

CRS Report for Congress

Stem Cell Research: Ethical Issues

Updated August 25, 2008

Erin D. Williams
Specialist in Public Health and Bioethics
Domestic Social Policy Division

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



Prepared for Members and
Committees of Congress

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 Senate passed S. 5 (63-34) on April 11, 2007. The House passed H.R. 3 (253-174) on January 11, 2007, and S. 5 on June 7, 2007 (247-176). Neither chamber passed S. 5 with enough votes to override President Bush's June 20, 2007, veto, which he issued with an executive order (E.O. 6/20) directing research into ESR alternatives. Supporters of expanded federal funding 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. The policy allows for initiatives proposed in S. 957 and H.R. 1892 (funding an amniotic fluid and placental stem cell bank), and in E.O. 6/20. Supporters contend that 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 (H.R. 322, S. 51, S. 30, S. 363, S. 997, S. 5, and E.O. 6/20). The Senate passed S. 30 (70-28) on April 11, 2007. Supporters assert that this 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 (H.R. 457, S. 2863), or limit it by restricting funding (H.R. 2807) or research (S. 812), banning certain cloning or scientific techniques (S. 1036, H.R. 2564, S. 2358/H.R. 5910), or giving embryos the Constitutional right to life (H.R. 618, H.R. 4157, S. 3111). Supporters claim their approaches respect human dignity; critics claim they harm 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.

Contents

Introduction	1
Proponents and Opponents	2
Legislation	4
June 20 Executive Order (E.O. 6/20)	7
Discussion of Ethical Issues	8
Embryo Destruction and Relief of Human Suffering	8
Viability of Embryos	10
Purpose of Embryo Creation	11
New and Existing Cell Lines	12
Consent of Donors	13
Egg Procurement	14
Effectiveness of Alternatives	17
Generating Embryonic Stem Cells Without Destroying Human Embryos	18
Use of Federal Funding	20

Stem Cell Research: Ethical Issues

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

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 In 2008, questions were raised about whether one quarter of the lines eligible for federal funding actually met policy's the informed consent requirements.⁴ Even before 2008, many supporters of ESR viewed 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.⁵ 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.⁶

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.”⁷ 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.⁸

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,⁹ Focus on the

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

⁴ See the “Consent of Donors” section of this report for more information.

⁵ Tracy Hampton, “US Stem Cell Research Lagging,” *Journal of the American Medical Association*, vol. 295, no. 19, May 17, 2006, p. 2233.

⁶ For further information, see CRS Report RL33524, *Stem Cell Research: State Initiatives*, by Judith A. Johnson and Erin D. Williams.

⁷ Wesley J. Smith, “Another Cloning Breakthrough,” at [http://www.cbc-network.org/redesigned/research_display.php?id=269], visited June 2, 2006.

⁸ 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.

⁹ 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.

Family,¹⁰ and the Christian Coalition¹¹ support the 2001 Bush policy. Others, such as the National Academies,¹² the Coalition for the Advancement of Medical Research (CAMR),¹³ former First Lady Nancy Reagan,¹⁴ former Presidents Gerald Ford, Jimmy Carter, and Bill Clinton,¹⁵ and the Union of Orthodox Jewish Congregations of America (UOJCA),¹⁶ favor more ESR than the Bush policy allows. 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

¹⁰ *Focus on the Family* was founded in 1977 by Dr. James Dobson to promote the teachings of Jesus Christ. See [<http://www.family.org>].

¹¹ The Christian Coalition is “the largest and most active conservative grassroots political organization in America,” at [<http://www.cc.org>].

¹² 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>].

¹³ 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.

¹⁴ “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.

¹⁵ *Ibid.*

¹⁶ 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.)

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.

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

Legislation. H.R. 3 and S. 5 would allow federal support of research that utilizes human embryonic stem cells regardless of the date on which the stem cells

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. xlviii.

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.

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 and House had additional provisions, which are discussed below.

