Stem Cell Research: Ethical and Legal Issues

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Summary

Recent court decisions in the case of *Sherley v. Sebelius* have called into question whether federal law prohibits the award of federal funding for embryonic stem cell research (ESR). As explained in the next paragraph, but for a brief period, federal funding has been available for research *using* established embryonic stem cell (ES) lines, but not for the *establishment* of ES lines. Neither the *Sherley* case nor the affected federal policy restricts or regulates ESR conducted solely with private, local, and/or state government funding, or with funding from other non-federal sources.

Since 1996, federal funding for research that involves the creation or destruction of human embryos has been prohibited. This prohibition is due to the Dickey Amendment, a rider placed on Health and Human Services' (HHS) annual appropriation each year since FY1997. Federal policy allowing research on established ES lines was based on an interpretation of Dickey, issued in 1999 by then-HHS General Counsel Harriet Rabb (HHS 1999 Opinion). The HHS 1999 Opinion concluded that Dickey prohibited the use of HHS funds to *establish* ES lines (which involves embryo destruction), but not to conduct research *using* ES from established lines (on the theory that ES themselves are not embryos). In the context of the HHS 1999 Opinion, the Obama Administration created its ES policy, which permits federal funding for research using established ES lines that meet certain ethical requirements. The Obama ES policy is articulated in two 2009 documents: Executive Order 13505 (Obama EO), and National Institutes of Health guidelines issued pursuant to the EO (NIH 2009 Guidelines). In *Sherley*, the court issued a preliminary injunction, enjoining HHS from "implementing, applying, or taking any action whatsoever pursuant to" the NIH 2009 Guidelines "or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines," holding that they violate Dickey. HHS appealed and the Court of Appeals for the D.C. Circuit issued a stay of the preliminary injunction, temporarily permitting federal funding of ESR to continue under the NIH 2009 Guidelines.

While the D.C. Circuit considers the appeal, Congress has four policy options. First, it could sanction or expand federal funding for ESR by eliminating or modifying the Dickey Amendment, or by passing other legislation (for example, H.R. 872, H.R. 873, S. 487, H.R. 4808, and S. 3766). (Note that the effect of such legislation could be questioned if Dickey and the *Sherley* holding are affirmed.) Second, Congress could encourage possible alternatives to ESR through research funding or tax incentives for activities that that do not involve the destruction of human embryos (S. 99, S. 3751, H.R. 877, H.R. 1230, H.R. 1654, H.R. 2107, H.R. 6081, and H.R. 6083). Third, it could restrict or eliminate ESR by prohibiting federal research funding, banning certain cloning techniques, or giving embryos a constitutional right to life (H.R. 110, H.R. 227, S. 346, H.R. 881, and H.R. 1050). (Enactment of a law banning federal ESR funding would preclude such funding even if *Sherley* were overturned or Dickey were eliminated.) Fourth, it could take no action, which would permit federal ESR funding unless or until the *Sherley* case is affirmed.

Many opinions about the ethics of ESR have been published. The positions could be broadly categorized as *for* or *against* ESR; however, there is an array of finer distinctions that reveal more subtle variation in ethical, moral, and factual beliefs. Breaking down ESR arguments according to these finer distinctions demonstrates both the complexity of the issues and the points of resonance among the opinions. The broadest discussion involves the balance of embryo destruction and relief of human suffering. More subtle issues focus on the relative importance of embryo viability, the purpose of embryo creation, new versus existing ES lines, donor consent, egg procurement, possible alternatives, and federal funding. This report presents background concepts, outlines legal arguments related to *Sherley*, and details the ethical arguments that surround ESR.

Contents

Contacts

Introduction

In order to fully understand the ethical and legal issues involved in stem cell research, it is useful to be familiar with a few basic terms and concepts:[1]

- *Stem cells* are those with the ability to divide for indefinite periods in culture and to give rise to specialized cells. There are two main types of stem cells: *adult stem cells* and *embryonic stem cells.*
- An *adult stem cell* is thought to be an undifferentiated cell, found among differentiated cells in a tissue or organ that can renew itself and can differentiate to yield some or many of the major specialized cell types of the tissue or organ. Adult stem cells have been identified in many organs and tissues, including brain, bone marrow, peripheral blood, blood vessels, skeletal muscle, skin, teeth, heart, gut, liver, ovarian epithelium, and testis. Blood-forming stem cells from bone marrow have been used for 50 years to treat patients for a variety of blood-related conditions.[2]
- *Embryonic stem cells (ES)* are derived from embryos, and have the potential to give rise to any type of specialized cell. (The process of obtaining ES from an embryo causes the destruction of the embryo.) ES could be used to repair spinal cord injury, or treat a variety of diseases such as Parkinson's and diabetes.
- *ES lines* consist of ES that have been cultured under *in vitro* (laboratory) conditions that allow proliferation without differentiation for months to years. (This means that an embryo can be used to generate an ES line, which, once established, can continue to produce ES for months to years.)

