



Stem Cell Research: Ethical Issues

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Summary

The central question before Congress in the debate over human stem cell research is how to treat human embryonic stem cell research (ESR), which may lead to lifesaving treatments, but which requires the destruction of embryos. Current federal law and policy address this question primarily through restrictions on federal funding for ESR. The Dickey amendment prohibits the use of Department of Health Human Services (HHS) 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 certain risks of injury or death. It thus prohibits the use of HHS funds to establish ES lines (line establishment involves embryo destruction), but not to conduct research using established lines. President Obama established current federal ESR policy with a March 9, 2009, executive order: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells* (Obama policy). The Obama policy authorizes HHS's National Institutes of Health (NIH) to support and conduct responsible, scientifically worthy human stem cell research, including ESR, to the extent permitted by law. As required by the order, the NIH issued *Draft National Institutes of Health Guidelines for Human Stem Cell Research* (NIH draft guidelines). These generally permit funding for research (1) with ES lines established from embryos that are created for reproductive purposes, and obtained with without inducement and with donor consent, and (2) for research that is properly documented, and that involves neither embryos created via cloning or parthenogenesis, nor specified techniques involving non-human biological materials.

Congress has several sets of policy options, each one prompting a set of ethical dilemmas. The first set of options involves permitting or expanding federal ESR funding, as proposed in H.R. 872, H.R. 873, and S. 487. One such option is to take no action, allowing the Obama policy to persist. This option would permit federal funding for ESR with a range of lines, and would allow the executive branch to change the ESR policy in the future. Another such option is to enact a law permitting ESR. Even if consistent with the Obama policy, this course would limit the opportunity for the executive branch to change the policy in the future. A final such option involves expanding ESR by eliminating the Dickey amendment, thus allowing the use of federal funds for the establishment of ES lines, and/or for the creation of embryos for ESR. Some supporters of this set of options assert that unused frozen embryos that are created for in vitro fertilization (IVF) could be used for federally regulated research instead of being destroyed. Other supporters seek federally regulated and funded research on embryos created specifically for research purposes, which might help to facilitate more targeted research. Critics seek to protect embryos and/or egg donors, and assert that federal funds should not be used for such purposes.

Congress's second set of options involves funding additional research that may eventually generate embryonic stem cells without destroying embryos, as proposed in H.R. 877. Supporters assert that this facilitates research without ethical dilemmas. Critics characterize it as unnecessary, costly, and a diversion from developing treatments. Congress's third set of options involves discouraging ESR via tax measures, or limiting or eliminating it by restricting research funding, banning certain cloning techniques, or giving embryos the Constitutional right to life. Examples include H.R. 110, H.R. 227, H.R. 881, H.R. 1050, H.R. 1654, S. 99, and S. 346. Supporters claim their approaches respect human dignity; critics claim they harm people already living.

This report, which will be updated, is one of several 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

Human 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 human stem cells, such as those derived from adult tissues and umbilical cord blood, has been 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.

Current Policy

Federal regulation of ESR primarily consists of one law, one policy, and one set of regulations: the Dickey amendment, the Obama policy, and NIH draft guidelines, respectively.² Each of these addresses the use of federal funding to support ESR. None of these restricts or regulates ESR conducted solely with private, local and/or state government funding, or with funding from other non-federal sources. The Dickey Amendment, the Obama policy, the NIH draft guidelines, and also the previous policy, which had been established by the George W. Bush Administration, are discussed below.

The Dickey Amendment

Since FY1996, the Dickey amendment, a provision added to each year's Labor-Health and Human Services-Education appropriations legislation, has prohibited the use of HHS 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.³ It is funding for research with these embryonic stem cell lines that is the subject of the Obama policy and of much of the current legislation before Congress.

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, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams.

³ 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 D. Williams.

