

APPENDIX D

Stem Cell Research Funding: Policy and Law

The central policy question in the United States relating to human embryonic stem cell research has not been its legality. While several state legislatures have addressed measures that would limit or ban human embryonic stem cell research, the central policy focus at the federal level has been whether and how such research would receive federal funding.

No one has a right to receive federal funding. The people, projects, and activities that receive federal taxpayer dollars do so as a matter of explicit policy decisions. In our democratic system, decisions about funding rightly take into account not only material costs and benefits but also moral judgments.¹

In the stem cell debates, this has meant balancing the public interest in finding new cures and treatments—part of our longstanding public consensus in support of practical scientific research generally—against the profound ethical problems raised by the research.

Policymakers Face the Embryo

The policy debate over funding human embryonic stem cell research was not wholly unprecedented. Scientists began experimenting on human fetal tissue as early as the 1930s; by the 1960s, a handful of non-therapeutic experiments had begun on “preivable human fetuses”—still-living fetuses that had been obtained by spontaneous and induced abortions.² In the 1970s, researchers became more interested in using fetal tissue for clinical purposes. They hoped that if fetal tissue were implanted into the brains of patients with degenerative diseases such as Alzheimer’s, Parkinson’s, or Huntington’s, there might be new growth of some of the brain tissue whose absence or defectiveness had caused the disease. The rapidly rising rate of abortions following the United States Supreme Court’s 1973 *Roe v. Wade* decision³ may have encouraged scientific interest in these possibilities.

During the administrations of Ronald Reagan and George H. W. Bush, no federal funding supported such research, and attempts by Democratic-controlled Congresses to fund it were blocked (although privately

funded fetal-tissue-transplant experiments proceeded). But President Clinton on January 23, 1993—just days after he took office—directed the Department of Health and Human Services (HHS) to lift the Bush administration’s moratorium on fetal-tissue research. On June 10, 1993, the Democratic-controlled Congress passed the National Institutes of Health Revitalization Act, which permitted federal funding for research on fetal transplantation, provided that the tissues came from miscarried or aborted fetuses that were donated with the mother’s consent.⁴ The act also included provisions intended to prevent the purchasing or commercialization of fetal tissue.

The lifting of the moratorium opened the door for government funding of research on *ex utero* embryos created by IVF, although research on embryos *in utero* was still prohibited under federal regulations for the protection of human subjects.

On February 2, 1994, the NIH established the Human Embryo Research Panel (HERP) as an ethics advisory body to provide recommendations on human embryonic research. In a report published September 27, 1994, the panel recommended funding research on human embryos created either for fertility treatments or specifically for the purposes of research.⁵ But there was widespread public unease over the research, including a voluminous negative public response submitted to the panel; so, just hours after the HERP report was released, President Clinton rejected part of its recommendations, saying, “I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research.”⁶

In the wake of this controversy, and following the 1994 election that brought Republican majorities to the House and Senate, Congress passed the Dickey-Wicker Amendment in 1995, named for its authors, Representatives Jay Dickey (R.-Ark.) and Roger Wicker (R.-Miss.). The amendment—a rider on the annual appropriations bill for HHS, which funds the NIH—prohibited federal funding for research that involves the creation or destruction of human embryos. The original amendment forbade funding for:

- (1) the creation of a human embryo or embryos for research purposes; [and]
- (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2)

and 42 U.S.C. 289g(b) [federal statutes relating to the protection of human subjects and fetuses specifically].

For purposes of this section, the phrase “human embryo or embryos” shall include any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.⁷

Ever since 1995, under presidents and congressional majorities of both parties, the Dickey-Wicker Amendment has been included in the annual appropriations legislation with largely the same language and purpose; it remains in effect to the present day. (The only non-trivial change to the language of the amendment appeared starting in 1997, when the definition of embryos was expanded to include organisms “derived...from one or more...human diploid cells”—a change presumably prompted by the announcement of the creation of Dolly the cloned sheep in early 1997.⁸)

In January 1999, two months after the announcement in *Science* that James Thomson had (using private funding) derived human ES cells, Harriet Rabb, the lead legal counsel for HHS, issued a memo advising the director of the NIH that the Dickey-Wicker ban on federal funding for embryo-destructive research would not apply to pluripotent stem cell lines “because such cells are not a human embryo within the statutory definition.”⁹ The Rabb memo thus drew an implicit distinction between the destruction of human embryos and the research that relies on the products of that destruction; federal funding for the former remained illegal, but funding for the latter was deemed permissible. This distinction would become central to the federal stem cell policies that followed.