The topic of stem cell research claimed news headlines in August 2010 due to a federal district court ruling in the case of *Sherley v. Sebelius.*[3] As described in the "Current Law and Policy" section of this report, prior to *Sherley*, ethical concerns about embryo research had prompted certain restrictions on the expenditure of federal funds for ESR; however, limited funding had been permitted and awarded since 2001. The *Sherley* opinion would have effectively precluded the award of federal funding for ESR if it had not been stayed by the Court of Appeals for the D.C. Circuit pending appeal. As described in the "Policy Options for Congress" section of this report, Congress has a range of policy options it could use to encourage, fund, restrict, or discourage ESR funding, which could affect or potentially be affected by the ultimate outcome of *Sherley*.

[1] Reference to stem cells in this report refer only to *human* stem cells unless otherwise specified. For further information about the science of stem cell research, see CRS Report RL33540, *Stem Cell Research: Science, Federal Research Funding and Regulatory Oversight*, by Judith A. Johnson and Erin D. Williams.

Unless bracketed or otherwise noted, bulleted definitions and background information are from NIH, *Stem Cell Information: Glossary*, August 20, 2010, http://stemcells.nih.gov/StemCells/Templates/StemCellContentPage.aspx?NRMODE=Published&NRNODEGUID=%7b3C35BAB6-0FE6-4C4E-95F2-2CB61B58D96D%7d&NRORIGINALURL=%2finfo%2fglossary%2easp&NRCACHEHINT=NoModifyGuest#embryonicline; and NIH, *Stem Cell Information: Stem Cells and Diseases*, August 19, 2010, http://stemcells.nih.gov/info/health.asp.

[2] Frederick R. Appelbaum, "Hematopoietic-Cell Transplantation at 50," The New England Journal of Medicine, v. 357, October 11, 2007, pp. 1472-1475.

[3] Sherley v. Sebelius, Civ. No. 1:09-cv-1575 RCL (D.D.C. Aug. 23, 2010) (preliminary injunction order).

The legal issues and policy options related to stem cell research are informed in part by the ethical issues. As described in the "Discussion of Ethical Issues" section of this report, what is now more than a decade of debate and writing about the ethics of ESR reveals a range of nuanced opinions about a variety of subtle issues. These include 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, and the use of federal funding, among others.

This report contains an overview of current law and policy (including an analysis of the *Sherley* case), presents policy options for Congress, and then details a range of ethical arguments that relate to stem cell research.

Current Law and Policy

Federal regulation of ESR primarily consists of the Dickey Amendment, the Department of Health and Human Services (HHS) 1999 Opinion, the Obama EO (13505), and the NIH 2009 Guidelines as potentially affected by *Sherley v. Sebelius*.[4] 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. None of the restrictions apply to adult stem cell research. For historical purposes, a description of the previous Administration's ES policy, which had been established by the George W. Bush Administration, is presented below at "Historical Note: The Bush Policy".

The Dickey Amendment

Since 1996, the Dickey Amendment 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. The Dickey Amendment precludes the use of federal funding to derive stem cells from embryos, which typically are produced via in vitro fertilization (IVF). Whether it precludes the use of federal funds for research on existing ES lines was the topic of the HHS 1999 Opinion as well as the 2010 *Sherley* case.

The Dickey Amendment language has been added to each of the Labor, HHS, and Education appropriations acts for FY1997 through FY2009.[5] Funding for FY2010 is provided in the Consolidated Appropriations Act, 2010 (P.L. 111-117). The Dickey Amendment is found in Section 509 of Division D—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2010, of P.L. 111-117. It states that:

[4] Sherley v. Sebelius, Civ. No. 1:09-cv-1575 RCL (D.D.C. Aug. 23, 2010). For further information, see CRS Report RL33540, *Stem Cell Research: Science, Federal Research Funding and Regulatory Oversight*, by Judith A. Johnson and Erin D. Williams.