The Obama Policy

The Obama policy took effect on March 9, 2009, in the form of an executive order.⁴ In the executive order, President Barack Obama authorized the HHS Secretary, including the NIH, to support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. The executive order also directed the NIH to review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with the executive order within 120 days (by early July 2009). On the same day that the executive order was issued, President Obama issued a memorandum on scientific integrity directing the head of the White House Office of Science and Technology Policy “to develop a strategy for restoring scientific integrity to government decision making.”⁵

NIH Draft Guidelines

Pursuant to the Obama policy, in April 2009, NIH issued its draft guidelines (Draft National Institutes of Health Guidelines for Human Stem Cell Research), specifying the requirements to receive federal funding for ESR.⁶ NIH is accepting written comments on its draft guidelines through May 26, 2009.

According to the NIH draft guidelines, ES may be used in research using NIH funds if the cells were derived from donated human embryos created for reproductive purposes. The NIH draft guidelines also require documentation ensuring that (1) options pertaining to use of embryos were explained to the potential donor(s); (2) donors were not offered inducements for making donations; (3) facilities where embryos were donated had policies stating that neither consent nor refusal consent would affect donors’ quality of care; (4) there was a clear separation between the decisions to create and donate embryos; (5) decisions to create embryos were made free from the influence of ES researchers; and (6) donors consented to the donation at the time of donation and signed consent forms that included specified criteria.

In addition to the requirements, the draft policy also prohibits the use of NIH funds in certain circumstances. These include the following: (1) ESR in which human embryonic stem cells or human induced pluripotent stem cells are introduced into non-human primate blastocysts; (2) research involving the breeding of animals where the introduction of human embryonic stem cells or human induced pluripotent stem cells may have contributed to the germ line; (3) NIH funding of the derivation of stem cells from human embryos, as prohibited by the Dickey Amendment; and (4) NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes.

⁴ “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,” March 9, 2009, at http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/.

⁵ The White House, Office of the Press Secretary, Remarks of President Barack Obama-As Prepared for Delivery, Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum, March 9, 2009, at http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/.

⁶ Raynard Kington, M.D., Ph.D., Acting Director, NIH, *Draft National Institutes of Health Guidelines for Human Stem Cell Research*, NIH, April 2009, <http://stemcells.nih.gov/policy/2009draft>.

Historical Note: The Bush Policy

Prior to the Obama policy, ESR had been regulated by the policy that President George W. Bush had established in August 2001 (Bush policy). The Bush policy had, for the first time, allowed federal money to be used to support ESR. It had also restricted that funding to research using ES 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. This date restriction was the most controversial component of the Bush policy. President Bush had later issued a companion policy in the form of *Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways* (E.O. 13435), which had directed the NIH to fund research on sources of pluripotent stem cells that did not involve the destruction of embryos.⁷ President Bush had issued E.O. 13435 on June 20, 2007, which was the same day that he vetoed a bill to expand federal funding for ESR (S. 5, 110th).

The Obama policy reversed the Bush policy, and also revoked E.O. 13435. The Obama policy thus allowed for the possibility of federal funding for ESR using many more stem cell lines than were previously eligible. While the Obama policy did not mandate funding for alternatives to ESR, it specifically authorized support for non-embryonic as well as embryonic stem cell research.

Legislation

Since ESR emerged bringing hope for medical cures and fears about ethical implications, a number of bills have been introduced that touch upon the subject. Enactment of any of these bills, even if consistent with the current executive policy, would limit or eliminate the opportunity for the executive branch to set the ESR policy in the future.

One set of bills would enact into law the authority to expend federal funds on ESR. Some of these bills were introduced prior to the Obama policy, and include restrictions greater than of those Obama policy. For example, some bills require that embryos used in federally funded ESR have been created for reproductive purposes, and/or that there have been no financial inducements made to embryo donors. However, none of these bills contains the August 2001 date restriction that had been imposed by the Bush policy. Examples of these bills in the 111th Congress include H.R. 872, H.R. 873, and S. 487.

A second set of bills would create incentives for activities that avoid ESR. Some of these bills would require federal support or tax benefits for research or activities that avoid damaging embryos. Others would create additional oversight for the conduct of ESR. Still others would create a bank of non-embryonic stem cells from amniotic fluid and placentas. Examples of these bills in the 111th Congress include H.R. 877, S. 99, and H.R. 1654.