Later that year, on September 7, 1999, the National Bioethics Advisory Commission (NBAC) published a report recommending that federal funding be permitted for research on embryonic stem cell lines, as well as for the derivation of new stem cell lines from unused embryos.¹⁰ Notably, the NBAC report rejected the Rabb memo’s implicit conclusion that research making use of ES cells is ethically distinct from the process that derives them from embryos:

An ethical problem is presented in trying to separate research in which human ES cells are used from the process of deriving those cells, because doing so diminishes the scientific value of the activities receiving federal support. This division—under which neither biomedical researchers at NIH nor scientists at universities and other research

institutions who rely on federal support could participate in some aspects of this research—rests on the mistaken notion that derivation and use can be neatly separated without affecting the expansion of scientific knowledge....

Instead, recognizing the close connection in practical and ethical terms between derivation and use of the cells, it would be preferable to enact provisions that apply to funding by all federal agencies....¹¹

The NBAC apparently believed that the Rabb memo's recommendation to fund ES cell derivation contradicted the Dickey-Wicker Amendment, since the NBAC felt it necessary to recommend "an exception" to Dickey-Wicker to permit federal funding for "research involving the derivation of human ES cells"¹² from unused IVF embryos.

Three months later, on December 2, 1999, the NIH released draft guidelines for funding research on ES cells. Under the guidelines, research on stem cell lines could be funded provided that their source embryos came from IVF undertaken for reproductive purposes, and that the embryos were voluntarily donated without financial inducement and free of influence or pressure from the researchers who were proposing to derive or make use of the embryonic stem cells.¹³ The guidelines went into effect on August 25, 2000, and the NIH began accepting grant proposals from scientists, although no grants were made before the Clinton administration ended.

The Bush Funding Policy

Stem cell research funding was among the first major policy issues confronted by the new Bush administration in 2001. President Bush faced considerable political pressures on both sides of the issue. Eighty Nobel laureates signed a letter dated February 21, 2001, asking the president to fund the research; meanwhile, a Christian IVF-adoption organization challenged the Clinton administration's NIH guidelines in court, arguing that they violated the Dickey-Wicker Amendment. Jay Lefkowitz, the general counsel of the Bush White House's Office of Management and Budget, later recounted that he

led a team of lawyers in our own evaluation of the Dickey Amendment. We decided that while spending federal dollars on such [ES cell] research might violate the spirit of the amendment, it would not violate the letter. Responsibility for adjudicating the divide between spirit and letter was necessarily the President's as the nation's chief executive officer.¹⁴

The Bush administration embarked on a months-long process of formulating a new policy, aiming to weigh the ethical and legal concerns against the medical promise held by stem cell research. In his memoirs, President Bush describes a defining moment of his deliberations, during a conversation with bioethicist Leon R. Kass on July 10, 2001. Kass advised the president that because embryos are an early form of human life, “we at least owe them the respect not to manipulate them for our purposes.”¹⁵ The president suggested that federal funds could be authorized for already-existing stem cell lines, on the reasoning that since the embryos had already been destroyed, it would make sense to allow the scientists to pursue research using them. There was a lingering concern that this policy might nonetheless tacitly endorse the destruction of embryos. The president’s memoirs paraphrase Kass’s advice:

[Kass] said he believed that funding research on already destroyed embryos would be ethical, with two conditions. I must reaffirm the moral principle that had been violated—in this case, the dignity of human life. And I must make clear that federal funds would not be used in the further destruction of embryos. So long as I did both, he said, the policy would pass the ethical test. “If you fund research on lines that have already been developed,” he said, “you are not complicit in their destruction.”