[5] The rider language has not changed significantly from year to year (however there was a technical correction in P.L. 109-149). The original rider can be found in Section 128 of P.L. 104-99; it affected NIH funding for FY1996 contained in P.L. 104-91. For subsequent fiscal years, the rider is found in Title V, General Provisions, of the Labor, HHS and Education appropriations acts in the following public laws: FY1997, P.L. 104-208; FY1998, P.L. 105-78; FY1999, P.L. 105-277; FY2000, P.L. 106-113; FY2001, P.L. 106-554; FY2002, P.L. 107-116; FY2003, P.L. 108-7; FY2004, P.L. 108-199; FY2005, P.L. 108-447; FY2006, P.L. 109-149; FY2007, P.L. 110-5; FY2008, P.L. 110-161; FY2009, P.L. 111-8.

> (a) None of the funds made available in this Act may be used for—
>
> (1) the creation of a human embryo or embryos for research purposes; or
>
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
>
> (b) For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 [the Human Subject Protection regulations] as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis [development from an egg without fertilization], cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells [cells that have two sets of chromosomes, such as somatic cells].

HHS 1999 Opinion

In 1999, HHS General Counsel Harriet Rabb issued an opinion as to whether the Dickey Amendment precluded federal funding for ESR (HHS 1999 Opinion).[6] The HHS 1999 Opinion concluded that federal funding for research performed with embryonic stem cells is not proscribed by the Dickey Amendment on the theory that ES themselves are not embryos. Thus, the HHS 1999 Opinion effectively permitted federal funding for ESR on established lines, but not for the establishment of those lines.

As described in the sections that follow, it was in the context of the HHS 1999 Opinion that the Obama Administration developed its ESR-funding policy, which includes the NIH 2009 guidelines. And it was the HHS 1999 Opinion that was examined in the *Sherley* case, which temporarily halted the award of federal funds under the NIH 2009 Guidelines.

The Obama EO

On March 9, 2009, President Barack Obama issued Executive Order 13505 regarding federal funding for stem cell research (Obama EO).[7] The Obama EO 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.[8]

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[6] Harriet Rabb, HHS General Counsel, *HHS, Office of the Secretary*, Letter to Harold Varmus re Federal Funding for Research Involving Human Pluripotent Stem Cells, Washington, DC, January 15, 1999.

[7] Executive Order 13505, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," 74 *Federal Register* 10667, March 11, 2009.

[8] 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." 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, http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-(continued...)

On July 30, 2009 (following NIH's publication of its guidelines, as described below), President Obama issued a memorandum directing the heads of executive departments and agencies that support and conduct stem cell research to adopt NIH's guidelines, to the fullest extent practicable in light of legal authorities and obligations.[9] Departments and agencies were to submit to the Director of the Office of Management and Budget (OMB) any proposed additions or revisions to any other guidance, policies, or procedures related to human stem cell research. The OMB Director, in coordination with the NIH Director, was to review proposals to ensure consistent implementation of the executive order and the July 30 memorandum.

NIH 2009 Guidelines

Pursuant to the Obama EO, on July 7, 2009, NIH issued its guidelines (National Institutes of Health Guidelines for Research Using Human Stem Cells), specifying the requirements to receive federal funding for ESR.[10] On December 2, 2009, the NIH director announced the approval of the first 13 embryonic stem cell (ES) lines for use in NIH-funded research under the NIH 2009 Guidelines.[11] As of July 25, 2010, there were 75 eligible lines listed in the NIH Human Embryonic Stem Cell Registry.[12] The NIH 2009 Guidelines have five parts, which are summarized below.

Part One (Scope of Guidelines)

Part one specifies that the guidelines apply to expenditures of NIH funds for research using human ES lines. It also references HHS regulations for the Protection of Human Subjects, which would apply to ESR that (1) involves testing on living people, and/or (2) in which ES can be linked to specific living individuals by the investigators.[13]

Part Two (Eligibility of Human Embryonic Stem Cells for Research with NIH Funding)

Part two specifies the requirements that must be met for an ES line to be eligible for use in NIH-funded research.[14] It also states that NIH will establish a new registry, listing ES lines eligible for

(...continued)

Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/.

[9] The President, "Memorandum of July 30th, 2009, Guidelines for Human Stem Cell Research: Memorandum for the Heads of Executive Departments and Agencies," 74 *Federal Register* 38885 - 38886, August 5, 2009.

