

SHERLEY V. SEBELIUS: STEM CELLS AND THE UNEASY INTERPLAY BETWEEN THE FEDERAL BENCH AND THE LAB BENCH

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ABSTRACT

After Barack Obama's election to the presidency, he promised that one of his top priorities in office would be to relieve the restrictions initiated by President George W. Bush on federal funding of embryonic stem cell research. President Obama followed through on his promise, but the celebrations in the nation's research labs were short-lived. Anti-abortion advocates and other scientists working in the field that would allegedly be out-competed in the federal funding arena brought a legal challenge to the new government position. The struggle culminated in August 2010 with a federal district court issuing a preliminary injunction to halt the new funding initiative. Although the government successfully appealed for a stay on the injunction pending arguments in the Court of Appeals, the decision has paralyzed research in the field. This iBrief argues that the injunction was wrongly granted, predicts how higher courts might treat the case, and suggests that the proper forum for addressing this controversy lies within the scientific community, not the judiciary.

INTRODUCTION

¶1 Over the last century, the United States has become the clear leader in scientific research and development worldwide due to governmental funding of research and relatively few limitations on its direction. From 1999 to 2008, out of more than 9.4 million scientific journal articles indexed by Thomson Reuters, approximately three million, or 31.8%, originated from researchers based in the United States.² The second most productive nation, Japan, published only 8.5% of all papers.³ Hundreds of

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² *National Rankings by Output in Sciences and Social Sciences, 1999–2008*, SCI-BYTES (Feb. 15, 2009), http://sciencewatch.com/dr/sci/09/feb15-09_1D/.

³ *Id.*

thousands of American citizens, permanent residents, and foreign nationals on temporary work visas in the United States are employed in the pursuit of scientific discovery. It is a substantial part of the U.S. economy, with more than \$400 billion spent on scientific research and development in the 2010 fiscal year.⁴

¶2 Federal funding is critical, and arguably essential, for the conduct of research in the modern era. Of the \$400 billion spent on research and development (R&D) in 2010, the federal government chipped in more than \$147 billion.⁵ Much of that support goes to researchers at universities and government labs. The passage of the Bayh-Dole Act in 1980 allowed these recipients of federal funds to retain some rights to subsequent inventions and discoveries.⁶ The Department of Defense provides more funding than any other federal agency, generally through government contracts, but the largest benefactors of biomedical research are the National Institutes of Health (NIH) and the National Science Foundation (NSF).⁷ The NIH alone spends more than \$28 billion every year through the disposition of more than 50,000 research grants.⁸

¶3 The government and the researchers that it funds generally have a symbiotic relationship. The researchers enjoy financial support while the government gains rights and licenses to the inventions, as well as full and rapid disclosure of experimental data gained under its patronage.⁹ Both

⁴ Sabine Vollmer, *White House: Tough Year Ahead for R&D Funding*, SCIENCE IN THE TRIANGLE (Sept. 9, 2010, 7:59 PM), <http://scienceinthetriangle.org/2010/09/white-house-tough-year-ahead-for-rd-funding/>.

⁵ JOHN F. SARGENT, JR., CONG. RESEARCH SERV., R40710, FEDERAL RESEARCH AND DEVELOPMENT FUNDING: FY2010 6 (2010), available at <http://www.fas.org/sgp/crs/misc/R40710.pdf>.

⁶ See The University and Small Business Patent Procedures Act of 1980, Pub. L. 96-517, 94 Stat. 3018 (codified as amended at 35 U.S.C. §§ 200–212 (2006); 37 C.F.R. § 401 (2010)) (“It is the policy and objective of the Congress . . . to promote the utilization of inventions arising from federally supported research . . . to promote collaboration between commercial concerns and nonprofit organizations . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor” 35 U.S.C. § 200).

⁷ SARGENT, *supra* note 5, at 9 tbl.1.

⁸ *About NIH*, NATIONAL INSTITUTES OF HEALTH, <http://www.nih.gov/about/NIHoverview.html> (last updated June 19, 2007).

⁹ See 42 U.S.C.A. § 282c (West 2010) (“[A]ll investigators funded by the NIH [must] submit . . . an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication”).

parties enter this relationship with expectations of one another: the government assumes that the research will be fruitful, frugal, and faithful to the project as outlined in the grant proposal, and the researchers presume that, once awarded funds, they will be allowed to freely pursue their research goals. The stakes are high; with only one-fifth of grant applications funded in a given fiscal year,¹⁰ it is critical to a researcher to compete for and obtain funds, get started on the work, and trust that the funds will continue to flow for the duration of the project. Failure may mean abandonment of experiments, getting “scooped” by a competing lab, or even the loss of tenure and other negative career outcomes.

¶4 In *Sherley v. Sebelius*,¹¹ the lab bench and the federal bench come into direct conflict. After President Obama loosened the restrictions on human embryonic stem cell (hESC) research¹² that had been instituted by President George W. Bush,¹³ two scientific researchers working on a different kind of stem cells feared their own chances of funding would be diminished with the influx of new human stem cell initiatives. They sued, joined by other plaintiffs with separate and individual interests in the abolition of the new stem cell guidelines. After a year of battling over jurisdiction and standing, Chief Judge Royce Lamberth of the U.S. District Court for the District of Columbia granted a preliminary injunction halting federal funding of hESC research on August 23, 2010.¹⁴ The Court of Appeals for the D.C. Circuit granted an emergency stay requested by the government in September 2010,¹⁵ but this left the entire case, and indeed the entire field, in limbo. The circuit court has granted expedited review of the

¹⁰ *Research Project Success Rates by NIH Institute for 2009*, NAT'L INSTS. OF HEALTH RESEARCH PORTFOLIO ONLINE REPORTING TOOLS, http://report.nih.gov/award/success/Success_ByIC.cfm (select “2009” from drop-down menu under “Fiscal Year”) (last visited Mar. 22, 2011).

¹¹ 704 F. Supp. 2d 63 (D.D.C. 2010).

¹² See Exec. Order No. 13,505, 74 Fed. Reg. 10,667–10,668 (2009) (“The purpose of this order is to remove these limitations on scientific inquiry [in hESCs], to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.”).

¹³ See Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953–56 (Aug. 9, 2001) (“I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life-and-death decision has already been made.”).

