[NOT YET SCHEDULED FOR ORAL ARGUMENT]
No. 10-5287

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DR. JAMES L. SHERLEY, et al.,

Plaintiffs-Appellees,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services, et al.,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties And Amici. Plaintiffs in the district court, and appellees in this appeal, are Dr. James L. Sherley and Dr. Theresa Deisher. Nightlight Christian Adoptions, Shayne Nelson, Tina Nelson, William Flynn, Patricia Flynn, Christian Medical Association, and Embryos were plaintiffs in the district court, but have been dismissed for lack of standing.

Defendants in the district court, and appellants in this appeal, are Kathleen Sebelius, in her official capacity as Secretary of the Department of Health and Human Services, Department of Health and Human Services, Francis S. Collins, in his official capacity as Director of National Institutes of Health, and National Institutes of Health.

The Regents of the University of California are amici in this Court.

The State of Wisconsin, the Coalition for the Advancement of Medical Research, and the Genetics Policy Institute have all moved to be amici in the district court.

B. Rulings Under Review. The rulings under review are the August 23, 2010, order and memorandum opinion of the district court, issuing a preliminary injunction. *Sherley v. Sebelius*, No. 1:09-cv-1575-RCL (D.D.C. Aug. 23, 2010) (Chief

Judge Royce C. Lamberth). The order and opinion appear at page 226 of the Joint Appendix. The district court's opinion is also available at 2010 WL 3296974.

C. Related Cases. This matter has previously come before this Court in *Sherley v. Sebelius,* No. 09-5374 (June 25, 2010). The opinion is available at 610 F.3d 69, and at page 214 of the Joint Appendix. Counsel is not aware of any other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(c).

Respectfully Submitted,

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GLOSSARY

Term	Definition
APA	Administrative Procedure Act
HHS	Department of Health and Human Services
IVF	*In Vitro* Fertilization
JA	Joint Appendix
NIH	National Institutes of Health

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STATEMENT OF JURISDICTION

Plaintiffs invoked the court's jurisdiction under 28 U.S.C. § 1331. JA 16 (Complaint ¶ 5). The district court entered the preliminary injunction that is under review on August 23, 2010, and defendants filed a timely notice of appeal on August 31. JA 242; Fed. R. App. P. 4(a). This Court has jurisdiction pursuant to 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUE

Whether the district court erroneously ruled that the embryonic stem cell research Guidelines issued by the National Institutes of Health in 2009 violate governing appropriations restrictions, and that considerations of irreparable harm and damage to the public interest justify its preliminary injunction.

STATUTES AND REGULATIONS

The relevant regulatory and statutory provisions are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

Plaintiffs Dr. James L. Sherley and Dr. Theresa Deisher are scientists who perform research using adult stem cells. They filed suit to enjoin application of the National Institutes of Health ("NIH") Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009) ("Guidelines"). JA 14. Plaintiffs asserted that the Guidelines violate an appropriations restriction, known as the Dickey-Wicker amendment, that was in effect at the time of suit, was reenacted as an appropriations restriction in the subsequent year as well, and remains in effect as part of the Continuing Resolution that is effective until December 3, 2010. Pub. L. No. 111-242; JA 14-15. The Dickey-Wicker amendment bars federal funding for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death . . . ." Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-

81. They also claimed that adoption of the Guidelines was arbitrary and capricious in violation of the Administrative Procedures Act. JA 15.

The two scientists were joined by several other plaintiffs in bringing the suit and the district court dismissed the entire complaint for lack of standing in October 2009. JA 177. Plaintiffs appealed the standing ruling with respect only to the two scientists and not with respect to any other plaintiff. This Court reversed, holding that the two scientists fell within the "competitor standing" doctrine, under which "plaintiffs may 'establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to compete with [their] own sales.'" JA 220. This Court reasoned that the increase in grant applications for embryonic cell research resulting from the Guidelines would "intensif[y] the competition for a share in a fixed amount of money." JA 223.

Within days of the issuance of the mandate, without a status hearing or any receipt of additional filings, and notwithstanding the passage of ten months during which there had been no stay and the NIH Guidelines had gone into effect, the district court entered a preliminary injunction against NIH and the other defendants. JA 227. The district court enjoined them from "implementing, applying, or taking any action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." JA 226.

The district court denied the government's motion for a stay pending appeal on September 7, 2010, JA 271; this Court issued an administrative stay on September 9 and a stay pending appeal on September 28, *see* JA 274-75.