[10] *National Institutes of Health Guidelines for Research Using Human Stem Cells* in National Institutes of Health, "National Institutes of Health Guidelines for Human Stem Cell Research," 74 *Federal Register* 128, July 7, 2009 (hereinafter *Guidelines*).

[11] Jenny Haliski, *First Human Embryonic Stem Cell Lines Approved for Use Under New NIH guidelines*, NIH, Office of Communications and Public Liaison, December 2, 2009, http://www.nih.gov/news/health/dec2009/od-02.htm.

[12] NIH, Office of Extramural Research, *NIH Human Embryonic Stem Cell Registry*, August 25, 2010, 2010, http://grants.nih.gov/stem_cells/registry/current.htm.

[13] *Protection of Human Subjects* is located at 45 C.F.R. § 46. For further information, 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.

[14] This part of the guideline also defines "human embryonic stem cells" to mean "cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived (continued...)

use in NIH-funded research. Lines can become eligible in one of three ways, depending on the date and location of embryo donation. The first path to funding eligibility applies to ES lines established from embryos donated in the United States on or after the policy date. ES lines in this category may be used for NIH-sponsored research if all of the following requirements are met:

- the cells were derived from donated human embryos created using in vitro fertilization (IVF) for reproductive purposes, but no longer needed for that purpose;
- donors gave voluntary informed consent; and
- assurances and documentation can be provided that (1) options available in the facility where treatment was sought pertaining to use of embryos were explained to the potential donor(s); (2) donors were not offered payments, cash or in kind, for making donations; (3) facilities where embryos were donated had policies stating that neither consent nor refusal to consent would affect donors' quality of care; (4) there was a clear separation between the decisions to create and donate embryos as specified in the policy; and (5) donors consented to the donation at the time of donation and signed consent forms that included specified criteria.

The second path applies to ES lines established from embryos donated in the United States before the policy date. Such ES lines may be used for NIH funded research if they meet the requirements set forth in the first path, or if an applicant submits certain materials to a Working Group of the Advisory Committee to the Director (ACD) [of NIH]. Materials must demonstrate that ES lines came from spare embryos that were created with IVF for reproductive purposes, and that were donated with voluntary informed consent. The ACD will make funding eligibility recommendations to the NIH Director, who will make the final decision regarding eligibility.

The third path to funding eligibility applies to ES lines established from embryos donated outside the United States. If the embryo was donated before the policy date, applicants may comply with the requirements of either of the first two eligibility paths. If the embryo was donated after the policy date, a line may become eligible by meeting the requirements of the first path, or by submitting to the ACD an assurance and supporting documentation that the alternative procedural standards of the foreign country where the embryo was donated provide protections at least equivalent to those of the first path.

Part Three (Use of NIH Funds)

Part three requires that prior to receiving funding, recipients should provide assurances, when endorsing applications and progress reports to NIH, that the ES lines used for the project are the ones listed in the registry.

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from embryos, such stem cells are not themselves human embryos." *Guidelines* at 32174.

Parts Four and Five (Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding; Other Research Not Eligible for NIH Funding)

Parts four and five specify that the following types of research are not eligible for NIH funding, regardless of whether they use ES lines listed in the registry: (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) the derivation of stem cells from human embryos, as prohibited by the Dickey Amendment; and (4) research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes.

Sherley v. Sebelius

On August 23, 2010, a federal district court issued a preliminary injunction enjoining HHS from "implementing, applying, or taking any action whatsoever pursuant to" the NIH 2009 Guidelines described above, "or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines."[15] The court issued the injunction upon the motion of two researchers of adult stem cells[16] who argued that the guidelines violated the Dickey Amendment, which prohibits federal funding of "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 federal law]."[17] In response, HHS sought appellate review and the Court of Appeals for the D.C. Circuit issued a stay of the preliminary injunction pending its consideration of the merits of the government's appeal.[18] Although federal funding of ESR is currently permitted to continue while the stay is effective, NIH had ceased all internal ESR and had stopped reviewing new ESR grant applications as well as pending grant renewals in the time period between the issuance of the preliminary injunction and the stay by the appellate court.[19]

HHS argues that the Dickey Amendment barred federal funding of the activities in which embryonic stem cells were derived, but did not prohibit federal funding of subsequent research

[15] Sherley v. Sebelius, Civ. No. 1:09-cv-1575 RCL (D.D.C. Aug. 23, 2010) (preliminary injunction order).

