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Stem Cell Research: Ethical Issues

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Stem Cell Research: Ethical Issues

Summary

The central question before Congress in the debate over stem cell research is how to treat embryonic stem cell research (ESR), which may lead to lifesaving treatments, but which requires the destruction of embryos. The current federal policy, established by the Bush Administration in 2001, allows federal money to be used to support ESR on cell lines created: (1) with appropriate informed consent of the donors; (2) using embryos created for reproductive purposes; and (3) before the date of the policy. The third element has generated the most debate, and prompted some states to fund ESR themselves, and others to further restrict ESR.

The 110th Congress faces a range of policy options, each one prompting a set of ethical dilemmas. First, Congress could allow federal funding for ESR regardless of the date the stem cell lines were established, as proposed in S. 5, H.R. 3, and S. 997, or push back the date, as proposed in S. 362. The House passed H.R. 3 (253-174) on January 11, 2007, and the Senate passed S. 5 (63-34) on April 11, 2007 — neither with enough votes to override a presidential veto. H.R. 3 is identical to H.R. 810 (109th), which Congress passed, President Bush vetoed, and the House failed to override. Supporters assert that many frozen embryos created for in vitro fertilization (IVF) will be destroyed, and could be used for research regulated by the federal government. Critics seek to limit embryo destruction and federal funding for it. Second, Congress could do nothing, allowing the current policy to endure. (This was the effect of the failure to override the veto of H.R. 810 in the 109th Congress.) Supporters contend that the current policy balances research interests and opposition to embryo destruction. Critics for and against ESR call the date delineation ethically irrelevant, either because it stifles research or provides a monopoly to those who first destroyed embryos.

Third, Congress could fund research that may eventually generate embryonic stem cells without destroying embryos, as proposed in H.R. 322, S. 51, S. 30, S. 363, S. 997, and S. 5. The Senate passed S. 30 (70-28) on April 11, 2007. No companion bill has been introduced in the House. Supporters assert that this approach facilitates research without ethical dilemmas. Critics characterize it as unnecessary, costly, and a diversion from developing treatments. Finally, Congress could discourage ESR via tax measures (S. 457), or restrict it by adding research requirements (S. 812), banning certain cloning techniques (S. 1036), or expanding to embryos the Constitutional right to life (H.R. 618). Supporters claim that their approaches are respectful of human dignity. Critics claim that they are detrimental to many people already living.

This report, which will be updated, is one of several Congressional Research Service (CRS) reports on stem cell research. It details the ethical arguments that surround ESR. The broadest is the balance of embryo destruction and relief of human suffering. More subtle issues focus on the relative importance of the viability of embryos, the purpose of embryo creation, new versus existing cell lines, the consent of donors, the ethics of egg procurement, the effectiveness of alternatives, the possibility of generating embryonic stem cells without destroying human embryos, and the use of federal funding.

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Introduction

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

Two policies are currently in force governing embryonic stem cell research (ESR). Since FY1996, the Dickey amendment, a provision added to each year's Labor-Health and Human Services (HHS)-Education appropriations legislation, has prohibited the use of National Institutes of Health (NIH) funds for the creation of human embryos for research purposes or 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 46.204(b). This policy effectively precludes the use of federal funding to derive stem cells from embryos, which typically are produced via in vitro fertilization (IVF). However, the extracted embryonic stem cells can be used to generate embryonic stem cell lines that may continue to divide for many months to years. According to a legal opinion issued by the HHS General Council in 1999, by contrast to funding restrictions that Dickey places on the derivation of stem cells from embryos, federal funding for research performed with embryonic stem cells themselves (which does not itself involve embryos or the extraction of stem cells from embryos) is not proscribed by the Dickey amendment.[2] It is funding for research with these embryonic stem cell lines that is the subject of the second policy and of much of the current legislation before Congress.

In August 2001, President Bush announced that federal funds could be used for research on human embryonic stem cells, but only on the 22 lines that had been established as of the date of the policy, in which the embryos had been obtained with

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[1] 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.

