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Stem Cell Research

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Summary

Embryonic stem cells have the ability to develop into virtually any cell in the body, and may have the potential to treat medical conditions such as diabetes and Parkinson's disease. In August 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." The National Institutes of Health (NIH) has established the Human Embryonic Stem Cell Registry which lists stem cell lines that are eligible for use in federally funded research. Although 78 cell lines are listed, 21 embryonic stem cell lines are currently available. Scientists are concerned about the quality, longevity, and availability of the eligible stem cell lines. For a variety of reasons, many believe research advancement requires new embryonic stem cell lines, and for certain applications, stem cells derived from cloned embryos may offer the best hope for progress in understanding and treating disease. A significant cohort of pro-life advocates support stem cell research; those opposed are concerned that the isolation of stem cells requires the destruction of embryos. Letters from Congress, one signed by 206 Members of the House and a second signed by 58 Senators, have been sent urging President Bush to expand the current federal policy concerning embryonic stem cell research.

Some have argued that stem cell research be limited to adult stem cells obtained from tissues such as bone marrow. They argue that adult stem cells should be pursued instead of embryonic stem cells because they believe the derivation of stem cells from either embryos or aborted fetuses is ethically unacceptable. Other scientists believe adult stem cells should not be the sole target of research because of important scientific and technical limitations. Groups make ethical distinctions in the debate on how to proceed with stem cell research based upon embryo protection, relief of suffering, viability, the purpose and timing of embryo creation and destruction, donor consent, scientific alternatives, federal funding, and cloning.

On February 27, 2003, the House passed H.R. 534 (Dave Weldon), which would ban the process of human cloning and 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.R. 801 (Greenwood) is similar to H.Amdt 5. S. 245 (Brownback) would ban reproductive cloning and research on therapeutic cloning; S. 303 (Hatch) would ban only reproductive cloning. Supporters of H.R. 534 argue that a partial ban on human cloning, such as S. 303 and H.R. 801, would be impossible to enforce. Critics argue that H.R. 534 would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. President Bush has stated his support for the Weldon bill, but 40 Nobel Laureates, who are in favor of nuclear transplantation technology for research and therapeutic purposes, are strongly opposed to the legislation. H.R. 3960 (Millender-McDonald) and H.R. 4682 (Castle) would fund research on embryonic stem cell lines derived after the August 9, 2001, policy established by the Bush Administration. This report will be updated as needed.

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Overview of Basic Research and Potential Applications

Most cells within an animal or human being are committed to fulfilling a single function within the body. In contrast, stem cells are a unique and important set of cells that are not specialized. Stem cells retain the ability to become many or all of the different cell types in the body and thereby play a critical role in repairing organs and body tissues throughout life. Although the term stem cells is often used in reference to these repair cells within an adult organism, a more fundamental variety of stem cells is found in the early stage embryo. Embryonic stem cells may have a greater ability to become different types of body cells than adult stem cells.

Stem Cells from Embryos or Fetal Tissue. Embryonic stem cells were first isolated from mouse embryos in 1981. Animal embryos were the only source for research on embryonic stem cells until November 1998, when two groups of U.S. scientists announced the successful isolation of human embryonic stem cells. One group, at the University of Wisconsin, derived stem cells from one-week-old embryos produced via *in vitro* fertilization (IVF).[1] The work is controversial, in the opinion of some individuals, because the stem cells are located within the embryo and the process of removing them destroys the embryo. The second group, at Johns Hopkins University, derived cells with very similar properties from five- to nine-week-old embryos or fetuses obtained through elective abortion.[2] Both groups reported the human embryos or fetuses were donated for research following a process of informed consent. The cells were then manipulated in the laboratory to create embryonic stem cell lines that may continue to divide for many months to years.

Another potential source of embryonic stem cells is somatic cell nuclear transfer (SCNT), also referred to as cloning.[3] In SCNT the nucleus of an egg is removed and replaced by the nucleus from a mature body cell, such as a skin cell. The cell created via SCNT is allowed to develop for a week and then the stem cells are removed. In 1996, scientists in Scotland used the SCNT procedure to produce Dolly the sheep,

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[1] The IVF embryos were originally created for the treatment of infertility. Excess embryos are often frozen in liquid nitrogen for future use. A couple may elect to discard their excess embryos, donate the embryos for research, or allow another couple to adopt an embryo.

[2] Scientists and physicians use the term embryo for the first eight weeks after fertilization, and fetus for the ninth week through birth. In contrast, the Department of Health and Human Services (HHS) regulations define fetus as "the product of conception from the time of implantation." (45 CFR 46.203)

[3] A somatic cell is a body cell. In contrast, a germ cell is an egg or sperm cell.

the first mammalian clone.[4] In February 2004, Korean scientists announced that they had created human embryos via the SCNT process and had succeeded in isolating human stem cells from a cloned embryo. This development and the unsubstantiated announcement by Clonaid in December 2002 of the birth of a cloned child have contributed to the controversy over research on human embryos.[5]

Stem Cells from Adult Tissue or Umbilical Cord Blood. Stem cells obtained from adult organisms are also the focus of research. There have been a number of recent publications on adult stem cells from a variety of different sources, such as bone marrow and the umbilical cord following birth. In addition, a number of private companies (such as MorphoGen, NeuralStem, Osiris Therapeutics, StemSource, ViaCell) are working on therapeutic uses of adult stem cells.

Some advocate that adult instead of embryonic stem cell research should be pursued because they believe the derivation of stem cells from either IVF embryos or aborted fetuses is ethically unacceptable. Others believe that adult stem cells should not be the sole target of research because of important scientific and technical limitations. Adult stem cells may not be as long lived or capable of as many cell divisions as embryonic stem cells. Also, adult stem cells may not be as versatile in developing into various types of tissue as embryonic stem cells, and the location and rarity of the cells in the body might rule out safe and easy access. For these reasons, many scientists argue that both adult and embryonic stem cells should be the subject of research, allowing for a comparison of their various capabilities.

Possible Sources of Stem Cells
— embryos created via IVF (for infertility treatment or for research purposes)
— embryos or fetuses obtained through elective abortion
— embryos created via SCNT (somatic cell nuclear transfer, or cloning)
— adult tissues (bone marrow, umbilical cord blood)

Potential Applications of Stem Cell Research. Stem cells provide the opportunity to study the growth and differentiation of individual cells into tissues. Understanding these processes could provide insights into the causes of birth defects, genetic abnormalities, and other disease states. If normal development were better understood, it might be possible to prevent or correct some of these conditions. Stem cells could be used to produce large amounts of one cell type to test new drugs for effectiveness and chemicals for toxicity. Stem cells might be transplanted into the body to treat disease (diabetes, Parkinson's disease) or injury (e.g., spinal cord). The damaging side effects of medical treatments might be repaired with stem cell

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[4] Dolly was euthanized in Feb. 2003 after developing a lung infection. Some claim her death at six years was related to being a clone, but her ailment may also have occurred because she was raised indoors (for security reasons) rather than as a pastured sheep, which often live to 12 years of age. G. Kolata, "First Mammal Clone Dies," *New York Times*, Feb. 15, 2003, p. A4.

[5] For further information, see CRS Report RL31358, *Human Cloning*, by Judith A. Johnson.

treatment. For example, cancer chemotherapy destroys immune cells in patients, decreasing their ability to fight off a broad range of diseases; correcting this adverse effect would be a major advance.

Before stem cells can be applied to human medical problems, substantial advances in basic cell biology and clinical technique are required. In addition, very challenging regulatory decisions will be required on the individually created tissue-based therapies resulting from stem cell research. Such decisions would likely be made by the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA). The potential benefits mentioned above would be likely only after many more years of research. Technical hurdles include developing the ability to control the differentiation of stem cells into a desired cell type (like a heart or nerve cell) and to ensure that uncontrolled development, such as a cancerous tumor, does not occur. If stem cells are to be used for transplantation, the problem of immune rejection must also be overcome. Some scientists think that the creation of many more embryonic stem cell lines will eventually account for all the various immunological types needed for use in tissue transplantation therapy. Others envision the eventual development of a "universal donor" type of stem cell tissue, analogous to a universal blood donor.