A third set of bills would further restrict or prohibit ESR. Some would accomplish this through legislation placing the language of the Dickey amendment in statute, and/or extending it by prohibiting federal funding using stem cells derived in violation of the other restrictions. Others would allow funding only in very specific circumstances, such as when using techniques with non-living embryos created for reproductive purposes. Still others would amend other law (such

⁷ George W. Bush, Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways, June 20, 2007, at <http://www.whitehouse.gov/news/releases/2007/06/20070620-6.html>.

as that governing the right to life, organ transplantation,⁸ cloning, or the creation of animal-human hybrids) to prohibit ESR or restrict some aspect its conduct. Examples of such bills in the 111th Congress include H.R. 110, H.R. 227, H.R. 881, H.R. 1050, and S. 346.

Along with the policy options articulated in the above bills, Congress has additional options that have been discussed in various forums. One of these is eliminating the Dickey amendment, thus allowing the use of federal funds for the establishment of ES lines, and/or for the creation of embryos for ESR. Another is to take no action, thus allowing the Obama policy to persist. This option would permit federal funding for ESR with a range of lines, and would allow the executive branch some latitude to change the ESR policy in the future.

Proponents and Opponents

In the ES debate, the Obama Administration, George W. Bush Administration (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 National Academies,⁹ the Coalition for the Advancement of Medical Research (CAMR),¹⁰ former First Lady Nancy Reagan,¹¹ former Presidents Gerald Ford, Jimmy Carter, and Bill Clinton,¹² and the Union of Orthodox Jewish Congregations of America (UOJCA),¹³ favor federal support ESR that is generally keeping with the Obama policy. Other groups, such as the Christian Legal Society,¹⁴ Focus on the Family,¹⁵ and the Christian Coalition¹⁶ favor restrictions on ESR, and had

⁸For 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.

⁹ 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>.

¹⁰ 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 January 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.

¹¹ “Nancy Reagan plea on stem cells,” *BBC News*, May 10, 2004, at <http://news.bbc.co.uk/2/hi/americas/3700015.stm>, visited January 18, 2007; Letter from Nancy Reagan to Senator Orrin Hatch, May 1, 2006, at http://www.camradvocacy.org/resources/Nancy_Reagan.pdf, visited January 18, 2007.

¹² Ibid.

¹³ 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.)

¹⁴ 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.

¹⁵ *Focus on the Family* was founded in 1977 by Dr. James Dobson to promote the teachings of Jesus Christ. See <http://www.family.org>.

¹⁶ The Christian Coalition is “the largest and most active conservative grassroots political organization in America,” at <http://www.cc.org>.

supported the Bush policy. Still others, such as the National Right to Life Committee¹⁷ and the United States Conference of Catholic Bishops,¹⁸ oppose all ESR.

Two presidential bioethics advisory panels have considered the issues involved in ESR. The President's Council on Bioethics (President's Council)¹⁹ published one report directly on the topic, *Monitoring Stem Cell Research*,²⁰ 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),"²¹ 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."²² 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."²³ A predecessor to the President's Council, the National Bioethics Advisory Commission (NBAC),²⁴ 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."²⁵

¹⁷ 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>.

¹⁸ 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.usccb.org/whoweare.shtml>.

¹⁹ The *President's Council* was created by President Bush in November 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, November 28, 2001.

²⁰ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004.

²¹ The President's Council on Bioethics, *Reproduction and Responsibility*, March 2004, p. xlvi.

²² 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, March 29, 2004.

²³ 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.

²⁴ 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.

²⁵ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, pp. 70-71.

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."²⁶ 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."²⁷

Some groups explore the moral standing of human embryos, and also consider the "duty to relieve the pain and suffering of others."²⁸ 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.²⁹ 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.³⁰ 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."³¹ 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-ESR opinions—including those of the Bush and Obama Administrations—and is usually modified with some combination of the distinctions and limitations that follow.

²⁶ American Life League, *The Bush Stem Cell Decision*, 2001, at <http://www.all.org/article.php?id=10746&search=2001>, visited January 18, 2007.