[2] For further information about the Dickey amendment and the HHS General Council's opinion, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin Williams.

appropriate informed consent from the donors, and in which the embryos had been created for reproductive purposes.[3] Many supporters of ESR view the Bush policy — particularly its August 2001 date — as too restrictive, pointing out that the United States is lagging behind other countries in publishing ESR studies.[4] In response, 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.[5]

Instead of focusing on the policy's restrictions, many opponents of ESR caution that spending any federal money to support the research is unethical. Some point to the actions of South Korean scientist Dr. Hwang Woo Suk, whose laboratory fabricated results of stem cells extracted from cloned embryos, as reflective of a research community "more than willing to play fast and loose with the facts in order to get their way."[6] Many of those in favor of ESR assert that regulation is desirable in order to ensure that the benefits of the research are affordable by all, that they do not endanger the well-being of women who provide eggs for research, and that they are not used for socially and ethically unacceptable purposes such as eugenics.[7]

Proponents and Opponents. In the embryonic stem cell debate, the Bush Administration, a group of Representatives, a group of Senators, and a group of Nobel Laureates have each presented their respective positions on ESR. In addition, various other organizations, individuals, and councils have issued opinions and reports on the topic. Some groups, such as the Christian Legal Society,[8] Focus on the Family,[9] and the Christian Coalition[10] support the 2001 Bush policy. Others, such as

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[3] For further information, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin Williams.

[4] Tracy Hampton, "US Stem Cell Research Lagging," *Journal of the American Medical Association*, vol. 295, no. 19, May 17, 2006, p. 2233.

[5] For further information, see CRS Report RL33524, *Stem Cell Research: State Initiatives*, by Judith A. Johnson and Erin D. Williams.

[6] Wesley J. Smith, "Another Cloning Breakthrough," at [http://www.cbc-network.org/redesigned/research_display.php?id=269], visited June 2, 2006.

[7] See, e.g., Tom Paine and Richard Hayes, "Stem Cell Caution," *Center for Genetics and Society website*, May 24, 2000, at [http://www.genetics-and-society.org/resources/cgs/20060524_tompaine_hayes.html], visited July 7, 2005.

[8] 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." At [http://www.clsnet.org/clsPages/vision.php], visited July 15, 2005.

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

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

the National Academies,[11] the Coalition for the Advancement of Medical Research (CAMR),[12] former First Lady Nancy Reagan,[13] former Presidents Gerald Ford, Jimmy Carter, and Bill Clinton,[14] and the Union of Orthodox Jewish Congregations of America (UOJCA),[15] favor more ESR than the Bush policy allows. Still others, such as the National Right to Life Committee[16] and the United States Conference of Catholic Bishops,[17] oppose all ESR.

Two presidential bioethics advisory panels have considered the issues involved in ESR. The President's Council on Bioethics (President's Council)[18] published one report directly on the topic, *Monitoring Stem Cell Research*,[19] 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

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[11] The National Academies brings together "committees of experts in all areas of scientific and technological endeavor" as "advisors to the Nation." For statements on ESR and cloning, see National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001); and 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].

[12] CAMR was formed in 2001 to ensure that the voices of patients, scientists, and physicians were heard in the debate over stem cell research and the future of regenerative medicine [http://www.camradvocacy.org/about_us.aspx]; visited Jan. 18, 2007. For a statement on ESR, see Coalition for the Advancement of Medical Research, "The Promise of Embryonic Stem Cells," [http://www.camradvocacy.org/resources/The_Promise_of_Embryonic_Stem_Cells.htm], visited Jan 18, 2007.

[13] "Nancy Reagan plea on stem cells," *BBC News*, May 10, 2004, at [http://news.bbc.co.uk/2/hi/americas/3700015.stm], visited Jan. 18, 2007; Letter from Nancy Reagan to Senator Orrin Hatch, May 1, 2006, at [http://www.camradvocacy.org/resources/Nancy_Reagan.pdf], visited Jan. 18, 2007.

[14] Ibid.

[15] 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.)

[16] 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].

[17] The United States Conference of Catholic Bishops "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].

[18] 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.

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

10 and 14 days after fertilization),"[20] 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."[21] 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."[22] A predecessor to the President's Council, the National Bioethics Advisory Commission (NBAC),[23] recommended federal funding for stem cell research using "embryos remaining after infertility treatments," but not for the "derivation or use of embryos ... made for research purposes."[24]

Legislation. The new majority leadership of the 110th Congress indicated that it would address the topic of stem cell research early in the first session. S. 5 (Reid) was introduced in the Senate on January 4, 2007. A companion bill, H.R. 3 (DeGette), the Stem Cell Research Enhancement Act of 2007, was introduced the following day. It passed the House on January 11, 2007, on a vote of 253-174, which would not be enough to override a presidential veto. S. 5 passed the Senate on April 11, 2007, on a vote of 63-34, which also would not be enough to override a presidential veto. H.R. 3 and S. 5 would allow federal support of research that

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

[21] The President's Council on Bioethics, Human Cloning and Human Dignity, July 2002, pp. xxxv-xxxviii). Note: At the June 20, 2002, meeting, 9 of 17 Council members voted to support cloning for medical research purposes, without a moratorium, provided a regulatory mechanism was established. Because one member of the Council had not attended the meetings and was not voting, the vote seemed to be 9 to 8 in favor of research cloning. However, draft versions of the Council report sent to Council members on June 28, 2002, indicated that 2 of the group of 9 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.