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. The House took up S. 5 on June 7, 2007, passing it by a vote of 247 - 176. Neither chamber had passed S. 5 with enough votes to override a veto, however, some senators are reportedly considering adding a stem cell provision to the FY2008 appropriations bill for the departments of Labor, Health and Human Services, and Education.²⁶ The White House vetoed S. 5 on June 20, 2007, and issued *Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways* (E.O. 6/20), the specifics of which are discussed in the next subsection.²⁷

Three 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 and House 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.

Six 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. The first is 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 or 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

²⁶ Alex Wayne, "Senate Bill Defies Bush on Stem Cells, Abstinence Education, Spending Total," *CQ Today*, *Round-the-clock coverage of news from Capitol Hill*, June 19, 1007, 8:28 p.m.

²⁷ 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>].

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, the second and third bills, 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. The fourth bill, 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,²⁸ and amend the National Organ Transplant Act (NOTA, 42 U.S.C. 274e) to prohibit the exchange of valuable consideration for a human gamete, embryo, or stem cell.²⁹

The fifth and sixth bills, S. 957 (Burr) and H.R. 1892 (Lipinski), would create a non-embryonic stem cell bank, which would be permissible under the current Bush policy. They would direct the HHS Secretary to establish a bank of stem cells from amniotic fluid and placentas. The bills are not identical, but would both authorize funds and set forth some specifics for the bank's establishment.

Eleven additional bills, which are discussed in the following three paragraphs, propose measures that may restrict or discourage ESR. H.R. 2807 (Forbes) would prohibit the use of federal funds for research that involves the creation of embryos for research purposes, or the destruction, discarding of, or risk of injury to a living embryo. In addition, the bill would prohibit federal funding using stem cells derived in violation of the other restrictions. H.R. 2807 would prevent federal funding for most ESR and would encourage research to derive stem cells without harming or destroying embryos. (It would allow federal funding for ESR using only techniques with non-living embryos that were created for reproductive purposes.) The bill is more restrictive than the Dickey Amendment, in that Dickey does not prohibit the use stem cells once they are derived.

S. 812 (Hatch) would proscribe reproductive human cloning (which, as defined, 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. S. 1036 (Brownback) and H.R. 2564 (Weldon) would prohibit all forms of human cloning, including somatic cell nuclear transfer (SCNT), thus proscribing one

²⁸ 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.

²⁹ 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.

method of generating embryos for ESR. S. 2358 (Brownback) and H.R. 5910 (Smith) would prohibit the creation of human-animal hybrids, including placing a human nucleus into a non-human egg. This restriction could potentially preclude one method of generating embryos for 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. S. 2863 (Vitter) proposes a tax credit for individuals' *qualified stem cell research expenses*, which is defined so as to disqualify many forms of ESR from the tax credit. Such expenses may not support either the creation, destruction, injury, discarding of a human embryo, or the use of stem cells derived from those activities. H.R. 618 (Hunter), S. 3111 (Wicker), and H.R. 4157 (Broun) 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.

June 20 Executive Order (E.O. 6/20). President Bush's E.O. 6/20 contains four sections: (1) Research on Alternative Sources of Pluripotent Stem Cells, (2) Policy, (3) Interpretation of this Order, and (4) General Provisions. None of the sections contains measures contrary to the President Bush's August 2001 policy. Some lawmakers have reportedly criticized the order as having no substance, adding no new money or research, and making no policy change.³⁰ The details of E.O. 6/20 are discussed below.

Section One directs the HHS Secretary to support research on pluripotent stem cells derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus. It also directs the Secretary to create an implementation plan that (i) determines the extent to which specific techniques may require research to ensure that any research involving human cells using these techniques is clearly consistent with the standards established under this order and applicable law; (ii) prioritizes research with the greatest potential for clinical benefit; (iii) takes into account techniques outlined by the President's Council on Bioethics, and any other appropriate techniques and research that clearly meet the standard set forth in the order; (iv) renames the "Human Embryonic Stem Cell Registry" the "Human Pluripotent Stem Cell Registry"; and (v) adds to the registry new human pluripotent stem cell lines that clearly meet the standard set forth in the order. Finally, it directs the Secretary to deliver an annual report to the President on progress made under the order.