¹⁴ *Sherley*, 704 F. Supp. 2d at 73.

¹⁵ *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010) (order granting emergency stay) [hereafter Emergency Stay Order]. This order and other filings, cited *infra* at, e.g., note 44, are available for free at <http://www.adfmedia.org/News/PRDetail/3959>.

preliminary injunction and heard oral arguments in December 2010,¹⁶ but Judge Lamberth can still decide, at any time, to rule on the case on the merits.¹⁷ Meanwhile, the NIH has halted all work by its own researchers on hESCs, but has told external independent labs receiving funding they can work until their current grant check runs out.¹⁸ With the field stuck at such an impasse, what should the role of the courts be in the regulation and conduct of scientific research?

¶5 Part I of this iBrief will briefly discuss the history of embryonic stem cell research and the government's response to it. Part II discusses the history and holding of the district court in *Sherley*. Part III analyzes how the ruling was misguided on legal and policy grounds. Finally, Part IV will argue that another reviewing body already has jurisdiction in this area—the scientific community.

I. EMBRYONIC STEM CELLS: AN INCUBATING CRISIS

¶6 Stem cells potentially can be valuable tools for research and therapeutic applications because they can differentiate, or grow, into any cell type in the body.¹⁹ The medical and scientific communities are still refining the best modes of stem cell usage; for all their potential, the cells are far from a cure-all to complicated human diseases. In 1964, researchers discovered that cells isolated from a tumor grew in cell culture as stem cells, and had the capability of becoming various types of cells.²⁰ Two research groups in 1981 independently discovered how to derive these stem cells from mouse embryos, and how to use them for research.²¹ Finally, in 1998,

¹⁶ Courtroom Minutes of Oral Argument, *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010) (No. 10-5287).

¹⁷ Jocelyn Kaiser, *Another Round of Filings in Stem Cell Court Case*, SCIENCEINSIDER (Oct. 29, 2010, 5:01 PM), <http://news.sciencemag.org/scienceinsider/2010/10/another-round-of-filings-in-stem.html>.

¹⁸ Jocelyn Kaiser, *NIH Orders Immediate Shutdown of Intramural Human Embryonic Stem Cell Research*, SCIENCEINSIDER (Aug. 30, 2010, 11:53 AM), <http://news.sciencemag.org/scienceinsider/2010/08/nih-orders-immediate-shutdown.html>.

¹⁹ See Nat'l Insts. of Health, *Stem Cell Basics: Introduction*, STEM CELL INFORMATION. <http://stemcells.nih.gov/info/basics/basics1.asp> (last modified Apr. 28, 2009) (“Stem cells have the remarkable potential to develop into many different cell types in the body during early life and growth.”).

²⁰ Lewis J. Kleinsmith & G. Barry Pierce, Jr., *Multipotentiality of Single Embryonal Carcinoma Cells*, 24 *CANCER RES.* 1544, 1544 (1964).

²¹ Martin Evans & Matthew Kaufman, *Establishment in Culture of Pluripotential Cells from Mouse Embryos*, 292 *NATURE* 154, 154 (1981); Gail R. Martin, *Isolation of a Pluripotent Cell Line from Early Mouse Embryos*

Dr. James Thomson at the University of Wisconsin discovered how to derive and use stem cells from human embryos.²² The use of the cells in research remains controversial, because, as part of the process of deriving the cells, the embryo—be it animal or human—is destroyed.²³

¶7 There are two other types of human stem cells besides hESCs also currently used in biomedical research. “Adult stem cells” are undifferentiated cells found in tissues and organs throughout the body among the cells already differentiated.²⁴ Harvesting these cells does not require the destruction of embryos as does the derivation of hESCs, but it has significant drawbacks nonetheless: they are not pluripotent (i.e., they can only become the cell type of the site where they were found), and they cannot be grown perpetually in cell culture.²⁵ This seriously limits their potential for research, and has led government scientists to declare that adult stem cells are “not to be an alternative to [human embryonic stem] . . . cell research.”²⁶ The second alternative type of stem cells is known as “induced pluripotent” stem cells. They represent a hybrid of the other two types; they are adult stem cells that have been genetically reprogrammed to act like hESCs, which are pluripotent and can differentiate into any other type of cell.²⁷ Although currently little is known about the full potential of these cells, they may one day represent a compromise in the adult stem cell versus hESC debate.²⁸ Recent studies have suggested, however, that, like adult stem cells, induced pluripotent stem cells also have significant

Cultured in Medium Conditioned by Teratocarcinoma Stem Cells, 78 PROC. NAT’L ACAD. SCI. 7634, 7634 (1981).

²² James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145, 1145 (1998).

²³ See Roseann B. Termini, *Does “Political” Science Exist Anymore? Embryonic Stem Cell Research in this New Political Era*, 5 J. HEALTH & BIOMED. L. 249, 256 (2009) (citing Jordan Saltzberg, Article, *The Current Embryonic Stem Cell Research Federal Funding Policy*, 29 J. LEGAL MED. 505, 507 (2008)) (describing derivation procedure and controversy).

²⁴ See Laura E. Gagnon, Note, *Embryonic Stem Cell Research: With Suitable Regulation and Federal Funding, Life Without Serious Disease Becomes an Attainable Goal*, 16 SYRACUSE SCI. & TECH. L. REP. ¶ 6 (2007) (describing differences between hESCs and adult stem cells).

²⁵ *Id.*

²⁶ *Id.* at ¶ 8 (quoting NATIONAL RESEARCH COUNCIL, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 17 (2005)).

²⁷ See Termini, *supra* note 23, at 255–56 (contrasting induced pluripotent and adult stem cells).

²⁸ See *id.* at 256 (noting that because induced pluripotent stem cells have the differentiation capabilities of hESCs but do not require derivation, they may solve the hESC quandary).

shortcomings with regard to differentiation ability.²⁹ For now, no other type of stem cell is as versatile as hESCs.

