Order Code RL31358

Human Cloning

Updated January 21, 2005

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Summary

In February 2004 scientists in South Korea announced that they had created human embryos using cloning procedures and had succeeded in isolating human stem cells from a cloned embryo. In December 2002 a representative of Clonaid announced the overseas birth of the first cloned human to a 31-year-old American woman. Clonaid's claim remains unsubstantiated. These announcements have rekindled 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); the embryos were to be used to derive stem cells for medical research on disease therapies.

President Bush announced in August 2001 that for the first time federal funds would be used to support research on human embryonic stem cells, but funding would 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 four-year moratorium on cloning for medical research purposes. The ethical issues surrounding reproductive cloning (safety, identity, and commodification, etc.), and therapeutic cloning (embryos' moral status, relief of suffering, and creation for destruction), impact various proposals for regulation, restrictions, bans, and uses of federal funding.

In January 2002, the National Academies released *Scientific and Medical Aspects of Human Reproductive Cloning*. It recommended that the U.S. ban human reproductive cloning aimed at creating a child. It suggested the ban be enforceable and carry substantial penalties. The panel noted that the ban should be reconsidered within five years. However, the panel concluded that cloning to produce stem cells should be permitted because of the potential for developing new therapies and advancing biomedical knowledge.

Legislative action during the 109th Congress will probably be limited to the same two targets that have been attempted in previous Congresses. During consideration of Labor, HHS, and Education appropriations, Members may renew efforts to alter or abolish the Dickey Amendment in order to permit embryo research and the development of stem cell lines with federal support. Even more likely, however, is reintroduction of the Weldon bill, which passed the House in the 108th Congress and stalled in the Senate. The bill bans the process of cloning as well as the importation of any product derived from an embryo created via cloning. It bans not only reproductive applications, but also research on therapeutic uses, which has implications for stem cell research. Advocates of the legislative ban say that allowing any form of human cloning research to proceed raises serious ethical issues and will inevitably lead to the birth of a baby that is a human clone. Critics of the ban argue that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. This report will be updated as needed.

Contents

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 cell[1] 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: there is no joining of egg and sperm.

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 six 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, horse, mule, pig, mouse, and rabbit), 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. Currently, cloned mice are used for basic research on human health applications.

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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] I. Wilmut et al., "Viable Offspring Derived from Fetal and Adult Mammalian Cells." *Nature*, vol. 385, Feb. 27, 1997, pp. 810-813.

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

Seoul National University. In February 2004, scientists at the Seoul National University in South Korea announced that they had created human embryos via the SCNT process and had succeeded in isolating human stem cells from a cloned embryo. The South Korean team obtained 242 eggs from 16 unpaid female volunteers; 30 embryos survived to the one-week-old stage, and only one produced a stem cell line. Although the team tried a number of different methods, the only approach that worked was when both the egg and the adult cell were from the same woman. The adult cell used was a cumulus cell, cells which cluster around the egg.

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 on December 26, 2002, at an undisclosed location outside the United States. Although the company offered no proof of its claim, Dr. Brigette 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 the test results have not been released; the company claims that the parents fear the test results could lead to legal actions and loss of custody of the child.[4] The Clonaid website indicates that "13 cloned babies are now alive," and that "each month, between 10 and 15 implantations will be performed" in the Clonaid laboratory.[5] 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.[6]

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.[7] In April 2001 FDA investigated a Clonaid laboratory in Nitro, WV; the laboratory closed shortly thereafter.[8]

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.[9] ACT used two techniques, SCNT and parthenogenesis, to produce human embryos. ACT researchers obtained eggs from seven women, ages 24 to 32, who were paid $3,000 to $5,000. In the SCNT approach, scientists removed the nucleus from 19 eggs and replaced it with a nucleus from another adult cell. The nucleus of a skin cell was used for 11 eggs, and for the remaining eight eggs, cumulus cells were used. Eggs that received a skin cell nucleus

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[4] K. Chang, "Scientist in Clone Tests Says Hoax Is Possible," *New York Times*, Jan. 7, 2003, p. A12.

[5] [http://www.clonaid.com/news.php]

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

[7] L. Greenhouse, "FDA Exploring Human Cloning Claim," *New York Times*, Dec. 30, 2002, p. A10.

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

[9] J. B. Cibelli, et al., "Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development," *Journal of Regenerative Medicine*, vol. 2, Nov. 26, 2001, pp. 25-31.

did not divide; seven of the eggs with the cumulus cell nucleus began to divide but division stopped at the four-to-six-cell stage. 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 five days, six eggs had matured into a larger mass of cells before division stopped. None of the embryos developed by ACT divided sufficiently to produce stem cells.

The goal of ACT's work was to produce human embryonic stem cells and develop new therapies for diseases such as diabetes and Parkinson's disease.[10] 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 would 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.

Others with Human Cloning Intentions. 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 three such pregnancies of six- to nine-weeks' duration, two in Russia and one in an Islamic state. His claim was disputed by his former partner Dr. Zavos. In January 2004 Dr. Zavos announced that he had implanted a cloned embryo into a woman's uterus; two weeks later he stated that the pregnancy had failed.[11]

Federal Policy Involving Human Embryo Research

At the present time, 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 the creation of stem cell lines from embryos, had been blocked by various policy decisions dating back 25 years.

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

[11] David Derbyshire and Oliver Poole, "I Am Doing God's Work, Insists Maverick Fertility Expert Who Wants to Clone Babies," *Daily Telegraph*, Feb. 14, 2004, p. 4.