Section Two sets forth principles with which the Secretary's actions are to be consistent: (i) to direct HHS, including NIH, to intensify peer reviewed research that may result in improved understanding of treatments for diseases and other adverse health conditions, and to promote the derivation of human pluripotent stem cell lines from a variety of alternative sources while clearly meeting the standard set forth in

³⁰ Jeannie Baumann, "Bush Vetoes Stem Cell Bill, Issues Order Authorizing Study of non-Embryo Alternatives," *Health Care Daily*, vol. 12, no. 9 (June 21, 2007), ISSN 1091-4021.

the order; (ii) it is critical to establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity; (iii) the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another; (iv) human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold; and (v) the Federal Government has a duty to exercise responsible stewardship of taxpayer funds, both supporting important medical research and respecting ethical and moral boundaries.

Section Three provides two definitions and one provision to be used when interpreting the order: (i) “human embryo” means any organism, not protected as a human subject under 45 CFR 46 as of the date of this order, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells; (ii) “subjecting to harm a human embryo” means subjecting such an embryo to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 USC 289g(b)) as of the date of this order; and (iii) nothing in this order shall be construed to affect any policy, guideline, or regulation regarding embryonic stem cell research, human cloning by SCNT, or any other research not specifically authorized by this order, or to forbid the use of existing stem cell lines deemed eligible for other federally funded research in accordance with the presidential policy decision of August 9, 2001, for research specifically authorized by this order.

Section Four specifies that the order shall be implemented consistent with applicable law and subject to the availability of appropriations. It also specifies that it is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

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.”³¹ 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.”³²

H.R.2807, by virtue of its proposed prohibition on use of federal funds to conduct research on any stem cell derived from the creation of an embryo for research purposes, destruction, discarding, or risk of injury to an embryo, would effectively end federal funding for ESR, except in the narrowly defined circumstances described above. None of the other bills proposed in the 110th Congress would completely prohibit funding for ESR or make the practice illegal. The bills that come the closest to this in their effect are H.R. 618, S. 3111, and H.R. 4157, which would endow embryos with the Constitutional right to life from the moment of fertilization/cloning. S. 1036 and H.R. 2564 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.”³³ 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.³⁴ 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.³⁵ 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.”³⁶ 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

³¹ American Life League, *The Bush Stem Cell Decision*, 2001, at [<http://www.all.org/article.php?id=10746&search=2001>], visited January 18, 2007.

³² 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>].

³³ The President’s Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, pp. 58, 62.

³⁴ Presentation by B. Steinbock, Department of Philosophy, SUNY, Albany, NY, NIH Human Embryo Research Panel Meeting, February 3, 1994.

³⁵ 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.

³⁶ UOJCA letter.

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.

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.³⁷ 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.³⁸ The NBAC report touches on the moral status of embryos in utero and those in vitro,³⁹ though NBAC does not specify whether viability was a key rationale for its recommendations. A group of Representatives,⁴⁰ a group of Senators,⁴¹ 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.⁴² 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

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

³⁸ The President's Council on Bioethics, *Reproduction and Responsibility*, March 2004.

³⁹ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 50.

⁴⁰ 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.)

⁴¹ 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.)

⁴² 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.

product of nuclear transplantation into a uterus or the functional equivalent of a uterus, which would ensure that the product remains non-viable.

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.⁴³

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 SCNT.⁴⁴ 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.”⁴⁵

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.⁴⁶ 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.⁴⁷ A group of Representatives, a group of Senators, and CAMR imply but do not state that embryos should not be

⁴³ 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.