STATEMENT OF THE FACTS

I. Human Stem Cell Research

Stem cells are cells that have an ability to further differentiate into a variety of specialized cells, and are of great value to scientists who seek to create medical treatments. *See* National Academies, *Understanding Stem Cells: An Overview of the Science and the Issues from the National Academies,* at 3.[1] Scientists currently perform research using three types of human stem cells: adult stem cells, embryonic stem cells, and induced pluripotent stem cells. NIH funds all three types of human stem cell research.

A. Adult stem cells have been identified in some of the organs and tissues of the human body, and may help replenish tissue cells when needed. Adult stem cells are somewhat specialized. For example, blood stem cells usually produce more blood cells, and nerve stem cells can only make the various types of nervous system cells. *Id.* at 8. Adult stem cells are not "pluripotent;" meaning that adult stem cells are not the type of cells that can transform into any of the approximately 200 types of cells in the

[1] *Available at* http://dels.nas.edu/bls/stemcells/basics.shtml.

human body. Adult stem cells are not readily identified in the human body and have not been identified in all of the various different types of tissue. *Understanding Stem Cells,* at 8; NIH, Understanding Stem Cells, Adult Stem Cells, *available at* http://stemcells.nih.gov/info/basics/basics4.asp. To date, it has also been difficult to grow large quantities of adult stem cells in cell culture. *Ibid.* Despite these limitations, various research using adult stem cells has been of enormous value and has led to successful treatments "that reconstitute the immune system after leukemia, lymphoma, and various blood or autoimmune disorders have been treated with chemotherapy." JA 247 (Declaration of Dr. Francis S. Collins, ¶ 7).

B. Embryonic stem cells, unlike adult stem cells, are pluripotent. They exist for a brief period in human embryos as undifferentiated stem cells and they then begin to differentiate into nearly all the different types of cells that exist in the human body. National Academies, *Understanding Stem Cells*, at 4. Unlike adult cells, embryonic stem cells can readily be identified, isolated, grown, and maintained in a laboratory.

To derive embryonic stem cells in the most commonly used method, scientists remove cells from the inner cell mass of an embryo after approximately 5 days of development, when the embryo is known as a "blastocyst." The inner cell mass consists of 30-34 cells. *Ibid.* These cells from the blastocyst are transferred to a laboratory culture dish where the cells divide. Some of those cells are pluripotent stem cells and are identified as such by scientists based on specific criteria such as the

appearance of the cells, their ability to self-renew, and the presence of particular cell surface markers. Understanding Stem Cells, Embryonic Stem Cells, *available at* http://stemcells.nih.gov/info/basics/basics3.asp. Those cells that continue to divide for a prolonged period of time without differentiating, and are shown to be pluripotent, constitute embryonic stem cells. Those cells will continue to divide if kept in the appropriate conditions, and all the cells that then are created through the continuing division of the stem cells constitute a stem cell line – a propagating collection of genetically identical cells. National Academies, *Understanding Stem Cells*, at 10. Stem cells can be removed from the line and the remaining cells will continue to divide and produce more stem cells, while those that are removed can also continue to divide and can be used by scientists conducting a range of research to create different types of specialized human cells.

Stem cell lines provide a long-term supply of multiplying cells that can be shared among scientists for different research, including research for the development of therapies to treat human disease. Stem cells that are derived from a single embryo to form a stem cell line may multiply over a period of years and provide stem cells for a broad range of subsequent research. For example, one stem cell line, known as "H9," which was created by a researcher at the University of Wisconsin in 1998, has been used in more than 360 published research studies and remains one of the most highly requested stem cell lines from the Wisconsin stem cell bank. Lines H1 and H7,

also developed at the University of Wisconsin, have been used in approximately 300 and 100 research studies, respectively. *See* Loser et al., *Human Embryonic Stem Cell Lines and Their Use in International Research, Stem Cells* 244 (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1002/stem.286/full.

These stem cell lines are generally managed by a university or associated research institute, or a private entity. In the typical case, a researcher chooses an existing stem cell line for use in her research based on scientific experience with that cell line in other research; for example, the H9 cell line is known to be particularly good at differentiating into nerve cells. The researcher would obtain thousands, or even millions, of cells from the owner or provider of the stem cell line. The provider often charges a fee; for example, the research institute associated with the University of Wisconsin charges $1,000 per line to researchers engaged in non-commercial research. This fee covers the cost to the institute of culturing, maintaining, and handling the stem cell lines. *See* Frequently Asked Questions For Requesting Cells, https://www.wicell.org/index.php?option=com_content&task=blogcategory&id=124&Itemid=197.

