Order Code RL31015

Stem Cell Research

Updated July 18, 2005

Judith A. Johnson
Specialist in Life Sciences
Domestic Social Policy Division

Erin D. Williams
Specialist in Bioethical Policy
Domestic Social Policy Division

Stem Cell Research

Summary

Embryonic stem cells have the ability to develop into virtually any cell in the body, and they 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 78 stem cell lines that are eligible for use in federally funded research. However, only 22 embryonic stem cell lines are currently available. Scientists are concerned about the quality, and longevity of these 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.

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. Some scientists are exploring the possibility of obtaining human embryonic stem cells that bypass the destruction of living human embryos. The President's Council on Bioethics identified four potential alternative sources of human embryonic stem cells in a paper released in May 2005.

On May 24, 2005, the House passed H.R. 810 (Castle) which would allow federal support of research that utilizes human embryonic stem cells regardless of the date on which the stem cells were derived from a human embryo, thus negating the Bush stem cell policy limitation on "existing stem cell lines." On the same day, the House also passed H.R. 2520 (Christopher Smith) which would provide for the collection and maintenance of human cord blood stem cells for the treatment of patients and for research. During consideration of Labor-HHS appropriations, Members may renew efforts to alter or abolish the Dickey Amendment in order to permit embryo research and the development of stem cell lines with federal support. Action on the Weldon bill (which passed the House in the 107th and 108th and stalled in the Senate) is also likely; it has been reintroduced in the 109th Congress as H.R. 1357 and S. 658 (Brownback). The bill bans the process of cloning as well as the importation of any product derived from an embryo created via cloning. It bans not only reproductive applications, but also research on therapeutic uses, which has implications for stem cell research. Advocates of the legislative ban say that allowing any form of human cloning research to proceed raises serious ethical issues and will inevitably lead to the birth of a baby that is a human clone. Critics argue that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas. This report will be updated as needed.

Contents

List of Tables

Stem Cell Research

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 some or all of the more than 200 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.

Embryonic Stem Cells from IVF Embryos or Fetal Tissue. Embryonic stem cells were first isolated from mouse embryos in 1981 and from primate embryos in 1995. 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 five-day-old embryos produced via *in vitro* fertilization (IVF).[1] The work is controversial, in the opinion of some, 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 stem 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 removed from embryos or fetuses were manipulated in the laboratory to create embryonic stem cell lines that may continue to divide for many months to years.

Embryonic Stem Cells Obtained via SCNT (Cloning). Another potential source of embryonic stem cells is somatic cell nuclear transfer (SCNT), also

---

[1] The IVF embryos were originally created for the treatment of infertility. Excess embryos are often frozen 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. According to a survey of over 430 infertility clinics performed by the Society for Assisted Reproductive Technology and RAND, nearly 400,000 embryos are being stored in the United States; 88% of the embryos are being held to help the couples have children at a later date.

[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 C.F.R. § 46.203).

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 several days and then the stem cells are removed. In 1996, scientists in Scotland used the SCNT procedure to produce Dolly the sheep, the first mammalian clone.[4]

In May 2005 scientists at the Seoul National University in South Korea announced they had achieved major advances in the efficiency of creating human embryos using SCNT and in isolating human stem cells from the cloned embryos.[5] Of the 11 new stem cell lines created by the South Korean team, nine were derived from people who have spinal cord injuries, another line was derived from a six-year old diabetes patient and another from a two-year old who has a genetic immune deficiency. The team attributes their improved success rate in part to the use of freshly harvested eggs from younger fertile women instead of eggs left over from fertility treatments.[6] These developments 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.[7]

Alternative Sources of Human Embryonic Stem Cells. Some scientists have begun to explore ways of obtaining human embryonic stem cells that bypass the destruction of living human embryos and therefore may be less troubling to some individuals. The President's Council on Bioethics identified four potential methods in a paper released in May 2005.[8] Each of these methods would require additional research to determine whether it could actually generate embryonic stem cells. One possible method under discussion is deriving human embryonic stem cells from dead embryos. Early embryos frequently fail to develop in naturally occurring conceptions.

> Slightly fewer than a third of all conceptions lead to a fetus that has a chance of developing. In other words, if you were to choose a zygote at random and follow it through the first week of development, the chances are less than one in three that it would still be there at full term, even though there has been no human intervention. Nature, it seems, performs abortions at a much higher rate than

---

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

[4] Dolly was euthanized in Feb. 2003 after developing a lung infection. Some claim her death at 6 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] Gretchen Vogel, "Korean Team Speeds Up Creation of Cloned Human Stem Cells," *Science*, vol. 308, May 20, 2005, pp. 1096-1097.

[6] Ibid.

[7] For further information, see CRS Report RL31358, *Human Cloning*, by Judith A. Johnson and Erin Williams.

[8] The President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells*, May 2005, at [http://www.bioethics.gov/reports/white_paper/index.html].

> human society. It is simply not true that most zygotes, if undisturbed, will produce a human being. The probability that a conception will result in a live birth is actually quite low. Note that since we have assumed that all conceptions lead to cell division, we have almost surely overestimated the true success rate.[9]

As many as 60% of IVF embryos produced by infertility clinics are judged to be incapable of developing to live birth, due to abnormal appearance or failure to divide appropriately, and are not used by the infertile couple. Although failure to divide is often caused by genetic abnormalities and might seem to eliminate any prospect of using these embryos even for research, several studies suggest that some normal cells may be obtained from such organismically dead embryos and may be useful in creating stem cell lines. However, the possibility that normal cells removed from dead embryos could potentially develop into an embryo (and if transferred into a uterus — a child) would be disturbing to some individuals. In addition, such a possibility would likely preclude federal funding for producing stem cell lines from such cells because of restrictions contained in the Dickey Amendment (see next paragraph). Research studies to determine the precise criteria for embryonic organismic death would be needed; however, such studies could not be conducted with federal dollars. Federal funding of any type of research involving human embryos, starting with IVF then later cloning and the creation of stem cell lines from embryos, has been blocked by various policy decisions dating back more than 25 years and is currently controlled by the Dickey Amendment (see section, below, *The Dickey Amendment and Clinton Administration Stem Cell Policy*).