¶8 In the turbulent aftermath of *Roe v. Wade*,³⁰ research involving embryos became especially controversial. In response, Congress imposed a moratorium on all human fetal and embryonic research in the year following the decision. This moratorium lasted twenty years.³¹ During President Bill Clinton's first term, an NIH panel recommended to the President that research involving embryos be federally funded.³² Progress was stymied in 1996, however, due to an otherwise obscure rider amendment on a Congressional budget bill. The bill, the Balanced Budget Downpayment Act,³³ contained the following language:

None of the funds made available by Public Law 104-91 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 46.208(a)(2) and 42 U.S.C. 289g(b). 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 gametes³⁴

¶9 This provision became known as the Dickey-Wicker Amendment, and it has appeared in similar form in every subsequent HHS funding bill.³⁵ Although the Clinton Administration's interpretation of the Amendment's language was that federal funding of research on the *cells* was permissible as long as the derivation and destruction of embryos occurred with non-federal funding, no grants were authorized for hESC work during Clinton's

²⁹ See Megan Scudellari, *The iPSC-ESC Gap*, THE SCIENTIST (Feb. 2, 2011, 6:00 PM GMT), <http://www.the-scientist.com/news/display/57971/> ("Human cells reprogrammed into multipotent stem cells display fundamental differences from true embryonic stem cells.").

³⁰ 410 U.S. 113 (1973).

³¹ Termini, *supra* note 23, at 265–66.

³² *Id.* at 266.

³³ Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996).

³⁴ *Id.* The Act of January 6, 1996, Public Law 104-91, continued funding for fiscal year 1995 activities and appropriated funds for fiscal year 1996. Pub. L. No. 104-91, 110 Stat. 7, 10 (1996). A bill actually implementing the funding for fiscal year 1996, which was also subject to the Dickey-Wicker provisions, was passed on April 26, 1996. Pub. L. No. 104-134, 110 Stat. 1321, 211 (1996).

³⁵ Termini, *supra* note 23, at 266.

presidency.³⁶ Shortly after taking office, President George W. Bush, while acknowledging that the “great promise” of hESC research “will come only with federal funds,” announced that funding would be limited only to the sixty hESC lines currently in existence at the time of the speech on August 9, 2001.³⁷ An NIH study conducted several years later found that only a quarter of the sixty permitted lines were actually accessible and suitable for research use by American scientists.³⁸ Congress attempted to soften restrictions and circumvent President Bush’s orders with bills that passed both houses in 2005 and 2007, but Bush vetoed both.³⁹ Limited research continued on the allowed lines, but the field languished overall.

¶10 Barack Obama emerged as the Democratic nominee for President in 2008, and one of his campaign promises was to roll back the Bush-era restrictions and expand hESC research.⁴⁰ In March 2009, less than two months into his term, Obama signed an executive order entitled “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,” and effectively cancelled the restrictions President Bush had placed on hESC lines.⁴¹ Pursuant to this executive order, the NIH promulgated new rules and procedures to accommodate the new research initiatives.⁴²

II. EVENTS LEADING TO THE PRELIMINARY INJUNCTION: HOW THREE WORDS HALTED AN ENTIRE FIELD OF RESEARCH

A. History of the Case

¶11 Shortly after the NIH Guidelines for Human Stem Cell Research took effect on July 7, 2009,⁴³ a collection of plaintiffs seeking to enjoin implementation of the Guidelines filed suit in the U.S. District Court for the District of Columbia.⁴⁴ The plaintiffs included Dr. James Sherley, a researcher at the Boston Biomedical Research Institute; Dr. Theresa

³⁶ *Id.* at 267.

³⁷ Address to the Nation on Stem Cell Research, *supra* note 13.

³⁸ Termini, *supra* note 23, at 268.

³⁹ *Id.* at 269.

⁴⁰ See, e.g., Mimi Hall, *Opponents Brace for End of Stem Cell Ban*, USA TODAY, Nov. 16, 2008, http://www.usatoday.com/news/washington/2008-11-16-stemcells_N.htm (“Obama’s campaign promised broad support for stem cell research.”).

⁴¹ Exec. Order No. 13,505, *supra* note 12.

⁴² RAYNARD S. KINGTON, NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR HUMAN STEM CELL RESEARCH (2009), available at <http://stemcells.nih.gov/policy/2009guidelines.htm>.

⁴³ *Id.*

⁴⁴ Complaint at 3, *Sherley v. Sebelius*, 686 F. Supp. 2d 1 (D.D.C. 2009) (Civ. A. No. 1:09-cv-01575-RCL). Plaintiff James Sherley’s name was misspelled in the caption of this first proceeding due to a typographical error.

Deisher, the head of a private research lab in Seattle, WA; and several religious interest groups and individuals suing on behalf of embryos and adoption agencies.⁴⁵ Drs. Sherley and Deisher both focused their research on adult stem cells, and they argued that approval of additional lines of funding for hESCs would unfairly limit their own access to federal research funding.⁴⁶ The other plaintiffs sought to enjoin the enforcement of the guidelines to protect embryos and to ensure the availability of embryos for in vitro fertilization treatments.⁴⁷

¶12 The defendants in the complaint were Kathleen Sebelius, Secretary of Health and Human Services; Dr. Francis Collins, newly-appointed Director of the NIH; and their respective institutions.⁴⁸ The defendants filed a motion to dismiss, stating that all of the plaintiffs lacked standing to pursue the complaint; none of the plaintiffs had alleged an actionable injury.⁴⁹ The district court, in an opinion by Chief Judge Royce Lamberth, agreed with the defendants and dismissed the case.⁵⁰

¶13 Shortly thereafter, the plaintiffs appealed the matter of standing to the Court of Appeals for the D.C. Circuit. The court upheld the dismissal with respect to the adoption agencies, embryos, and prospective parents, but reversed the district court's ruling with regard to the two researchers.⁵¹ The district court held that the researchers lacked standing on the grounds that a "competitor standing doctrine" theory was insufficient to maintain standing.⁵² But the court of appeals stated that competitor standing was available to anyone "competing for a government benefit" when "the Government takes a step that benefits his rival and therefore injures him economically."⁵³

B. The District of D.C.'s August 2010 Injunction

¶14 Upon resolution of the standing issues by the court of appeals, the court remanded the case back to the district court and reinstated the motion for a preliminary injunction.⁵⁴

⁴⁵ *Id.* at 3–7.

⁴⁶ *Id.* at 3–5.

⁴⁷ *Id.* at 5–7.