However, if the SCNT technique (cloning) was employed using a cell nucleus from the patient, stem cells created via this method would be genetically identical to the patient, would presumably be recognized by the patient's immune system, and thus would avoid any tissue rejection problems that could occur in other stem cell therapeutic approaches. Because of this, many scientists believe that the SCNT technique may provide the best hope of eventually treating patients using stem cells for tissue transplantation.

Current Federal Regulatory Landscape

The Dickey Amendment and Clinton Administration Stem Cell Policy. Prior to an August 2001 Bush Administration decision (see below), no federal funds had been used to support research on stem cells derived from either human embryos or fetal tissue.[6] The work at the University of Wisconsin and Johns Hopkins University was supported by private funding from the Geron Corporation. Private funding for experiments involving embryos was required because Congress attached a rider to legislation that affected FY1996 National Institutes of Health (NIH) funding. The rider, an amendment originally introduced by Representative Jay Dickey, prohibited HHS from using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. The Dickey amendment language has been added to each of the Labor, HHS and Education appropriations acts for FY1997 through FY2004.[7] For FY2004,

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[6] However, federal funds have been provided for research on both human and animal adult stem cells and animal embryonic stem cells.

[7] The rider language has not changed significantly from year to year. The original rider can be found 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,

(continued...)

the provision is found in Section 510 of Division E, which is the Labor, HHS and Education division of the FY2004 Consolidated Appropriations bill (P.L. 108-199). It prohibits HHS from using FY2004 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 [the Human Subject Protection regulations] ... that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells [cells that have two sets of chromosomes, such as somatic cells].

There is no similar federal prohibition on fetal tissue research; however, other restrictions do apply.

Following the November 1998 announcement on the derivation of human embryonic stem cells, NIH requested a legal opinion from HHS on whether federal funds could be used to support research on human stem cells derived from embryos. The January 15, 1999, response from HHS General Counsel Harriet Rabb found that the Dickey amendment would not apply to research using human stem cells "because such cells are not a human embryo within the statutory definition." The finding was based, in part, on the determination by HHS that the statutory ban on human embryo research defines an embryo as an *organism* that when implanted in the uterus is capable of becoming a human being. Human stem cells are not and cannot develop into an organism; they lack the capacity to become organisms even if they are transferred to a uterus. As a result, HHS maintained that NIH could support research that uses stem cells derived through private funds, but could not support research that itself, with federal funds, derives stem cells from embryos because of the federal ban in the Dickey amendment.

Shortly after the opinion by the HHS General Counsel was released, NIH disclosed that the agency planned to fund research on stem cells derived from human embryos once appropriate guidelines were developed and an oversight committee established. NIH Director Harold Varmus appointed a working group that began drafting guidelines in April 1999. Draft guidelines were published in the *Federal Register* on December 2, 1999. About 50,000 comments were received during the public comment period, which ended February 22, 2000. On August 25, 2000, NIH published in the *Federal Register* final guidelines on the support of human embryonic stem cell research. The guidelines stated that studies utilizing "stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the

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[7] (...continued)
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, and FY2003, P.L. 108-7.

individuals seeking such treatment." Under the guidelines, NIH would not fund research directly involving the derivation of human stem cells from embryos; this was prohibited by the Dickey amendment.

Other areas of research ineligible for NIH funding under the guidelines include (1) research in which human stem cells are utilized to create or contribute to a human embryo; (2) research in which human stem cells are combined with an animal embryo; (3) research in which human stem cells are used for reproductive cloning of a human; (4) research in which human stem cells are *derived* using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (5) research *utilizing* human stem cells that were derived using somatic cell nuclear transfer; and (6) research utilizing stem cells that were derived from human embryos created for research purposes, rather than for infertility treatment.

NIH began accepting grant applications for research projects utilizing human stem cells immediately following publication of the guidelines; the deadline for submitting a grant application was March 15, 2001. All such applications were to be reviewed by the NIH Human Pluripotent Stem Cell Review Group (HPSCRG), which was established to ensure compliance with the guidelines. James Kushner, director of the University of Utah General Clinical Research Center, served briefly as chair of the HPSCRG. Applications would also have undergone the normal NIH peer-review process.[8] The first meeting of the HPSCRG was scheduled for April 25, 2001. The HPSCRG was to conduct an ethical review of human pluripotent stem cell lines to determine whether the research groups involved had followed the NIH guidelines in deriving the cell lines. However, in mid April 2001, HHS postponed the meeting until a review of the Clinton Administration's policy decisions on stem cell research was completed by the new Bush Administration.[9] According to media sources, the 12 HPSCRG members, whose names were not made public, represented a wide range of scientific, ethical and theological expertise and opinion, as well as at least one "mainstream Catholic."[10]

The Bush Administration conducted a legal review of the policy decisions made during the Clinton Administration regarding federal support of stem cell research, as

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[8] According to media sources, as of Apr. 2001 only three grant applications had been submitted to NIH, and one was subsequently withdrawn. (*Washington FAX*, Apr. 19, 2001.) Presumably, scientists were reluctant to invest the time and effort into preparing the necessary paperwork for the NIH grant application process when the prospects of receiving federal funding were uncertain under the new Bush Administration. (P. Recer, "Stem Cell Studies said Hurt by Doubt." *AP Online*, May 2, 2001.) In a related development, one of the leading U.S. researchers on stem cells, Roger Pederson of the University of California, San Francisco, decided to move his laboratory to the United Kingdom for "the possibility of carrying out my research with human embryonic stem cells with public support." (Aaron Zitner, "Uncertainty Is Thwarting Stem Cell Researchers." *Los Angeles Times*, July 16, 2001, pp. A1, A8.) Human embryonic stem cell research was approved overwhelmingly by the House of Commons in Dec. 2000 and the House of Lords in Jan. 2001.

[9] Rick Weiss, "Bush Administration Order Halts Stem Cell Meeting; NIH Planned Session To Review Fund Requests." *The Washington Post*, Apr. 21, 2001, p. A2.

[10] ibid.

well as a scientific review, prepared by NIH, of the status of the research and its applications. The scientific review was released on July 18, 2001, at a hearing on stem cell research held by the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education.[11] The NIH report did not make any recommendations, but argued that both embryonic and adult stem cell research should be pursued.

Bush Administration Stem Cell Policy. 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 where the life and death decision has already been made."[12] President Bush stated that the decision "allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life." The President also stated that the federal government would continue to support research involving stem cells from other sources, such as umbilical cord blood, placentas, and adult and animal tissues, "which do not involve the same moral dilemma."

Under the Bush policy, federal funds may only be used for research on existing stem cell lines that were derived (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors.[13] NIH was tasked with examining the derivation of all existing stem cell lines and creating a registry of those lines that satisfy the Bush Administration criteria. According to the White House, this will ensure that federal funds are used to support only stem cell research that is scientifically sound, legal, and ethical. Federal funds will not be used for (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose.

Agency Regulation. Many entities and individuals that conduct research on humans ("human subjects" research) are both federally and institutionally regulated. Ex vivo embryos (those not in a uterus) are not considered "human subjects" for these purposes, though federally funded research on them is regulated by the Dickey Amendment as described above. Stem cells and stem cell lines are not considered "human subjects," nor are they governed by the Dickey Amendment.

Two HHS agencies, FDA and NIH, regulate some aspects of stem cell research, even if research on stem cell lines is not classified as "human subjects" research. FDA, the agency that ensures the safety and efficacy of food, drugs, medical devices and cosmetics, regulates stem cell research aimed at the development of any

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[11] National Institutes of Health, Department of Health and Human Services. *Stem Cells: Scientific Progress and Future Research Directions*, June 2001. The NIH scientific report can be found at [http://stemcells.nih.gov/info/scireport/]

[12] The Aug. 9, 2001, *Remarks by the President on Stem Cell Research* can be found at [http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html].

[13] The White House, *Fact Sheet on Embryonic Stem Cell Research*, Aug. 9, 2001, found at [http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html].