²⁷ Office of Communications, United States Conference of Catholic Bishops, *Catholic Bishops Criticize Bush Policy on Embryo Research* (August 9, 2001), at <http://www.usccb.org/comm/archives/2001/01-142.shtml>.

²⁸ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, pp. 58, 62.

²⁹ Presentation by B. Steinbock, Department of Philosophy, SUNY, Albany, NY, NIH Human Embryo Research Panel Meeting, February 3, 1994.

³⁰ 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.

³¹ 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 Obama policy does not reference the viability of embryos, but the NIH draft guidelines require that only ESR on embryos no longer needed for reproductive purposes (and thus in one sense, not viable) be used in federally funded research. In a similar manner, the Bush policy had referenced viability, requiring, among other things, use of stem cells derived from only excess 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.³² 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.³³ The NBAC report touches on the moral status of embryos in utero and those in vitro,³⁴ though NBAC does not specify whether viability was a key rationale for its recommendations. A group of Representatives,³⁵ a group of Senators,³⁶ 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.³⁷ 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. 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.³⁸

³² The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, p. 87.

³³ The President's Council on Bioethics, *Reproduction and Responsibility*, March 2004.

³⁴ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 50.

³⁵ Letter from 206 Members of the House of Representatives to President George W. Bush, April 28, 2004, at <http://www.house.gov/degette/news/releases/040428.pdf>. (Hereafter cited as Letter from 206 Members of the House of Representatives.)

³⁶ 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.)

³⁷ International Society for Stem Cell Research, "Alternative Methods of Producing Stem Cells: No Substitute for Embryonic Stem Cell Research," *Press Release*, (August 2, 2005), at http://www.isscr.org/press_releases/camr_alternatives.htm, visited April 10, 2007.

³⁸ 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.

As is the case regarding embryo viability, the Obama policy does not reference the purpose of embryo creation. However, the NIH draft guidelines require that embryos have been created for reproductive purposes to receive federal funding, and they also require documentation to assure that this was the case. Most groups at least note the potential ethical significance of reproductive versus research motives for creating embryos. The Bush policy had drawn 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 SCNT.³⁹ 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.”⁴⁰

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.⁴¹ 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.⁴² 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.⁴³ 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.”⁴⁴ 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.

³⁹ 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.

⁴⁰ UOJCA letter.

⁴¹ The President’s Council on Bioethics, *Reproduction and Responsibility*, March 2004, p. xlviii.

⁴² 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.

⁴³ Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

⁴⁴ National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 58.

Neither the Obama policy nor the NIH draft guidelines make a distinction based on the timing of when ES lines were created. By contrast, the timing of ES-line creation was one central concept in the Bush policy, which had limited the use of federal funding to research on lines derived on or before the date of the policy. Supporters of a distinction based on timing favor this distinction as a compromise because allows research on some embryonic stem cell lines and deters the future destruction of embryos for research. The President's Council writes that a policy based on timing mixes "prudence" with "principle, in the hope that the two might reinforce (rather than undermine) each other."⁴⁵ The Council notes that a timing-based policy is supported by what it titled 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.⁴⁶ The same report also contains alternative analyses that characterize the act of drawing a distinction between new and existing cell lines as "arbitrary," "unsustainable," and "inconsistent."⁴⁷ The Council itself takes no position in the report on this or any other issue.

Opponents of any distinction based on timing come from both sides of the issue. They 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 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 dwindling⁴⁸ and are "contaminated with mouse feeder cells."⁴⁹ 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"),⁵⁰ 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."⁵¹

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

⁴⁵ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, pp. 33-34.

⁴⁶ Ibid.

⁴⁷ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, pp. 63-67.

⁴⁸ 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.

⁴⁹ Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

⁵⁰ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 49.

⁵¹ UOJCA letter.

health effects of egg donation.⁵² 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.

While the Obama policy does not explicitly require the consent of the donors, it does require that NIH support ESR conducted responsibly, which may include informed consent requirements.⁵³ The resulting NIH draft guidelines specify nine elements that must be included in the informed consent document, and several focused on both sharing information and avoiding potential conflicts in the consent process. The Bush policy had contained a donor consent requirement that had limited approved stem cell lines to those derived with the informed consent of the donors, and obtained without any financial inducements to the donors. Despite the policy, a 2008 report raised questions about whether one quarter of the lines eligible for federal funding actually met policy's the informed consent requirements.⁵⁴

Like the Bush policy, 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

Egg Procurement

Egg procurement from women has raised a number of issues, most notably, those of informed consent and payment. 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.