Ethics Advisory Board. Following the birth of the first IVF baby, Louise Brown, in July 1978, the federal Ethics Advisory Board (EAB) was tasked with considering the scientific, ethical, legal, and social issues surrounding human IVF.[12] 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 (45 C.F.R. Part 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 C.F.R. § 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 to 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. The panel identified areas of human embryo research it considered to be unacceptable, or to warrant additional review. It determined that certain types of cloning[13] 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 NIH Panel recommended that some areas of human embryo research should be considered for federal funding, including SCNT, stem cells and, under certain limited conditions, *embryos created solely for the purpose of research*.[14] 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

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[12] 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 C.F.R. Part 46).

[13] 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.

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

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 Appropriations Acts for FY1997 through FY2005.[15] For FY2005, the provision is found in Section 509 of Division F, which is the Labor, HHS and Education division of the FY2005 Consolidated Appropriations bill (H.R. 4818, H.Rept. 108-792). It prohibits HHS from using FY2005 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.

Actions During the Current Bush Administration. On August 9, 2001, President Bush announced that for the first time federal funds would be used to support research on human embryonic stem cells, but funding would 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

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[15] The original rider, introduced by Rep. 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; FY2002, P.L. 107-116; FY2003, P.L. 108-7; and, FY2004, P.L. 108-199.

used for "the cloning of human embryos for any purpose."[16] 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 two years by Executive Order 13237 on November 28, 2001. The White House announced the other 17 members of the council on January 16, 2002.

The first topic addressed by the Council was human cloning.[17] Although all Council members voted in opposition to reproductive cloning, they could not come to an agreement on articulating the precise nature of their objection, whether solely safety concerns or which of the various moral objections were most important. In an informal vote on the issue of therapeutic cloning, about half of the 18 members of the Council voiced their support for the therapeutic use of human cloning. Dr. Kass proposed that the Council's final report reflect both the arguments supporting cloning for the purpose of medical treatment and those against.

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.[18] Because one member of the Council had not attended the meetings and was not voting, the vote seemed to be nine to eight in favor of research cloning. However, the draft 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.[19] 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."[20] The final report, *Human Cloning and Human Dignity: An Ethical Inquiry*, was released on July 11, 2002.

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.[21] FDA stated that

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

[17] Transcripts of the Council meetings and papers developed by staff for discussion during the meetings can be found at [http://www.bioethics.gov].

[18] S.S. Hall, "President's Bioethics Council Delivers," *Science*, vol. 297, July 19, 2002, pp. 322-324.

[19] Ibid., p. 324.

[20] Ibid., p. 322.

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

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.[22] 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.[23]

On January 18, 2002, the National Academies released its report, entitled *Scientific and Medical Aspects of Human Reproductive Cloning*.[24] The panel recommended that the U.S. ban human reproductive cloning. 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. The ban should be legally enforceable, rather than voluntary, and carry substantial penalties. The ban should be reconsidered in five 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.[25]

Because of the lack of federal regulation, the National Academies established in July 2004 the Committee on Guidelines for Human Embryonic Stem Cell Research to develop voluntary guidelines for deriving, handling, and using human embryonic stem cells. The guidelines will take into account important scientific, ethical, and policy issues in this new area of research, including the use and derivation of new stem cell lines created by nuclear transplantation, from surplus IVF embryos, and from embryos created with donated gametes. The stated position of the National Academies is that there should be a global ban on human reproductive cloning and therefore the guidelines will focus only on therapeutic and research uses of human embryonic stem cells and somatic cell nuclear transfer. A final report from the Committee is expected in January 2005.

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

[23] Ibid.

[24] 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].

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

The U.S. Supreme Court has recognized in past cases certain personal rights as being fundamental and protected from government interference.[26] 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."[27] 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."[28]

State Legislation on Cloning

As of March 12, 2004, nine states have passed laws which prohibit reproductive cloning (Arkansas, California, Iowa, Michigan, New Jersey, North Dakota, Rhode Island, South Dakota, Virginia).[29] In addition, Louisiana has enacted legislation prohibiting reproductive cloning but the law expired in July 2003. Five of the nine states also prohibit cloning for research or therapeutic purposes (Arkansas, Iowa, Michigan, North Dakota, South Dakota). The Virginia law may also prohibit therapeutic cloning, "but it may be unclear because the law does not define the term 'human being' which is used in the definition of human cloning."[30] The California and New Jersey laws specifically permit cloning for research purposes. The Rhode Island law is silent on therapeutic cloning and cloning for research purposes, and has a sunset date of July 7, 2010. Missouri "bans the use of state funds for human cloning research which seeks to develop embryos into newborn children," but does not prohibit reproductive cloning or therapeutic cloning.[31]

Federal Legislation on Cloning

Legislative action during the 109th Congress will probably be limited to the same two targets that have been attempted in previous Congresses. During consideration of Labor HHS and Education appropriations, Members may renew efforts to alter or abolish the Dickey Amendment in order to permit embryo research and the development of stem cell lines with federal support. Even more likely, however, is reintroduction of the Weldon bill which passed the House in the 108th and stalled in

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[26] 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.

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

[28] Ibid., p. 667.

[29] National Conference of State Legislatures, State Human Cloning Laws, Mar. 12, 2004, at [http://www.ncsl.org/programs/health/genetics/rt-shcl.htm]

[30] Ibid.