⁴⁸ *Id.* at 7–8.

⁴⁹ Motion to Dismiss at 14, *Sherely v. Sebelius*, 686 F. Supp. 2d 1 (D.D.C. 2009) (Civ. A. No. 1:09-cv-01575-RCL).

⁵⁰ *Sherely v. Sebelius*, 686 F. Supp. 2d 1, 3 (D.D.C. 2009).

⁵¹ *Sherley v. Sebelius*, 610 F.3d 69, 70 (D.C. Cir. 2010).

⁵² *Sherely*, 686 F. Supp. 2d at 6–7.

⁵³ *Sherley*, 610 F.3d at 72.

⁵⁴ *Id.* at 70.

¶15 There are four factors that must be established in order for a preliminary injunction to be granted in the District of Columbia:

1. Substantial likelihood of success on the merits;
2. That plaintiff(s) would suffer irreparable injury if the injunction is not granted;
3. That an injunction would not substantially injure other parties;
4. That the public interest would be furthered by the injunction.⁵⁵

¶16 The Court of Appeals for the D.C. Circuit has not settled the question of whether a plaintiff must definitively prevail on each of the four factors, but the development of the case law suggests that at least some showing must be made for each one.⁵⁶ The factors are to be considered on a sliding scale; if a showing on one of the factors is particularly strong, showings on the others may be weaker.⁵⁷ Historically, however, federal courts in the District of Columbia have followed the lead of other federal courts, emphasizing the first two factors of success on the merits and irreparable injury.⁵⁸

¶17 On August 23, 2010, with no notice to the parties of the ensuing decision,⁵⁹ Chief Judge Lamberth granted the preliminary injunction on behalf of the two remaining plaintiffs, Drs. Sherley and Deisher.⁶⁰ In a concise opinion, the court evaluated the four factors and held that all four weighed in favor of the plaintiffs.⁶¹

¶18 On the question of likelihood of success on the merits, the court rejected the government's argument that the language of the Dickey-Wicker Amendment was ambiguous.⁶² The government argued that the agency decision should be given deference under *Chevron U.S.A., Inc., v. Natural*

⁵⁵ *Mova Pharma. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998).

⁵⁶ *Adair v. England*, 217 F. Supp. 2d 1, 3 n.7 (D.D.C. 2002).

⁵⁷ *CSX Transp., Inc. v. Williams*, 406 F.3d 667, 670 (D.C. Cir. 2005).

⁵⁸ *See, e.g., Van Valin v. Locke*, 628 F. Supp. 2d 67, 72 (D.D.C. 2009).

⁵⁹ In their brief on appeal to the Court of Appeals for the D.C. Circuit, the government's lawyers stated that "the district court issued its preliminary injunction without notice 10 months after dismissing the case, providing no opportunity for NIH to address the current state of research and application review before it had to file its stay motion." Reply Brief for Appellants at 24 n.4, *Sherley v. Sebelius*, No. 10-5287 (D.C. Cir. Nov. 4, 2010).

⁶⁰ *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 73 (D.D.C. 2010).

⁶¹ *Id.* at 69–70.

⁶² *Id.* at 70.

*Resources Defense Council, Inc.*⁶³ Courts must choose whether to defer to Congress's or the agency's interpretation, depending on the specificity of the issue and the ambiguity of the language.⁶⁴ Chief Judge Lamberth ruled that Congress had spoken to the "precise question at issue" and that "research," as written in the statute, unambiguously connoted all research.⁶⁵ The court then determined that the NIH Guidelines were in violation of the Dickey-Wicker Amendment, despite the government's argument that derivation (i.e., actual destruction of embryos) occurred prior to the actual research being performed.⁶⁶

¶19 The court held that the factor of irreparable harm also was satisfied. Chief Judge Lamberth found that the increased competition over limited federal funding was an "actual, imminent injury" for the two plaintiff adult stem cell researchers, which met the "high standard" of circuit precedent.⁶⁷ Although the asserted injury was economic in nature, and as such would not meet the standards of the circuit,⁶⁸ the court ruled that the Guidelines threatened "the very livelihood" of the plaintiffs and that there was "no after-the-fact remedy" for their prospective losses.⁶⁹ Therefore, the irreparable injury factor was satisfied.

¶20 With regard to the balance of hardships, the defendants argued that two large populations would be harmed if the injunction was granted: the hundreds, if not thousands, of researchers who work or would work on hESC research; and the millions of individuals suffering from diseases for which treatments could be developed through new research.⁷⁰ The court,

⁶³ 467 U.S. 837, 843 (1984).

⁶⁴ *Id.*; *Sherley*, 704 F. Supp. 2d at 70.

⁶⁵ *Id.* at 70–71.

⁶⁶ *Id.* at 71–72. The court's interpretation of "research" will be analyzed further in Part IV, *infra*. In short, the court held that if destruction of the embryos occurred at *any* point, the entire ensuing research project violated Dickey-Wicker. This decision effectively would end *all* hESC research, because all hESCs were at some point derived from a subsequently-destroyed embryo. The basis of the government's argument was that the majority of hESC researchers does not derive or destroy the embryos themselves and merely receive cells, possibly years old, already in culture.

⁶⁷ *Sherley*, 704 F. Supp. 2d at 72 (citing *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)). The Court of Appeals for the D.C. Circuit has developed in its case law a stiff standard for irreparable injury.

⁶⁸ *See, e.g., Am. Ass'n for Homecare v. Leavitt*, CIV A. 08-0992 RMU, 2008 WL 2580217 (D.D.C. June 30, 2008) ("Harm that is 'merely economic' in character is not sufficiently grave under this standard. . . . Only monetary losses that 'cause extreme hardship to the business, or even threaten destruction of the business' will suffice." (citations omitted)).

⁶⁹ *Sherley*, 704 F. Supp. 2d at 72–73.