In an August 9, 2001 speech, President Bush announced that his administration would fund research conducted on human ES cell lines that had already been derived before his policy was announced.¹⁶ Research on ES cell lines established after August 9, 2001 was ineligible for federal support; in this way, the government would avoid creating any incentive for new acts of embryo destruction.

On November 7, 2001, the NIH officially established a registry listing the ES cell lines eligible for funding under the new policy. It also published a set of criteria for federal funding of research on ES cells.¹⁷ Altogether, more than twenty human ES cell lines from across the world would prove available for federal funding under the Bush policy.¹⁸

In a January 11, 2002 memo, Alex Azar, general counsel for HHS, reported his conclusion that the Bush policy “comports with the plain language” of the Dickey-Wicker Amendment.¹⁹ Azar argued that, while the amendment prohibits federal funding for “research in which a human embryo or embryos are destroyed,” the Bush policy was limited to funding research on “a discrete set of stem cell lines with respect to which the life and death decision had been made prior to the announcement of his policy.”

The Bush policy created no incentives for the destruction of additional embryos, Azar wrote, and therefore did not provide funding for *research in which* embryos are destroyed. Azar also noted that the legislative history of the most recent reenactment of the Dickey-Wicker Amendment could be taken as a congressional endorsement of the Bush policy. He referred to a House Committee report on the amendment, issued on October 9, 2001, which stated that the amendment's language should not be construed to limit federal support for stem cell research "carried out in accordance with policy outlined by the President."²⁰

In his August 9, 2001 speech, President Bush also formed the President's Council on Bioethics, naming Kass as its first chairman and charging it with monitoring stem cell research. The Council's first report, released in July 2002, dealt with human cloning, addressing not only questions concerning cloning to produce children but also the use of cloning for biomedical research. A majority of the members of the Council supported a moratorium on cloning for biomedical research, and many among that majority would also have supported a ban. Among those Council members who disapproved of cloning for biomedical research, the report noted, most believed that "it is immoral to create human embryos for purposes that are foreign to the embryos' own well-being and that necessarily require their destruction."²¹ A later Council report on stem cell research, published in January 2004, gave an outline of the moral foundations of the Bush policy—namely "the principle that *public funds* should not be used to encourage or support the destruction of embryos *in the future*," balancing a respect for human life with the importance of relieving suffering.²² And in May 2005, the Council published a white paper exploring four proposals for creating pluripotent stem cells without destroying embryos.²³

Further Policy Developments under President Bush

Over the course of his administration, President Bush sought opportunities to expand support for non-embryo-destroying stem cell research. So, for example, in late 2005 he signed into law the Stem Cell Therapeutic and Research Act, which established a program to help increase the amount of bone marrow and cord blood available for transplantation.²⁴ Meanwhile, some members of Congress from both parties objected to President Bush's ES cell research funding policy, and there were attempts to undo it through legislation. In May 2005, the House of Representatives passed the Stem Cell Research Enhancement Act of 2005, which would have permitted funding on any human ES cell lines derived from IVF embryos that had

been donated with informed consent and without financial inducement. The bill passed the Senate fourteen months later, on July 18, 2006.²⁵

President Bush vetoed the bill the next day—his first use of the presidential veto power. In announcing his decision, the president explained that the bill crossed “a moral boundary” in its support for “the taking of innocent human life in the hope of finding medical benefits for others.”²⁶ Several children who had been born after having been adopted as “spare” IVF embryos were present in the White House for the announcement; the president said they served as a reminder “of what is lost when embryos are destroyed in the name of research.”²⁷ That same day, President Bush signed into law another bill, the Fetus Farming Prohibition Act of 2006, which prohibits the solicitation or acceptance of tissue from fetuses gestated specifically for research purposes.²⁸ Congress attempted to override the Bush policy again the next year. The House and Senate both passed the Stem Cell Research Act of 2007,²⁹ and on June 20, 2007, President Bush again vetoed the legislation. In justifying his decision, he reaffirmed the moral principle underlying his policy: “destroying human life in the hopes of saving human life is not ethical.”³⁰