[16] The case had initially been dismissed for lack of standing. Sherley v. Sebelius, 686 F. Supp. 2d 1 (D.D.C. 2009). However, the case was reinstated after an appellate court ruled that the researchers had sufficiently alleged that they would suffer increased competition for NIH grants if more embryonic stem cell lines were made eligible for federal funds. Sherley v. Sebelius, 610 F.3d 69 (D.C. Cir. 2010).

[17] P.L. 111-8, div. F, § 509(a)(2).

[18] Sherley v. Sebelius, Civ. No. 1:09-cv-1575 RCL (D.D.C. August 31, 2010) (notice of appeal); and Sherley v. Sebelius, No. 10-5287 (D.C. Cir. Sept. 9, 2010) (granting stay of preliminary injunction). The district court had earlier declined to stay its own injunction. Sherley v. Sebelius, Civ. No. 1:09-cv-1575 RCL (D.D.C. Sept. 7, 2010) (order denying defendants' emergency motion to stay preliminary injunction pending appeal).

[19] NIH, Status of Applications and Awards Involving Human Embryonic Stem Cells, and Submissions of Stem Cell Lines for Eligibility Consideration, available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-126.html; and Jocelyn Kaiser, NIH Orders Immediate Shutdown of Intramural Human Embryonic Stem Cell Research, SCIENCE, available at http://news.sciencemag.org/scienceinsider/2010/08/nih-orders-immediate-shutdown.html (quoting email sent to NIH staff by Michael Gottesman, M.D., Deputy Director for Intramural Research, NIH).

which uses those embryonic stem cell lines. The district court disagreed, holding that the use of the word "research" in the Dickey Amendment unambiguously referred to "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[20] The court further reasoned that:

> Despite defendants' attempt to separate the derivation of ESC's [embryonic stem cells] from research on ESCs, the two cannot be separated. Derivation of ESCs from an embryo is an integral step in conducting ESC research. Indeed, it is just one of the many steps in the "systematic investigation" of stem cell research. *Simply because ESC research involves multiple steps does not mean that each step is a separate 'piece of research' that may be federally funded, provided the step does not result in the destruction of an embryo.* If one step or "piece of research" of an ESC research project results in the destruction of an embryo, the entire project is precluded from receiving federal funding by the Dickey-Wicker Amendment.[21]

Upon appeal, the issues before the appellate court are likely to include (1) whether the plaintiffs have met the criteria for a preliminary injunction; (2) whether the language of the Dickey Amendment contains any ambiguity; and (3) whether the district court afforded the appropriate amount of deference to HHS's interpretation of the Dickey Amendment.[22] The appeal may also raise questions about the extent to which recent legislative history should inform application of the Dickey Amendment. For example, federal funds have been available for some types of ESR since 2001 under both the George W. Bush and Obama Administrations. During the same period, Congress has continued to annually enact the same Dickey Amendment language that is found in the most recent Labor-HHS appropriations act. Based on this history of co-existence between the Dickey Amendment and federal funding of ESR, one might argue that Congress has not intended to prohibit federal funding of those categories of ESR which have historically been eligible for federal funds under executive branch policies.

Historical Note: The Bush Policy

Prior to the Obama EO, 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.[23] 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 Congress).

[20] Sherley v. Sebelius, Civ. No. 1:09-cv-1575 RCL, slip op. at 10 (D.D.C. Aug. 23, 2010).

[21] *Id.* at 12 (emphasis added).

[22] *See* Chevron v. Natural Res. Defense Council, Inc., 467 U.S. 837 (1984) (executive agencies' interpretations of statutes are entitled to deference if statutory language is ambiguous and should not be disturbed unless they are unreasonable).

[23] George W. Bush, Executive Order: Expanding Approved Stem Cell Lines in Ethically Responsible Ways, June 20, 2007, http://georgewbush-whitehouse.archives.gov/news/releases/2007/06/20070620-6.html.

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

Policy Options for Congress

Congress has four broad types of policy options regarding ESR: (1) permitting or expanding federal ESR funding; (2) incentivizing activities that avoid ESR; (3) prohibiting ESR; and (4) taking no action.