A second potential method of obtaining embryonic stem cells without destroying the embryo employs a technique used by IVF clinics that offer pre-implantation genetic diagnosis (PGD). At the 6-8 cell stage, one or two cells are removed from the embryo created via IVF; these cells are then screened for genetic or chromosomal abnormalities before the embryo is transferred to a woman's uterus. More than 1,000 children have been born following PGD, though it is still unclear whether subtle or late onset injuries may occur in children born following PGD.[10] It may be possible to create stem cell lines using cells obtained in this manner; after cell removal, the embryo could presumably be used to initiate a pregnancy. However, like the method described above, this approach is highly speculative and has not yet been attempted. Although it is understandable that couples who are at risk of having a child with a genetic disease may willingly agree to the potential added risk of PGD, it is difficult to understand what circumstances might motivate a couple to agree to such a procedure for the sole purpose of creating stem cell lines for research. Furthermore, the possibility that a biopsied cell may have "the potential to develop into an embryo and a child on its own" could potentially preclude federal funding for producing stem cell lines from such cells because of restrictions contained in the Dickey Amendment (see CRS-5).[11]

---

[9] Harold J. Morowitz and James S. Trefil, *The Facts of Life: Science and the Abortion Controversy* (Oxford University Press, 1992), p. 51.

[10] The President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells*, May 2005, pp. 24-25.

[11] Ibid., p. 29.

A third possible method involves using the techniques of genetic engineering and SCNT to obtain human embryonic stem cells from embryo-like groups of cells which are not, in the strict sense, human embryos. This newly proposed approach, called altered nuclear transfer (ANT), might serve as a temporary bridge until other technologies are developed, such as direct nuclear reprogramming of somatic cells. Until then, with federal support ANT would allow embryonic stem cell research collaboration on a national level without the ethical concerns involved in using leftover IVF embryos. A remaining obstacle, acquiring human eggs, is the subject of intense scientific research. Researchers are trying to develop methods of obtaining eggs without resorting to superovulation of female patients, an expensive procedure that some find morally questionable.

The fourth method identified by the President's Council on Bioethics involves the dedifferentiation of somatic cells, literally reprogramming or winding back the clock on cell development to produce cells with the capabilities of embryonic stem cells. This proposed method is totally hypothetical and basic research is at a preliminary stage. However, the President's Council on Bioethics expresses some concern that dedifferentiation might proceed too far, resulting in the functional equivalent of an embryo. This possibility would raise serious ethical issues for some, and presumably the Dickey Amendment would again preclude the use of this method in the production of human embryonic stem cells for research. Moreover, such an embryo would be a clone of the individual who donated the somatic cell and any attempt to "save" such an embryo through the implantation in a woman's uterus would raise additional moral and ethical questions.

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 the abilities and characteristics of adult stem cells from a variety of different sources, such as bone marrow and the umbilical cord following birth. In fact, bone marrow transplantation, a type of adult stem cell therapy, has been used for 30 years to successfully treat patients for a variety of blood-related conditions. Several private companies (such as MorphoGen, NeuralStem, Osiris Therapeutics, StemSource, ViaCell) are working on additional 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.

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 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. Some experiments may involve the creation of a chimera, an organism that contains two or more genetically distinct cell types, from the same species or different species.[12] 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.[13] The work at the University of Wisconsin and Johns

---

[12] Chimeras have been created by scientists in a variety of different ways and have been the subject of research studies for many years. Human chimeras occur naturally when two eggs become fertilized and, instead of developing into twins, they fuse in the uterus creating a single embryo with two distinct sets of genes. For one example, see Constance Holden, "Chimera on a Bike?" *Science*, June 24, 2005, p. 1864.

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

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 FY2005.[14] For FY2006, the provision is found in Section 509 of the Labor, HHS and Education, and Related Agencies Appropriations Act, 2006 (H.R. 3010, H. Rept 109-143). It states that:

> (a) None of the funds made available in this Act may be used 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)).
>
> (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] as of the date of enactment of this Act, 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

---

[14] 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, of the Labor, HHS and Education appropriations acts in the following public laws: FY1997, P.L. 104-208; FY1998, P.L. 105-78; FY1999, P.L. 105-277; FY2000, P.L. 106-113; FY2001, P.L. 106-554; FY2002, P.L. 107-116; FY2003, P.L. 108-7; FY2004, P.L. 108-199; and, FY2005, P.L. 108-447.

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 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.[15] The first meeting of the HPSCRG was scheduled for April 25,

---

[15] 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.

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.[16] 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."[17]

The Bush Administration conducted a legal review of the policy decisions made during the Clinton Administration regarding federal support of stem cell research, as 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.[18] 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."[19] 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.[20] 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,

---

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

[17] Ibid.

[18] 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/]

[19] 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].

[20] 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].

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: FDA and NIH. 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 "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."[21] 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

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

guidance documents and the U.S. Public Health Service has developed guidelines on infectious disease issues associated with xenotransplantation.[22]

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 developing human embryonic stem cells that can be maintained without the use of mouse feeder cells.[23]

NIH Research Funding and Stem Cell Registry. The August 9, 2001, Bush Administration 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.[24]

Table 1. National Institutes of Health Funding

($ in millions)

	FY99	FY00	FY01	FY02	FY03	FY04	FY05	FY06
Stem cell research	$226	$256	$306	$387	$517	$553	$566	$568
Human embryonic stem cell research	(0)	(0)	(0)	(10.7)	(20)	(24)	N/A	N/A

Source: NIH Budget Office, May 3, 2005.

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.[25] 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

---

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

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

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

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

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 22 stem cell lines available from seven sources.

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	3
University of California, San Francisco, CA	2	2
Wisconsin Alumni Research Foundation, Madison, WI	5	5
Total	**78**	**22**

a. Entities in italics 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."

Concerns Over 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 22 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.[26] 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 of xenotransplantion (described in the previous section on FDA regulation), 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.

Reproductive Genetics Institute. 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.[27] 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.[28] The new stem cell lines are to be used to understand the origins of disease-related symptoms and to develop and test new treatments.

Harvard Stem Cell Institute. 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.[29] One year later the Harvard team has increased that number to 28 new human embryonic stem cell lines.[30] 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 Harvard 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 research institute in order to continue the work begun by Melton and his group of scientists;

---

[26] 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].