Once a researcher obtains the necessary stem cells from the stem cell line, she may differentiate the stem cells into the kind of cell she needs for her research. National Academies, *Understanding Stem Cells,* at 10. For example, a researcher studying Parkinson's disease might develop the stem cells into a specific kind of nerve cell that

produces dopamine. *Id.* at 16. Researchers have made substantial progress toward treating disease, and are using these differentiated cells to develop new therapeutic drugs to treat conditions such as spinal muscular dystrophy and amyotrophic lateral sclerosis ("ALS"). Research using the H1 cell line has recently progressed to an FDA-approved clinical trial to treat spinal cord injuries that has enrolled its first patient. JA246, ¶ 6; http://www.geron.com/media/pressview.aspx?id=1235 (announcing enrollment of first patient on October 11, 2010).

2. NIH's Guidelines allow federally funded researchers to use human embryonic stem cells only if the original cell line was derived from an embryo that was produced as part of an *in vitro* fertilization ("IVF") process for reproductive purposes. In many cases, when couples participate in an IVF process, they create more embryos than they will ultimately use to meet their reproductive goals.

No uniform procedure governs the treatment of these embryos, which varies from clinic to clinic. Some embryos are deemed not suitable for implantation from the outset, such as embryos with a genetic defect or embryos that are failing to develop normally, and thus will never be used for implantation and are typically discarded. Stem cell lines derived from embryos with genetic mutations may be particularly valuable to scientists because they allow scientists to study a particular genetic disease, such as cystic fibrosis or Marfan syndrome, and its potential therapies. *See* Sermon, et al.*, Creation Of A Registry For Human Embryonic Stem Cells Carrying An*

Inherited Defect, Human Reproduction, Vol. 24, 1557 (2009), *available at* http://humrep.oxfordjournals.org/content/24/7/1556.full.

With regard to the embryos created through IVF that are suitable for implantation, excess embryos (*i.e.,* embryos other than the ones that are implanted) are almost always frozen so patients can implant them later, if the first implantation attempt fails to result in a live birth or if the patient desires additional pregnancies. Lyerly et al., *Fertility Patients' Views About Frozen Embryo Disposition: Results of a Multi-institutional U.S. Survey, Fertility and Sterility,* Vol. 93, 499-509 (2008)*; see also* Gurmankin et al., *Embryo Disposal Practices in IVF Clinics in the United States*, *Politics and the Life Sciences*, Vol. 22 (August 2004) (describing variations among IVF clinics), *available at* http://repository.upenn.edu/bioethics_papers/7/. One recent study found that nearly half of the patients who have embryos that currently are being held in a frozen state no longer intend to use them for reproductive purposes. Lyerly at al., at 506. Patients who have embryos remaining that they do not intend to use may thaw and discard the embryos, donate the embryos to another woman for implantation, donate the embryos for scientific research, or continue to freeze the embryos indefinitely, which often involves a continuing fee. *Id.* at 501; *see also, e.g.,* Cost Sheet, Advanced Fertility Center of Chicago, http://www.advancedfertility.com/ivfprice.htm.

C. The third type of human stem cells are induced pluripotent stem cells, which were recently developed by researchers. Scientists have developed a procedure to reprogram adult cells to assume a state similar to embryonic stem cells. JA 247-48, Decl. ¶ 7. It is not yet known whether induced pluripotent stem cells differ from embryonic stem cells in clinically significant ways that would limit their usefulness. NIH, *Stem Cell Basics*, http://stemcells.nih.gov/info/basics/basics10.asp; *see also* JA 247-48, Decl ¶ 7; Rob Stein, *Scientists Overcome Obstacles To Stem Cell Alternatives, Washington Post, available at* http://www.washingtonpost.com/wp-dyn/content/article/2010/09/30/AR2010093003211.html?hpid=topnews (researchers state that "embryonic stem cells are still crucial because, among other things, they remain irreplaceable for evaluating alternatives").

II. Regulatory Background

Congress first enacted the Dickey-Wicker amendment in 1996 and has included the same language in subsequent appropriations bills ever since, without substantive change. In its current form, it prohibits the use of federal funds 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))." Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81.