[22] 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.

[23] 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 June 30, 2004.

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

utilizes human embryonic stem cells regardless of the date on which the stem cells were derived from a human embryo, thus negating the August 2001 Bush stem cell policy limitation. H.R. 3 and the version of S. 5 introduced in the Senate (S. 5 (IS)) were identical to legislation introduced in the 109th Congress, H.R. 810 (Castle), which passed the House and Senate but did not overcome President Bush's veto. The version of S. 5 that passed the Senate had additional provisions, which are discussed below.

Three other bills have been introduced with provisions that would allow federal funding for an expanded number of embryonic stem cell lines. The version of S. 5 that passed the Senate contains provisions like those in H.R. 3/S. 5 (IS), but would also require the HHS Secretary to conduct and support basic and applied research with stem cells that are like embryonic stem cells but are not derived from a human embryo. The bill's text is identical to the second bill, S. 997 (Harkin). The third bill, S. 362 (Coleman), would expand the number of embryonic stem cell lines available for federal funding to include any created prior to January 23, 2006.

Five bills would maintain the current Bush policy and promote or authorize the funding of alternative methods for deriving stem cells with methods that do not harm, or diminish harm, to human embryos. S. 30 (Coleman), which passed the Senate on April 11, 2007, by a vote of 70-28, would maintain the current Bush funding policy. The bill would authorize funding for and direct the HHS Secretary to (1) develop techniques for the isolation, derivation, production, or testing of stem cells that have the flexibility of embryonic stem cells, provided that such techniques do not involve the creation of a human embryo or embryos for research purposes, or the destruction or discarding of, or risk of injury to, a human embryo of embryos other than those that are naturally dead; (2) provide guidance for additional research; (3) prioritize research with the greatest potential for near-term clinical benefits; (4) take into account techniques outlined by the PCBE and any other appropriate techniques and research; (5) require assurances from grant applicants that no alteration of the timing, methods, or procedures used to create, maintain, or intervene in the development of a human embryo was made solely for the purpose of deriving the stem cells; and (6) enter into a contract with the Institute of Medicine to conduct a study to recommend an optimal structure for an amniotic and placental stem cell bank program and address pertinent issues to maximize the potential of such technology. No companion bill has been introduced in the House.

Like S. 30, S. 51 (Isakson) and H.R. 322 (Bartlett) specify that they would not alter the current federal funding policy for ESR. These bills would authorize funding for methods that do not create embryos — including via cloning — for research, destroy or discard them, or subject them to more risk than is allowable for research on fetuses. S. 363 (Coleman) contains provisions similar to S. 51/H.R. 322, and would also create a National Stem Cell Research Review Board to monitor and prioritize research, apply privacy protections promulgated under the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d) to donors,[25] and amend the National Organ Transplant Act (NOTA, 42 U.S.C. 274e) to prohibit the exchange

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[25] For further information about 42 U.S.C. 1320d, see CRS Report RS20934, *A Brief Summary of the HIPAA Medical Privacy Rule*, by Gina Marie Stevens.

of valuable consideration for a human gamete, embryo, or stem cell.[26] S. 957 (Burr) does not specify its relationship to the current ESR funding policies, but authorizes funds for the collection and maintenance of 100,000 new units of high-quality amniotic fluid and placental stem cells to be made available for treatment through the C.W. Bill Young Cell Transplantation and Treatment Program.[27]

Four additional bills propose measures that may restrict or discourage ESR. S. 812 (Hatch) would proscribe reproductive human cloning (which would not have an effect on ESR), but would also create ethical guidelines for federal funding of research cloning, thus adding additional requirements for cloning-based ESR. H.R. 457 (Paul) proposes a tax credit for individuals who store umbilical cord blood in or donate it to a facility that does not conduct ESR, thus creating an incentive to support organizations that do not engage in ESR. H.R. 618 (Hunter) would declare that the Constitutional right to life be applied to human beings at any stage of life, including from the moment of fertilization or cloning, which would presumably limit research involving embryos, including ESR. S. 1036 (Brownback) would prohibit human cloning for research and reproductive purposes, prohibit the shipment, receipt or importation of any product of cloning, and create criminal and civil penalties for violations. The bill would curtail any ESR conducted with cloning techniques.