Congress's first set of options involves permitting or expanding federal ESR funding. Congress could accomplish this by passing legislation that would enact into law the authority to expend federal funds on ESR. Examples in the 111th Congress include, H.R. 872 H.R. 873, S. 487, H.R. 4808, and S. 3766. Enactment of any of these bills, even if consistent with the current executive policy, would clarify the intent of Congress with respect to funding ESR, and could thus nullify the potential effect of the *Sherley* case. Passage of any of these bills would also limit or eliminate the opportunity for the executive branch to set the ESR policy via executive order in the future. None of these bills contains the August 2001 date restriction that had been imposed by the Bush policy. Congress could also expand federal funding for ESR by passing HHS appropriations legislation without the Dickey Amendment, or with a modified version of it. Depending on the final text, this option could allow the use of federal funds for the establishment of ES lines, and/or for the creation of embryos for ESR, and would likely nullify the potential effect of the *Sherley* case.

Congress's second set of options involves incentivizing activities that avoid ESR, as proposed during the 111th Congress in S. 99, S. 3751, H.R. 877, H.R. 1230, H.R. 1654, H.R. 2107, H.R. 6081, and H.R. 6083. 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, or would encourage cord blood collection and donation.

Congress's third set of options involves limiting or eliminating ESR, as effectively proposed during the 111th Congress in H.R. 227, S. 346, H.R. 881, and H.R. 1050. Some of these bills would place the language of the Dickey Amendment in statute, and/or extend 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 as that governing the right to life, organ transplantation,[24] cloning, or the creation of animal-human hybrids) to prohibit ESR or restrict some aspect its conduct.

A fourth option is for Congress to take no action, thus allowing the effect of the *Sherley* case to persist, permitting federal funding for ESR unless and until the district court's decision is affirmed. Note that the result of taking no action may be dependent on the appellate court's ultimate decision in *Sherley*. For example, if the D.C. Circuit reverses the lower court and holds

[24]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.

that federal funding is permitted under the terms of the NIH 2009 Guidelines, taking no action would permit federally funded research to continue, and would allow the executive branch some latitude to change the ESR policy in the future. In contrast, if the D.C. Circuit affirms the lower court, the preliminary injunction would be reinstated and could effectively bar federal funding of ESR.

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.

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,[25] the Coalition for the Advancement of Medical Research (CAMR),[26] former First Lady Nancy Reagan,[27] former Presidents Gerald Ford, Jimmy Carter, and Bill Clinton,[28] and the Union of Orthodox Jewish Congregations of America (UOJCA),[29] favor federal support of ESR that is generally keeping with the Obama EO. Other groups, such as the Christian Legal Society,[30] Focus on the Family,[31] and the Christian Coalition,[32] favor restrictions on ESR,

[25] 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) http://www.nationalacademies.org/about/#org.

[26] 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. For a statement on ESR, see Coalition for the Advancement of Medical Research, *A Catalyst for Cures: Embryonic Stem Cell Research*, January 12, 2009, http://www.camradvocacy.org/resources/camr_wp.pdf.

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

[28] Ibid.

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

[30] The Christian Legal Society is a "national grassroots network of lawyers and law students, committed to ... advocating biblical conflict reconciliation, public justice, religious freedom and the sanctity of human life," http://www.clsnet.org/society/about-cls/statement-faith.

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

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

and had supported the Bush policy. Still others, such as the National Right to Life Committee[33] and the United States Conference of Catholic Bishops,[34] oppose all ESR.

Two presidential bioethics advisory panels have considered the issues involved in ESR. The President's Council on Bioethics (President's Council)[35] published one report directly on the topic, *Monitoring Stem Cell Research*,[36] 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),"[37] 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."[38] In 2005, 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."[39] A predecessor to the President's Council, the National Bioethics Advisory Commission (NBAC),[40] 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."[41]

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

[34] 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," http://www.usccb.org/whoweare.shtml.

[35] 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.

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

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

[38] 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.

[39] President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells* , May 2005, http://bioethics.georgetown.edu/pcbe/reports/white_paper/ (hereinafter, PCBE White Paper).

[40] In 1995, President Clinton created the National Bioethics Advisory Commission by Executive Order, to advise him on bioethical issues. The Order expired in 2001. The Presidential Commission for the Study of Bioethical Issues, *Former Bioethics Commissions*, http://www.bioethics.gov/commissions/.

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

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."[42] 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."[43]

Some groups explore the moral standing of human embryos, and also consider the "duty to relieve the pain and suffering of others."[44] 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.[45] 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.[46] 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."[47] 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.