"product" subject to its approval. NIH, the medical and behavioral research agency within HHS, regulates stem cell research that it funds in compliance with President Bush's 2001 policy. In accordance, NIH has created a Human Embryonic Stem Cell Registry that lists the human embryonic stem cell lines that meet the eligibility criteria as outlined in the Bush Administration stem cell policy.

FDA Regulation. All of the human embryonic stem cell lines listed on the NIH Human Embryonic Stem Cell Registry (see **Table 2**) have been grown on beds of mouse "feeder" cells. The mouse cells secrete a substance that prevents the human embryonic stem cells from differentiating into more mature cell types (nerve or muscle cells). Infectious agents, such as viruses, within the mouse feeder cells could transfer into the human cells. If the human cells were transplanted into a patient, these infected human cells may cause disease in the patient which could be transmitted to close contacts of the patient and eventually to the general population. Public health officials and regulatory agencies such as the FDA are specifically concerned about retroviruses, which may remain hidden in the DNA only to cause disease many years later, as well as any unrecognized agents which may be present in the mouse cells.

The FDA defines xenotransplantation as "any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman source, or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live nonhuman animal cells, tissues or organs."[14] So transplantation therapy involving Bush approved stem cell lines, which all have been exposed to mouse feeder cells, would constitute xenotransplantation. Xenotransplantation products are subject to regulation by the FDA under Section 351 of the Public Health Service Act (42 USC 262) and the Federal Food, Drug and Cosmetic Act (21 USC 321 et. seq.). FDA has developed guidance documents and the U.S. Public Health Service has developed guidelines on infectious disease issues associated with xenotransplantation.[15]

During a Senate hearing on stem cell research held by the Health, Education, Labor and Pensions Committee on September 5, 2001, HHS Secretary Thompson stated that the FDA is overseeing 17 investigational protocols involving xenotransplantation in other areas of clinical research that involve patients. Therefore, the xenotransplantation-related public health concerns over the human embryonic stem cell lines may not necessarily preclude the development of treatments for patients. While the problems presented by xenotransplantation for clinical research are neither unique to stem cell research nor insurmountable, many scientists believe it will be preferable to use sterile cell lines when attempting to treat patients via stem cell transplantation, and scientists have been successful in

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[14] Xenotransplantation Action Plan: FDA approach to the regulation of xenotransplantation. Available at [http://www.fda.gov/cber/xap/xap.htm].

[15] These documents are available at [http://www.fda.gov/cber/xap/xap.htm].

developing human embryonic stem cells that can be maintained without the use of mouse feeder cells.[16]

NIH Research Funding and Stem Cell Registry. The Bush Administration's August 9, 2001, policy statement on stem cell research and the NIH Stem Cell Registry effectively replaced the NIH stem cell guidelines that were developed under the Clinton Administration and never fully implemented . Grant proposals for embryonic stem cell research undergo only the normal peer-review process without the added review of the HPSCRG as had been specified under the Clinton NIH stem cell guidelines. In February 2002, NIH announced the approval of the first expenditures for research on human embryonic stem cells. Funding for stem cell research by NIH is shown in **Table 1**. The NIH website provides additional information about current stem cell activities and funding opportunities.[17]

Table 1. National Institutes of Health Funding

($ in millions)

	FY2001	FY2002	FY2003
Stem cell research	$306	$387	$521
Human embryonic stem cell	(0)	(10.7)	(25)

Source: NIH Budget Office, May 7, 2004.

The NIH Human Embryonic Stem Cell Registry lists stem cell lines that are eligible for use in federally funded research and currently available to be shipped to scientists.[18] As shown in **Table 2**, the NIH registry originally listed universities and companies that had derived a total of 78 human embryonic stem cell lines which were eligible for use in federally funded research under the August 2001 Bush Administration policy. However, many of these stem cell lines were found to be either unavailable or unsuitable for research. As of August 11, 2004, the NIH registry listed a total of 21 stem cell lines available from seven sources as shown below.

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[16] National Institutes of Health, Department of Health and Human Services, *Stem Cells: Scientific Progress and Future Research Directions*, June 2001, pp. 95-96.

[17] See [http://stemcells.nih.gov/research/funding/].

[18] Information about the NIH Human Embryonic Stem Cell Registry is available at [http://stemcells.nih.gov/research/registry/index.asp].

Table 2. NIH List of Human Embryonic Stem Cell Lines Eligible for Use in Federal Research

Name[a]	Number of stem cell lines	
	Eligible	Available
BresaGen, Inc., Athens, GA	4	3
Cell & Gene Therapy Institute (Pochon CHA University), Seoul, Korea	2	
Cellaritis AB, Goteborg, Sweden	3	2
CyThera, Inc., San Diego, CA	9	0
ES Cell International, Melbourne, Australia	6	6
Geron Corporation, Menlo Park, CA	7	
Goteborg University, Goteborg,, Sweden	16	
Karolinska Institute, Stockholm, Sweden	6	0
Maria Biotech Co. Ltd. — Maria Infertility Hospital Medical Institute, Seoul, Korea	3	
MizMedi Hospital — Seoul National University, Seoul, Korea	1	1
National Center for Biological Sciences/Tata Institute of Fundamental Research, Bangalore, India	3	
Reliance Life Sciences, Mumbai, India	7	
Technion University, Haifa, Israel	4	2
University of California, San Francisco, CA	2	2
Wisconsin Alumni Research Foundation, Madison, WI	5	5
Total	**78**	**21**

a. Entities in gray do not have stem cell lines available for shipment to U.S. researchers because of a variety of scientific, regulatory and legal reasons. The zeros entered in the "Available" column indicate that "the cells failed to expand into undifferentiated cell cultures."

Access to Stem Cell Lines. Many scientists, disease advocates and others remain concerned that federally supported research on human embryonic stem cells is limited to the number of cell lines that meet the criteria of the August 9, 2001 Bush policy. As stated above, currently 21 cell lines are available for research with federal dollars, and an unpublished NIH report indicates that under a best case scenario, a total of 23 human embryonic stem cell lines will ever be ready for use in research.[19] Because the pre-August 9 cell lines were developed in the early days of human stem cell research using older 1990s techniques, the cell lines not only have the problems

[19] Farhad Manjoo, "Thou Shalt Not Make Scientific Progress," *Salon.com*, Mar. 25, 2004, [http://www.salon.com/tech/feature/2004/03/25/stem_cells/index_np.html].

of xenotransplantion described above, but they are harder to work with, not well characterized, and somewhat unstable.

In reaction to the limitations imposed by the Bush policy, some U.S. research groups have decided to develop additional human embryonic stem cell lines using private funding. In June 2004, a team of scientists at the Reproductive Genetics Institute, a private fertility clinic in Chicago, announced that they had isolated 50 new human embryonic stem cell lines from frozen embryos that were donated by patients following fertility treatment.[20] By using genetic diagnosis techniques, the Chicago team was able to create stem cell lines that carry the gene for muscular dystrophy as well as stem cell lines with the gene for six other diseases.[21] The new stem cell lines are to be used to understand the origins of disease-related symptoms and to develop and test new treatments.

In March 2004, a Harvard University laboratory headed by Douglas Melton announced that using private research dollars they had isolated 17 new human embryonic stem cell lines.[22] In order to perform this work it was necessary to build a new laboratory so that the group's federally funded research would be conducted separately from research on the new stem cell lines. Likewise, although the 17 stem cell lines are available for use by other laboratories, any research using the new stem cell lines must be performed at a facility that does not receive federal support. The Harvard group intends to raise $100 million in private funding to establish a stem cell center in order to continue the work begun by Melton and his group of scientists.

In December 2002, Stanford University announced that a gift of $12 million from an anonymous donor would be used to establish an institute that will use expertise in stem cell biology and cancer biology to develop novel treatments for cancer and other diseases.[23] The new institute is headed by Dr. Irving Weissman, a Professor in Cancer Biology at Stanford. Scientists at the Institute for Cancer/Stem Cell Biology and Medicine are developing new stem cell lines, some through the process of SCNT, to study the disease process of a wide range of disorders including cancer, diabetes, cardiovascular disease, autoimmune disease, allergies, and neurological disorders such as Parkinson's and Lou Gehrig's disease. Initial studies are performed in mice; however, the work may be extended to human cells and eggs. The new stem cell lines may allow investigators to better understand the biological and genetic basis of a disorder and thereby develop new treatments.