As we discuss elsewhere in this report (see especially Appendices A and C), the arrival of new, less ethically problematic sources of pluripotent stem cells transformed the factual and moral landscape of the stem cell debate. The Bush policy had been intended in part to encourage the development of such alternative sources of stem cells. In his June 20, 2007 announcement, the president lauded these developments, and took steps to further advance that work, issuing an executive order “to ensure that any human pluripotent stem cell lines produced in ways that do not create, destroy, or harm human embryos will be eligible for federal funding.”³¹ The order directed the NIH to expand funding for research on the “isolation, derivation, production, and testing” of pluripotent stem cells “derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus.”³² In recognition of the change, the NIH registry of stem cell lines was renamed from the Human Embryonic Stem Cell Registry to the Human Pluripotent Stem Cell Registry. (The subsequent registry established under the Obama policy reverted to the old name.)³³

The Obama Funding Policy

On March 9, 2009, President Barack Obama fulfilled a campaign pledge³⁴ by issuing an executive order revoking President Bush’s 2001 stem cell

funding policy as well as Bush's 2007 executive order encouraging research into alternative sources. The new executive order allowed the NIH to support and conduct "human stem cell research, including human embryonic stem cell research, to the extent permitted by law."³⁵

The order further directed the NIH to draft guidelines for funding research on stem cells newly derived from human embryos. These new NIH Guidelines on Stem Cell Research, which went into effect on July 7, 2009, provide criteria for NIH funding of stem cell research in accordance with President Obama's executive order.³⁶ For stem cell lines derived *after* July 7, 2009 to be eligible for funding, they must have been derived from IVF embryos left over and unwanted in fertility clinics. Donors must have been informed ahead of time that the embryos would be used to derive stem cells and that the embryos would be destroyed in the process. Donors also must have been informed that the stem cell line derived from the embryo might be kept indefinitely, and must also confirm that the donation was made without any restrictions or directions regarding the people who may receive medical benefit from the stem cells. Furthermore, donors must have been informed that the research would not be intended to provide them with any direct medical benefit, and that the donors would not receive any financial benefits from any commercial developments that might come from the stem cells. Finally, donors must have been notified whether any information that could identify them would be available to researchers. The Guidelines also stipulate that there should be a "clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes."³⁷ To this end, the IVF clinician should not have been the same person as the researcher proposing to derive or utilize stem cells, "unless separation was not practical."³⁸

For ES cell lines derived from donated embryos *before* July 7, 2009, if there is documentary evidence proving that the lines meet all the criteria described above, they will be eligible for funding. Alternatively, if full documentation is not available—as it probably would not be for cells derived before the Obama informed-consent rules were published—researchers can submit what documentation they do have to a special NIH working group. The working group will review the materials and recommend the ES cell line be eligible for funding if the embryo donation satisfied "core ethical principles and procedures" for obtaining informed consent. Stem cell lines derived outside the United States must meet the same requirements in order to be eligible for research funding.³⁹

The Guidelines also prohibit funding for research in which pluripotent stem cells, either embryonic or induced, are “introduced into non-human primate blastocysts.” And no funding is permitted for breeding animals that have had pluripotent human stem cells introduced to them in such a way that they may contribute to the animal’s germ line.⁴⁰

As of this writing, there are 136 human embryonic stem cell lines eligible for funding under the new Obama policy.⁴¹ There is not yet any comprehensive data on how many of the ES cell lines newly available for funding under the Obama Guidelines have actually been used, and there is reason to believe that the lawsuit described below may have delayed some research projects by creating an atmosphere of legal and funding uncertainty.⁴² In 2010, the NIH spent \$125.5 million on funding for embryonic stem cell research, providing grants for 293 projects—not counting the additional \$39.7 million in funding provided by the American Recovery and Reinvestment Act.⁴³

The Legal Challenge to the Obama Policy

In a lawsuit that has been moving through the federal court system, *Sherley v. Sebelius*, two research scientists argue that President Obama’s NIH Guidelines are in violation of the Dickey-Wicker Amendment.