⁴⁴ 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.

⁴⁵ UOJCA letter.

⁴⁶ The President’s Council on Bioethics, *Reproduction and Responsibility*, March 2004, p. xlviii.

⁴⁷ 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.

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.⁴⁸ 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.”⁴⁹ 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. H.R.2807 effectively draws the same distinction, disallowing funding for research using embryos created for research purposes, among other things. 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 and H.R. 2564 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.”⁵⁰ 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.⁵¹ The same report also contains analyses of the Bush policy that characterize distinction between new and existing cell lines as “arbitrary,” “unsustainable,” and “inconsistent.”⁵² The Council itself takes no position in the report on this or any other issue.

⁴⁸ Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

⁴⁹ National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 58.

⁵⁰ The President’s Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, pp. 33-34.

⁵¹ *Ibid.*

⁵² The President’s Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, pp. 63-67.

Opponents of the Bush policy on both sides of the issue view the distinction between new and existing stem cell lines with reproach. One side, which includes The National Right to Life Committee and the United States Conference of Catholic Bishops, objects because the distinction validates destruction of embryos, and 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 dwindling⁵³ and are “contaminated with mouse feeder cells.”⁵⁴ 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”),⁵⁵ 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.”⁵⁶ 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. 957, S. 812, S. 1036, and H.R. 2564 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.⁵⁷ 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.

⁵³ 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.

⁵⁴ Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

⁵⁵ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 49.

⁵⁶ UOJCA letter.

⁵⁷ 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].

The 2001 Bush policy contains a donor consent requirement. It limits approved stem cell lines to those derived with the informed consent of the donors, and obtained without any financial inducements to the donors. Despite the policy, a 2008 report indicated that there may have been ethical lapses in the way some of the Bush-approved cells were obtained from embryo donors. The author found two categories of problems with the consent forms: (1) they omitted information important for informed consent, and (2) they set restrictions that obstructed key areas of research.⁵⁸ A subsequent article suggested that NIH staff were pressured to make these stem cell lines eligible for federal funding:

NIH insiders, speaking on condition of anonymity, said they had little choice at the time. The administration was adamant that as many cell lines as possible that were derived before the August 9, 2001 deadline be included on the approved list, NIH sources said, in the hope that scientists would be mollified.⁵⁹

Like the 2001 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.⁶⁰ A group of Representatives and a group of Senators mention and imply their support for donor consent requirements.⁶¹ 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. 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.⁶² The wide consensus regarding the need for informed

⁵⁸ Robert Streiffer, "Informed Consent and Federal Funding for Stem Cell Research," *Hastings Center Report*, vol. 38, no. 3 (May-June 2008), p. 40.

⁵⁹ Rick Weiss, "Ethically Challenged: One Quarter of Stem Cell Lines Eligible for Federal Funding Fail Ethics Guidelines," *Science Progress* (July 25, 2008), at [<http://www.scienceprogress.org/2008/07/ethically-challenged/>].

⁶⁰ National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 53.

⁶¹ Letter from 206 Members of the House of Representatives; Letter from 58 Senators.

⁶² "Egg Donation Ethics Study Wins Award," *Research at Penn*, (March 7, 2005), at (continued...)

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.⁶³ Offers of much higher amounts (\$50,000-\$100,000) have been reported elsewhere.⁶⁴ Dr. Huang's laboratory reportedly made payments of \$1,400 to each woman who donated eggs.⁶⁵ 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.⁶⁶ 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.⁶⁷ 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,

⁶² (...continued)

[<http://www.upenn.edu/researchatpenn/article.php?113&soc>], visited December 5, 2005.

⁶³ American Society of Reproductive Medicine, "Financial Incentives in Recruitment of Oocyte Donors," *Fertility and Sterility*, vol. 74, no. 2 (August 2000), p. 216.

⁶⁴ 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.

⁶⁵ 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.

⁶⁶ 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.

⁶⁷ 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].