In August 2002, the University of California at San Francisco established the UCSF Developmental and Stem Cell Biology Program with a $5 million matching

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[20] Gareth Cook, "Clinic in U.S. Isolates 50 Lines of Stem Cells," *Boston Globe*, June 9, 2004, p. A1.

[21] The six diseases are beta thalassemia, neurofibromatosis type 1, Marfan's syndrome, myotonic dystrophy, fragile X syndrome, and Fanconi's anemia.

[22] Rick Weiss and Justin Gillis, "New Embryonic Stem Cells Made Available," *The Washington Post*, Mar. 4, 2004, p. A2.

[23] For further information, see the Stanford University Medical Center website at [http://mednews.stanford.edu/stemcellQA.html].

grant from Andy Grove, the chairman of Intel Corporation. The program funds basic studies (using both animal and human cells) in stem cell biology and their translation into clinical practice with a goal of developing treatments for such diseases as diabetes, cardiovascular disease, Parkinson's disease, Alzheimer's disease and spinal cord injury. UCSF and the University of Wisconsin are the only two universities in the United States that have derived human embryonic stem cell lines that qualified for inclusion on the NIH Stem Cell Registry. This past winter, the new UCSF stem cell program announced it had met the Grove "Stem Cell Challenge" and had raised the total funding for the program to more than $11 million in gifts and matching funds. The program recently awarded $50,000 grants to four scientists who are studying various aspects of stem cell biology.[24]

A worldwide survey of laboratories conducted by the Boston Globe found that as of May 23, 2004, 128 human embryonic stem cell lines had been created since August 9, 2001; all would be ineligible for use in federally funded research under the Bush policy on stem cell research.[25] More lines are being created in laboratories overseas than in the United States, according to the survey. The survey found that 94 were created in labs outside the United States and 34 were created in this country. Of the 128 lines, 51 of the new stem cell lines are currently available for use, the remaining cell lines are not available for a variety of technical or legal reasons. For example, some cell lines have not yet been fully characterized to determine their stability or suitability for research. However, eventually their status is to be determined by using laboratory techniques. In Japan, stem cell lines are not allowed to be shipped to laboratories in other countries. In the United Kingdom, stem cell lines cannot be shipped abroad until they have been processed by the new UK Stem Cell Bank.[26]

In response to concerns over access to human embryonic stem cell lines, in April 2004, a group of over 200 Members of the House of Representatives sent a letter to President Bush requesting that the Administration revise the current stem cell policy and utilize the embryos that are created in excess of need during the treatment of infertile couples.[27] The letter points out that an estimated 400,000 frozen IVF embryos[28] "will likely be destroyed if not donated, with informed consent of the couple, for research." According to the letter, "scientists are reporting that it is increasingly difficult to attract new scientists to this area of research because of

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[24] UCSF News Office, *UCSF Names First Director of its Stem Cell Biology Program*, Apr. 26, 2004. See [http://pub.ucsf.edu/newsservices/releases/200404261/].

[25] Gareth Cook, "94 New Cell Lines Created Abroad Since Bush Decision," *Boston Globe*, May 23, 2004, p. A14.

[26] For further information on the UK Stem Cell Bank, see [http://www.nibsc.ac.uk/divisions/cbi/stemcell.html].

[27] See [http://www.house.gov/degette/news/releases/040428.pdf].

[28] A survey conducted in 2002 and published in 2003 by the Society for Assisted Reproductive Technology and RAND determined that nearly 400,000 frozen embryos are stored in the United States, but most are currently target for patient use. See David I. Hoffman et al., "Cryopreserved Embryos in the United States and Their Availability for Research," *Fertility and Sterility*, v. 79, May 2003, p. 1063-1069.

concerns that funding restrictions will keep this research from being successful. ... We have already seen researchers move to countries like the United Kingdom, which have more supportive policies. In addition, leadership in this area of research has shifted to the United Kingdom, which sees this scientific area as the cornerstone of its biotech industry."

Under the direction of the White House, NIH Director Elias A. Zerhouni sent a letter in response to the House Members which restates the Bush Administration position against using federal funds for research involving the destruction of human embryos.[29] The letter from NIH Director Zerhouni did contain the following sentence which some observers believe indicates a potential future policy shift: "And although it is fair to say that from a purely scientific perspective more cell lines may well speed some areas of human embryonic stem cell research, the president's position is still predicated on his belief that taxpayer funds should not 'sanction or encourage further destruction of human embryos that have at least the potential for life."[30] Although White House spokesperson Claire Buchan stated that the sentence does not indicate the president's position has changed, supporters of stem cell research point out that it concedes that science could benefit from additional stem cell lines and that the president's position now rests solely on ethical arguments.

A letter signed by 58 Senators urging President Bush to expand the current federal policy concerning embryonic stem cell research was sent on June 4, 2004.[31] The letter states that "despite the fact that U.S. scientists were the first to derive human embryonic stem cells, leadership in this area of research is shifting to other countries such as the United Kingdom, Singapore, South Korea and Australia."

On July 14, 2004, HHS Secretary Thompson announced in a letter to Speaker of the House Dennis Hastert that NIH would establish Centers of Excellence in Translational Stem Cell Research.[32] The new centers will be funded by $18 millions in grants over a four year period and will investigate how stem cells can be used to treat a variety of diseases. NIH will also create a National Embryonic Stem Cell Bank that will collect in one location many of the stem cell lines that are eligible for federal research funding. In the letter to Speaker Hastert, Secretary Thompson stated that "before anyone can successfully argue the stem cell policy should be broadened, we must first exhaust the potential of the stem cell lines made available with the policy."[33] In reaction to the announcement, the President of the Coalition for the Advancement of Medical Research stated that "creating a bank to house stem cell lines created before August 2001 does nothing to increase the wholly inadequate

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[29] Rick Weiss, "Bush's Stem Cell Policy Reiterated, but Some See Shift," *The Washington Post*, May 16, 2004, p. A18.

[30] Letter from Elias A. Zerhouni, Director, National Institutes of Health, to The Honorable Diana DeGette and The Honorable Michael Castle, May 14, 2004.

[31] See [http://feinstein.senate.gov/04Releases/r-stemcell-ltr.pdf].

[32] Andrew J. Hawkins, "NIH Stem Cell Bank, Centers of Excellence Will Fast-Track Translational Research, Says Thompson," *Washington FAX*, July 15, 2004.

[33] ibid.

supply of stem cell lines for research."[34] The co-sponsors of the Stem Cell Research Enhancement Act (H.R. 4682), Representative Michael Castle and Representative Diana DeGette are quoted as saying that the plan is "a positive step forward but stops short of providing researchers the full support they need."[35]

State Legislation on Embryonic Stem Cell Research

The Dickey Amendment restricts federal funding for embryo research; however, states are the principal sources of direct regulation of non-federally funded embryo research. State laws vary widely in their application and content. Nebraska, New Jersey, California and New Hampshire have enacted legislation directly regarding stem cell research. Nebraska prohibits the use of state funds for embryonic stem cell research (Nebraska Health Care Funding Act §71-7606(3)). New Hampshire's Safety and Welfare statutes (Title VXII §168-B: 16 (I, II)) circumscribe the boundaries of permissible embryo research.[36] New Jersey and California encourage embryonic stem cell research, and permit state funding for it. Kansas restricts its bioscience funding to exclude research that would be "contrary to federal laws that are in effect on the date of enactment of [the] act."[37] New Hampshire, Massachusetts, Pennsylvania, Louisiana and Minnesota are currently considering pro-stem cell legislation.[38]

California's law, enacted in September 2002, was the nation's first to expressly permit and encourage research involving the derivation of human embryonic stem cells and cloned embryos (California Health and Safety Code § 123440, 24185, 12115-7, 125300-320). The law does not authorize practices that were previously proscribed, but instead provides assurances to researchers and sponsors hesitant to invest in embryonic stem cell research since the 2001 Bush policy took effect. The law has reportedly enticed several prominent researchers to move there from other states. A pro-stem cell coalition in California has placed an initiative on the November 2004 ballot that would generate $3 billion in state-bond funding for embryonic stem cell research over the next 10 years and the establishment of a California Institute for Regenerative Medicine.[39]

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[34] ibid.