On August 19, 2009, several parties, including two researchers on adult stem cells, an adoption agency, and a Christian medical association, filed a lawsuit in the United States District Court for the District of Columbia seeking to block HHS from implementing the new Guidelines.⁴⁴ The case was assigned to Chief Judge Royce Lamberth, an appointee of President Reagan. Judge Lamberth initially dismissed the entire suit, ruling on October 27, 2009 that all of the plaintiffs lacked legal standing to file the suit because they were not materially harmed by the new federal policy.⁴⁵ But on June 25, 2010, the U.S. Court of Appeals for the D.C. Circuit overturned Judge Lamberth’s decision, concluding that the two stem cell scientists, Dr. James L. Sherley and Dr. Theresa Deisher, had standing, because the new Obama administration policy would divert federal funds away from their research on adult stem cells. The D.C. Circuit returned the case to Judge Lamberth for a decision on the substantive merits of the case.⁴⁶

On August 23, 2010, Judge Lamberth ruled in favor of the plaintiffs and issued a preliminary injunction ordering HHS to cease funding embryonic stem cell research.⁴⁷ His analysis turned on the question of whether the wording of the Dickey-Wicker 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” (emphasis added), is broad enough to include a researcher’s work on stem cells derived from embryos if the researcher being funded had not himself participated in the initial phase of embryo destruction. On that point, Judge Lamberth rejected the government’s position that HHS funded only one “piece of research”⁴⁸—namely, research using stem cells already derived from embryos—and not the related activities of deriving those stem cells from embryos and destroying the embryos. Judge Lamberth concluded that

despite defendants’ attempt to separate the derivation of ESCs from research on the ESCs, the two cannot be separated. Derivation of ESCs from an embryo is an integral step in conducting ESC research....The Dickey-Wicker Amendment is unambiguous. It prohibits research in which a human embryo is destroyed, discarded, or knowingly subject to risk of injury or death greater than that allowed under applicable regulations. The [Obama administration’s NIH] Guidelines violate that prohibition by allowing federal funding of ESC research because ESC research depends upon the destruction of a human embryo.⁴⁹

As some commentators noted,⁵⁰ Judge Lamberth’s reasoning not only rejected the Obama administration policy for funding embryonic stem cell research, but implicitly also rejected President Bush’s funding policy—since Judge Lamberth denies the claim, first articulated in the 1999 Rabb memo, that the embryo-destroying act of deriving embryonic stem cells is separable under the law from the act of using those stem cells for research. However, since the plaintiff scientists did not challenge the funding of the Bush lines in this litigation, a ruling in their favor would enjoin only the Obama Guidelines.

The Obama administration appealed the decision to the D.C. Circuit, which on September 9, 2010 granted an administrative stay on the injunction, permitting the funding of embryonic stem cell research to continue while the appeal was underway. (A few weeks later, on September 28, 2010, the same court issued a slightly different order, a stay pending appeal, for technical reasons.)

Then on April 29, 2011, the D.C. Circuit ruled in favor of the government, voiding Judge Lamberth’s injunction.⁵¹ Judge Douglas Ginsburg, writing for himself and Judge Thomas Griffith, filed the opinion for the court, arguing that

Dickey-Wicker is ambiguous and the NIH seems reasonably to have concluded that, although Dickey-Wicker bars funding for the destruc-

tive act of deriving an ESC from an embryo, it does not prohibit funding a research project in which an ESC will be used.

In an accompanying dissent, Judge Karen Henderson criticized the majority opinion for its interpretation of Dickey-Wicker, which depended on “breaking the simple noun ‘research’ into temporal bits,” “narrowing the verb phrase ‘are destroyed’ to an unintended scope,” and other acts of “linguistic jujitsu.”

The case then returned to the U.S. District Court for the District of Columbia, where the plaintiffs sought a summary judgment on the merits of the case. Judge Lamberth wrote that while he had “initially agreed with plaintiffs’ understanding of the Dickey-Wicker Amendment,” the higher court’s interpretation of Dickey-Wicker as “ambiguous” overrode his own interpretation—and so, after analyzing the other merits of the plaintiffs’ case, he denied their motion for summary judgment.⁵² On the binding basis of the higher court’s interpretation, Judge Lamberth dismissed the case against the government on July 27, 2011. On September 19, 2011, the plaintiffs filed an appeal to the U.S. Court of Appeals for the District of Columbia as part of their stated effort to “exhaust all of our judicial remedies” to the Obama policy.⁵³