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

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

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

[30] Gareth Cook, "Harvard Provost OKs Procedure," *Boston Globe*, Mar. 20, 2005, p. A29. (Hereafter cited as Cook, "Harvard Provost OKs Procedure.")

as of March 2005 $26 million had been raised. In October 2004 media reports stated that researchers at the newly formed Harvard Stem Cell Institute intend to produce cloned human embryos for research studies on juvenile diabetes, Parkinson's disease, and several other diseases.[31] In November 2003 Melton and collaborators submitted their proposal to a Harvard committee composed of ethicists, scientists and public policy experts. Permission to proceed with the research was granted in January 2005 provided that approval was received from the Standing Committee on the Use of Human Subjects in Research.[32]

Stanford Institute for Cancer/Stem Cell Biology. 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.[33] 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.

UCSF Developmental and Stem Cell Biology Program. In August 2002, the University of California at San Francisco established the UCSF Developmental and Stem Cell Biology Program with a $5 million matching 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.[34]

Worldwide Survey of Stem Cell Lines. A worldwide survey of laboratories conducted by the Boston Globe found that as of May 23, 2004, 128

---

[31] Gareth Cook, "Harvard Team Wants OK to Clone; Human-Cell Work Would Be First in Nation," *Boston Globe*, Oct. 13, 2004, p. A1.

[32] Cook, "Harvard Provost OKs Procedure."

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

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

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.[35] 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.[36]

Congressional Letters on Bush Policy. 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.[37] The letter points out that an estimated 400,000 frozen IVF embryos[38] "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 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.[39] 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

---

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

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

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

[38] 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 targeted for patient use. See David I. Hoffman et al., "Cryopreserved Embryos in the United States and Their Availability for Research," *Fertility and Sterility*, vol. 79, May 2003, pp. 1063-1069.

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

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."[40] 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.[41] 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.[42] The new centers will be funded by $18 million 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."[43] 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 supply of stem cell lines for research."[44]

National Academies Guidelines. Because of the current lack of federal regulation, the National Academies established in July 2004 the Committee on Guidelines for Human Embryonic Stem Cell Research to develop voluntary guidelines for deriving, handling and using human embryonic stem cells. The stated position of the National Academies is that there should be a global ban on human reproductive cloning and therefore the guidelines will focus only on therapeutic and research uses of human embryonic stem cells and somatic cell nuclear transfer.

The Committee released its "Guidelines for Human Embryonic Stem Cell Research" on April 26, 2005. The guidelines recommend that each institution conducting human embryonic stem cell research establish an oversight committee, including experts in the relevant areas of science, ethics and law, as well as members of the public, to review all proposed experiments. The guidelines recommend that

---

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

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

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

[43] Ibid.

[44] Ibid.

a national panel also be established to oversee the issue in general on a continuing basis. The guidelines state that culture of any intact embryo, regardless of derivation method, for more than 14 days should not be permitted at the present time. The insertion of any embryonic stem cells into a human embryo or the insertion of human embryonic stem cells into a nonhuman primate embryo should also not be permitted. Such an organism containing two or more genetically distinct cell types, from the same species or different species, is often called a chimera. The guidelines state that chimeric animals in which human embryonic stem cells have been introduced, at any stage of development, should not be allowed to breed. The document also provides guidance on informed consent of donors and states that there should be no financial incentives in the solicitation or donation of embryos, sperm, eggs, or somatic cells for research purposes.

State Actions 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.

States that Prohibit Research on an Aborted Fetus or Embryo. 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.

States that Prohibit Research on Tissue Derived from IVF or Cloning. 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

research on cloned embryos or fetuses.[45] Arkansas and Iowa prohibit research on cloned embryos. Thirty-seven states have no such restrictions.

State Initiatives to Encourage Stem Cell Research. Despite federal policy, many states are moving forward with their own initiatives to encourage or provide funding for stem cell research (in some cases therapeutic cloning as well) in order to remain competitive and prevent the relocation of scientists and biotechnology firms to other states or overseas. However, without the central direction and coordinated research approach that the federal government can provide, many are concerned that the states' actions will result in duplication of research effort among the states, a possible lack of oversight for ethical concerns and ultimately a loss of U.S. preeminence in this important area of basic research.

California. In September 2002 California enacted the nation's first law that expressly permits and encourages 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 to California from other states.

In November 2004, with the endorsement of Governor Arnold Schwarzenegger, Californians passed Proposition 71 with 59% of the vote, amending the state Constitution to facilitate embryonic stem cell research. Proposition 71 establishes a California Institute for Regenerative Medicine (CIRM), and generates $3 billion in state-bond funding for embryonic stem cell research over the next 10 years. Ninety percent of the funds will be spent on research, 10% will go toward facilities. All grants will be limited to scientists and facilities in California. Funds may not be used for reproductive cloning.[46] However, funds may be used for therapeutic cloning. In early May 2005 the 29 member governing board of CIRM, the Citizens Oversight Committee, announced the selection of San Francisco as the headquarters for CIRM which is expected to employ about 50 people. CIRM's first request for grant applications is expected to be for the training of postdocs and fellows in stem cell science.[47]

---

[45] "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].

[46] *Proposition 71*, at [http://www.voterguide.ss.ca.gov/propositions/prop71text.pdf].

[47] Shirley Haley, "More Than Dollars, California Stem Cell Initiative Offers Predictability," *Washington Fax*, Apr. 29, 2005.

Wisconsin. In response to the California initiative, Wisconsin Governor Jim Doyle announced on November 17, 2004, that the state was providing nearly $750 million in public-private investment for biotechnology, health sciences and stem cell research over the next several years.[48] The Wisconsin investment strategy includes $375 million for a new research institute, the Wisconsin Institute for Discovery, on the University of Wisconsin, Madison campus. WiCell, a foundation that is using private and federal funds to support stem cell research, will be a part of the Institute. The state also plans to invest $105 million over the next five years in research, education, and public health efforts at the University of Wisconsin Medical School and the Medical College of Wisconsin for stem cell research as well as regenerative medicine, molecular medicine, neuroscience, and cancer research.

New Jersey. In January 2004 New Jersey became the second state in the nation to enact a law that specifically permits embryonic stem cell research. The state law bans human cloning for reproductive purposes but permits the use of cloned embryos for stem cell research (NJ Permanent Statutes, Title 26:2Z-2). Like the 2002 California law, New Jersey's stem cell statute provides assurances to researchers and sponsors and does not contradict the 2001 Bush policy which only limits federal funding.