[31] Ibid.

the Senate. Given the changed composition of the Senate, it is more likely that this legislation would move forward for a vote in that body during the 109th Congress.

The 108th Congress addressed the issue of cloning and embryo research in the Consolidated Appropriations Act of 2005 (H.R. 4818, H.Rept. 108-792) by again including the Dickey Amendment, which has banned, since FY1996, almost all publically funded human embryo research. The act also bars the Patent and Trademark Office from spending money "to issue patents on claims directed to or encompassing a human organism." This restriction, which was first included in the FY2004 act, could potentially deter human embryo research and stem cell research because researchers might not be able to claim ownership of their work.

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. 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 that 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 Government Accountability Office (GAO) (formerly the General Accounting Office), 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 two 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 three 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.[32] 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 GAO 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 four 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 would amend the Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.) and would require that all researchers performing SCNT on human cells 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 (C.F.R.). 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 21 C.F.R. In addition to the requirements under Parts 50 and 56 of 21 C.F.R., 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 would require 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 and H.R. 801 amend different titles of the United States Code (S. 303 amends Title 18 and H.R. 801 amends Title 21), both bills have the same effect: human reproductive cloning would be banned but cloning for medical research purposes would be allowed, including

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[32] By seeking to amend Title 18 of the U.S. Code rather than the Public Health Service Act, S. 245 would likely be subject to different committee jurisdiction.

stem cell research.[33] 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 would require the Comptroller General to prepare a report within one 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 one 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 one 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 45 C.F.R. Part 46, or Parts 50 and 56 of 21 C.F.R. In contrast, H.R. 801 requires that all such research shall be conducted in accordance with Part 50 and 56 of 21 C.F.R. and does not refer to subpart A of 45 C.F.R. Part 46.[34]

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.

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[33] Ibid.

[34] Subpart A of 45 C.F.R. Part 46, often referred to as the Common Rule, "applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any 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 (21 C.F.R. Parts 50 and 56), which are generally but not entirely the same as subpart A of 45 C.F.R. Part 46. 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, Aug. 2001.

Supporters of a ban on human cloning, such as that contained in H.R. 534, argue that a partial ban on human cloning, like the one contained in S. 303, would be impossible to enforce. Critics of the ban on human cloning argue that SCNT creates a "clump of cells" rather than an embryo, and that the ban would curtail medical research and prevent Americans from receiving life-saving treatments created overseas.

International Actions on Cloning

On December 1, 1998, the Council of Europe (COE)[35] introduced a measure to prohibit reproductive but not therapeutic cloning. The measure, *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*, prohibits "[a]ny intervention seeking to create a human being genetically identical to another human being, whether living or dead."[36] Of the 50 counties in the COE, the protocol has been signed by 29[37] and ratified by 14.[38]

On September 7, 2000, a separate European organization, the European Parliament,[39] voted 271 to 154 to reaffirm its support for a ban on both research and reproductive human cloning.[40] The Parliament's resolution does not have authority in the governments of the European Union, but rather seeks to guide the legislation

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[35] Founded in 1949, the Council of Europe (COE) is the continent's oldest political organization. The COE groups together 45 countries, including 21 countries from Central and Eastern Europe, and has granted observer status to five more countries, including the United States. It is distinct from the 25-nation European Union, but no country has ever joined the Union without first belonging to the Council of Europe. [http://www.coe.int/T/e/Com/about_coe/].

[36] "Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings," *Council of Europe*, CETS no. 168, Dec. 1, 1998, at [http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm].

[37] Signatories include Croatia, Cypress, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Moldova, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, Macedonia, and Turkey at [http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=168&CM=8&DF=29/06/04&CL=ENG].

[38] Croatia, Cypress, Czech Republic, Estonia, Georgia, Greece, Hungary, Lithuania, Moldova, Portugal, Romania, Slovakia, Slovenia, and Spain have ratified the Protocol at [http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=168&CM=8&DF=29/06/04&CL=ENG].

[39] Governance of the European Union is shared by the European Parliament, directly elected by the 374 million citizens of the member countries, and a Council of the European Union, made up of delegates from each member country at [http://www.europarl.eu.int/presentation/default_en.htm].

[40] European Parliament Supports Full Cloning Ban," *Genetic Crossroads*, no. 26, Nov. 22, 2002, p. 1, at [http://www.genetics-and-society.org/newsletter/archive/26.html#I2].

of those countries.[41] The resolution calls for "each Member State to enact binding legislation prohibiting all research into any kind of human cloning within its territory and providing for criminal penalties for any breach."

In November 2004, a third multinational organization, the United Nations General Assembly (UNGA),[42] "averted a divisive vote" on two international conventions against human cloning by adopting Italy's proposal "to take up the issue again as a declaration at a resumed February session."[43] "A convention is a legally binding treaty, coming into force upon ratification by a certain number of states. A declaration is not legally binding but carries moral weight because it is adopted by the international community."[44] Two convention proposals had been under consideration. One, introduced by Costa Rica and backed by the United States, aimed to proscribe all human embryonic cloning. A second proposal, introduced by Belgium, sought to proscribe only reproductive cloning. Both convention proposals were supplanted by the adoption of Italy's proposal for a declaration.