⁷⁰ *Id.* at 72.

however, ruled that harms to these populations were not substantial enough to prevent granting the injunction because the injunction would merely preserve the *status quo*.⁷¹ Further, the injury to the plaintiffs was “actual and imminent” while any damages to other parties were merely speculative.⁷² The balance of harms was found to favor the plaintiffs.⁷³

¶21 The final factor of public interest was also held to favor the plaintiffs.⁷⁴ The court stated that it was firmly in the public interest “for courts to carry out the will of Congress and for an agency to implement properly the statute it administers.”⁷⁵ The Dickey-Wicker Amendment was held, as passed legislation, to be the “will of Congress” and the Guidelines were found to be in violation of the Amendment.⁷⁶

¶22 With all four factors determined to weigh in favor of the plaintiffs, the injunction was granted.⁷⁷ Thus, three words—“research” and “status quo”—brought the work of thousands of researchers nationwide to a screeching halt. After an emergency appeal by the government, the Court of Appeals for the D.C. Circuit issued an administrative stay on September 9, 2010.⁷⁸ After hearing oral arguments, the Court of Appeals for the D.C. Circuit issued a stay pending expedited appeal on September 28, 2010.⁷⁹

III. THE INJUNCTION WAS GRANTED IN ERROR AS A MATTER OF LAW

*“His decision on every point seems wrong and, on two out of three, seems quite wrong.”*⁸⁰

⁷¹ *Id.* (emphasis added). The court’s interpretation of what exactly constitutes the “status quo” will be analyzed in part IV, *infra*.

⁷² *Id.*

⁷³ *Id.* at 73.

⁷⁴ *Id.*

⁷⁵ *Id.* (quoting *Mylan Pharm. Inc. v. Shalala*, 81 F. Supp. 2d 30, 45 (D.D.C. 2000)).

⁷⁶ *Sherley*, 704 F. Supp. 2d at 73.

⁷⁷ *Id.*

⁷⁸ *Sherley v. Sebelius*, Civ. A. No. 10-5287 (D.C. Cir. Sept. 9, 2010) (order granting administrative stay) [hereinafter Administrative Stay Order].

⁷⁹ See Russell Korobkin, *D.C. Circuit Issues Second Stay Order in Stem Cell Case*, THE VOLOKH CONSPIRACY (Sept. 29, 2010, 1:20 PM), <http://volokh.com/2010/09/29/d-c-circuit-issues-second-stay-order-in-stem-cell-case/>.

⁸⁰ Hank Greely, *Stem Cell Madness – Judge Lamberth’s Opinion and Order Enjoining HESC Research*, STANFORD LAW AND BIOSCIENCES BLOG (Aug. 31, 2010), <http://blogs.law.stanford.edu/lawandbiosciences/2010/08/31/stem-cell-madness-judge-lamberths-opinion-and-order-enjoining-hesc-research/>.

¶23 Outcry and controversy in the aftermath of Chief Judge Lamberth's order was substantial and immediate. Many commentators quickly attacked the decision as being incorrect as a matter of law, with one noting that "Judge Lamberth is a very able judge, but has also been somewhat aggressive in his injunction practice over the last few years and has had a series of . . . overreaching injunctions stayed and overturned by the D.C. Circuit."⁸¹ One such injunction was ordered in the saga of *Cobell v. Norton*.⁸² The Court of Appeals for the D.C. Circuit eventually ordered that case re-assigned to a new judge after reversing eight of Lamberth's orders in the case.⁸³ With regard to the *Sherley* injunction, Stanford University law professor Hank Greely disagreed with the district court's interpretation of all four preliminary injunction factors as a matter of law, and also disagreed with the language used in the order.⁸⁴ The language and citations used by the court of appeals in the stay pending appeal gave strong support to the notion that the government had a strong case on the merits.⁸⁵ This section will proceed to examine the district court's analysis of the four factors in turn.

A. Likelihood of Success on the Merits

¶24 The plaintiffs presented two arguments for why they would succeed on the merits: (1) the NIH Guidelines violated the plain language of the Dickey-Wicker Amendment, and (2) the NIH's procedures in implementing the Guidelines violated the Administrative Procedure Act.⁸⁶ The district court only moved forward with analysis of the Dickey-Wicker argument, leaving an open question of whether the APA argument could be raised again in a future proceeding on this issue.⁸⁷

¶25 The district court reasoned that the language in the Dickey-Wicker Amendment was not only unambiguous, but also that the Guidelines clearly violated it.⁸⁸ This logic is questionable for two reasons. First, as the government presented, the plaintiffs' (and later, the court's) extremely

⁸¹ Glenn Cohen, *On the Stem Cell Injunction*, CONCURRING OPINIONS (Aug. 25, 2010, 12:04 PM), <http://www.concurringopinions.com/archives/2010/08/on-the-stem-cell-injunction.html>.

⁸² 334 F.3d 1128 (D.C. Cir. 2003).

⁸³ Cohen, *supra* note 81.

⁸⁴ Greely, *supra* note 80.

⁸⁵ Administrative Stay Order, *supra* note 78; *see* Korobkin, *supra* note 79

("According to the citations provided, a stay pending appeal is appropriate when the petitioner demonstrates either a strong likelihood of prevailing on the merits or that the petitioner has a serious case on merits that deserves careful attention . . .").

⁸⁶ *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70 (D.D.C. 2010).

⁸⁷ *Id.*

⁸⁸ *Id.* at 71.

broad interpretation of “research” invites an absurd result.⁸⁹ Because the Dickey-Wicker Amendment bans “research in which a human embryo or embryos *are* destroyed, discarded, or knowingly subjected to risk,”⁹⁰ how could the court enjoin funding of grants seeking to use embryonic stem cells from previously derived embryos? But this is exactly what the court did in August.⁹¹ Nothing in Congress’s language indicates that all past, present, and future derivations automatically disqualify research that seeks to use the resulting cells, perhaps long since divorced from the derivation itself.⁹² At the very least, this use of present tense is enough to trigger the ambiguity in language triggering *Chevron* deference to the NIH’s implementation of the executive order. At oral argument, Circuit Judge Thomas Griffith repeatedly keyed in on the definition of research, stating that the government’s argument “rises or falls” on it,⁹³ and it seems clear it will be the deciding factor in the case.⁹⁴

¶26 Second, the court of appeals weighed the *exact same factors* in deciding to stay the injunction as the district court did originally.⁹⁵ Based on the principle of *stare decisis*, it seems unlikely the court of appeals would have disturbed Chief Judge Lamberth’s ruling if they believed there was a legitimate chance of prevailing on the merits.