In May 2004, Governor James McGreevey signed a bill to create the first state-funded embryonic stem cell research center, a $25 million endeavor.[49] 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.[50] The state money is supposed to attract private investment, which Dr. Ira Black, the Institute's founding Director, says has already happened.[51]

In a January 11, 2005, State of the State speech, Acting Governor Richard Codey called for $380 million for stem cell research.[52] The plan entails using $150 million to construct a facility for the Stem Cell Institute of New Jersey near the Rutgers University campus in New Brunswick; the money would come from the state's share of the national tobacco settlement. The remaining $230 million for research grants would be raised by putting a bond initiative on the November 2005 ballot; the bond initiative would require legislative approval.

Massachusetts. In March 2005, the Massachusetts legislature overwhelming approved a bill that clarifies state law on research involving human embryonic stem cells and therapeutic cloning and ensures that such research is permitted within a regulatory framework. The bill passed the Senate in a 35 to 2 vote and passed the House one day later with a vote of 117 to 37, more than enough to override a

---

[48] [http://www.wisgov.state.wi.us/journal_media_detail_print.asp?prid=832]

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

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

[51] Ibid.

[52] Andrew J. Hawkins, "NJ Stem Cell Initiative Supports Research Institute, Grant Making, Governor Codey Says," *Washington Fax*, Jan. 12, 2005.

threatened veto from Governor Mitt Romney who is opposed to the therapeutic cloning portion of the bill. A House-Senate conference committee obtained a compromised version of the bill at the end of April 2005.[53] On May 27, 2005, Governor Romney vetoed the stem cell bill. On May 31, 2005, the House overrode the Governor's veto on a vote of 112 to 42, the Senate did the same later that day on a vote of 35-2.[54]

Maryland. On March 28, 2005, in an 81-53 vote the Maryland House approved a bill that would provide $23 million each year for human embryonic stem cell research, including therapeutic cloning, beginning in FY2007. However, the bill died in the Senate in April 2005 on the last day of the legislative session due to a threatened filibuster.[55] Governor Robert L. Ehrlich had not indicated his support or opposition to the bill.

Illinois. In November 2004 State Comptroller Dan Hynes proposed creating the Illinois Regenerative Medicine Institute (IRMI) which would be funded by a 6% tax on elective cosmetic surgery.[56] The first so-called vanity tax was approved in New Jersey in September 2004. Texas and the state of Washington are also considering such a tax to provide funding for public schools or health care for children. In Illinois, the vanity tax is projected to fund $1 billion in grants and loans over a ten year period. The General Assembly would need to approve placing a referendum question on the 2006 general ballot. Legislation creating the IRMI was introduce in April 2005; it provides support for stem cell research including research using cloned embryos. However, in November 2004 the Senate failed to approve, by two votes, a purely symbolic measure that proclaimed the state's support of privately funded human embryonic stem cell research. Following the defeat of several stem cell research measures during the spring session of the Illinois legislature, on July 12, 2005, Governor Rod Blagojevich signed an executive order authorizing $10 million in funding for adult, cord blood, and embryonic stem cell research. The money was added to the budget of the Illinois Department of Public Health.[57]

Connecticut. In January 2005, Connecticut Governor M. Jodi Rell proposed $20 million in funding for human embryonic stem cell research; the funds would come from a $315 million state budget surplus.[58] A number of bills have been introduced in 2005 that provide funding for such research; some specifically exclude

---

[53] Kimberly Atkins, "Stem Cell Bill Gains Senate OK," *Boston Herald*, Apr. 27, 2005, p. 8.

[54] Raphael Lewis, "Stem Cell Bill Override Turns to Talk of Research Support," *The Boston Globe*, June 1, 2005. P. A1.

[55] David Nitkin, Sumathi Reddy, and Ivan Penn, "Stem-cell Bill Dies in Senate Threatened Filibuster on Research Funding Spelled End For Legislation," *Baltimore Sun*, Apr. 12, 2005, p. A1.

[56] [http://www.ioc.state.il.us/office/IOCNews/ViewNewsRelease.cfm?ID=2070837170]

[57] John Chase, "Governor slips stem-cell grant by lawmakers," *Chicago Tribune*, July 13, 2005, p. 1.

[58] Marcel Przymusinski and Susie Poppick, "Locals Seek More Stem Cell Funds," *Yale Daily News*, Jan. 26, 2005.

therapeutic cloning. Both Yale University and the University of Connecticut at Storrs have labs engaged in stem cell research. In March 2005 the Storrs lab announced that, in collaboration with the Institute of Zoology of the Chinese Academy of Sciences, it has become the first lab to create embryonic stem cells from cloned cattle embryos.[59] The Storrs lab would now like to begin a human therapeutic cloning program. The lab chief, Xiangzhong "Jerry" Yang, is being recruited by the National Center for Stem Cell Research in Beijing to head their stem cell effort; Yang may leave for China if the state legislation does not pass. On June 15, 2005, Governor Jodi Rell signed legislation that provides $100 million over 10 years for human embryonic stem cell research.[60]

Ohio. The Center for Stem Cell and Regenerative Medicine was started in 2003 with a $19.5 million in funding from the state of Ohio.[61] The Center is composed of researchers from Case Western Reserve University, University Hospitals of Cleveland, The Cleveland Clinic Foundation, Athersys, Inc., and Ohio State University. The Center uses adult human stem cells and tissue engineering technology to develop treatments for human disease.

Other states, including Delaware, Pennsylvania, Texas, New York, and Florida, are considering available options to remain competitive and prevent the relocation of their scientists and biotechnology firms.[62]

Congressional Actions

Legislative action during the 109th Congress may include efforts to alter or abolish the Dickey Amendment, during consideration of Labor, HHS, and Education appropriations, in order to permit embryo research and the development of stem cell lines with federal support. Also likely is passage of the Weldon bill, which passed the House in the 107th and the 108th and stalled in the Senate. Given the changed composition of the Senate, it is more likely that this legislation would move forward for a vote in that body during the 109th Congress.

The 108th Congress addressed the issue of stem cell research in the Consolidated Appropriations Act, 2005 (P.L. 108-447) by again including the Dickey Amendment, which has banned, since FY1996, almost all publically funded human embryo research. The act also bars the Patent and Trademark Office from spending money "to issue patents on claims directed to or encompassing a human organism." This restriction, which was first included in the Consolidated Appropriations Act, 2004

---

[59] William Hathaway, "State Lab Nears Cloning Goal, UConn Scientist: Creating Human Embryonic Cells is Within Sight," *The Hartford Courant*, Mar. 25, 2005, A1.