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 EO does not reference the viability of embryos, but the NIH 2009 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.[48] In a similar manner, the Bush policy had referenced viability, requiring, among other things, use of stem cells derived from only excess

[42] American Life League, *The Bush Stem Cell Decision*, 2001, http://www.all.org/article.php?id=10746&search=2001.

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

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

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

[46] 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.

[47] UOJCA letter.

[48] While the implementation of the Obama policy and NIH guidelines was enjoined by a federal district court in the *Sherley* case (as discussed above), the content and ethical implications of the policy and guidelines themselves have not been modified, and remain relevant to this discussion.

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.[49] 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.[50] The NBAC report touches on the moral status of embryos in utero and those in vitro,[51] though NBAC does not specify whether viability was a key rationale for its recommendations. A group of Representatives,[52] a group of Senators,[53] 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.[54] 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.[55]

As is the case regarding embryo viability, the Obama EO does not reference the purpose of embryo creation. However, the NIH 2009 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.[56] UOJCA argues similarly that

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

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

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

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

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

[54] International Society for Stem Cell Research, "Alternative Methods of Producing Stem Cells: No Substitute for Embryonic Stem Cell Research," *Press Release*, (August 2, 2005), http://www.isscr.org/press_releases/camr_alternatives.htm.

[55] 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.

[56] 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 (continued...)

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."[57]

The President's Council recommended 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.[58] 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.[59] 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.[60] 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."[61] 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.

The Obama EO itself does make a distinction based on the timing of when ES lines were created. The NIH 2009 Guidelines do draw a distinction—one of process more than eligibility—based on when and where the embryo was donated for research. (Embryos donated in the United States after the policy date must meet more specific requirements, while those donated before, or those donated in another country, may receive funding at the discretion of the NIH Director.) The timing of ES-line creation was one central concept in the Bush policy, in that E.O. 13435 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 it allows research on some embryonic stem cell lines and deters the future destruction of embryos for research. The President's Council wrote that a policy based on timing mixes "prudence" with "principle, in the hope that the two might reinforce (rather than undermine) each other."[62] The

(...continued)

first mammalian clone.

[57] UOJCA letter.

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

[59] 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.

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

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

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

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.[63] 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."[64] 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 dwindling[65] and are "contaminated with mouse feeder cells."[66] 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"),[67] 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."[68]

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.[69] 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.

[63] Ibid.

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

[65] 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.

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

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

[68] UOJCA letter.

[69] Kathy Hudson, "International Society for Stem Cell Research Draft Guidelines," *Genetics & Public Policy Center ENews*, Issue 10 (July 2006), http://www.dnapolicy.org/news.enews.article.nocategory.php?action=detail&newsletter_id=13&article_id=31. (Note that finalized guidelines are available: International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, December 21, 2006, http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf.)

While the Obama EO does not explicitly require the consent of the donors, it does require that NIH support ESR conducted responsibly, which may include informed consent requirements.[70] The resulting NIH 2009 Guidelines specify 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 the policy's informed consent requirements.[71]

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.[72] A group of Representatives and a group of Senators mention and imply their support for donor consent requirements.[73]

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.[74] The wide consensus regarding the need for informed consent necessarily implies similar consensus on the need for an information-rich, coercion-free method of obtaining eggs, however there is some disagreement on the specifics of whether payment for eggs necessarily constitutes coercion.

Paying women for their eggs, which has been debated in the context of seeking donor eggs both for reproductive purposes (for example, to enable women who do not produce their own eggs to become pregnant), and for research purposes, is not unheard of in the United States. According to a 2000 study by the American Society of Reproductive Medicine (ASRM), some IVF programs reportedly offered as much as $5,000 for one egg retrieval cycle, though $2,500 appeared to be a more common amount.[75] Offers of much higher amounts ($50,000-$100,000) have been reported

[70] 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.)

[71] See the "Consent of Donors" section of this report for more information.

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

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

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

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

elsewhere.[76] Dr. Hwang's laboratory reportedly made payments of $1,400 to each woman who donated eggs.[77] Payments are not illegal in the United States, nor were they illegal in South Korea at the time Dr. Hwang's laboratory allegedly made them. The questions remain, is payment for egg donation ever acceptable, and if so, in what amount?