Discussion of Ethical Issues

Detailed review of the assorted reports and statements reveals that while positions on ESR 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 ESR 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 ESR 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."[28] Similarly, the United States

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[26] For further information about 42 U.S.C. 274e and valuable consideration, see CRS Report RL33902, *Living Organ Donation and Valuable Consideration*, by Erin D. Williams, Bernice Reyes-Akinbileje, and Kathleen S. Swendiman.

[27] P.L 109-129 required the HHS Secretary to establish the C.W. Bill Young Cell Transplantation and Treatment Program, which consists of a new cord blood stem cell initiative, and adds program requirements with respect to bone marrow donation, among other things.

[28] American Life League, *The Bush Stem Cell Decision*, 2001, at [http://www.all.org/article.

(continued...)

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."[29] None of the bills proposed in the 110th Congress would completely prohibit funding for ESR or make the practice illegal. The bill that comes the closest to this in its effect is H.R. 618, which would endow embryos with the Constitutional right to life from the moment of fertilization/cloning. S. 1036 would curtail some ESR by banning human cloning techniques, including those used solely for research purposes. The Dickey amendment, a provision added to each year's Labor-HHS-Education appropriations legislation since FY1996, has prohibited the use of National Institutes of Health funds for research on embryos.

Some groups explore the moral standing of human embryos, and also consider the "duty to relieve the pain and suffering of others."[30] 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.[31] 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.[32] 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 protections."[33] 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. None of the bills proposed in the 110th Congress would end the Dickey Amendment's ban on the use of federal funds for research involving the destruction of human embryos. H.R. 3, S. 5, and S. 997 would expand the group of stem cell lines eligible for federal funding by removing the date restriction imposed by President Bush. S. 362 expands the group of stem cell lines eligible for federal funding by permitting ESR with lines created before January 16, 2006.

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[28] (...continued)
php?id=10746&search=2001], visited Jan. 18, 2007.

[29] 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].

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

[31] Presentation by B. Steinbock, Department of Philosophy, SUNY, Albany, NY, NIH Human Embryo Research Panel Meeting, Feb. 3, 1994.

[32] 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.

[33] UOJCA letter.

Viability of Embryos

Some proponents of ESR 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 stem cells derived from 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.[34] 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.[35] The NBAC report touches on the moral status of embryos in utero and those in vitro,[36] though NBAC does not specify whether viability was a key rationale for its recommendations. A group of Representatives,[37] a group of Senators,[38] 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.[39] 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. H.R. 3, S. 5, and S. 997 imply a distinction based on viability, proposing that federal funding be available only for ESR on lines derived from excess embryos. S. 812 also implies such a distinction by proposing a prohibition on implanting the product of nuclear transplantation into a uterus or the functional equivalent of a uterus, which would ensure that the product remains non-viable.

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

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

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

[37] Letter from 206 Members of the House of Representatives to President George W. Bush, Apr. 28, 2004, at [http://www.house.gov/degette/news/releases/040428.pdf]. (Hereafter cited as Letter from 206 Members of the House of Representatives.)

[38] Letter from 58 Senators to President George W. Bush, June 7, 2004, at [http://feinstein.senate.gov/04Releases/r-stemcell-ltr.pdf]. (Hereafter cited as Letter from 58 Senators.)

[39] International Society for Stem Cell Research, "Alternative Methods of Producing Stem Cells: No Substitute for Embryonic Stem Cell Research," *Press Release*, (Aug. 2, 2005), at [http://www.isscr.org/press_releases/camr_alternatives.htm], visited April 10, 2007.

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. Others worry that moral lines will erode quickly — from using only "spare" embryos left over in fertility clinics to creating human embryos solely for research to creating (or trying to create) cloned embryos solely for research.[40]

Most groups at least note the potential ethical significance of reproductive versus research motives for creating embryos. The 2001 Bush policy draws a motive distinction by including a requirement that federally funded research be conducted only on embryonic stem cell lines derived from embryos created solely for reproductive purposes. NBAC draws the same distinction by recommending that federal funding be used for embryos remaining after infertility treatment but not for research involving the derivation or use of stem cells from embryos made for research purposes or from cloned embryos produced by somatic cell nuclear transfer (SCNT).[41] 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."[42]

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.[43] 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.[44] 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

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[40] See, e.g., Eric Cohen and Robert George, "Stem Cells Without Moral Corruption: Congress Can Give Research a Boost Without Supporting the Misuse of Human Embryos," *Washington Post*, July 6, 2006, p. A21.

[41] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, pp. 70-72. In SCNT the nucleus of an egg is removed and replaced by the nucleus from a mature body cell, such as a skin cell obtained from a patient. In 1996, scientists in Scotland used the SCNT procedure to produce Dolly the sheep, the first mammalian clone.

[42] UOJCA letter.