[60] Fran Silverman, "$100 million Commitment for Stem Cell Research," *The New York Times*, June 19, 2005, p. 2.

[61] [http://ora.ra.cwru.edu/stemcellcenter/]

[62] Kelly Rayburn, "States Grapple with Stem Cell Research," *The Wall Street Journal*, Dec. 24, 2004, p. A4; Martin Kasindorf, "Calif. Moves Fast on Stem Cell Grants," *USA Today*, Dec. 17, 2004, p. A3; Andrew J. Hawkins, State Stem Cell Efforts Gain Momentum in Wake of California's Prop 71, *Washington Fax*, Jan. 18, 2005.

(P.L. 108-199), could potentially deter human stem cell research because researchers might not be able to claim ownership of their work.

In FY2004, the Consolidated Appropriations Act, 2004 (P.L. 108-199) provided $10,000,000 to establish a National Cord Blood Stem Cell Bank within the Health Resources and Services Administration (HRSA). HRSA was directed to use $1,000,000 to contract with the Institute of Medicine (IoM) to conduct a study that would recommend the optimal structure for the cord blood program. The IoM study, *Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program*, was released on April 14, 2005. The blood cell forming stem cells found in cord blood can be used as an alternative to bone marrow transplantation in the treatment of leukemia, lymphoma, certain types of anemia, and inherited disorders of immunity and metabolism. The report provides the logistical process for establishing a national cord blood banking system, establishes uniform standards for cord blood collection and storage, and provides recommendations on ethical and legal issues associated with cord blood collection, storage and use. For FY2005, the Consolidated Appropriations Act, 2005 (P.L. 108-447) provides $9,941,000 for the National Cord Blood Stem Cell Bank Program in HRSA.

On May 24, 2005, the House passed H.R. 2520 (Christopher Smith), the Stem Cell Therapeutic and Research Act of 2005, on a vote of 431-1. H.R. 2520 would provide for the collection and maintenance of human cord blood stem cells for the treatment of patients and for research. It stipulates that amounts appropriated in FY2004 or FY2005 for this purpose shall remain available until the end of FY2006 (about $18.9 million, see above paragraph), and authorizes $60 million over FY2007-FY2010. The Act also reauthorizes the national bone marrow registry with $158 million over FY2006-FY2010. In addition, it creates a database to enable health care workers to search for cord blood and bone marrow matches and links all these functions under a new name, the C.W. Bill Young Cell Transplantation program. H.R. 596 (Christopher Smith) is an earlier version of this legislation.

A bill similar to H.R. 2520, S. 1317 (Hatch), the Bone Marrow and Cord Blood Therapy and Research Act of 2005, was introduced in the Senate on June 27, 2005. S. 1317 was reported (without a written report) with an amendment in the nature of a substitute by the Committee on Health, Education, Labor, and Pensions on July 11, 2005. S. 681 (Hatch) is an earlier version of this legislation.

H.R. 162 (Millender-McDonald), the Stem Cell Replenishment Act of 2005, was introduced on January 4, 2005. H.R. 162 would authorize 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 would direct 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. 162 was referred to the House Committee on Energy and Commerce.

On May 24, 2005, the House passed H.R. 810 (Castle), the Stem Cell Research Enhancement Act of 2005, on a vote of 238-194. H.R. 810 would amend the Public Health Service Act and direct the Secretary of HHS to conduct and support research

that utilizes human embryonic stem cells regardless of the date on which the stem cells were derived from a human embryo. Stem cell lines derived after 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. 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. A companion bill, S. 471 (Specter) was introduced on February 28, 2005.

H.R. 1650 (Nancy Johnson), the Stem Cell Research Investment Act of 2005, was introduced on April 14, 2005. The bill would amend the Internal Revenue Code of 1986 to allow tax credits to holders of stem cell research bonds. It would make available $10 billion in bonding authority to the states over calendar years 2006 through 2008. H.R. 1650 has been referred to the House Ways and Means Committee.

H.R. 3144 (Bartlett), the Respect for Life Pluripotent Stem Cell Act of 2005, was introduced on June 30, 2005. H.R. 3144 would amend the Public Health Service Act to provide for a program at NIH to conduct and support stem cell research that does not harm human embryos. Such research may include research on animal embryos or human postnatal tissues or umbilical cord blood. The bill specifically prohibits research that (1) involves the use of human embryos; (2) involves the use of stem cells not otherwise eligible for funding by NIH; (3) involves the use of any stem cell to create or to attempt to create a human embryo; or (4) poses a significant risk of creating a human embryo by any means. H.R. 3144 authorizes $15 million for research in FY2006 and such sums as may be necessary for FY2007 through FY2010. H.R. 3144 was referred to the House Committee on Energy and Commerce. H.R. 2574 (Bartlett), the Respect for Life Embryonic Stem Cell Act of 2005, introduced on May 24, 2005, appears to be an earlier version of this legislation.

S. 1373 (Brownback), the Human Chimera Prohibition Act of 2005, was introduced on July 11, 2005. S. 1373 amends the federal criminal code to prohibit and to set penalties for (1) creating or attempting to create a human chimera (a being with human and non-human tissue as specified in this Act); (2) transferring or attempting to transfer a human embryo into a non-human womb, or a non-human embryo into a human womb; or (3) transporting or receiving a human chimera. S. 1373 defines a human chimera as (A) a human embryo into which a non-human cell or cells (or the component parts thereof) have been introduced to render its membership in the species Homo sapiens uncertain through germline or other changes; (B) a hybrid human/animal embryo produced by fertilizing a human egg with non-human sperm; (C) a hybrid human/animal embryo produced by fertilizing a non-human egg with human sperm; (D) an embryo produced by introducing a non-human nucleus into a human egg; (E) an embryo produced by introducing a human nucleus into a non-human egg; (F) an embryo containing haploid sets of chromosomes from both a human and a non-human life form; (G) a non-human life form engineered such that human gametes develop within the body of a non-human

life form; or (H) a non-human life form engineered such that it contains a human brain or a brain derived wholly or predominantly from human neural tissues. S. 1373 was referred to the Senate Committee on the Judiciary. S. 659, introduced on March 17, 2005, was an earlier version of this legislation.