B. Irreparable Harm

¶27 Perhaps the most baffling part of the ruling was the finding, with less than a single reporter page column of discussion, that the plaintiffs had suffered an irreparable injury.⁹⁶ Most curious of all was the fact that the same judge, in the same court and on the same facts, remarked ten months previously that “increased competition for funding is an insufficient injury to impart standing.”⁹⁷ Further, Chief Judge Lamberth went on to state that “[t]he guidelines neither prevent nor hinder either doctor’s opportunity to

⁸⁹ See Motion to Dismiss, *supra* note 49, at 31–33.

⁹⁰ Omnibus Appropriations Act of 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (emphasis added). This is the most recently-passed version of the Dickey-Wicker Amendment.

⁹¹ Administrative Stay Order, *supra* note 78.

⁹² See Motion to Dismiss, *supra* note 49, at 33 (offering one interpretation of statutory language).

⁹³ Amy Swinderman, *Stem Cell Case Makes its Way Through Courts*, DRUG DISCOVERY NEWS, Jan. 2011,

<http://www.drugdiscoverynews.com/index.php?newsarticle=4535>.

⁹⁴ See *Appeals Court Hears Human Embryonic Stem Cell Case*, SEEKING ALPHA (Dec. 13, 2010, 12:01 AM), <http://seekingalpha.com/news-article/207701-appeals-court-hears-human-embryonic-stem-cell-case>.

⁹⁵ See Korobkin, *supra* note 79.

⁹⁶ *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 72 (D.D.C. 2010).

⁹⁷ *Sherley v. Sebelius*, 686 F. Supp. 2d 1, 6 (D.D.C. 2009).

compete for funding. Indeed, Drs. Sherley and Deisher’s proposals for adult stem cell research can receive funding if they survive the two-tier review process that *all* applications undergo.”⁹⁸

¶28 Chief Judge Lamberth had it right the first time he saw the case, when he dismissed it. In no way does a speculated increase in competition for funds meet the standard of “certain and great . . . actual and not theoretical” injury required by the federal courts of the District of Columbia.⁹⁹ Even if the court were to accept that the injury was certain and actual, it seems highly unlikely that the injury would be deemed irreparable. Only one-fifth of NIH grant applications are funded.¹⁰⁰ In that context, it is worth noting that Dr. Deisher had *never submitted* an NIH grant application, and Dr. Sherley’s four previous grant applications were regarded as so uncompetitive for funding as to not even proceed to the second round of consideration.¹⁰¹ This lack of success occurred *before* the Guidelines were even contemplated.

¶29 The United States Supreme Court, in quoting a decision from the Court of Appeals for the District of Columbia Circuit, has stated “The key word in this consideration is *irreparable*. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.”¹⁰² The injunction in *Sherley* was granted despite the plaintiffs’ showing of irreparable harm falling well short of what the law requires. The law on irreparable injuries with respect to economic harm and employment settings is well-settled in the D.C. Circuit—and it is a high bar that the plaintiffs do not reach.¹⁰³

⁹⁸ *Id.* at 7 (emphasis in original). The “review process” the court describes is further discussed in Part IV, *infra*.

⁹⁹ *Wis. Gas Co. v. Fed. Energy Regulatory Comm’n*, 758 F.2d 669, 674 (D.C. Cir. 1985).

¹⁰⁰ NAT’L INSTS. OF HEALTH RESEARCH PORTFOLIO ONLINE REPORTING TOOLS, *supra* note 10.

¹⁰¹ Reply Brief for Appellants, *supra* note 59, at 26.

¹⁰² *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (quoting *Va. Petroleum Jobbers Ass’n v. Fed. Power Comm’n*, 259 F.2d 921, 925 (D.C. Cir. 1958)).

¹⁰³ *See, e.g.*, *Washington v. Dist. of Columbia*, 530 F. Supp. 2d 163, 169–71 (D.D.C. 2008) (termination of employment not an irreparable injury); *Int’l Ass’n of Machinists & Aerospace Workers v. Nat’l Mediation Bd.*, 374 F. Supp. 2d 135, 142 (D.D.C. 2005) (loss of income is not irreparable injury); *Zirkle v. Dist. of Columbia*, 830 A.2d 1250, 1256–57 (D.D.C. 2003) (denial of a prospective job offer not irreparable injury); *Farris v. Rice*, 453 F. Supp. 2d 76, 80 (D.D.C. 2006) (mere loss of job and salary not irreparable injury).

C. Balance of Hardships

¶30 Chief Judge Lamberth analyzed the balance of hardships as favoring an injunction. The injunction “would not seriously harm ESC researchers because [it] would simply preserve the *status quo*.”¹⁰⁴ Again, this is a situation where the court misunderstands the current state of the field and of federal funding. As one commentator noted, “Judge Lamberth does not seem to recognize that the status quo includes many federal grants for hESC research and lots and lots of applications for more such grants.”¹⁰⁵ The order, as written, most certainly does not preserve the status quo—it halts all federally-funded research that purportedly violates the Dickey-Wicker Amendment.¹⁰⁶ With the NIH already halting the work of its own researchers who had been supported under the Clinton, Bush, and Obama administrations,¹⁰⁷ it is impossible to see how the court can view the balance of hardships in favor of the plaintiffs’ highly-speculative arguments while hESC researchers suffer very real damage nationwide today. In the federal courts of the District of Columbia, when “a preliminary injunction might harm other interested parties,” the balance of hardships factor cannot support the movant.¹⁰⁸ It is clear that federally-funded scientists, who have suffered now *the exact injury* plaintiffs sought to prevent for themselves, have been harmed. Lamberth also dismisses the dashed hopes of the millions waiting for cures as “speculative.”¹⁰⁹ One must hope that the court of appeals will act quickly on their behalf.

D. Public Interest

¶31 Finally, the district court finds the public interest factor weighs in favor of the plaintiffs because “[i]t is in the public interest for courts to carry out the will of Congress and for an agency to implement properly the statute it administers.”¹¹⁰ With the court’s focus on the status quo for the hardship factor, it is perhaps instructive to look at the numbers of researchers that were approved by three presidents and five Congresses to work on hESC research. As one commentator noted, “[t]he combination of Congress’s inaction—not inaction by failing to amend an existing law, but inaction by failing to change the language in any of ten independently passed appropriations riders—and Congress’s action in approving broader

¹⁰⁴ *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 72 (D.D.C. 2010) (emphasis in original).

