banned but cloning for medical research purposes would be allowed, including stem cell research. S. 303 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than $1 million.

S. 303 requires the Comptroller General to prepare a report within 1 year of enactment that describes the actions taken by the Attorney General to enforce the prohibition on human reproductive cloning, the personnel and resources used to enforce the prohibition, and a list of any violations of the prohibition. The Comptroller General must also prepare a report within 1 year of enactment on similar state laws that prohibit human cloning and actions taken by the States' attorney general to enforce the provisions of any similar state law along with a list of violations. A report on the coordination of enforcement actions among the federal, state and local governments must also be prepared by the Comptroller General within 1 year of enactment, as well as a report on laws adopted by foreign countries related to human cloning.

S. 303 also would amend the Public Health Service Act by requiring that nuclear transplantation research be conducted in accordance with the ethical requirements (such as informed consent, examination by an Institutional Review Board, and protections for safety and privacy) contained in subpart A of 45CFR46, or Parts 50 and 56 of 21CFR. In contrast, H.R. 801 requires that all such research shall be conducted in accordance with Part 50 and 56 of 21CFR and does not refer to subpart A of 45CFR46.[27]

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[27] Subpart A 45CFR46, often referred to as the Common Rule,"applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any (continued...)

S. 303 contains a prohibition on conducting SCNT on fertilized human eggs (oocytes), and states that "unfertilized blastocysts" shall not be maintained after more than 14 days from its first cell division, aside from storage at temperatures less that zero degrees centigrade. S. 303 stipulates that a human egg may not be used in SCNT research unless the egg is donated voluntarily with the informed consent of the woman donating the egg; H.R. 801 contains a similar egg donation and informed consent provision. S. 303 also specifies that human eggs or unfertilized blastocysts may not be acquired, received or otherwise transferred for valuable consideration if the transfer affects interstate commerce. Under S. 303, SCNT may not be conducted in a laboratory in which human eggs are subject to assisted reproductive technology treatments or procedures, such as in vitro fertilization, for the treatment of infertility. Violation of these provisions in S. 303 regarding ethical requirements would result in a civil penalty of not more than $250,000. S. 303 has been referred to the Senate Judiciary Committee.

During floor debate in the 107th Congress, supporters of a ban on human cloning (such as that contained in H.R. 534 introduced in the 108th Congress) argued that a partial ban on human cloning (such as that contained in S. 303 introduced in the 108th Congress) would be impossible to enforce. Critics of the ban on human cloning 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.

President Bush has stated his support for a prohibition on all forms of human cloning and has endorsed the cloning ban legislation introduced in the 107th Congress (H.R. 2505) and the 108th Congress (H.R. 534). However, 40 Nobel Laureates, who are in favor of nuclear transplantation technology (SCNT) for research and therapeutic purposes, announced their strong opposition to the legislation.[28] The statement asserted that the legislation "would impede progress against some of the most debilitating diseases known to man."

Former President Gerald Ford stated his strong opposition to the legislation in a April 25, 2002, letter to President Bush.[29] In the letter, Ford indicated that during his administration, the controversy over recombinant DNA research was "successfully addressed with 'careful thought' and the implementation of safety

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[27] (...continued)
federal department or agency which takes appropriate administrative action to make this policy applicable to such research." The Common Rule covers 18 federal agencies by force of law or Executive Order. FDA has regulatory authority over research on the products the agency regulates (food, drugs, medical devices) and applies its own set of regulations on the protection of human subjects (21CFR 50, 56) that are generally but not entirely the same as subpart A of 45CFR46. For further information, see National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, Appendix C: The Current Oversight System: History and Description, August 2001.

[28] The American Society for Cell Biology statement by the 40 Nobel Laureates is available at: [http://www.ascb.org/publicpolicy/Nobelletter.html].

[29] Hafner, L. Revised Feinstein/Kennedy Cloning Bill Has Criminal and Civil Penalties, Requires Research Review. *Washington Fax*, May 2, 2002.

regulations."[30] Former President Ford expressed his "full support for therapeutic cloning, arguing a prohibition of this technology 'would adversely impact scientific research and should not become law.'"[31]

Former First Lady Nancy Reagan has indicated she also is opposed to legislation that would limit embryonic stem cell research and its promise in aiding patients afflicted with serious diseases which have no treatment, such as Alzheimer's disease. In 1994, it was disclosed that former President Ronald Reagan was suffering from the effects of Alzheimer's disease. In a recent letter to Senator Orrin Hatch, Mrs. Reagan states her support for stem cell research and S. 303 which will allow the use of therapeutic cloning.[32]

The U.S. Supreme Court has recognized in past cases certain personal rights as being fundamental and protected from government interference.[33] Some legal scholars believe a ban on human cloning may be struck down by the Supreme Court 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."[34] Other scholars do not believe that noncoital, asexual reproduction, such as cloning, would be considered a fundamental right by the Supreme Court. A ban on human cloning research may raise 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."[35] However, no case involving these issues is scheduled to come before the Supreme Court this term.

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[30] Ibid.

[31] Ibid.

[32] Complete text of the Reagan letter can be found at: [www.senate.gov/~hatch/].

[33] For further discussion of these issues and their relationship to human cloning, see CRS Report RL31422, *Substantive Due Process and a Right to Clone*, by Jon O. Shimabukuro.

[34] 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.

[35] Ibid., p. 667.