H.R. 1357 (Dave Weldon), the Human Cloning Prohibition Act of 2005, was introduced on March 17, 2005. H.R. 1357 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. 1357 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than $1 million. H.R. 1357 is essentially identical to the measure that passed the House in the 107th Congress (H.R. 2505) and the 108th Congress (H.R. 534). H.R. 1357 was referred to the House Committee on the Judiciary.

A companion bill, S. 658 (Brownback), was introduced on March 17, 2005. It is similar to H.R. 1357, 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.[63] S. 658 includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than $1 million. It requires GAO to conduct a study to assess the need (if any) for any changes of the prohibition on cloning in light of new developments in medical technology, the need for SCNT to produce medical advances, current public attitudes and prevailing ethical views on the use of SCNT and potential legal implications of research in SCNT. The study is to be completed within four years of enactment. S. 658 has been referred to the Senate Health, Education, Labor, and Pensions Committee.

S. 876 (Hatch), the Human Cloning Ban and Stem Cell Research Protection Act of 2005, was introduced on April 21, 2005. A similar bill, H.R. 1822 (Bono), the Human Cloning Ban and Stem Cell Research Protection Act of 2005, was introduced on April 26, 2005. S. 876 amends Title 18 of the United States Code and H.R. 1822 amends the Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.).[64] Both bills would ban human reproductive cloning but allow cloning for medical research purposes, including stem cell research. S. 876 and H.R. 1822 include a criminal penalty of imprisonment of not more than 10 years; S. 876 has a civil penalty of not less than $1 million, H.R. 1822 has a civil penalty not to exceed $10 million.

S. 876 requires the Comptroller General to prepare a series of four reports within one year of enactment. The first report 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. A second report describes similar state laws that prohibit human

---

[63] By seeking to amend Title 18 of the U.S. Code rather than the Public Health Service Act, S. 658 would likely be subject to different committee jurisdiction.

[64] Because they amend different titles of the U.S. Code, the bills would likely be subject to different committee jurisdiction.

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 third report describes the coordination of enforcement actions among the federal, state and local governments. A fourth report describes laws adopted by foreign countries related to human cloning. H.R. 1822 requires a similar set of three reports to be prepared by the Secretary of Health and Human Services.

S. 876 and H.R. 1822 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 45 C.F.R. Part 46,[65] or Parts 50 and 56 of 21 C.F.R.[66] S. 876 and H.R. 1822 have a prohibition on conducting SCNT on fertilized human eggs (oocytes), and both state 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. 876 and H.R. 1822 stipulate 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. Both bills also specify that human eggs or unfertilized blastocysts may not be acquired, received or otherwise transferred for valuable consideration if the transfer affects interstate commerce. In addition, SCNT may not be conducted in a laboratory in which human eggs are subject to assisted reproductive technology treatments or procedures, such as in vitro fertilization for the treatment of infertility. Violation of these provisions in S. 876 and H.R. 1822 regarding ethical requirements would result in a civil penalty of not more than $250,000. S. 876 has been referred to the Senate Judiciary Committee. H.R. 1822 has been referred to the House Energy and Commerce Committee.

Supporters of a total ban on human cloning, such as that contained in H.R. 1357, argue that a partial ban on human cloning, like the one in S. 876, 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.[67] 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

---

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

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

[67] 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.

liberty."[68] 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."[69] 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. In November 2004, the UNGA "averted a divisive vote" on two international conventions against human cloning by adopting Italy's proposal "to take up the issue again as a declaration at a resumed February session."[70] "A convention is a legally binding treaty, coming into force upon ratification by a certain number of States. A declaration is not legally binding but carries moral weight because it is adopted by the international community."[71] Two convention proposals had been under consideration. One, introduced by Costa Rica and backed by the United States, aimed to proscribe all human embryonic cloning. A second proposal, introduced by Belgium, sought to proscribe only reproductive cloning. Both convention proposals were supplanted by the adoption of the Italy's proposal for a declaration. On March 8, 2005, the United Nations General Assembly (UNGA)[72] approved a nonbinding resolution urging member states to adopt legislation "to prohibit all forms of human cloning in as much as they are incompatible with human dignity and the protection of human life." The resolution passed with a vote of 84 to 34 and 37 abstentions; the United States voted for the measure.

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.[73] Under the terms of its sixth research framework program(FP6), the EU

---

[68] 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.

[69] Ibid., p. 667.

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

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

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

[73] 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.

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.[74] FP6 allows funding for research on tissue derived from "spontaneous or therapeutic abortion," but not for the creation of human embryos for the purpose of stem cell procurement.[75] 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."[76] 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."[77]

EU member states have a range of legislation on the subject. According to the European Commission, the following distinctions can be made as of July 2004:[78]

- **Allowing for the procurement of human embryonic stem cells from excess IVF embryos[79] by law under certain conditions:** Belgium, Denmark, Finland, France, Greece, the Netherlands, Spain,[80] Sweden, Switzerland,[81] and the United Kingdom.[82]

---

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

[75] Ibid.

[76] "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].

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

[78] Matthiessen-Guyader, ed., "Survey on Opinions from National Ethics Committees or Similar Bodies, Public Debate and National Legislation in Relation to Human Embryonic Stem Cell Research and Use," *European Commission, Directorate General: Research*, July 2004, at [http://www.europa.eu.int/comm/research/biosociety/pdf/mb_states_230804.pdf].

[79] The European Commission used the term "supernumerary" rather than "excess IVF" throughout their description.

[80] Spain "will initially have two ES cell research centers." "Spain to Begin ES Cell Research," *Bionews*, no. 278, Sept. 27-Oct. 3, 2004, at [http://www.bionews.org.uk/new.lasso?storyid=2292]. In October 2004, Spain's new Socialist government "made it easier for stem cell research to be undertaken" by providing a "framework for granting authorization for embryo use as well as setting out requirements for corresponding embryo studies." Xavier Bosch, "Spain Eases Embryo Research," *The Scientist*, Nov. 1, 2004, at [http://www.the-scientist.com/news/20041101/01].

[81] In November 2004, Swiss voters "endorsed legislation on stem cell research that forbids the cloning of human embryos but allows scientists to extract the cells from unwanted embryos to use in research." "Swiss Voters Back Stem Cell Research," *Los Angeles Times*, Nov. 29, 2004, A4.