[35] ibid.

[36] New Hampshire Safety and Welfare statutes (Title VXII §168-B: 16 (I, II) prohibit "noncryo-preserved" embryos from being maintained for more than 14 days post-fertilization, and prohibit embryos "donated for use in research" from being "transferred to a uterine cavity."

[37] HB 2647 (2004); 12-1770a (Supp) (2004). It is unclear whether the 2001 Bush stem cell policy would be interpreted to be a "law" for purposes of Kansas' HB 2647. If so, Kansas' funding of stem cell research would be limited to those lines approved for federal funding under the Bush policy.

[38] John T. Softcheck, "Massachusetts Measure Would Permit Use of State Funds for Stem Cell Research," *The Washington Fax*, Dec. 11, 2002; "U.S. States Making Stem Cell Policies," *Bionews*, no. 258, May 5, 2004.

[39] *Stem Cell Research, Funding, Bonds, Initiative Constitutional Amendment and Statute,* (continued...)

New Jersey's law, enacted in January 2004, specifically permits embryonic stem cell research, but bans human cloning for reproductive purposes (NJ Permanent Statutes, Title 26:2Z-2). Like the California law, New Jersey's stem cell statute provides assurances to researchers and sponsors and does not contradict the 2001 Bush policy. In May 2004, Governor James McGreevey signed a bill to create the first state-funded embryonic stem cell research center, a $25 million endeavor.[40] The legislature funded the measure on June 25, 2004, passing a state budget that allocates $9.5 million to the newly chartered Stem Cell Institute of New Jersey.[41] The state money is supposed to attract private investment, which Dr. Ira Black, the Institute's founding Director, says has already happened.[42]

In an effort to discourage abortion, 15 states restrict research on fetuses and embryos that have been aborted, which may preclude some forms of stem cell research. Among the states with such restrictions are California, which encourages stem cell research in other law, Pennsylvania, which is considering pro-stem cell research legislation, and Nebraska, which prohibits the use of state funds for stem cell research. The restrictions on aborted fetal and embryonic tissue research vary in scope among the states. Arizona, Indiana, North Dakota, Ohio, Oklahoma, and South Dakota prohibit research on living and nonliving fetuses or embryos. Arkansas, California, Florida, Montana, and Nebraska prohibit research on aborted live fetuses. Massachusetts and Pennsylvania prohibit research on embryos and live fetuses. Illinois prohibits research on aborted living and nonliving fetuses. Missouri prohibits research on live fetuses before abortion. The remaining 35 states do not prohibit research using aborted fetal tissue.

Thirteen states have restrictions on research using fetal or embryonic tissue derived from processes other than abortion (such as in vitro fertilization (IVF) or cloning), which may also preclude some forms of stem cell research. Among them are Louisiana, which is considering pro-stem cell legislation, and North Dakota, South Dakota and Illinois, which also prohibit research on fetuses and embryos. Illinois prohibits research on fetuses and embryos. Louisiana prohibits research on fetuses and embryos in utero and in vitro. Maine, New Mexico, Rhode Island and Utah prohibit research on fetuses or embryos born or extracted alive. This restriction does not apply to pre-implantation in vitro fertilized embryos. South Dakota prohibits research on embryos outside of a woman's body or on cells or tissues derived from an embryo outside a woman's body. Minnesota prohibits research on fetuses and on some live embryos. Michigan and North Dakota prohibit research on live embryos and fetuses, or cloned embryos. The law in Virginia may prohibit

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[39] (...continued)
1021,(SA03RF0055, Amdt. #1-NS), at [http://www.ss.ca.gov/elections/elections_j.htm #2004General].

[40] "U.S. States Making Stem Cell Policies," *Bionews*, no. 258, May 5, 2004.

[41] Barbara Mantel, "Analysis: New Jersey Is First State to Fund Research on Stem Cell," *NPR: All Things Considered*, June 25, 2004.

[42] ibid.

research on cloned embryos or fetuses.[43] Arkansas and Iowa prohibit research on cloned embryos. Thirty-seven states have no such restrictions.

Congressional Actions

A number of hearings have been held by both House and Senate committees on the topic of stem cell research. With regard to legislation, Congress addressed the issue of stem cell research in the Consolidated Appropriations Act of 2004 (P.L. 108-199) by including the Dickey Amendment which bans 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 could potentially deter human stem cell research because researchers might not be able to claim ownership of their work.

P.L. 108-199 provides support for research using stem cells found in umbilical cord blood by making $10,000,000 available to establish a National Cord Blood Stem Cell Bank. Two other bills, H.R. 2852 (Christopher Smith) and S. 1717 (Hatch), both titled the Cord Blood Stem Cell Act of 2003, would amend the Public Health Service Act to establish a National Cord Blood Stem Cell Bank Network to prepare, store, and distribute human umbilical cord blood stem cells for the treatment of patients and to support peer-reviewed research using this type of stem cell. H.R. 2852 was referred to the Committee on Energy and Commerce. S. 1717 was referred to the Committee on Health, Education, Labor and Pensions.

H.R. 3960 (Millender-McDonald), the Stem Cell Replenishment Act of 2004, was introduced on March 11, 2004. H.R. 3960 authorizes the use of federal funds for research on human embryonic stem cells irrespective of the date on which the derivation process for the stem cells was initiated or completed. The bill directs the Director of NIH to review the guidelines and notices published by NIH with respect to human embryonic stem cell research and revise the guidelines and notices to ensure the availability of not less than 60 stem cell lines that are able to be used for scientific research. H.R. 3960 was referred to the House Committee on Energy and Commerce on March 30, 2004.

H.R. 4682 (Castle), the Stem Cell Research Enhancement Act, was introduced on June 24, 2004. H.R. 4682 amends the Public Health Service Act and directs the Secretary of HHS, in consultation with the Director of NIH, to fund research on embryonic stem cell lines derived after the August 9, 2001 policy established by the Bush Administration. In accordance with the Dickey Amendment, no federal funds shall be used to derive stem cells or destroy embryos. Stem cell lines derived after

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[43] "Virginia law does not expressly prohibit research on cloned embryos, but it is forbidden to possess the product of human cloning. Under the state human cloning statute human cloning is defined as the creation of or attempt to create a human being by transferring the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed. Human being is not defined as to whether it includes neonates, embryos or fetuses only." Alissa Johnson, "State Embryonic and Fetal Research Laws," *National Council of State Legislatures*, Jan.27, 2004, at [http://www.ncsl.org/programs/health/genetics/embfet.htm#b], visited May 17, 2004.

enactment must meet ethical guidelines established by the NIH. Only embryos that were originally created for fertility treatment purposes and in excess of clinical need are eligible for stem cell derivation. Only embryos that the individuals seeking fertility treatments have determined will not be implanted in a woman and will be discarded are eligible for stem cell derivation. Written consent is required for embryo donation. The Secretary in consultation with the Director of NIH shall promulgate guidelines 60 days after enactment. These guidelines shall ensure that federally funded researchers adhere to ethical considerations. No federal funds shall be used to conduct research on unapproved stem cell lines. The Secretary shall annually report to Congress about stem cell research. H.R. 4682 has been referred to the House Committee on Energy and Commerce.

On February 27, 2003, the House passed H.R. 534 (Dave 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 which passed the House in the 107th Congress (H.R. 2505).

During floor debate on H.R. 534, an amendment, H.Amdt. 4 (Robert 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 two years of enactment. An amendment in the nature of a substitute, H.Amdt. 5 (Greenwood), failed 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.[44] 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 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 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 HHS Secretary; such registration would most likely be submitted to the FDA.

H.R. 801 stipulates that all research involving human SCNT 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 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 would have the same effect: human reproductive cloning would be banned, but cloning for medical research purposes would be allowed,

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[44] 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.

including stem cell research.[45] 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 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 human SCNT 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[46], or Parts 50 and 56 of 21CFR.[47] 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.[48]

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.