A November 2003 survey of various countries' positions on cloning and other genetic technologies revealed that, of the 192 countries surveyed, 23% prohibited reproductive cloning, 16% prohibited cloning for research purposes, and 3% expressly permitted cloning for research purposes.[45] For example, according to the survey and other updated sources, China[46] and Australia[47] prohibit cloning for

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[41] "European Parliament Wants Total Ban on Human Cloning," *ZENIT — The World Seen From Rome*, Nov. 21, 2002, p. 1, at [http://www.zenit.org/english/visualizza.phtml?sid=27981].

[42] The General Assembly is the main deliberative organ of the United Nations. It is composed of representatives of all 191 member states, each of which has one vote. Decisions on important questions, such as those on peace and security, admission of new Members and budgetary matters, require a two-thirds majority. Decisions on other questions are reached by a simple majority, at [http://www.un.org/ga/58/ga_background.html].

[43] Press Release GA/L/3270 "Legal Committee Text Calls for Further Discussions on Human Cloning aimed at 'Declaration'," *United Nations*, November 19, 2004, at [http://www.un.org/News/Press/docs/2004/gal3270.doc.htm].

[44] United Nations, "Human Rights at your Fingertips," 1997 at [http://www.un.org/rights/50/game.htm#28].

[45] Isasi Rosario, "National Polices Governing New Technologies of Human Genetic Modification: A Preliminary Survey," *Center for Genetics and Society*, Nov. 2003, at [http://www.genetics-and-society.org/policies/survey.html#4].

[46] "Guidelines on Assisted Reproductive Technologies for Human Beings," Ministry of Public Health, Oct. 2003, "Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank", Ministry of Health, Aug. 2003, The Human Reproductive Technology Ordinance, An Ordinance No. 47 (Amended 2002). The Government of the Hong Kong Special Administrative Region (Gazette, Legal Supplement nos. 1 to 26, vol. 4, June 30, 2000, pp. A1691-A1777), Ministry of Science and Technology and the Ministry of Public Health, Interim Measures for the Administration of Human Genetic Resources (June 10, 1998).

[47] Prohibition of Human Cloning Act No. 144-2002, Jan. 7, 2003, "An Act to Prohibit Human Cloning and Other Unacceptable Practices Associated with Reproductive

(continued...)

reproductive but not for research purposes. France,[48] and Germany[49] prohibit cloning for both purposes. The United Kingdom[50] and South Korea[51] prohibit reproductive cloning, but specifically permit and regulate cloning for research purposes. In August 2004, the United Kingdom's Human Fertilization and Embryology Authority granted to Newcastle Centre for Life, the country's first licence to conduct therapeutic cloning, which will be used to generate embryonic stem cells.[52] Japan permits embryo research but banned cloning in 2001; however on June 23, 2004, a government panel recommended permitting the limited cloning of embryos for scientific research.[53]

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. As previously mentioned, the Bush Administration and the National Academies have made their positions clear. In July 2002, the President's Council on Bioethics issued its report, *Human Cloning and Human Dignity*, which contained two opinions and sets of recommendations: one of the 10-7 majority, and one of the minority.[54] The

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[47] (...continued)
Technology and for Related Purposes," Research Involving Embryos Act no. 145-2002, Jan. 7, 2003.

[48] Law No. 94-653 of July 29 1994, on Respect for the Human Body; this law was updated in July 2004, prohibiting therapeutic and reproductive cloning, but permitting embryonic stem cell research. "France Says No to Human Cloning," *Cordis News* (July 9, 2004), RCN 22309, at [http://www.cordis.lu/en/home.html] (enter 22309 in search box), accessed July 15, 2004.

[49] Federal Embryo Protection Law (1990).

[50] Human Reproductive Cloning Act (2001), Human Embryology and Fertilization Act (1990).

[51] Life Ethics Law, Jan. 29 2004; South Korean Bioethics Advisory Commission, *Recommendations for Biotechnological Research and Application* (May 18, 2001).

[52] Human Fertilization and Embryology Authority of the UK, "HFEA Grants the First Therapeutic Cloning Licence for Research," press release, Aug. 11, 2004 at [http://www.hfea.gov.uk/PressOffice/Archive/1092233888].

[53] The "Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques," Nov. 2000, in effect since June 2001. Guidelines to the "Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques," Minister of Education and Science, Dec. 4, 2001; "Panel Urges Japan to Permit Limited Cloning of Humans," *Orlando Sentinel*, June 24, 2004, p. A4.

[54] At the June 20, 2002 meeting, 9 of 17 Council members voted to support cloning for medical research purposes, without a moratorium, provided a regulatory mechanism was established. Because one member of the Council had not attended the meetings and was not voting, the vote seemed to be nine to eight 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
(continued...)

majority and minority both opposed reproductive cloning. It was on the topic of therapeutic cloning, which the majority opposed and the minority favored, that the Council was split.

A predecessor to the President's Council, the National Bioethics Advisory Commission (NBAC), recommended, in *Cloning Human Beings*,[55] the continuation of a moratorium on federal funding for reproductive purposes with a call for voluntary compliance from the private sector. It further recommended the enactment of legislation with a three- to five-year sunset clause banning cloning for reproductive purposes. However, it made clear that all measures taken should "be carefully written so as not to interfere with other important areas of scientific research."[56]

Various other organizations, individuals, and councils have issued opinions and reports on cloning as well. Some, such as The United States Conference of Catholic Bishops (USCCB)[57] oppose human cloning for any purpose: "The cloning procedure is so dehumanizing that some scientists want to treat the resulting human beings as subhuman, creating them solely so they can destroy them for their cells and tissues."[58] Others, such as a group of forty Nobel Laureates,[59] former First Lady Nancy Reagan,[60] and former President Gerald Ford,[61] would allow regulated cloning for

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[54] (...continued)
a moratorium would provide time for additional discussion. 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." (Transcripts of the Council meetings and papers developed by staff for discussion during Council meetings can be found at [http://www.bioethics.gov]; S.S. Hall, "President's Bioethics Council Delivers," *Science*, vol. 297, July 19, 2002, pp. 322-324.) "Wise Words from Across the Pond?" *BioNews*, no. 252, Mar. 29, 2004.