[82] The UK opened "the world's first embryonic stem cell bank," in May 2004, and two months later "founded a new £16.5 million (USD $30 million) stem cell center in Cambridge ... with a commitment to fundamental research on both human embryonic and adult stem cells as a precursor to studying therapeutic applications." Philip Hunter, "UK to Open Stem

- **Allowing some research activities on excess IVF embryos, but having no specific reference to human embryonic stem cell research:** Estonia, Hungary, Latvia and Slovenia.
- **Prohibiting the procurement of human ES cells from excess IVF embryos but allowing by law for the import and use of human embryonic stem cell lines under certain conditions:** Germany. The import and use of human ES cell lines is not explicitly prohibited in, e.g., Austria and Italy.
- **Prohibiting the procurement of human ES cells from excess IVF embryos:** Austria, Ireland Lithuania, Poland and Slovak Republic.
- **No specific legislation regarding human embryo research or human ES cell research:** Czech Republic, Luxembourg, Malta, Portugal and the republic of Cyprus.
- **Allowing by law for the creation of human embryos for research purposes:** UK and Belgium are for the moment the only Member States, which allow by law for the creation of human embryos either by fertilization of an egg by a sperm, or by somatic cell nuclear transfer (SCNT, also called therapeutic cloning) for stem cell procurement. The Dutch Embryo Act of 2002 includes a five-year moratorium for the creation of embryos for research purposes including by SCNT.
- **Prohibiting the creation of human embryos for research purposes and for the procurement of stem cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on April 4, 1997:** Austria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy,[83] Ireland, Netherlands, Lithuania, Portugal, Slovak Republic, Slovenia and Spain.

Other countries' activities designed to regulate and promote stem cell research have come to the attention of Congress.[84] For example, in March 2004, the Canadian

---

Cell Center," *The Scientist*, June 22, 2004, at [http://www.the-scientist.com/news/20040622/04]. In August 2004, the UK's Human Fertilisation and Embryology Authority granted the first license to create embryonic stem cells using SCNT. "HFEA Grants the First Therapeutic Cloning License for Research" *HFEA*, Aug. 11, 2004, at [http://www.hfea.gov.uk/PressOffice/Archive/1092233888].

[83] A 2003 Italian law prohibits experiments on human embryos, the production of embryos for research purposes, and any destruction of human embryos. Guidelines for the Italian law's implementation, revealed in July 2004, have been criticized by some, and have buttressed calls "for the resignation of Health Minister, Girolamo Sirchia," a supporter of the law. The new law compels couples using IVF to transfer all fertilized embryos to the uterus (including those with genetic disorders), despite the fact that, once implanted, they could legally aborted. Criticism has also arisen due to the law's chilling effect on stem cell research. Rosella Lorsnzi, "Italian Minister in Trouble," *The Scientist*, Sept. 9, 2004, at [http://www.the-scientist.com/news/20040909/04]; Rosella Lorsnzi, "Outrage Over Italian Law," *The Scientist*, Aug. 2, 2004, at [http://www.the-scientist.com/news/20040802/03].

[84] 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.

government enacted legislation allowing stem cell and other research to be conducted on donated embryos created but no longer needed for reproductive purposes.[85] Japan allows the creation of embryos for stem cell and other research, so that its researchers can "obtain intellectual property rights based on such research."[86] Australia permits the use of spare IVF embryos for stem cell research,[87] and its government has reportedly allotted $57.9 million to its National Stem Cell Centre.[88] 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."[89] 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.[90]

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.[91] In addition, because cloning is one method of producing embryos for research, the ethical issues surrounding cloning are also relevant.

---

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

[86] "Embryo Stem Cell Research OK'd," *The Japan Times*, Feb. 14, 2004, available online at [http://search.japantimes.co.jp/print/news/nn02-2004/nn20040214b1.htm]; *See also*, "Japan Allows for Creation of Embryos for Research," *BioNews* no. 269, Jul. 26-Aug. 1, 2004, at [http://www.bionews.org.uk/new.lasso?storyid=2209].

[87] Research Involving Human Embryos Act, no. 145, 2002.

[88] "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].

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

[90] "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.

[91] For an overview of various religious perspectives on embryonic stem cell research, *see* LeRoy Walters, "Human Embryonic Stem Cell Research: An Intercultural Perspective," *Kennedy Institute of Ethics Journal*, vol. 14, no. 1 (March 2004), p. 3.

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,[92] Focus on the Family,[93] and the Christian Coalition,[94] support the 2001 Bush policy. Others, such as the National Academies,[95] the Coalition for the Advancement of Medical Research (CAMR),[96] former First Lady Nancy Reagan,[97] former Presidents Gerald Ford, Jimmy Carter, Bill Clinton,[98] and the Union of Orthodox Jewish Congregations of America (UOJCA),[99] favor more embryonic stem cell research than the Bush policy allows. Still others, such as the National Right to Life Committee[100] and the United States Conference of Catholic Bishops,[101] oppose all embryonic stem cell research.

---

[92] 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], visited July 15, 2005.

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

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

[95] 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 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].

[96] 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.

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

[98] Ibid.

[99] Letter from Harvey Blitz, President, UOJCA, *et al.*, to President George W. Bush, July 26, 2001, at [http://www.ou.org/public/statements/2001/nate34.htm], visited July 14, 2005. (Hereafter cited as UOJCA letter.)

[100] 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].

[101] 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].

Two presidential bioethics advisory panels have considered the issues involved in embryonic stem cell research. The President's Council on Bioethics (President's Council)[102] published one report directly on the topic, *Monitoring Stem Cell Research*,[103] 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),"[104] 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 biomedical research."[105] More recently, the President's Council published *Alternative Sources of Human Pluripotent Stem Cells*, a white paper exploring the ethics of four proposals to attempt to generate human embryonic stem cells "without creating, destroying, or harming human embryos."[106] A predecessor to the President's Council, the National Bioethics Advisory Committee (NBAC),[107] recommended federal funding for stem cell research using

---

[102] 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.

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

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

[105] The 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*, vol. 297, July 19, 2002, pp. 322-324.) "Wise Words from Across the Pond?," *BioNews*, no. 252, Mar. 29, 2004.

[106] The President's Council on Bioethics, *Alternative Sources of Human Pluripotent Stem Cells*, (May 2005) at [http://www.bioethics.gov/reports/white_paper/index.html], visited July 14, 2005.

[107] 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.