¹⁰⁵ Greely, *supra* note 80.

¹⁰⁶ Administrative Stay Order, *supra* note 78.

¹⁰⁷ Kaiser, *supra* note 17.

¹⁰⁸ Int’l Ass’n of Machinists & Aerospace Workers, 374 F. Supp. 2d at 142.

¹⁰⁹ *Sherley*, 704 F. Supp. 2d at 72.

¹¹⁰ *Id.* at 73 (quoting *Mylan Pharm. Inc. v. Shalala*, 81 F. Supp. 2d 30, 45 (D.D.C. 2000)).

human embryonic stem cell research”¹¹¹ suggests that Congress had no intention of rejecting all embryonic stem cell research. If “the will of Congress” was to stop evil scientists from working on embryonic stem cells, it seems likely that they would have acted to do so at the very least between 2001 and 2009 during the Bush presidency. Instead, they reviewed ESC grant data time and time again, approved NIH budgets and appropriations to those grants, and saw the scientific community benefit from that research. The true interests of the public surely lie in promoting scientific and economic advancement, and in finding cures to human diseases. For this reason, and the others elucidated above, the district court’s granting of the preliminary injunction was in clear error.

IV. THE SCIENTIFIC COMMUNITY SHOULD HANDLE THE ISSUE, NOT THE COURTS

¶32 The August 23rd injunction and order likely reach too far. As part of the order, “defendants and their officers, employees, and agents are enjoined from implementing, applying, or taking *any* action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research . . . or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines.”¹¹² Interpretation of this order has been varied, but some commentators have argued that its language not only has the effect of enjoining the NIH Guidelines, but also halting *all* embryonic stem cell research, even research previously authorized by the Bush and Obama administrations.¹¹³ Lending credence to the latter interpretation, the NIH suspended all embryonic stem cell research by its own employees within a week of the decision, and advised other researchers using its funds for such studies that no money beyond what had already been allocated would be forthcoming until the case was resolved.¹¹⁴ The consequences of the decision are far-reaching and extremely harmful to the scientific community, regardless of whether the injunction is permanently dissolved on appeal or the case is decided in favor of the government in the future. Significant damage has already been done to researchers and to the progress of the field. Just as Sherley and Deisher could not be compensated down the road per Chief Judge Lamberth’s reasoning, it is certain that recompense for the embryonic stem cell researchers whose work was interrupted (perhaps irretrievably), for the sick awaiting a cure, and for a decline in nation’s position as a global science leader also will be unavailable.

¹¹¹ Greely, *supra* note 80.

¹¹² Administrative Stay Order, *supra* note 78 (emphasis added).

¹¹³ Greely, *supra* note 80.

¹¹⁴ Kaiser, *supra* note 17.

¶33 Perhaps the only outcome worse than a judgment against the NIH Guidelines altogether is exactly what has transpired—placing the scientific community in a chaotic state of limbo. No further grants involving embryonic stem cell research are under consideration for now, but what about the grants that have already been awarded? One commentator questioned what will happen to those grants. “Do they have to stop? Do they have to stop when it comes time for an annual renewal? Do they have to stop when the institution that got the grant needs another tranche of money from the grant to be transferred to it?”¹¹⁵ By painting a narrow issue with a broad brush, the district court has done more harm than any other possible outcome.

¶34 The 2010 midterm elections, which saw the Republican Party gain control of the U.S. House of Representatives on a platform of across-the-board cuts in all federal spending, lend little confidence to scientists and those interested in research.¹¹⁶ Funding of science appears poised to drop by as much as twelve percent.¹¹⁷ A lame duck Democratic Congress could potentially have solved the whole stem cell issue by passing the Stem Cell Research Advancement Act of 2009, which would have expressly permitted hESC research on “human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of reproductive treatment, and were in excess of the clinical need of the individuals seeking such treatment,” so long as “[i]t was determined through consultation with the individuals seeking reproductive treatment that the embryos . . . would never be implanted . . . and would otherwise be discarded.”¹¹⁸ Although FASEB and a coalition of medical school professors actively petitioned Congress to enact it, the bill failed to pass before the 111th Congress adjourned.¹¹⁹

¹¹⁵ Greely, *supra* note 80.

¹¹⁶ See Jean-Louis Santini, *Republicans Could Scale Back US Science Budgets*, PHYSORG (Nov. 10, 2010), <http://www.physorg.com/news/2010-11-republicans-scale-science.html> (“Budgets for scientific research in the United States could be scaled back with the return of a Republican-majority in Congress as conservatives aim to slash spending to reduce the ballooning deficit.”).

¹¹⁷ *Id.* (“But if Republicans hold to their pledge, non-defense related federal research spending could dip more than 12 percent to around 58 billion dollars compared to 66 billion requested by the White House for 2011.”)

¹¹⁸ Stem Cell Research Advancement Act of 2009, H.R. 4808, 111th Cong. § 3 (2009) (seeking to amend Part H, Title IV of the Public Health Service Act, 42 U.S.C. § 289 (2006)).

¹¹⁹ See Jennifer Zeitzer, *Inside (The Beltway) Scoop*, FASEB WASHINGTON UPDATE 2–3 (2010), <http://opa1.faseb.org/pages/WashingtonUpdate/Oct0110/pdf/Oct0110.pdf> (outlining FASEB’s efforts to continue previously-approved hESC research during the injunction); Roxanne Palmer, *What Can the Lame Duck US Congress*

¶35 In an era of tight funds, the allocation of resources becomes even more important. Peer review is a critical tool in science on two levels: it helps determine how precious funds are spent, and it self-polices the scientific community. When a judge needs guidance on a complex case, she can nominate a special master—an expert who can assume a quasi-judicial role and help the court make key decisions and reduce complexities.¹²⁰ In cases like *Sherley*, the duties of the expert can be performed through the established system of peer review that has powered science for decades. The scientific community has already helped regulate the stem cell issue—as in 2005 when South Korean scientist Hwang Woo Suk falsified data and then claimed he had successfully cloned human embryonic stem cells. Although Hwang’s paper initially passed the peer review stage, it was also his peers who eventually investigated and sanctioned him.¹²¹

¶36 It is scientific community, via the peer review process, that should evaluate the evidence, deliberate, and rule on the funding of embryonic stem cell research, not the federal courts. Congress and federal agencies should set the budgets, but the scientists “in the trenches” every day should be the ones who decide how to operate within those budgets. All federally-funded research involving human subjects (thus encompassing all research involving embryos) must be reviewed ahead of time by an Institutional Review Board (IRB) made up of a diverse panel of experts.¹²² This arrangement avoids situations like the current misguided freeze on all hESC research.