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

[56] Ibid., p. iv.

[57] The United States Conference of Catholic Bishops is "is an assembly of the hierarchy of the United States and the U.S. Virgin Islands who jointly exercise certain pastoral functions on behalf of the Christian faithful of the United States," at [http://www.nccbuscc.org/whoweare.htm].

[58] Bishop Gregory, President of the United States Conference of Catholic Bishops, quoted in "Bishops' President Says Cloning Turns Human Reproduction into a Manufacturing Process, *United States Conference of Catholic Bishops Communications*, Nov. 27, 2001, at [http://www.usccb.org/comm/archives/2001/01-205.htm].

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

[60] Complete text of a letter from Mrs. Reagan to Senator Orrin Hatch specifying her position on cloning can be found at [http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=674].

[61] L. Hafner, "Revised Feinstein/Kennedy Cloning Bill Has Criminal and Civil Penalties, (continued...)

therapeutic purposes, but disallow it for reproductive ones. Still others, such as such as Dr. Severino Antinori, and Clonaid,[62] favor cloning for reproductive purposes, and even claim to have created human clones via SCNT.[63]

The human cloning debate centers around number of different ethical and pragmatic issues. Exploration of these issues reveals variation in ethical and moral as well as factual beliefs. The following discussion breaks down the arguments surrounding human cloning according to these issues, demonstrating both the complexity of the issues and the points of resonance among the groups.

Issues Involved in Cloning for Reproductive Purposes. As Clonaid advertised and the President's Council acknowledged, supporters of reproductive cloning favor it because it might "allow infertile couples to have genetically-related children,"[64] enable families to avoid genetic disease in their genetically-related children, facilitate the replication of specific persons (such as lost loved ones), or to create ideal transplant donors.[65] Likewise, the NBAC recognized that some of the principles that underlie these purposes are a "presumption in favor of individual liberty," that "human reproduction [is] particularly personal and should remain free of constraint, ... [and] as a society, we ought not limit the freedom of scientific inquiry."[66] However, for a number of other reasons, the idea of cloning for reproductive purposes is presently rejected by most groups and organizations, including the President's Council and NBAC. Of the groups and individuals listed in the Ethical and Social Issues section, only Clonaid and Dr. Antinori favor reproductive cloning at this time. Despite the apparent uniformity of views rejecting reproductive cloning, there is a great deal of variation in the lines of reasoning underlying such objections.

Procreation Without Conjugal Union. According to the USCCB, *Donum Vitae*[67] instructs that "attempts or hypotheses for obtaining a human being without

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[61] (...continued)
Requires Research Review," *Washington Fax*, May 2, 2002.

[62] "CLONAID™ ,the first human cloning company in the world, was founded in Feb. 1997, by RAËL and a group of investors who created the Valiant Venture Ltd Corporation based in the Bahamas." The organization was founded by the leader of the Raelian Movement, "the world's largest UFO-related organization." "A historical background" *Clonaid*, at [http://www.clonaid.com/content.php?content], visited July 1, 2004.

[63] See, for example, "Alive and Well" *Clonaid*, at [http://www.clonaid.com/news.php], visited July 1, 2004; Abu Dhabi, "Human Cloning Project Claims Progress," *Gulf News Online Edition*, Apr. 3, 2002, at [http://www.gulf-news.com/Articles/news.asp?ArticleID=46275].

[64] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxvii. (Hereafter cited as President's Council, *Human Cloning*.)

[65] See, for example, President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxvii; "Frequently Asked Questions," *Clonaid*,at [http://www.clonaid.com/content.php?content.6], visited July 9, 2004.

[66] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 72.

[67] *Donum Vitae*, ("The Gift of Life"), which addresses the Catholic view of morality of (continued...)

any connection with sexuality through 'twin fission,' cloning or parthenogenesis are to be considered contrary to the moral law, since they are in opposition to the dignity both of human procreation and of the conjugal union."[68] This objection to reproductive cloning, that procreation should be limited to conjugal unions, is not supported by most groups. If accepted, it would lead to a rejection of other forms of assisted reproduction, such as in vitro fertilization (IVF). Of the groups and individuals listed above, only UCCSB cites the need for a conjugal union as a persuasive argument against reproductive cloning.

Safety. The most agreed upon objection to human reproductive cloning is one of safety. The President's Council on Bioethics concluded that, "[g]iven the high rates of morbidity and mortality in the cloning of other mammals, we believe that cloning-to-produce-children would be extremely unsafe, and that attempts to produce a cloned child would be highly unethical."[69] The National Bioethics Advisory Commission reached a consensus in its objection to reproductive cloning "because current scientific information indicate[d] that this technique [was] not safe in humans...."[70] The National Academies agrees with this line of reasoning, given that animal experimentation has demonstrated that "only a small percentage of attempts are successful," "many of the clones die during gestation," and "newborn clones are often abnormal, or die."[71] While these objections about safety are widely held, they may be temporary in nature. As research advances, it may become less risky, and thus some may find it less objectionable to attempt reproductive human cloning.