Several arguments have been put forth in favor of payment for egg donation, many focused on donation for reproductive purposes.[78] 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.[79] 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.[80] Second, some have argued that payment for eggs for research purposes might undermine public confidence in endeavors such as human ESR.[81] Arguments such as these 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

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

[77] James Brooke, "Korean Leaves Cloning Center in Ethics Furor ," *The New York Times*, November 25, 2005, http://www.nytimes.com/2005/11/25/international/asia/25clone.html?_r=1.

[78] 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 Caludia Kalb, "Ethics, Eggs and Embryos," *Newsweek*, June 20, 2005, http://www.newsweek.com/id/50156?tid=relatedcl.

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

[80] See e.g., PCBE White Paper, pp. 40-41.

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

(noted above in the *Purpose of Embryo Creation* section) effectively take the process of egg procurement from women out of the research arena. As is the case regarding other issues, the Obama EO does not reference the topic of egg donation directly. However, the NIH 2009 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 2009 Guidelines also prohibit the use of federal funding for ESR unless documentation ensures that no payment, cash or in kind, was 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 has 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.[82] 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.[83] 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 EO neither requires nor precludes research into ESR alternatives explicitly, but does require that research be responsible and scientifically worthy. The NIH 2009 Guidelines do not address the issue. By contrast, the Bush Administration's E.O. 13435 had affirmatively directed the pursuit of alternative methods of deriving embryonic stem cells.

Findings regarding the effectiveness of alternatives to ESR are mixed. The President's Council noted that there is a "debate about the relative merits of embryonic stem cells and adult stem cells."[84] 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."[85] 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."[86] 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."[87] CAMR supports both embryonic and adult stem cell research, and adds that access to ES cells "is crucial to continued progress. These pluripotent cells that can self-renew are an unmatched research tool for understanding the body and what goes wrong in disease. Researchers refer to

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

[83] 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).

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

[85] Carrie Gordon Earll, "Talking Points on Stem Cell Research," *Focus on the Family*, September 17, 2003.

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

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

them as 'the gold standard' because these are the cells with the greatest potential for making any cell type in the body."[88]

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 a President's Council white paper developed in 2005 during the Bush Administration.[89] 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.[90]

In the white paper, the President's Council examined the ethical acceptability of each method mentioned above. 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.[91]

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.[92] In addition, the technique was criticized on one side

[88] Coalition for the Advancement of Medical Research, *A Catalyst for Cures: Embryonic Stem Cell Research*, Washington, DC, January 12, 2009, p. 2, http://www.camradvocacy.org/resources/camr_wp.pdf.

[89] President's Council on Bioethics, *White Paper: Alternative Sources of Human Pluripotent Stem Cells* , May 2005, http://bioethics.georgetown.edu/pcbe/reports/white_paper/ (PCBE White Paper).

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

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

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

for effectively "creating a twin and then killing that twin,"[93] and on the other for being an inefficient method for deriving stem cell lines.[94] 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.[95]

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."

As is generally the case regarding alternatives to ESR, on its face the Obama EO 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 2009 Guidelines do not address the issue. By contrast, the Bush Administration's 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.[96] They point out that embryo destruction violates the "deeply held moral beliefs of some citizens," and suggest that "funding alternative research is morally preferable."[97] 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

[93] Ibid.

[94] See e.g., Josephine Quintavalle, "The Lanza Protocol: Damned With Very Faint Praise," *BioNews*, vol. 373, (August 22-28, 2006), http://www.bionews.org.uk/page_37894.asp.

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

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

[97] Ibid.

democratic principles or infringe on the rights of dissent of those in the minority."[98] 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.[99]

Groups' positions on federal funding tend to mirror their positions on stem cell research generally. The Obama EO authorizes federal funding for ESR, and requires funded research be responsible and scientifically worthy. It also requires that research be funded only to the extent permitted by law, thus adopting the restrictions of the Dickey Amendment and precluding federal funding for the establishment of ES lines. The NIH 2009 Guidelines further specify requirements for obtaining federal funding for ESR, and overtly refer to the Dickey Amendment. The Bush policy had also authorized federal funding, but not in a way designed to affect how stem cell lines were established.[100] The 2005 President's Council did not take a position on the issue, but noted the pros and cons and stressed that there is a "difference between *prohibiting* embryo research and *refraining from funding* it."[101] Focus on the Family opposes ESR, including federal funding for it.[102] NBAC finds the arguments in favor of federal funding more persuasive than those against it.[103] 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.[104]

[98] Ibid.

[99] 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.

[100] 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.

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

[102] *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.

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

[104] 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.

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