"embryos remaining after infertility treatments," but not for the "derivation or use of embryos ... made for research purposes."[108]

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."[109] Similarly, the United States Conference of Catholic Bishops states that the research is immoral because it "relies on the destruction of some defenseless human beings for the possible benefit to others."[110]

Some groups explore the moral standing of human embryos, and also consider the "duty to relieve the pain and suffering of others."[111] 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.[112] They also argue that viewing embryos as persons would "rule out all fertility treatments that involve the creation and discarding of excess embryos," and further assert that we do not have the same "moral or religious" response to the natural loss of embryos (through miscarriage) that we do to the death of infants.[113] Some have also rooted their arguments in religious texts, which inform them that an "isolated fertilized egg does not enjoy the full status of person-hood and its attendant

---

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

[109] 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.

[110] 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.shtml].

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

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

[113] Michael Sandel, "Embryo Ethics — The Moral Logic of Stem-Cell Research," *New England Journal of Medicine*, vol. 351, no. 3, July 15, 2004, p. 208.

protections."[114] 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 base their support on the question of whether an embryo is viable. The relevance of the viability distinction rests on the premise 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.

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.[115] 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.[116] The NBAC report touches on the moral status of embryos in utero and those in vitro,[117] though NBAC does not specify whether viability was a key rationale for its recommendations. A group of Representatives, a group of Senators,[118] 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.[119] UOJCA makes a similar argument in its letter. 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

---

[114] UOJCA letter.

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

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

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

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

[119] 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.)

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).[120] UOJCA argue similarly that they "believe it is entirely appropriate to utilize for this research existing embryos, such as those created for IVF purposes that would otherwise be discarded but for this research. We think it another matter to create embryos ab initio for the sole purpose of conducting this form of research."[121]

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.[122] Two Council members expressed a dissenting opinion in a medical journal article, arguing that SCNT "resembles a tissue culture" and that the products of SCNT should be available for research.[123] 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.[124] 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."[125] Mrs. Nancy Reagan, her supporters, and the group of Nobel Laureates also take this position.

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

---

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

[121] UOJCA letter.

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

[123] Paul McHugh, "Zygote and "Clonote" — The Ethical Use of Embryonic Stem Cells," *New England Journal of Medicine*, vol. 351, no. 3, July 15, 2004, p. 210.

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

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

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."[126] 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.[127] The same report also contains analyses of the Bush policy that characterize distinction between new and existing cell lines as "arbitrary," "unsustainable," and "inconsistent."[128] 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."[129] 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"),[130] it still recommended future development of embryonic stem cell lines. UOJCA also recognizes a distinction between new and existing lines: "research on embryonic stem cells must be conducted under careful guidelines [that] ... relate to where the embryonic stem cells to be researched upon are taken from."[131]

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

---

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

[127] Ibid.

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

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

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

[131] UOJCA letter.

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, the President's Council, and the UOJCA also favor donor consent requirements. The National Academies notes the importance of informed consent in its discussion of stem cell research oversight requirements.[132] A group of Representatives and a group of Senators mention and imply their support for donor consent requirements.[133]

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. Alternatives such as those proposed for consideration by the PCBE are discussed in the next section. 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. On a related note, some have pointed out that benefits from one alternative to embryonic stem cell research, umbilical cord blood banking, may only be available to families who can afford to pay private companies' storage fees.

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."[134] 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."[135] 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."[136] NBAC finds in its deliberations that "the claim that there are alternatives to using stem cells derived

---

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

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

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

[135] 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].

[136] 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."[137] 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."[138] Mrs. Nancy Reagan and her supporters favor expedient approaches including embryonic stem cell research.[139]

Generating Embryonic Stem Cells Without Destroying Human Embryos. As described in the introductory section of the report, the President's Council in 2005 released a white paper that discussed four potential methods of obtaining embryonic stem cells without having to destroy embryos.[140] Those methods, the scientific and practical merits of which remain far from settled, are (1) extracting cells from organismically dead embryos; (2) non-harmful biopsy of living embryos; (3) bioengineering embryo-like artifacts; and (4) dedifferentiating somatic cells.

In the white paper, the President' Council examined the ethical acceptability of each method. The first two seek to avoid the destruction of embryos either by developing standards for declaring an embryo "dead" when its cells have stopped dividing or by removing a cell from an embryo without destroying the embryo itself. The other two methods would avoid having to use an embryo altogether, by attempting to obtain embryonic stem cells through the destruction of something that is not an embryo.

The Council concluded that the use of organismically dead embryos raises a number of ethical questions that have yet to be answered. They include whether it is possible to be certain that an embryo is really dead, whether the proposal would put embryos at additional risk, and whether IVF practitioners would be encouraged to create extra embryos. Regarding the use of non-harmful biopsy, the Council found that it would be ethically unacceptable to test in humans because risks should not be imposed on living embryos destined to become children for the sake of getting stem cells for research.

The Council also concluded that bioengineering embryo-like artifacts raises many serious ethical concerns, including whether the artifact would really be a very defective embryo, the ethics of egg procurement, concerns about ANT (the use of genetic engineering) itself, and the possibility if its use creating a "slippery slope." Finally, the Council found the proposal to dedifferentiate somatic cells to be ethically

---

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

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

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

[140] The President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells*, May 2005, online at [http://www.bioethics.gov/reports/white_paper/index.html].

acceptable if and when it became scientifically practical, provided that de facto embryos were not created.

Although some Council members expressed their support for efforts to identify means of obtaining human embryonic stem cells for biomedical research that do not involve killing or harming human embryos, not all of the members agreed. Some expressed concern that all four methods would "use financial resources that would be better devoted to proposals that are likely to be more productive." One member wrote that he did not support publishing the white paper "with the implied endorsement that special efforts be made in the scientific areas described. While some of the suggestions could be explored in a scientific setting, most are high-risk options that only have an outside chance of success and raise their own complex set of ethical questions."

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.[141] They point out that embryo destruction violates the "deeply held moral beliefs of some citizens," and suggest that "funding alternative research is morally preferable."[142] 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."[143] 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."[144] 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."[145] NBAC finds the arguments in favor of federal funding more persuasive than those against it.[146] The

---

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

[142] Ibid.

[143] Ibid.

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

[145] 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].

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

National Academies, a group of Representatives, a group of Senators, Mrs. Nancy Reagan and her supporters, CAMR, the Nobel Laureates, and the UOJCA favor federal funding for embryonic stem cell research.[147]

[147] 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.