Although the lawsuit is still pending final resolution in the courts, the NIH has continued to announce grant opportunities and provide funding for research on human ES cell lines eligible under the Obama policy.⁵⁴ All told, the NIH is on track to provide \$562 million for human ES cell research during the years of the Obama administration (from 2009 through estimates for 2011 and 2012), compared to a total of \$294 million during the years of the Bush administration (2002 through 2008).⁵⁵

Notes

1. For more on the balance of funding, democratic politics, and ethical judgment, see Peter Berkowitz, “The Meaning of Federal Funding,” Appendix F in President’s Council on Bioethics (PCBE), *Monitoring Stem Cell Research*, Washington, D.C., 2004, 225-236, http://bioethics.georgetown.edu/pcbe/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf.

2. L. Lawn and R. A. McCance, “Ventures with an Artificial Placenta,” *Proceedings of the Royal Society of London. Series B, Biological Sciences* 155, no. 961 (1962): 500-509; M. Pavone-Macaluso, Letter to the Editor, “Artificial Placenta,” *The Lancet* 280, no. 7256 (1962): 608-609; Björn Westin, Rune Nyberg, and Göran Enhörning, “A Technique for Perfusion of the Previsible Human Fetus,” *Acta Paediatrica* 47, no. 4 (1958): 339-349.

3. Guttmacher Institute, “Trends in Abortion in the United States, 1973-2008,”

January 2011, <http://www.guttmacher.org/presentations/trends.pdf>.

4. *National Institutes of Health Revitalization Act I*, Public Law No. 103-43, 107 Stat 122 (1993): §111, <http://www.hhs.gov/ohrp/policy/publiclaw103-43.htm.html>, also archived at <http://www.gpo.gov/fdsys/pkg/STATUTE-107/pdf/STATUTE-107-1-2.pdf>.

5. National Institutes of Health (NIH), *Report of the Human Embryo Research Panel*, (Bethesda, Md.: NIH, 1994), archived at http://bioethics.georgetown.edu/pcbe/reports/past_commissions/human_embryo_vol_1.pdf.

6. William J. Clinton, “Statement on Federal Funding of Research on Human Embryos,” *Public Papers of the Presidents of the United States: William J. Clinton (1994, Book II)*, December 2, 1994, Washington, D.C., p. 2142, <http://www.gpo.gov/fdsys/pkg/PPP-1994-book2/pdf/PPP-1994-book2-doc-pg2142.pdf>.

7. *Balanced Budget Downpayment Act I*, Public Law No. 104-99, 110 Stat 26 (1996): §128, <http://www.gpo.gov/fdsys/pkg/PLAW-104publ99/pdf/PLAW-104publ99.pdf>.

8. *Department of Labor Appropriations Act 1998*, Public Law No. 105-78, 111 Stat 1467 (1997), <http://www.gpo.gov/fdsys/pkg/PLAW-105publ78/pdf/PLAW-105publ78.pdf>.

9. Letter from HHS General Counsel Harriet Rabb to Harold Varmus, Director, NIH, January 15, 1999.

10. National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research Volume 1: Report and Recommendations of the National Bioethics Advisory Commission*, Washington, D.C., 1999, iv, http://bioethics.georgetown.edu/pcbe/reports/past_commissions/nbac_stemcell1.pdf.

11. *Ibid.*, v.

12. *Ibid.*, iv.

13. NIH, “Guidelines for Research Using Human Pluripotent Stem Cells,” *Stem Cell Information*, August 25, 2000, <http://stemcells.nih.gov/news/newsArchives/stemcellguidelines.asp>.

14. Jay Lefkowitz, “Stem Cells and the President—An Inside Account,” *Commentary*, January 2008, <http://www.commentarymagazine.com/article/stem-cells-and-the-president%E2%80%94an-inside-account>.

15. George W. Bush, *Decision Points* (New York: Crown, 2010), 117.

16. George W. Bush, “Address to the Nation on Stem Cell Research,” August 9, 2001, *Public Papers of the Presidents of the United States: George W. Bush (2001, Book II)*, Washington, D.C., pp. 953-956, <http://www.gpo.gov/fdsys/pkg/PPP-2001-book2/pdf/PPP-2001-book2-doc-pg953-2.pdf>.