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

[44] 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.

developed for IVF and make no mention of embryos created expressly for research.[45] 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."[46] Mrs. Nancy Reagan, her supporters, and the group of Nobel Laureates also take this position. H.R. 3, S. 5, and S. 997 draw a distinction based on the purpose of embryo creation by proposing that federal funding be available only for ESR on lines derived from embryos created for individuals seeking fertility treatments. S. 812 implies a similar distinction based upon purpose by proposing a prohibition on the creation of embryos via cloning for reproductive purposes, but not for therapeutic ones. S. 1036 would prohibit all human cloning, regardless of its purpose.

New and Existing Cell Lines

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

This was one central distinction drawn in the 2001 Bush policy, which limited the use of federal funding to research on lines derived on or before the date of the policy. Supporters of the Bush policy on both sides of the issue favor this distinction as a compromise. It allows research on some embryonic stem cell lines. It deters the future destruction of embryos for research. The President's Council writes that the Bush policy mixes "prudence" with "principle, in the hope that the two might reinforce (rather than undermine) each other."[47] 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.[48] The same report also contains analyses of the Bush policy that characterize distinction between new and existing cell lines as "arbitrary," "unsustainable," and "inconsistent."[49] 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

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

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

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

[48] Ibid.

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

Bishops, objects because the distinction validates destruction of embryos, and 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[50] and are "contaminated with mouse feeder cells."[51] 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"),[52] 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."[53] S. 362 draws a distinction based upon the timing by permitting funding for research with lines created before January 16, 2006. S. 51, S. 363, and S. 30 also draw a distinction based on timing by specifying that they would not amend the current guidelines for federal funding, which only fund lines created before the August 2001. S. 975, S. 812, and S. 1036 imply a distinction based on timing in that they make no mention of, and thus presumably would not alter the current federal funding guidelines.

Consent of Donors

There is consensus throughout a wide array of viewpoints about ESR 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, which may, in fact, be complicated by conflicting studies regarding the long-term health effects of egg donation.[54] 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 potential drawback of the requirement is that it may restrict the number of embryos available for research purposes.

The 2001 Bush policy contains a donor consent requirement. It limits approved stem cell lines to those derived with the informed consent of the donors, and obtained

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[50] Bridget M. Kuehn, "Genetic Flaws Found in Aging Stem Cell Lines," *Journal of the American Medical Association*, vol. 294, no. 15 (October 2005), p. 1883.

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

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

[53] UOJCA letter.

[54] Kathy Hudson, "International Society for Stem Cell Research Draft Guidelines," *Genetics & Public Policy Center ENews*, Issue 10 (Jul. 2006), available online at [http://www.dnapolicy.org/news.enews.article.nocategory.php?action=detail&newsletter_id=13&article_id=31].

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.[55] A group of Representatives and a group of Senators mention and imply their support for donor consent requirements.[56] H.R. 3, S. 5, S. 997, S. 363, S, 957, and S. 812 all contain specific consent provisions. S. 51/H.R. 322 and S. 30 would maintain the current federal funding policy for ESR, which contains consent provisions. Consent is one NIH funding requirement.

Egg Procurement. The topic of informed consent in egg procurement came to the public's attention in November 2005 with allegations that some human eggs used in South Korean scientist Dr. Hwang's laboratory had been obtained under coercive conditions. Informed consent can be undermined when a coercive situation prevents a free choice from being made, or when insufficient information is provided to the person making a decision. The situation alleged in Dr. Hwang's laboratory raises the issue of coercion both because subordinate women in the laboratory allegedly donated eggs, and because some women were allegedly paid for their eggs. A 2002 study conducted by a University of Pennsylvania student raised the issue of insufficient information, finding that a number of programs seeking donor eggs for reproductive purposes downplayed the risks involved in egg retrieval.[57] The wide consensus regarding the need for informed consent necessarily implies similar consensus on the need for an information-rich, coercion-free method of obtaining eggs, however there is some disagreement on the specifics of whether payment for eggs necessarily constitutes coercion.

Paying women for their eggs, which has been debated in the context of seeking donor eggs both for reproductive purposes (for example, to enable women who do not produce their own eggs to become pregnant), and for research purposes, is not unheard of in the United States. According to a 2000 study by the American Society of Reproductive Medicine (ASRM), some IVF programs reportedly offered as much as $5,000 for one egg retrieval cycle, though $2,500 appeared to be a more common amount.[58] Offers of much higher amounts ($50,000-$100,000) have been reported elsewhere.[59] Dr. Huang's laboratory reportedly made payments of $1,400 to each woman who donated eggs.[60] Payments are not illegal in the Unites States, nor were they illegal in South Korea at the time Dr. Huang's laboratory allegedly made them.