Unlike concerns about safety, other types of objections, while not so widely held, may be more lasting because they are not likely to be alleviated by scientific progress. These tend to be philosophical in nature. These concerns, listed in the following paragraphs, have been acknowledged by the President's Council, NBAC, UCSSB, and the National Academies. According to the President's Council, "[d]ifferent Council members give varying moral weight to [the following] different concerns."[72] Only the UCSSB found the concerns persuasive in total.

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[67] (...continued)
many modern fertility procedures, was issued in 1987 by the Sacred Congregation for the Doctrine of the Faith at [http://www.nccbuscc.org/prolife/tdocs/donumvitae.htm], visited July 9, 2004.

[68] John Haas, "Begotten Not Made: A Catholic View of Reproductive Technology," *United States Conference of Catholic Bishops, Pro Life Activities*, June 2003, at [http://www.usccb.org/prolife/programs/rlp/98rlphaa.htm], visited July 9, 2004.

[69] President's Council, *Human Cloning*, p. xxiii.

[70] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. iii.

[71] *Scientific and Medical Aspects of Human Reproductive Cloning* (Washington: National Academies Press, 2002), p. 93. The report on human cloning is available at [http://www.nap.edu/catalog/10285.html?onpi_topnews_011802].

[72] The number of Council members who give moral weight to each argument, and the amount of weight they give to each issue is not specified. President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxviii.

Identity. Some objections to reproductive cloning are based upon fears that cloned children will have difficulty with their identities "because each will be genetically virtually identical to a human being who has already lived and because the expectations for their lives may be shadowed by constant comparisons to the life of the 'original.'"[73] These concerns are dismissed by others, who point out that this argument rests largely on "the crudest genetic determinism."[74] They cite both the effect that environment plays on individual development, and the lack of difficulty with identity experienced by naturally occurring identical twins.[75]

Commodification. Other philosophical objections have to do with a fear that cloned children "might come to be considered more like products of a designed manufacturing process than 'gifts' whom their parents are prepared to accept as they are. Such an attitude toward children could also contribute to increased commercialization and industrialization of human procreation."[76] This, in turn, may fuel a new eugenics in which parents select not only whether to have a child, but which child to have.[77] Others point out that these types of concerns were raised about most forms of assisted reproduction (such as in vitro fertilization and preimplantation genetic diagnosis), which have not led to objectification. In addition, if being born is a considered to be a benefit to the one born, "to the extent that the technology is used to benefit the child ... no objectification of the child takes place."[78]

Familial Relationships. A complicated lineage has also been introduced as an objection to reproductive cloning: "By confounding and transgressing the natural boundaries between generations, cloning could strain the social ties between them. Fathers could become "twin brothers" to their "sons"; mothers could give birth to their genetic twins; and grandparents would also be the "genetic parents" of their grandchildren. Genetic relation to only one parent might produce special difficulties for family life."[79] Others point out that children "born through assisted reproductive technologies may also have complicated relationships to genetic, gestational, and rearing parents ... [yet] there is no evidence that confusion over family roles has harmed children born through assisted reproductive technologies, although the subject has not been carefully studied."[80]

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[73] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxviii.

[74] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 65. Note: *genetic determinism* is the idea that a person's identity and development are primarily or entirely the result of his or her genetic makeup. Genetic determinism is generally viewed as a flawed concept because of its failure to acknowledge the impact of environmental factors and the opportunity for individual choice.

[75] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. 103.

[76] Ibid., pp. xxviii-xxix.

[77] Ibid., p. xxix.

[78] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 70.

[79] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxix.

[80] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 66.

Societal View of Children. Concerns have been voiced about the effects of cloning on society: "Cloning-to-produce-children would affect not only the direct participants but also the entire society that allows or supports this activity. Even if practiced on a small scale, it could affect the way society looks at children and set a precedent for future nontherapeutic interventions into the human genetic endowment or novel forms of control by one generation over the next."[81] This objection is rejected by others, who argue that "people can, and do, adapt in socially redeeming ways to new technologies ... [A] child born through somatic cell nuclear transfer could be loved and accepted like any other child...."[82]

Issues Involved in Cloning for Therapeutic Purposes.[83] Cloning for therapeutic purposes is more broadly supported than reproductive cloning, and the issues involved are somewhat different. The safety concerns of reproductive cloning do not apply in therapeutic cloning, placing much of the scientific community, such as the National Academies, in favor of it. In addition, the NBAC, a minority of the President's Council, the group of Nobel Laureates, Nancy Reagan, and Gerald Ford also generally support cloning for therapeutic purposes. Opponents include a majority of the President's Council, and the USCCB.

Relief of Human Suffering and Moral Status of Cloned Embryos. The central debate over therapeutic cloning rests on the relative weight ascribed to potential research benefits, and that ascribed to cloned embryos themselves. All sides generally agree that research involving cloning may generate biomedical advancements that relieve human suffering. As described the President's Council, the research "may offer uniquely useful ways of investigating and possibly treating many chronic debilitating diseases and disabilities, providing relief to millions."[84] Yet a majority of Council members were dissuaded from the research, arguing that "[i]f we permit this research to proceed, we will effectively be endorsing the complete transformation of nascent human life into nothing more than a resource tool."[85] Similar arguments are made by the USCCB.