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[45] ibid.

[46] This provision specifies protections due to human beings who participate in research conducted or supported by HHS and many other departments.

[47] This provision specifies protections due to human beings who participate in research involved in testing a drug or medical device for FDA approval.

[48] Often referred to as the Common Rule, 45CFR46, Subpart A, "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, 21CFR 50 and 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, Aug. 2001.

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.

Supporters of a total ban on human cloning, such as that contained in H.R. 534, argue that a partial ban on human cloning, like the one in H.R. 801 or S. 303, would be impossible to enforce. Critics of the total 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.

The U.S. Supreme Court has recognized in past cases certain personal rights as being fundamental and protected from government interference.[49] 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."[50] 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."[51] However, no case involving these issues is scheduled to come before the Supreme Court this term.

International Actions on Embryonic Stem Cell Research

The international community has taken a variety of action regarding stem cell research. Action by the United Nations, which was considering a restrictive human cloning treaty, is currently on hold until 2005. The European Union (EU) clarified its stem cell rules in November 2003, smoothing the path for EU funding and support for human embryonic stem cell research.[52] Under the terms of its sixth research framework program(FP6), the EU may fund embryonic stem cell research regardless of the date that the stem cells were procured from embryos. A cut-off date, which would have created a restriction similar to the one in the 2001 Bush policy, was under consideration, but was dropped.[53] FP6 allows funding for research on tissue derived from "spontaneous or therapeutic abortion," but not for the creation of

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[49] 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.

[50] 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.

[51] ibid., p. 667.

[52] Committee on Industry, External Trade, Research and Energy, "Integrating and Strengthening the European Research Area" (2002-2006) (COM(2003) 390 — C5-0349/2003 — 2003/0151(CNS)) European Parliament, (A5-0369/2003) (Nov. 4, 2003).

[53] John T. Softcheck, "European Union Moves Close to Funding Stem Cell Research with Two Parliament Votes," *Washington Fax*, Nov. 10, 2003.

human embryos for the purpose of stem cell procurement.[54] FP6 implies but does not state that it will allow funding for research on embryos that remain after IVF, in that it "no longer requir[es] parental consent where embryos have to be destroyed in order to produce embryonic stem cell lines."[55] According to Members of the European Parliament, FP6 funding decisions should depend "both upon the contents of the scientific proposal and the legal framework of the Member States involved."[56]

EU member states are considering a range of legislation on the subject. In Italy, a proposal would prohibit any experiments on human embryos, the production of embryos for research purposes, and any destruction of human embryos. By contrast, a proposal before the Spanish Parliament would allow research using surplus frozen embryos that can no longer be used for reproductive purposes, provided that the consent of the donor is given. Sweden's parliamentary committee on genetic integrity reviewed the country's regulation of stem cell research and proposed that no prohibition relating to the production of fertilized eggs for research be introduced.

Other countries' activities designed to regulate and promote stem cell research have come to the attention of Congress.[57] For example, in March 2004, the Canadian government enacted legislation allowing stem cell and other research to be conducted on donated embryos created but no longer needed for reproductive purposes.[58] Australia permits the use of spare IVF embryos for stem cell research,[59] and its government has reportedly allotted $57.9 million to its National Stem Cell Centre.[60] Singapore, which allows scientists to clone human embryos and keep them alive for up to 14 days to extract the stem cells, is reported to have "research-friendly policies and generous government funding have already helped jump-start the tiny city-state's nascent stem cell sector. ... Singapore and the New York-based Juvenile Diabetes Research Foundation International launched a $3 million funding program to support stem cell research [in Singapore], ... [and in May 2004, Singapore unveiled] its resort-like Biopolis, created to give biotech researchers and their families a place to live and work."[61] The United Kingdom's Human Fertilisation and Embryology Authority can issue licences permitting research on embryos less than 14 days old as

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[54] ibid.

[55] "Sixth Framework Programme," *Bulletin EU 11-2003, Research and technology (8/10)*, Nov. 26, 2003, at [http://europa.eu.int/abc/doc/off/bull/en/200311/p103069.htm].

[56] John T. Softcheck, "European Union Moves Close to Funding Stem Cell Research with Two Parliament Votes," *Washington Fax*, Nov. 10, 2003.

[57] *See, e.g.*, Letter from 58 Senators to President George W. Bush, June 4, 2004; Letter from 206 Members of the House of Representatives to President George W. Bush, Apr. 28, 2004.

[58] Assisted Human Reproduction Act (Canadian Bill No. C-6, 2004), LS-466E.

[59] Research Involving Human Embryos Act, No. 145, 2002.

[60] "The National Stem Cell Centre," *Commonwealth of Australia's Department of Education, Science and Training*, Jun. 2, 2004, at [http://backingaus.innovation.gov.au/2004/commercial/stem_cell.htm], visited July 15, 2004.

[61] "Singapore Hosts Stem Cell Meeting" *MSNBC*, May 19, 2004, at the MSNBC website [http://msnbc.msn.com/id/3341644/], visited July 15, 2004.

well as cloning for research purposes.[62] The UK "founded a new £16.5 million (USD $30 million) stem cell center in Cambridge this week with a commitment to fundamental research on both human embryonic and adult stem cells as a precursor to studying therapeutic applications."[63] South Korea, the home of the doctor who announced in February 2004 that he had cloned human embryos and extracted stem cells from them, subsequently enacted legislation to regulate and license reproductive cloning.[64]

Ethical Issues

Stem cell research is controversial not because of its goals, but rather because of the means of obtaining some of the cells. Research involving most types of stem cells, such as those derived from adult tissues and umbilical cord blood, is uncontroversial, except when its effectiveness as an alternative to embryonic stem cells is debated. The crux of the debate centers around embryonic stem cells, which enable research that may facilitate the development of medical treatments and cures, but which require the destruction of an embryo to derive. In addition, because cloning is one method of producing embryos for research, the ethical issues surrounding cloning are also relevant.

As previously mentioned, the Bush Administration, a group of Representatives, a group of Senators, and a group of Nobel Laureates have each presented their respective positions on embryonic stem cell research. In addition, various other organizations, individuals, and councils have issued opinions and reports on the topic. Some groups, such as the Christian Legal Society,[65] Focus on the Family,[66] and the Christian Coalition,[67] support the 2001 Bush policy. Others, such as the National Academies,[68] the Coalition for the Advancement of Medical Research

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[62] Human Fertilisation and Embryology (Research Purposes) Regulations 2001, S1 2001 No. 188.

[63] Philip Hunter, "UK to Open Stem Cell Center," *The Scientist*, June 22, 2004 at [http://www.biomedcentral.com/news/20040622/04], visited July 15, 2004.

[64] "Stem Cells Extracted from Human Clone," *MSNBC*, Feb. 12, 2004, at [http://www.msnbc.msn.com/id/4244988/], visited July 12, 2004; Dr. Hwuang, the South Korean scientist referenced herein, stated on July 13, 2004 that he is still awaiting his license from the South Korean Government to continue his cloning and stem cell research. Dr. Wu-Suk Hwuang, *Press conference on stem cell research*, Gijon, Spain, July 13, 2004, 10:30 AM.

[65] The Christian Legal Society is a "national grassroots network of lawyers and law students, committed to ... advocating biblical conflict reconciliation, public justice, religious freedom and the sanctity of human life." [http://www.clsnet.org/clsPages/vision.php].

[66] *Focus on the Family* was founded in 1977 by Dr. James Dobson to promote teachings of Jesus Christ. [http://www.family.org].

[67] The Christian Coalition is "the largest and most active conservative grassroots political organization in America," [http://www.cc.org].

[68] The National Academies brings together "committees of experts in all areas of scientific and technological endeavor" as "advisors to the Nation." For statements on embryonic stem

(continued...)

(CAMR),[69] former First Lady Nancy Reagan,[70] and former Presidents Gerald Ford, Jimmy Carter, Bill Clinton[71] favor more embryonic stem cell research than the Bush policy allows. Still others, such as the National Right to Life Committee[72] and the United States Conference of Catholic Bishops,[73] oppose all embryonic stem cell research.