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

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

[57] "Egg Donation Ethics Study Wins Award," *Research at Penn*, (Mar. 7, 2005), at [http://www.upenn.edu/researchatpenn/article.php?113&soc], visited Dec. 5, 2005.

[58] American Society of Reproductive Medicine, "Financial Incentives in Recruitment of Oocyte Donors," *Fertility and Sterility*, vol. 74, no. 2 (August 2000), p. 216.

[59] See e.g., "Egg Donation Ethics Study Wins Award," *Research at Penn*, (Mar. 7, 2005), at [http://www.upenn.edu/researchatpenn/article.php?113&soc], visited Dec. 5, 2005.

[60] James Brooke, "Korean Leaves Cloning Center in Ethics Furor," Professional Ethics website (Nov. 25, 2005), at [http://ethics.tamucc.edu/article.pl?sid=05/11/26/1524206&mode=thread] visited Dec. 12, 2005.

The questions are, is payment for egg donation ever acceptable, and if so, what amount is appropriate?

Several arguments have been put forth in favor of payment for egg donation, many focused on donation for reproductive purposes.[61] First, some have argued that payment creates incentives to increase the number of egg donors, thus facilitating research and benefitting infertile couples. Second, some reason that payment for eggs gives women parity with sperm donors, who may be compensated for donating gametes at a lower rate given that they require a much less involved procedure. In addition, some argue that participants should be offered an amount commensurate with the time, inconvenience, discomfort, and risks of the procedure, as is the general practice in biomedical research.[62] Third, some allege that fairness dictates that women who donate eggs ought to be able to benefit from their action. Fourth, some claim that pressures created by financial incentives may be no greater than those experienced by women asked to make altruistic egg donations for relatives or friends, and may thus not rise to the level of coercion. These are the types of arguments that led ASRM to recommend in 2000 that sums of up to $5,000 may be appropriate for typical egg donation, while sums of up to $10,000 may possibly be justified if there are particular difficulties a woman must endure to make her donation.

Several arguments have also been put forth against payment for egg donation. First, some voiced fears that payment might lead to the exploitation of women, particularly poor women, and the commodification of reproductive tissues.[63] Second, some have argued that payment for eggs for research purposes might undermine public confidence in endeavors such as human ESR.[64] Arguments such as these have prompted both the National Academies and the President's Council to recommend that women not be paid for donating their eggs for research purposes. It also led the President's Council to note that in theory, there is the possibility that eggs could be procured from ovaries harvested from cadavers, which might at least alleviate concerns related to coercion.

It is worth noting that a woman may choose to undergo egg retrieval for her own reproductive purposes, which would effectively take the process of egg procurement

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[61] Unless otherwise noted, these arguments can be found, among other places, at American Society of Reproductive Medicine, "Financial incentives in recruitment of oocyte donors," *Fertility and Sterility*, vol. 74, no. 2 (August 2000), p. 218; and Claudia Kalb, "Ethics, Eggs and Embryos," *MSNBC.com, Newsweek website*, at [http://www.msnbc.msn.com/id/8185339/site/newsweek/], visited Dec. 12, 2005.

[62] Kathy Hudson, "International Society for Stem Cell Research Draft Guidelines," *Genetics & Public Policy Center ENews*, Issue 10 (Jul. 2006), available online at [http://www.dnapolicy.org/news.enews.article.nocategory.php?action=detail&newsletter_id=13&article_id=31].

[63] See e.g., President's Council on Bioethics, *White Paper: Alternative Sources of Pluripotent Stem Cells* (May 2005), pp. 40-41 at [http://www.bioethics.gov/reports/white_paper/index.html], visited Dec. 12, 2005.

[64] National Academies, *Guidelines for Human Embryonic Stem Cell Research*, (Washington, DC: National Academies Press, p. 87, at [http://books.nap.edu/books/0309096537/html/87.html], visited, Dec. 12, 2005.

out of the research arena and avoids the question of payment entirely. (For example, this could be an option for a woman seeking IVF because her fallopian tubes are blocked). While not making specific recommendations about payment for research-related egg donation, several groups' recommendations that only embryos left over from IVF procedures be used for stem cell research (noted above in the *Purpose of Embryo Creation* section) effectively takes the process of egg procurement from women out of the research arena. The Bush policy keeps the consent process for egg retrieval separate from donation by funding research only on lines derived from embryos originally created for fertility treatments. H.R. 3, S. 5, and S. 997 contain a provision to do the same.