⁵² Kathy Hudson, "International Society for Stem Cell Research Draft Guidelines," *Genetics & Public Policy Center ENews*, Issue 10 (July 2006), available online at http://www.dnapolicy.org/news.eneews.article.nocategory.php?action=detail&newsletter_id=13&article_id=31.

⁵³ The HHS regulations that generally require informed consent for research involving human subjects research do not generally apply to gametes, embryos, or other tissue, once donated or discarded. (See 45 C.F.R. § 46, subparts A & B.)

⁵⁴ See the "Consent of Donors" section of this report for more information.

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*, (March 7, 2005), at <http://www.upenn.edu/researchatpenn/article.php?113&soc>, visited December 5, 2005.

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 United States, nor were they illegal in South Korea at the time Dr. Huang's laboratory allegedly made them. 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

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.* (March 7, 2005), at <http://www.upenn.edu/researchatpenn/article.php?113&soc>, visited December 5, 2005.

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

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 December 12, 2005.

⁶² Kathy Hudson, "International Society for Stem Cell Research Draft Guidelines," *Genetics & Public Policy Center ENews*, Issue 10 (July 2006), available online at http://www.dnapolicy.org/news.eneews.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 December 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, December 12, 2005.

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 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. As is the case regarding other issues, the Obama policy does not reference the topic of egg donation directly. However, the NIH draft guidelines, keep the consent process for egg retrieval separate from donation by funding research only on lines derived from embryos originally created for fertility treatments. The Bush policy had done the same. On a related note, the NIH draft guidelines also prohibit the use of federal funding for ESR unless documentation ensures that no inducements were offered for the embryo 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 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 Perhaps more promising, scientists claim to have generated pluripotent stem cells from adult cells, though technical and safety concerns regarding the cells' therapeutic use remain unresolved.⁶⁶ 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. The Obama policy neither requires nor precludes research into ESR alternatives on its face, but does require that research be responsible and scientifically worthy. The NIH draft guidelines do not address the issue. By contrast, E.O. 13435 had affirmatively directed the pursuit of alternative methods of deriving embryonic stem cells, implying both a belief in the promise and necessity of such actions.

Not all scientists agree that adult stem cells or pluripotent stem cells derived from adult tissue 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 water. I think they are overstated."⁶⁷ Concerns have been raised that pluripotent stem cells derived from

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

⁶⁶ Junying Yu et al., "Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells," *Science*, vol. 318, no. 5858 (21 December 2007; originally published in *Science Express* on 20 November 2007).

⁶⁷ 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 (continued...)*

adult tissue may not be as versatile as embryonic stem cells, and may induce tumors.⁶⁸ 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."⁶⁹ 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."⁷⁰ 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."⁷¹ 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."⁷² 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."⁷³ Mrs. Nancy Reagan and her supporters favor expedient approaches including ESR.⁷⁴

Several laws 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, Congress enacted P.L. 109-129 for the collection and maintenance of human cord blood stem cells for the treatment of patients and for research.

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,⁷⁵ described in the introductory section of this report. The white

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Related Agencies (March 19, 2007).

⁶⁸ "The News: Scientists for the first time have generated human stem cells from adult cells," *Bioethics Responder from the Hastings Center*, (20 November 2007).

⁶⁹ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, p. 10.

⁷⁰ Carrie Gordon Earll, "Talking Points on Stem Cell Research," *Focus on the Family*, September 17, 2003 at <http://www.family.org/cforum/fosi/bioethics/faqs/a0027980.cfm>.

⁷¹ National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 56.

⁷² National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 53.

⁷³ 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 January 18, 2007.