The Council's minority offered an opposing viewpoint: "We believe there are sound moral reasons for not regarding the embryo, in its earliest stages as the moral equivalent of a human person" but rather as having a "developing and intermediate moral worth that commands our special respect."[86] The minority based its opinion on the fact that, at the blastocyst stage (the one useful for stem cell research, for example), the cells are still undifferentiated and could still be split and develop into

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[81] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxix.

[82] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 67.

[83] For purposes of this section, the term "therapeutic purposes" is meant to include the use of cloning technology for both the research underlying treatments and the treatments themselves.

[84] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, pp. xxxi, xxxiii.

[85] Ibid., p. xxxiii.

[86] Ibid., p. xxxi

two separate twinned embryos, "suggesting that the earliest stage embryo is *not yet* an individual."[87] Furthermore, they note that the possibility for the development of a human child from a cloned embryo would require its transference to a uterus, as is currently the case with IVF.[88] IVF often results in the creation of embryos that remain unimplanted, and is permitted in the United States. For all of the above reasons, the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates support therapeutic cloning.

Dr. Hwuang, the South Korean scientist who cloned human embryos to extract stem cells, summarized another argument in favor of research on cloned embryos. While he believes that life begins when egg and sperm meet, and is opposed to abortion, he pointed out that cloned embryos do not have the capacity to develop into children. In fact, he described reproductive human cloning as "impossible." Therefore, he concluded that, because cloned embryos do not have the capacity to develop into children even if they were implanted into a uterus, cloned embryos deserve no more moral consideration than other groups of cells.[89] This argument is linked inversely to safety concerns related to reproductive cloning. If researchers ever perfect human reproductive cloning techniques, anti-reproductive cloning arguments based upon safety will be diminished, while anti-therapeutic cloning arguments based on the ability of cloned embryos to develop will be strengthened.

In July 2004, Dr. Paul McHugh, a member of the President's Council who objects to the destruction of human embryos and who had voted with the Council majority for a moratorium on cloning-for-biomedical research, expressed an opinion similar to Dr. Hwang's in a medical journal article. Dr. McHugh argued that SCNT "resembles a tissue culture," and that the products of SCNT should be available for research once regulations are in place to ensure that SCNT is conducted ethically.[90] At the December 2004 Council meeting, Dr. William Hurlbut, another Council member who objects to the destruction of human embryos and voted for the moratorium, made a proposal to explore the possibility of using SCNT in combination with techniques to ensure that the group of cells created cannot give rise to human life but can generate embryonic stem cells. Dr. Hurlbut explained, "using the technique of nuclear transfer, it may be possible to produce embryonic stem cells within a limited cellular system that is biologically and morally akin to a complex tissue culture and thereby bypass moral concerns about the creation and disruption of human embryos."[91] Some have criticized Dr. Hurlbut's proposal to create something that is not an embryo, yet generates embryonic stem cells, as one focused

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[87] Ibid., p. 136.

[88] Ibid.

[89] Dr. Wu-Suk Hwuang, "Overview of Research," *Presentation to the Gijon Medical School*, Gijon, Spain (July 12, 2004).

[90] Paul McHugh, "Zygote and 'Clonote' — The Ethical Use of Embryonic Stem Cells," *New England Journal of Medicine*, vol. 351, no. 3 (July 15, 2004), p. 210, at [http://content.nejm.org/cgi/content/full/351/3/209].

[91] President's Council on Bioethics, Presentation of Dr. William Hurlbut in "Transcript of the President's Council on Bioethics," Dec. 3, 2004, Washington, D.C., at [http://www.bioethics.gov/transcripts/dec04/session6.html].

on a "semantic issue, not a scientific one."[92] Others have lauded Dr. Hurlbut's proposal as a potential scientific solution to a moral problem. Included among them is Dr. Leon Kass, the Chair of the Council and a well-known opponent of embryo destruction, who said the proposal raises the possibility that, "the partisans of scientific progress and the defenders of nascent human life can go forward in partnership without anyone having to violate things they hold dear."[93]

Deliberate Creation for Use/Destruction. A second set of considerations underlying the debate have to do with a moral aversion to the prospect of creating life in order to destroy it. As a majority of the President's Council pointed out, cloning for therapeutic purposes requires "the creation of human life expressly and exclusively for the purpose of its use in research, research that necessarily involves its destruction, ... transform[ing] nascent human life into nothing more than a resource tool."[94] The USCCB agrees with this characterization.

The Council minority countered that the "embryos would not be 'created for destruction,' but for use in the service of life and medicine."[95] Further, the"practice of sacrificing the life of the unborn in order to save the live of the pregnant woman — while not a moral parallel to the case of using cloned embryos for biomedical research — shows that there is some moral precedent for subordinating nascent human life to more developed human life."[96] The NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates agree with this characterization.

Moral Harm or Benefit to Society. The effect of therapeutic cloning upon society has been debated by opponents and proponents alike. The President's Council majority fear negative effects, such as the subjugation of weak members of society, or genetic manipulation of developing life: "As much as we wish to alleviate suffering now and to leave our children in a world where suffering can be more effectively relieved, we also want to leave them in a world ... that honors moral limits, that respects all life whether strong or weak, and that refuses to secure the good of some human beings by sacrificing the lives of others."[97] Approving therapeutic cloning would harm society by "crossing the boundary from sexual to asexual reproduction, thus approving in principle the genetic manipulation and control of nascent human life."[98] USCCB also shares this point of view.