S. 363 would amend NOTA to prohibit the exchange of valuable consideration for the acquisition, receipt, or other transfer of human oocytes or unfertilized blastocysts. NOTA's definition of valuable consideration does not include the reasonable payments associated with the removal, transplantation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation. S. 812 would prohibit the acquisition, receipt, or other transfer of a human oocyte or unfertilized blastocyst for valuable consideration if the transfer affects interstate commerce. The bill's definition of valuable consideration does not include reasonable payments associated with the transportation, processing, preservation, or storage of a human oocyte or of the product of nuclear transplantation research, or to compensate a donor of one or more human oocytes for the time or inconvenience associated with such a donation.

Effectiveness of Alternatives

One factual distinction that has been used to support competing ethical viewpoints is the efficacy of alternatives to ESR. The promise of stem cell therapies derived from adult tissue and umbilical cord blood have buttressed opposition to ESR. A January 2007 report that stem cells similar to embryonic stem cells can be found in amniotic fluid may do the same, although the lead scientist conducting research on the amniotic cells and others have stated that amniotic cells will not make embryonic stem cells irrelevant.[65] Alternatives such as those proposed for consideration by the President's Council are discussed in the next section. Some opponents of the current method of obtaining embryonic stem cells argue that therapies and cures can be developed without the morally undesirable destruction of embryos.

Not all scientists agree that adult stem cells hold as much potential as embryonic stem cells. Notably, during a congressional subcommittee hearing, when the NIH Director, Dr. Elias Zerhouni, was asked if other avenues of research should be pursued instead, he stated that "the presentations about adult stem cells holding as much or more potential than embryonic stem cells, in my view, do not hold scientific

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[65] Rick Weiss, "Scientists See Potential In Amniotic Stem Cells," *Washington Post*, Jan. 8, 2007, p. A1, at [http://www.washingtonpost.com/wp-dyn/content/article/2007/01/07/AR2007010700674.html], visited Jan 8, 2007.

water. I think they are overstated."[66] Most supporters of ESR 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 ESR, 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 ESR are mixed. The President's Council notes that there is a "debate about the relative merits of embryonic stem cells and adult stem cells."[67] 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."[68] 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."[69] NBAC finds in its deliberations that "the claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically."[70] 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."[71] Mrs. Nancy Reagan and her supporters favor expedient approaches including ESR.[72]

Several pieces of legislation have supported the development of stem cells from sources other than embryos. For each of fiscal years 2004 through 2006, Congress allocated money in the HHS appropriations for the establishment and continuation of a National Cord Blood Stem Cell Bank within the Health Resources and Services Administration. In 2005, the 109th Congress passed H.R. 2520 (P.L. 109-129) for the

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[66] Dr. Elias Zerhouni's answer to a question during the "Fiscal 2008 budget for the National Institutes of Health," *Hearing of the U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies* (March 19, 2007).

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

[68] 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].

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

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

[71] Coalition for the Advancement of Medical Research, "The Promise of Embryonic Stem Cells," at [http://www.camradvocacy.org/resources/The_Promise_of_Embryonic_Stem_Cells.htm], visited Jan. 18, 2007.

[72] "Nancy Reagan plea on stem cells," *BBC News*, May 10, 2004, at [http://news.bbc.co.uk/2/hi/americas/3700015.stm], visited Jan. 18, 2007; Letter from Nancy Reagan to Senator Orrin Hatch, May 1, 2006, at [http://www.camradvocacy.org/resources/Nancy_Reagan.pdf], visited Jan. 18, 2007.

collection and maintenance of human cord blood stem cells for the treatment of patients and for research. S. 997, S. 5, S. 51, H.R. 322, S. 363, and S. 30 would authorize funding for research to attempt to generate pluripotent stem cells without involving human embryos. S. 957 would authorize funding for the collection and maintenance of amniotic fluid and placental cells, both of which can generate non-embryonic stem cells.

Generating Embryonic Stem Cells Without Destroying Human Embryos. One possible alternative to ESR as it has typically been conducted, the ability to generate embryonic stem cells without destroying human embryos, was explored by the President's Council in its 2005 white paper,[73] described in the introductory section of this report. The white paper discusses four potential methods of obtaining embryonic stem cells without having to destroy embryos. 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.[74]

In the white paper, the President's 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. A September 2006 report that a team based in Serbia and England had derived stem cells from "dead" embryos prompted precisely these types of questions, as well some regarding whether the stem cells might carry some defect that had made the embryos non-viable.[75]

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. This same response was prompted by an August 2006 report in the journal *Nature* that a California company had used the non-harmful biopsy method to derive

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[73] 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].

[74] For more information, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight,* by Judith A. Johnson and Erin D. Williams.