Two presidential bioethics advisory panels have considered the issues involved in embryonic stem cell research. The President's Council on Bioethics (President's Council)[74] published one report directly on the topic, *Monitoring Stem Cell Research*,[75] in which it sought to characterize the issues. While the Council made no recommendations there, in two other reports it has recommended that "Congress should ... [p]rohibit the use of human embryos in research beyond a designated stage in their development (between 10 and 14 days after fertilization),"[76] and unanimously recommended "a ban on cloning-to-produce-children," with a 10-member majority also favoring "a four-year moratorium on cloning-for-biomedical-research," and a seven-member minority favoring "regulation of the use of cloned embryos for

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[68] (...continued)
cell research and cloning, see National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001); Committee on Science, Engineering and Public Policy and Global Affairs Division et al., *Scientific and Medical Aspects of Human Reproductive Cloning*, (Washington National Academy Press, 2002) at [http://www.nationalacademies.org/about/#org].

[69] CAMR is a nonprofit organization comprised of patient organizations, universities, scientific societies, foundations, and individuals with life-threatening illnesses and disorders, [http://www.camradvocacy.org/fastaction/]. For a statement on embryonic stem cell research, see Coalition for the Advancement of Medical Research, "Embryonic Stem Cell Research," talking points [http://www.camradvocacy.org/fastaction/news.asp?id=167], visited May 14, 2004.

[70] "Nancy Reagan Urges Stem Cell Research," *MSNBC*, May 9, 2004, at [http://www.msnbc.msn.com/id/4937850/], visited May 14, 2004.

[71] ibid.

[72] The National Right to Life Committee was founded in 1973 to "restore legal protection to innocent human life," at [http://www.nrlc.org/Missionstatement.htm].

[73] 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].

[74] The *President's Council* was created by President Bush in Nov. 2001 to "advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology." George W. Bush, "Creation of The President's Council on Bioethics," *Executive Order 13237*, Nov. 28, 2001, at [http://www.bioethics.gov/reports/executive.html].

[75] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004.

[76] The President's Council on Bioethics, Reproduction and Responsibility, Mar. 2004, p.xlviii.

biomedical research."[77] A predecessor to the President's Council, the National Bioethics Advisory Committee (NBAC),[78] recommended federal funding for stem cell research using "embryos remaining after infertility treatments," but not for the "derivation or use of embryos ... made for research purposes."[79]

Detailed review of the assorted reports and statements reveals that, while positions on embryonic stem cell research may be broadly categorized as *for* or *against*, there is an array of finer distinctions present. These finer distinctions in turn reveal the variation in ethical and moral as well as factual beliefs. The following discussion breaks down the arguments about embryonic stem cell research according to these finer distinctions, demonstrating both the complexity of the issues and the points of resonance among the groups.

Embryo Destruction and Relief of Human Suffering. Most positions on embryonic stem cell research rest at least in part on the relative moral weight accorded to embryos and that accorded to the prospect of saving, prolonging, or improving others' lives. For some, the inquiry begins and ends with this question. For instance, one opponent of the research, the American Life League, posits that "human life begins at conception / fertilization and that there is never an acceptable reason for intentionally taking an innocent human life."[80] Similarly, the United States Conference of Catholic Bishops states that the research is immoral because it "relies

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[77] President's Council on Bioethics, Human Cloning and Human Dignity, July 2002, pp. xxxv- xxxviii). Note: At the June 20, 2002, meeting, nine 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 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, v. 297, July 19, 2002, pp. 322-324.) "Wise Words from Across the Pond?," BioNews, no. 252, Mar. 29, 2004.

[78] In 1995, President Clinton created the National Bioethics Advisory Commission by Executive Order, to advise him on bioethical issues. The Order expired in 2001. "Former Bioethics Commissions," *President's Commission on Bioethics* website, at [http://www.bioethics.gov/reports/past_commissions/index.html], visited Jun. 30, 2004.

[79] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, Sept. 1999, pp. 70-71.

[80] American Life League, *Analysis of George W. Bush's Stem Cell Decision*, 2001, at [http://www.all.org/issues/scanalyz.htm] visited May 11, 2004.

on the destruction of some defenseless human beings for the possible benefit to others."[81]

Some groups explore the moral standing of human embryos, and also consider the "duty to relieve the pain and suffering of others."[82] Others take the position that embryos do not have the same moral status as persons. They acknowledge that embryos are genetically human, but hold that they do not have the same moral relevance because they lack specific capacities, including consciousness, reasoning and sentience.[83] They conclude that performing research to benefit persons justifies the destruction of embryos. Acceptance of the notion that the destruction of embryos can be justified in some circumstances forms the basis of pro-stem cell research opinions, and is usually modified with some combination of the distinctions and limitations that follow.

Viability of Embryos. Some proponents of embryonic stem cell research draw distinctions based upon whether an embryo is viable. The idea behind this distinction is that it is morally preferable for embryos that will not grow or develop beyond a certain stage and/or those that would otherwise be discarded to be used for the purpose of alleviating human suffering. This distinction has led some, though not all, pro-life advocates to support embryonic stem cell research that does not destroy embryos that are viable, meaning pre-implantation embryos, those created via cloning that are incapable of full development, or those without a woman willing to carry them to term.

Most supporters of some type of embryonic stem cell research touch on the question of viability. The 2001 Bush policy requires, among other things, use of only excess (non-viable) embryos for federally-funded research. One report of the President's Council explores the moral significance of viability that is based upon "human choices" rather than an embryo's "own intrinsic nature," but draws no conclusions.[84] A second report broaches the subject of viability, recommending that Congress ban both the transfer of a human embryo to a woman's uterus for any purpose other than to produce a live-born child, and also research conducted on embryos more than 10 to 14 days after fertilization.[85] The NBAC report touches on the moral status of embryos in utero and those in vitro,[86] though NBAC does not specify whether viability was a key rationale for its recommendations. A group of

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[81] Office of Communications, United States Conference of Catholic Bishops, *Catholic Bishops Criticize Bush Policy on Embryo Research*,(Aug. 9, 2001) at [http://www.usccb.org/comm/archives/2001/01-142.htm] accessed May 11, 2004.

[82] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004, pp. 58,62.

[83] Presentation by B. Steinbock, Dept. Of Philosophy, SUNY, Albany, NY, NIH Human Embryo Research Panel Meeting, Feb. 3, 1994.

[84] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004, p. 87.

[85] The President's Council on Bioethics, *Reproduction and Responsibility*, Mar. 2004.

[86] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research, vol. 1*, Sept. 1999, p. 50.

Representatives, a group of Senators,[87] and CAMR imply but do not state a distinction based on viability by expressly calling for the use of "excess" embryos developed for IVF, and making no mention of those in utero.[88] By contrast, the National Academies and the group of Nobel Laureates more broadly support research on embryos, making no mention of viability.

Purpose of Embryo Creation. A separate distinction that often leads to the same conclusions as viability is the purpose for which embryos are created. This distinction draws an ethical line based upon the intent of the people creating embryos. In the view of some, it is permissible to create an embryo for reproductive purposes (such as IVF), but impermissible to create one with the intention of destroying it for research.

Most groups at least note the potential ethical significance of reproductive versus research motives for creating embryos. The 2001 Bush policy draws a motive distinction by including a requirement that federally funded research be conducted only on embryonic stem cell lines derived from embryos created solely for reproductive purposes. NBAC draws the same distinction by recommending that federal funding be used for embryos remaining after infertility treatment but not for research involving the derivation or use of stem cells from embryos made for research purposes or from embryos made using cloning (SCNT).[89] The President's Council recommends that Congress ban attempts at conception by any means other than the union of egg and sperm (essentially banning cloning via SCNT), but does not specify whether embryos might be created in vitro specifically for research purposes.[90] A group of Representatives, a group of Senators, and CAMR imply but do not state that embryos should not be created for research purposes. They overtly call for the use of "excess" embryos developed for IVF, and make no mention of embryos created expressly for research.[91] By contrast, the National Academies supports the creation of embryos for research purposes, including via cloning (SCNT), to "ensure that stem cell-based therapies can be broadly applied for many conditions and people [by] overcoming the problem of tissue rejection."[92] Mrs. Nancy Reagan, her supporters, and the group of Nobel Laureates also take this position.