17. NIH, “NIH Human Embryonic Stem Cell Registry under Former President Bush,” *Stem Cell Information*, <http://stemcells.nih.gov/research/registry/eligibilitycriteria.asp>.

18. *Ibid.*

19. HHS General Counsel Memorandum, January 11, 2002, Alex M. Azar II to Ruth Kirchstein, Acting Director, NIH, AR 303.

20. Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2002, H.R. Rep. No. 107-229, 107th Congress, 1st Session, p. 180, <http://www.gpo.gov/fdsys/pkg/CRPT-107hrpt229/pdf/CRPT-107hrpt229.pdf>.
 21. PCBE, *Human Cloning and Human Dignity: An Ethical Inquiry*, Washington, D.C., 2002, <http://bioethics.georgetown.edu/pcbe/reports/cloningreport/recommend.html>.
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 23. PCBE, *Alternative Sources of Pluripotent Stem Cells: A White Paper*, Washington, D.C., 2005, http://bioethics.georgetown.edu/pcbe/reports/white_paper/index.html.
 24. *Stem Cell Therapeutic and Research Act of 2005*, Public Law No. 109-129, 119 Stat 2550 (2006): §3, <http://www.gpo.gov/fdsys/pkg/PLAW-109publ129/pdf/PLAW-109publ129.pdf>.
 25. *Stem Cell Research Enhancement Act of 2005*, H.R. 810, 109th Congress (July 18, 2006), <http://thomas.loc.gov/cgi-bin/bdquery/z?d109:HR00810:>.
 26. George W. Bush, "Remarks on Signing the Fetus Farming Prohibition Act and Returning Without Approval to the House of Representatives the 'Stem Cell Research Enhancement Act of 2005,'" July 19, 2006, *Weekly Compilation of Presidential Documents* 42, no. 29, Washington, D.C., 1362-1365, <http://www.gpo.gov/fdsys/pkg/WCPD-2006-07-24/pdf/WCPD-2006-07-24-Pg1362-3.pdf>.
 27. *Ibid.*
 28. *Fetus Farming Prohibition Act of 2006*, Public Law No. 109-242, 120 Stat 570 (2006), <http://www.gpo.gov/fdsys/pkg/PLAW-109publ242/pdf/PLAW-109publ242.pdf>.
 29. *Stem Cell Research Enhancement Act of 2007*, S. 5, 110th Congress, (June 7, 2007), <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:SN00005:>.
 30. George W. Bush, "Remarks on Returning Without Approval to the Senate the 'Stem Cell Research Enhancement Act of 2007,'" June 20, 2007, *Weekly Compilation of Presidential Documents* 43, no. 25, pp. 831-833, <http://www.gpo.gov/fdsys/pkg/WCPD-2007-06-25/pdf/WCPD-2007-06-25-Pg831-2.pdf>.
 31. *Ibid.*
 32. Executive Order no. 13435, "Expanding Approved Stem Cell Lines in Ethically Responsible Ways," *Federal Register* 72, no. 120 (June 22, 2007): 34591, <http://edocket.access.gpo.gov/2007/pdf/07-3112.pdf>.
 33. *Ibid.*; NIH, *NIH Human Embryonic Stem Cell Registry*, http://grants.nih.gov/stem_cells/registry/current.htm.
 34. Then-Senator Obama promised on August 30, 2008 to "lift the [Bush] administration's ban on federal funding of research on embryonic stem cell lines created after August 9, 2001 through executive order." ScienceDebate2008, "ScienceDebate2008.com Presents: Presidential Answers to the Top 14 Science Questions Facing America," August 30, 2008, <http://www.sciencedebate.org/debate08.html>.
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35. Executive Order no. 13505, “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,” *Federal Register* 74, no. 46 (March 11, 2009): 10667, <http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf>.
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37. *Ibid.*
38. *Ibid.*
39. *Ibid.*
40. *Ibid.*
41. NIH, *NIH Human Embryonic Stem Cell Registry*, http://grants.nih.gov/stem_cells/registry/current.htm, accessed November 29, 2011. The registry notes that three of the 136 lines are designated as “currently on hold and should not be used in NIH-funded research.”
42. Aaron D. Levine, “Policy Uncertainty and the Conduct of Stem Cell Research,” *Cell Stem Cell* 8, no. 2 (2011): 132–135. See also Christopher T. Scott *et al.*, “Federal Policy and the Use of Pluripotent Stem Cells,” *Nature Methods* 7, no. 11 (2010): 866–867.
43. *American Recovery and Reinvestment Act of 2009*, Public Law No. 111–5, 123 Stat 115 (2009); NIH, NIH Research Portfolio Online Reporting Tools (RePORT), <http://www.report.nih.gov/rcdc/categories/ProjectSearch.aspx?FY=2010&ARRA=N&DCat=Stem%20Cell%20Research%20-%20Embryonic%20-%20Human>.
44. Executive Order no. 13505, March 11, 2009.
45. *Sherley v. Sebelius*, 686 F Supp 2d 1 (DDC 2009), available at https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv1575-36.
46. *Sherley v. Sebelius*, 610 F3d 69 (DC App 2010), available at [http://www.cadc.uscourts.gov/internet/opinions.nsf/654D067319DDFA2D852578070070585A/\\$file/09-5374-1251802.pdf](http://www.cadc.uscourts.gov/internet/opinions.nsf/654D067319DDFA2D852578070070585A/$file/09-5374-1251802.pdf).
47. *Sherley v. Sebelius*, 704 F Supp 2d 63 (DDC 2010), available at https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv1575-44.
48. *Ibid.*, p. 10.
49. *Ibid.*, p. 12.
50. See, for example, William Saletan, “Dickey Waiver: A Crazy Judge Throws Out Obama’s Stem-Cell Policy—and Bush’s,” *Slate*, August 25, 2010, <http://www.slate.com/id/2264996/>.
51. *Sherley v. Sebelius*, 10–5287 (DC App 2011), available at [http://www.cadc.uscourts.gov/internet/opinions.nsf/DF210F382F98EBAC852578810051B18C/\\$file/10-5287-1305585.pdf](http://www.cadc.uscourts.gov/internet/opinions.nsf/DF210F382F98EBAC852578810051B18C/$file/10-5287-1305585.pdf).
52. *Sherley v. Sebelius*, No 84–1, slip op (DDC 2011), available at https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv1575-84-1. In issuing his decision,