[75] See, e.g., Rick Weiss "Researchers Report Growing Stem Cells From Dead Embryos," *Washington Post*, Sep. 23, 2006, p. A03, available online at [http://www.washingtonpost.com/wp-dyn/content/article/2006/09/22/AR2006092201377.html].

stem cells.[76] In addition, the technique was criticized on one side for effectively "creating a twin and then killing that twin,"[77] and on the other for being an inefficient method for deriving stem cell lines.[78] In November 2006, *Nature* issued an addendum to the August article to clarify that, while the company's lead scientist maintained that his method could be used to derive stem cells without destroying embryos, in fact, he had destroyed all of the embryos during his own experiments.[79]

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 the use of genetic engineering itself, and the possibility of its use creating a "slippery slope." Finally, the Council found the proposal to dedifferentiate somatic cells to be ethically 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."

S. 997, S. 5, S. 51, H.R. 322, S. 363, and S. 30 each specify that the HHS Secretary should consider the techniques outlined by the President's Council, and fund attempts to generate sources of pluripotent stem cell therapies that were not derived from human embryos.

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[76] See e.g., Nicholas Wade, "Stem Cell News Could Intensify Political Debate," *New York Times*, August 24, 2006, available online at [http://www.nytimes.com/2006/08/24/science/24stem.html?ex=1164862800&en=1d51ef92cddc3e82&ei=5070].

[77] Ibid.

[78] See e.g., Josephine Quintavalle, "The Lanza Protocol: Damned With Very Faint Praise," *BioNews*, vol. 373, (Aug. 22-28, 2006), available online at [http://www.bionews.org.uk/commentary.lasso?storyid=3157].

[79] Robert Laza et al., "Human Embryonic Stem Cell Lines Derived from Single Blastomeres," *Nature*, vol. 444, p. 481 (Nov. 23, 2006), available online at [http://www.nature.com/nature/journal/v444/n7118/full/nature05366.html].

Use of Federal Funding

Some division over the support for and opposition to ESR 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.[80] They point out that embryo destruction violates the "deeply held moral beliefs of some citizens," and suggest that "funding alternative research is morally preferable."[81] 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."[82] 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. Requirements attached to federal funding are one traditional mechanism that Congress has used to regulate scientific research that might otherwise be conducted without federal oversight.[83]

Groups' positions on federal funding tend to mirror their positions on stem cell research generally. The Bush policy authorizes federal funding for some ESR. 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."[84] Focus on the Family generally supports President Bush and his policy, but is "disappointed by his decision to allow federal funding of research on the existing stem cell lines."[85] NBAC finds the arguments in favor of federal funding more persuasive than those against it.[86] The 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 ESR.[87]

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

[81] Ibid.

[82] Ibid.

[83] For further information about Congressional regulation of research involving human subjects, see CRS Report RL32909, *Federal Protection for Human Research Subjects: An Analysis of the Common Rule and Its Interactions with FDA Regulations and the HIPAA Privacy Rule*, by Erin D. Williams.

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

[85] 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].

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

[87] See, e.g., National Research Council, Institute of Medicine, National Academies, *Stem*

(continued...)

Several pieces of legislation would use federal funding to add ethical requirements to the conduct of ESR. While the Bush policy does contain some ethical requirements regarding the creation of stem cell lines eligible for federal funding, those requirements would serve only to evaluate researchers' previous activities, not to influence their future ones. This is because researchers who created stem cell lines before the policy took effect could not have been influenced by its ethical constraints regarding the derivation of stem cells from embryos, as the policy did not yet exist. Researchers who created stem cell lines after the policy took effect would not be motivated to follow the Bush policy's ethical guidelines regarding the creation of stem cell lines, because the results of their work would be ineligible for federal funding regardless of their methodology.

S. 51, H.R. 322, S. 363, S. 812, and S. 30 would maintain the current federal funding policy, and thus have the same limitations as the Bush policy on the scope of research they regulate. Likewise, S. 362 — which contains a cutoff date for the establishment of embryonic stem cell lines eligible for funding (January 16, 2006) that is later than the Bush policy date but earlier than the introduction of the bill — would have a parallel limitation. However, several of these bills authorize funding to develop alternatives to ESR and attach ethical requirements to funding for research in those areas. By contrast to the Bush policy and the bills that would maintain it, H.R. 3, S. 5, and S. 997 would allow federal funding of ESR regardless of the date on which the lines were established, and would thus enable federal regulations to have an impact on the way in which future stem cell lines were established.

[87] (...continued)
Cells and the Future of Regenerative Medicine (Washington: National Academies, 2001), p. 49.