⁷⁴ "Nancy Reagan plea on stem cells," *BBC News*, May 10, 2004, at <http://news.bbc.co.uk/2/hi/americas/3700015.stm>, visited January 18, 2007; Letter from Nancy Reagan to Senator Orrin Hatch, May 1, 2006, at http://www.camradvocacy.org/resources/Nancy_Reagan.pdf, visited January 18, 2007.

⁷⁵ The President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells*, May (continued...)

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.⁷⁶

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.⁷⁷

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 stem cells.⁷⁸ In addition, the technique was criticized on one side for effectively "creating a twin and then killing that twin,"⁷⁹ and on the other for being an inefficient method for deriving stem cell lines.⁸⁰ 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.⁸¹

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

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2005, online at http://www.bioethics.gov/reports/white_paper/index.html.

⁷⁶ For more information, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams.

⁷⁷ See, e.g., Rick Weiss "Researchers Report Growing Stem Cells From Dead Embryos," *Washington Post*, September 23, 2006, p. A03, available online at <http://www.washingtonpost.com/wp-dyn/content/article/2006/09/22/AR2006092201377.html>.

⁷⁸ 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>.

⁷⁹ Ibid.

⁸⁰ See e.g., Josephine Quintavalle, "The Lanza Protocol: Damned With Very Faint Praise," *BioNews*, vol. 373, (August 22-28, 2006), available online at <http://www.bionews.org.uk/commentary.lasso?storyid=3157>.

⁸¹ Robert Laza et al., "Human Embryonic Stem Cell Lines Derived from Single Blastomeres," *Nature*, vol. 444, p. 481 (November 23, 2006), available online at <http://www.nature.com/nature/journal/v444/n7118/full/nature05366.html>.

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.”

As is generally the case regarding alternatives to ESR, on its face the Obama policy neither requires nor precludes funding research to obtain ES without destroying embryos, but does require that research be responsible and scientifically worthy. Likewise, the NIH draft guidelines do not address the issue. By contrast, E.O. 13435 had specifically directed the HHS Secretary to consider the techniques outlined by the President’s Council, and to fund attempts to generate sources of pluripotent stem cell therapies that were not derived from human embryos.

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.⁸² They point out that embryo destruction violates the “deeply held moral beliefs of some citizens,” and suggest that “funding alternative research is morally preferable.”⁸³ 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.”⁸⁴ 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.⁸⁵

Groups’ positions on federal funding tend to mirror their positions on stem cell research generally. The Obama policy authorizes federal funding for ESR, and requires funded research be responsible and scientifically worthy. The NIH draft guidelines further specify requirements for obtaining federal funding for ESR. The Bush policy had also authorized federal funding, but not

⁸² National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 57.

⁸³ Ibid.

⁸⁴ Ibid.

⁸⁵ 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.

in a way designed to effect how stem cell lines were established.⁸⁶ 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."⁸⁷ Focus on the Family opposes ESR, including federal funding for it.⁸⁸ NBAC finds the arguments in favor of federal funding more persuasive than those against it.⁸⁹ 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.⁹⁰

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⁸⁶ Because the Bush policy only allowed funding for work with previously established ES lines, researchers who had 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 their work preceded the policy. Similarly, researchers who created stem cell lines after the policy took effect would not have been motivated to follow the Bush policy's ethical guidelines regarding the creation of stem cell lines, because the results of their work would have remained ineligible for federal funding regardless of their methodology. By contrast, E.O. 13435 may have affected the future derivation of embryonic stem cells to the extent that it encouraged that such activities take place without creating embryos for research or harming, endangering, or destroying them.

⁸⁷ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, p. 37.

⁸⁸ *Stem Cell Research: Our Position (Stem Cells)*, Focus on The Family, 2009, http://www.focusonthefamily.com/socialissues/sanctity_of_life/stem_cell_research/our_position.aspx. The group had previously expressed general support for President Bush and his ESR policy, but was "disappointed by his decision to allow federal funding of research on the existing stem cell lines." Carrie Gordon Earll, "Talking Points on Stem Cell Research," *Focus on the Family*, September 17, 2003 at <http://www.family.org/cforum/fosi/bioethics/faqs/a0027980.cfm>.

⁸⁹ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 70.

⁹⁰ 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.