¶37 In their complaint, Sherley and Deisher alleged there would be irreparable harm to their research because of funding shortages if the NIH Guidelines were implemented. In truth, the Guidelines and the subsequent funding of new projects would have presented little threat to grant applications submitted by Sherley because they had already been rejected through peer review. In its appeal briefs filed with the district court and the court of appeals, the government noted that Sherley’s last four grant applications were rejected by peer review panels.¹²³ “The fact that Sherley’s

Do for Biomedicine?, NATURE.COM SPOONFUL OF MEDICINE (Nov. 8, 2010, 2:39 PM),

http://blogs.nature.com/nm/spoonful/2010/11/what_can_the_lame_duck_us_cong.html. As of March 9, 2011, two months into the more hostile 112th Congress, the House Bill and its Senate counterpart remained in committee.

¹²⁰ FED. R. CIV. P. 53.

¹²¹ See, e.g., Op-Ed, *A Cloning Scandal Rocks a Pillar of Science Publishing*, N.Y. TIMES, July 7, 2010,

<http://www.nytimes.com/2005/12/18/international/asia/18clone.html> (outlining timeline of investigation into Hwang).

¹²² See 45 C.F.R. 46 §§ 102–124 (2010).

¹²³ Reply Brief of Appellants, *supra* note 59, at 26.

applications were unscored demonstrates that . . . Sherley's peers did not deem them scientifically worthy enough to be considered for funding."¹²⁴ Applications that "were not even eligible for consideration for funding" are not competing with hESC applications.¹²⁵

¶38 In a telling statement, Sherley's own home institution, the Boston Biomedical Institute, moved to join an *amici curiae* brief in the case in late November 2010—on behalf of the defendants.¹²⁶ It seems the peers who were most familiar with Dr. Sherley and his work—who might have been most willing to speak on his behalf—instead chose not to support him, but to save their own research and patients.¹²⁷ In a recent interview, Sherley, who once went on a hunger strike to protest the Institute's decision to deny him tenure—another peer review verdict—revealed that much of his opposition to the Guidelines is grounded in disagreements over the science, not over the law.¹²⁸ He believes adult stem cells are superior therapeutically to hESCs, and the promise of hESCs is based on false data and misleading presentation.¹²⁹ His voice is both welcome and vital to the debate, but his choice of forum—federal court rather than conferences or scientific journals, has caused wide-sweeping harms and threatens the field at large. Deisher admitted that as much of her opposition comes from her Catholic faith as from any scientific belief, and that she is fighting because ESC uses "make it difficult for many physicians, pharmacists, scientists, and healthcare professionals to navigate their fields of expertise without sacrificing their consciences."¹³⁰ Again, this debate has taken place in the wrong forum. Halting the course of medical research for years to come on the basis of religious convictions would hardly seem to meet the high criteria the U.S. Supreme Court has set for any sort of First Amendment accommodation.¹³¹

¶39 Instead of artificially protecting one set of researchers from the "threat" of hESC research, the court should have deferred to the prior ruling

¹²⁴ Reply Memorandum at 3, *Sherley v. Sebelius*, Civ. A. No. 1:09-cv-01575-RCL (D.D.C. Oct. 28, 2010).

¹²⁵ *Id.*

¹²⁶ Motion of Boston Biomedical Research Institute for Leave to Appear as *Amicus Curiae* at 1–2, *Sherley v. Sebelius*, Case No. 10-5287 (D.C. Cir. Nov. 22, 2010).

¹²⁷ *Id.* at 2–3.

¹²⁸ Amy Swinderman, *Q&A With the Stem Cell Case Plaintiffs*, DRUG DISCOVERY NEWS, Dec. 2010, <http://www.drugdiscoverynews.com/index.php?newsarticle=4439>.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *See, e.g., Goldman v. Weinberger*, 475 U.S. 503 (1986) (involving a Jewish Air Force chaplain who was not permitted to wear a yarmulke indoors in violation of military uniform regulations banning headgear indoors).

of the “court” of peer review—a true jury of their peers. To avoid the disruption, uncertainty, and damage caused by decisions like *Sherley*, future scientific problems should be left to the people who know how to solve them: scientists.

CONCLUSION

¶40 *Sherley* is about embryonic stem cell research, but its implications stretch far beyond the instant case. Should courts be able to start and stop scientific research initiatives? These projects require months, if not years, of preparation and lead time. In many cases, the reagents and equipment are so costly and time-sensitive that if the window of opportunity is missed once, it is closed forever.

¶41 Conducting research can be likened to waging war. Imagine Congress were to declare war on a foreign enemy, allocating billions of dollars to fund the war effort and deploy the troops. Imagine then, at the last minute, a federal judge were to step in and demand they come home. In *Sherley*, the enemy was human disease. Congress and the appropriate federal agency had approved, allocated, and planned to spend taxpayer funds. Suddenly, it was all frozen, and the devastating effects are yet to be calculated.

¶42 The logistics and realities of scientific research demand consistency and predictability for the enterprise to function at all. In order for the United States to maintain its position as the world’s preeminent home for research, government funding must be maintained predictably and without outside interference. Once Congress and the relevant agencies have decided where funding will be granted, the allocation and spending of such funds must be up to the scientific community’s discretion. The peer review system is not perfect, but allowing experts to make decisions that could impact millions of lives down the road remains far preferable to allowing a federal court to make those decisions. For this reason, the Court of Appeals for the D.C. Circuit, and, should it be necessary, the United States Supreme Court should expeditiously review the matter in *Sherley v. Sebelius* on the merits, rule in favor of the defendants, and free America’s scientific community from the prison of uncertainty and fear where it currently resides.