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[87] Letter from 58 Senators to President George W. Bush, June 4, 2004. (Hereafter cited as Letter from 58 Senators.)

[88] Letter from 206 Members of the House of Representatives to President George W. Bush, Apr. 28, 2004. (Hereafter cited as Letter from 206 Members of the House of Representatives.)

[89] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, Sept. 1999, pp. 70-72.

[90] The President's Council on Bioethics, *Reproduction and Responsibility*, Mar. 2004, p. xlviii.

[91] Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

[92] National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 58.

New and Existing Cell Lines. A further distinction has been drawn based upon the timing of the creation of embryonic stem cell lines. Here, the premise is that it is unacceptable to induce the destruction of embryos for the creation of new lines. However, in cases in which embryos have already been destroyed and the lines already exist, it is morally preferable to use those lines for research to improve the human condition.

This was one central distinction drawn in the 2001 Bush policy, which limited the use of federal funding to research on lines derived on or before the date of the policy. Supporters of the Bush policy on both sides of the issue favor this distinction as a compromise. It allows research on some embryonic stem cell lines. It deters the future destruction of embryos for research. The President's Council writes that the Bush policy mixes "prudence" with "principle, in the hope that the two might reinforce (rather than undermine) each other."[93] The Council notes that the policy is supported by what it titles a *moralist's* notion of when one may benefit from prior bad acts (referring to embryo destruction): it prevents the government from complying in the commission of or encouraging the act in the future, and it reaffirms the principle that the act was wrong.[94] The same report also contains analyses of the Bush policy that characterize distinction between new and existing cell lines as "arbitrary," "unsustainable," and "inconsistent."[95] The Council itself takes no position in the report on this or any other issue.

Opponents of the Bush policy on both sides of the issue view the distinction between new and existing stem cell lines with reproach. One side, which includes The National Right to Life Committee and the United States Conference of Catholic Bishops, objects because the distinction validates destruction of embryos, and in fact rewards those who did so first with a monopoly. The other side, which includes the National Academies, a group of Representatives, a group of Senators, Nancy Reagan and her supporters, Gerald Ford, CAMR, and the group of Nobel Laureates, objects because the distinction limits the number of embryonic stem cell lines available for research, particularly since the number of authorized lines are dwindling and are "contaminated with mouse feeder cells."[96] Likewise, though NBAC recognized the distinction between destroying embryos and using ones previously destroyed (e.g., "derivation of [embryonic stem] cells involves destroying the embryos, whereas abortion precedes the donation of fetal tissue and death precedes the donation of whole organs for transplantation"[97]), it still recommended future development of embryonic stem cell lines.

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[93] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004, pp. 33-34.

[94] ibid.

[95] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004, pp. 63-67.

[96] Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

[97] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, Sept. 1999, p. 49.

Consent of Donors. There is consensus throughout a wide array of viewpoints about embryonic stem cell research that embryos should only be obtained for research with the consent of their biological donors. This consent requirement necessitates that embryos be taken only with donors' knowledge, understanding, and uncoerced agreement. The donor consent requirement is consistent with the rules governing human beings' participation in research, and with individuals' general legal authority to make decisions regarding embryos they procreate. A drawback of the requirement is that it may restrict the number of embryos available for research purposes.

The 2001 Bush policy contains a donor consent requirement. It limits approved stem cell lines to those derived with the informed consent of the donors, and obtained without any financial inducements to the donors. The NBAC and the President's Council also favor donor consent requirements. The National Academies notes the importance of informed consent in its discussion of stem cell research oversight requirements.[98] A group of Representatives and a group of Senators mention and imply their support for donor consent requirements.[99]

Effectiveness of Alternatives. One factual distinction that has been used to support competing ethical viewpoints is the efficacy of alternatives to embryonic stem cell research. The promise of stem cell therapies derived from adult tissue and umbilical cord blood have buttressed opposition to embryonic stem cell research. These opponents argue that therapies and cures can be developed without the morally undesirable destruction of embryos. However, not all scientists agree that adult stem cells hold as much potential as embryonic stem cells. Most supporters of embryonic stem cell research believe that it is the quickest and, perhaps in some cases, the only path that will yield results. Supporters also stress that embryonic and other stem cell research should be conducted collaboratively, so that they can inform one another.

Findings regarding the effectiveness of alternatives to embryonic stem cell research are mixed. The President's Council notes that there is a "debate about the relative merits of embryonic stem cells and adult stem cells."[100] Focus on the Family cites promising non-embryonic stem cell research: "adult stem cells may be as "flexible" as embryonic ones and equally capable of converting into various cell types for healing the body."[101] By contrast, the National Academies finds that the "best available scientific and medical evidence indicates that research on both embryonic and adult human stem cells will be needed."[102] NBAC finds in its deliberations that "the claim that there are alternatives to using stem cells derived

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[98] National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 53.

[99] Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

[100] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004, p. 10.

[101] Carrie Gordon Earll, "Talking Points on Stem Cell Research," *Focus on the Family*, Sept. 17, 2003 at [http://www.family.org/cforum/fosi/bioethics/faqs/a0027980.cfm], visited May 14, 2003.

[102] National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 56.

from embryos is not, at the present time, supported scientifically."[103] CAMR supports both embryonic and adult stem cell research, and adds that "many scientists believe and studies show that embryonic stem cells will likely be more effective in curing diseases because they can grow and differentiate into any of the body's cells and tissues and thus into different organs."[104] Mrs. Nancy Reagan and her supporters favor expedient approaches including embryonic stem cell research.[105]

Use of Federal Funding. Some division over the support for and opposition to embryonic stem cell research focuses on the question of whether the use of federal funding is appropriate. Those who oppose federal funding argue that the government should not be associated with embryo destruction.[106] They point out that embryo destruction violates the "deeply held moral beliefs of some citizens," and suggest that "funding alternative research is morally preferable."[107] Proponents of federal funding argue that it is immoral to discourage life-saving research by withholding federal funding. They point out that consensus support is not required for many federal spending policies, as it "does not violate democratic principles or infringe on the rights of dissent of those in the minority."[108] They argue that the efforts of both federally supported and privately supported researchers are necessary to keep the United States at the forefront of what they believe is a very important, cutting edge area of science. Furthermore, supporters believe that the oversight that comes with federal dollars will result in better and more ethically controlled research in the field.

Groups' positions on federal funding tend to mirror their positions on stem cell research generally. The Bush policy authorizes federal funding for some embryonic stem cell research. The President's Council does not take a position on the issue, but notes the pros and cons, and stresses that there is a "difference between *prohibiting* embryo research and *refraining from funding* it."[109] Focus on the Family generally supports the President Bush and his policy, but is "disappointed by his decision to allow federal funding of research on the existing stem cell lines."[110] NBAC finds the

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[103] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, Sept. 1999, p. 53.

[104] Coalition for the Advancement of Medical Research, "Embryonic Stem Cell Research," talking points [http://www.camradvocacy.org/fastaction/news.asp?id=167], visited May 14, 2004.

[105] "Nancy Reagan Urges Stem Cell Research," *MSNBC*, May 9, 2004, at [http://www.msnbc.msn.com/id/4937850/], accessed May 14, 2004.

[106] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, Sept. 1999, p. 57.

[107] ibid.

[108] ibid.

[109] The President's Council on Bioethics, *Monitoring Stem Cell Research*, Jan. 2004, p. 37.

[110] Carrie Gordon Earll, "Talking Points on Stem Cell Research," *Focus on the Family*, Sept. 17, 2003 at [http://www.family.org/cforum/fosi/bioethics/faqs/a0027980.cfm], visited May 14, 2003.

arguments in favor of federal funding more persuasive than those against it.[111] The National Academies, a group of Representatives, a group of Senators, Mrs. Nancy Reagan and her supporters, CAMR, and the Nobel Laureates favor federal funding for embryonic stem cell research.[112]

[111] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, Sept. 1999, p. 70.

[112] See e.g., National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 49.