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.⁶⁸ Second, some have argued that payment for eggs for research purposes might undermine public confidence in endeavors such as human ESR.⁶⁹ 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 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, S. 997, and H.R.2807 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. S.

⁶⁸ 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.

⁶⁹ 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.

2358 and H.R. 5910 would prohibit the creation of embryos by injecting human nuclei into animal eggs, stemming one potential means of generating embryos for research without requiring women to donate eggs.

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.⁷⁰ 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.⁷¹ 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. E.O. 6/20 affirmatively directs 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."⁷² Concerns have been raised that pluripotent stem cells derived from adult tissue may not be as versatile as embryonic stem cells, and may induce tumors.⁷³ 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.

⁷⁰ 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.

⁷¹ 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).

⁷² 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).

⁷³ "The News: Scientists for the first time have generated human stem cells from adult cells," *Bioethics Responder from the Hastings Center*, (20 November 2007).

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."⁷⁴ 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."⁷⁵ 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."⁷⁶ 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."⁷⁷ 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."⁷⁸ Mrs. Nancy Reagan and her supporters favor expedient approaches including ESR.⁷⁹

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 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, S. 30, and H.R.2807 would authorize funding for research to attempt to generate pluripotent stem cells without involving human embryos. S. 957 and H.R. 1892 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

⁷⁴ The President's Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, p. 10.

⁷⁵ 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>].

⁷⁶ National Research Council, Institute of Medicine, National Academies, *Stem Cells and the Future of Regenerative Medicine* (Washington: National Academies, 2001), p. 56.

⁷⁷ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 53.

⁷⁸ 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.

⁷⁹ "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.

explored by the President's Council in its 2005 white paper,⁸⁰ 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.⁸¹

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.⁸²

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.⁸³ In addition, the technique was criticized on one side for effectively "creating a twin and then killing that twin,"⁸⁴ and on the other for being an inefficient

⁸⁰ 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].

⁸¹ For more information, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams.

⁸² 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>].

⁸³ 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>].

⁸⁴ *Ibid.*

method for deriving stem cell lines.⁸⁵ 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.⁸⁶

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."

E.O. 6/20, S. 997, S. 5, S. 51, H.R. 322, S. 363, S. 30, and H.R.2807 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. S. 2358 and H.R. 5910 would prohibit the creation of embryos by injecting human nuclei into animal eggs. If the product of a human nucleus and an animal egg were defined as something other than a human embryo, then using such hybrids in ESR could be considered to be one method of generating embryonic stem cells without destroying human embryos. The proposed bills would ban such methods.

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

⁸⁵ 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>].

⁸⁶ 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>].

destruction.⁸⁷ They point out that embryo destruction violates the “deeply held moral beliefs of some citizens,” and suggest that “funding alternative research is morally preferable.”⁸⁸ 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.”⁸⁹ 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.⁹⁰

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.”⁹¹ 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.”⁹² NBAC finds the arguments in favor of federal funding more persuasive than those against it.⁹³ 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.⁹⁴

Several pieces of legislation would use federal funding to add ethical requirements to the conduct of ESR. While the August 2001 Bush policy does contain some ethical requirements regarding the creation of stem cell lines eligible

⁸⁷ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 57.

⁸⁸ *Ibid.*

⁸⁹ *Ibid.*

⁹⁰ 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.

⁹¹ The President’s Council on Bioethics, *Monitoring Stem Cell Research*, January 2004, p. 37.

⁹² 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>].

⁹³ National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, vol. 1, September 1999, p. 70.

⁹⁴ 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.

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. By contrast, E.O. 6/20 may affect the future derivation of embryonic stem cells to the extent that it encourages that such activities take place without creating embryos for research or harming, endangering, or destroying them.

S. 2807 would be more restrictive than the current Bush policy, in that it would allow federal funding for ESR only if it involved non-living embryos created for reproductive purposes, or stem cells derived from such embryos. 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.