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[92] Kirsty Horsey, "When Is an Embryo Not an Embryo?" *BioNews*, no. 287, Dec. 6, 2004, at [http://www.bionews.org.uk/commentary.lasso?storyid=2372].

[93] David Brown, "Two Stem Cell Options Presented; Human Embryos Wouldn't Be Killed," *Washington Post*, Dec. 4, 2004, A1.

[94] President's Council on Bioethics, *Human Cloning and Human Dignity*, July 2002, p. xxxiii.

[95] Ibid., p. xxxi.

[96] Ibid., pp. 137-138.

[97] Ibid., p. xxxiv.

[98] Ibid., p. xxxiv.

Counter arguments have been made by those who note that "[h]istorically, scientific inquiry has been protected and even encouraged because of the great societal benefit the public recognizes in maintaining the sanctity of knowledge and the value of intellectual freedom."[99] In addition, they note that cloning is replication, rather than transformation: "In an important sense, cloning is not the most radical thing on the horizon. Much more significant ... would be the ability to actually alter or manipulate the genome of offspring, ... which could then lead to a child being born with characteristics other than it would have had...."[100] The Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates share this perspective.

Going Too Far or Drawing Appropriate Limitations. Some, such as the majority of the President's Council and USCCB, believe that policies allowing therapeutic cloning would create a slippery slope, "opening the door to other moral hazards, such as cloning-to-produce-children or research on later-stage embryos and fetuses."[101] Others, such as the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates, believe that it is possible to circumscribe acceptable practices with good policy. "Both the federal government and the states already regulate the researchers' methods in order to protect the rights of research subjects and community safety."[102] Government might regulate, "the secure handling of embryos, licensing and prior review of research projects, the protection of egg donors, and the provision of equal access to benefits."[103]

Types of Restrictions. One final set of arguments center around the types of actions that the government may take with respect to therapeutic and/or reproductive cloning. These include permitting, regulating, funding, discouraging, and temporarily or permanently banning the practices. As a starting point, NBAC offers: "In the United States, governmental policies that prohibit or regulate human actions require justification because of a general presumption against governmental interference in individual activities."[104] As may be expected, the opinions regarding appropriate courses of action are largely linked to points of view about the appropriateness of the various endeavors.

The most permissive approach available, permitting cloning with no restrictions, is not supported by any of the individuals or organizations referenced herein. By contrast, the next most permissive approach, regulating cloning, is supported by the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates as appropriate for therapeutic cloning, so as to enable it to continue in accordance with socially accepted scientific research practices. As summarized by the Council

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[99] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 75.

[100] J.A. Robertson, "A Ban on Human Cloning Research Is Unjustified," *Testimony before the National Bioethics Advisory Commission* (Mar. 14, 1997), in National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 68.

[101] President's Council, *Human Cloning*, p. xxxiv.

[102] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 75.

[103] President's Council, *Human Cloning*, p. xxxviii.

[104] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 78.

minority, "We believe that this research could provide relief to millions of Americans, and that the government should therefore support is, within sensible limits imposed by regulation."[105]

A voluntary prohibition, the third most permissive approach, was recommended by NBAC as the appropriate immediate response to reproductive cloning by the private sector. NBAC called for "an immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium."[106]

As a longer term approach, NBAC recommended the fourth most permissive approach, a temporary ban on reproductive cloning. "Federal legislation [should] be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed."[107] Readers may be interested to note that, if enacted in 1997 when NBAC's report was published, a five-year ban on reproductive cloning would have expired in 2002. The National Academies also recommended a ban on reproductive cloning, and did not call it temporary but did add that it should be reconsidered every five years. On the topic of therapeutic rather than reproductive cloning, a majority of the Council recommended a temporary moratorium as the proper approach, because it would "reaffirm the principle that science can progress while upholding the community's moral norms, and would therefore reaffirm the community's moral support for science and biomedical technology."[108]

The most restrictive approach to cloning, a permanent ban, was proposed by the Council minority and majority, and Nancy Reagan as appropriate for reproductive cloning. "By permanently banning cloning-to-produce children, this policy gives force to the strong ethical verdict against [it], unanimous in the Council ... and widely supported by the American people."[109] This approach is also favored by the USCCB not only for reproductive cloning, but also for therapeutic cloning.

One related issue, that of the use of federal funding for therapeutic cloning, has also been discussed. No proposals have been made by any of the groups or individuals listed above for the use of federal funding for reproductive cloning. Opponents of funding therapeutic cloning, such as the Council majority, have expressed concern that use of federal funding for therapeutic cloning would put "the federal government in the novel and unsavory position of mandating the destruction

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[105] President's Council, *Human Cloning*, p. xxxviii.

[106] National Bioethics Advisory Commission, *Cloning Human Beings*, June 1997, p. 105.

[107] Ibid.

[108] President's Council, *Human Cloning*, p. xxxvii.

[109] President's Council, *Human Cloning*, p. xxxiv.

of nascent human life."[110] Proponents of federal funding for therapeutic cloning, such as the Council minority, NBAC, Nancy Reagan, Gerald Ford, and the Nobel Laureates, cite as support the advancements that might be powered by the infusion of federal dollars into the research, as well as the ethical protections that would attach with the money.

[110] President's Council, *Human Cloning*, p. xxxvi