Judge Lamberth regretted that his court had become “a grudging partner in a bout of ‘linguistic jujitsu’” regarding the definition of the word “research,” but remarked that “such is life for an antepenultimate court.”

53. Law of Life Project, “Adult Stem Cell Researchers Ask Federal Court to Reverse Ruling That Existing Federal Law Does Not Ban Federal Funding of Illegal, Unnecessary, and Unethical ‘Research’ in Which Human Embryos are ‘Knowingly Subjected to Risk of Injury or Death,’” press release, September 19, 2011, <http://www.christiannewswire.com/news/694317814.html>.

54. The NIH announced a grant opportunity involving research on approved human ES cell lines as recently as September 21, 2011. Furthermore, there are a number of human ES cell research projects currently receiving funding from the NIH, with some projects receiving grants starting as recently as September 1, 2011. NIH, “Environmental Influences on Stem Cells in Development, Health, and Disease (R21),” request for applications, <http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-11-010.html>; NIH RePORTER, “Project Information: 1R01GM094220-01A1,” http://projectreporter.nih.gov/project_info_details.cfm?aid=8108690.

55. In 2008, the NIH implemented a new methodology for reporting research funding, which the agency used to recalculate funding figures for 2007. The Bush administration total funding figure of \$294 million we report here uses this revised 2007 data, found on the new NIH RePORT website, along with the data found on the NIH Stem Cell Research website. NIH, “NIH Stem Cell Research Funding, FY 2002-2010,” <http://stemcells.nih.gov/research/funding/funding.htm>; NIH Research Portfolio Online Reporting Tools (RePORT), <http://report.nih.gov/rcdc/categories/>.