When the amendment was first enacted in 1996, use of human embryonic stem cells was not at issue because they had not yet been isolated and thus were not available to be used in research. *See* JA 246, Decl. ¶ 6 (embryonic stem cells were first isolated in 1998). Congress reacted to a 1994 NIH panel report that had recommended funding for some research that was to be done directly on human embryos in order to improve *in vitro* fertilization techniques and to screen embryos for genetic defects before implantation, among other things. *See* NIH, Report of the Human Embryonic Research Panel 75-76, *available at* http://www.bioethics.gov/commissions/.

After human embryonic stem cells became available for use in research in 1998, the General Counsel of the Department of Health and Human Services ("HHS") addressed the amendment's applicability to research using embryonic stem cells in an opinion letter. The opinion concluded that the amendment did not prohibit federal funding for research that uses embryonic stem cells, because stem cells are not embryos. *See* JA 161 (Rabb Memorandum).

After notice-and-comment, NIH adopted this view in final guidelines issued in 2000. 65 Fed. Reg. 51,976 (Aug. 25, 2000). Those 2000 guidelines concluded that the Dickey-Wicker amendment does not prohibit federal funding for human embryonic stem cell research because stem cells are not embryos. *Ibid.*

Although different Presidential Administrations have had different policies on the scope of their support for research using embryonic stem cells, none has interpreted the Dickey-Wicker amendment to bar federal funding for research using embryonic stem cell lines. President Bush supported federal funding for research using embryonic stem cells so long as the stem cells were obtained from lines that were in existence at the time of his 2001 address. *See* Executive Order No. 13,435, 72 Fed. Reg. 34,591; Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001) (noting that his policy would limit funding to research using stem cell lines that were created from "embryos that have already been destroyed").

When Congress reenacted the Dickey-Wicker amendment after President Bush's announcement of his policy, the relevant Committees made clear that the legislative language did not impose a ban on research using embryonic stem cells and that President Bush's policy was consistent with the amendment. *See* H.R. Rep. No. 107-229, at 180 (Oct. 9, 2001) ("The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President."); *see also* S. Rep. No. 107-84, at 18 (Oct. 11, 2001) ("The Committee urges the NIH to move quickly to support all types of stem

cell research, including embryonic [and] adult . . . ."). Congress continued to express this view throughout the Bush administration. *See* H.R. Rep. No. 110-231, at 288 (July 13, 2007); H.R. Rep. No. 108-636, at 199 (Sept. 7, 2004).

On March 9, 2009, President Obama issued Executive Order No. 13,505. *See* JA 276 (74 Fed. Reg. 10,667). The President stated that he would "remove . . . limitations on scientific inquiry" involving stem cells, "expand NIH support for the exploration of human stem cell research," and thereby "enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." JA 278 § 1. The President provided that NIH "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." JA 278, § 2. The President further directed NIH to review existing guidelines on human stem cell research, and to "issue new NIH guidance on such research that is consistent with this order." JA 278, § 3.

NIH's 2009 Guidelines were issued pursuant to that Presidential directive. They reaffirm the understanding of the Dickey-Wicker amendment that was set out in NIH's 2000 guidelines. NIH noted that federal funding "of the derivation of stem cells from human embryos is prohibited" but also noted that NIH has consistently interpreted the amendment to not apply to research using embryonic stem cells,

because embryonic stem cells are not embryos. JA 45 (74 Fed. Reg. at 32,173 (July 7, 2009)).

NIH's 2009 Guidelines set forth strict standards that researchers must meet when choosing the stem cell lines to use in research funded by NIH. Research funded by NIH may use stem cell lines derived from human embryos only if they "were created using *in vitro* fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by individuals . . . who gave voluntary consent for the human embryos to be used for research purposes." JA 46. For stem cell lines derived from embryos donated after the Guidelines, the donor must also have been informed of all options available at the facility for the disposition of embryos. JA 46. NIH maintains a registry of stem cell lines that meet these criteria and are therefore eligible to be used in federally funded research. *See* http://grants.nih.gov/stem_cells/registry/current.htm.

When Congress reenacted the Dickey-Wicker amendment for FY 2010, after issuance of NIH's 2009 Guidelines, Congress again noted that the language "should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 111-220, at 273 (July 22, 2009); *see also* S. Rep. 111-66, at 121-22 (Aug. 4, 2009) (welcoming the guidelines and noting the "congressional intent to expedite this important area of research"); Conf. Rep. No. 111-366 at 982 (Dec. 8, 2009) ("In

implementing this conference agreement, the Departments and agencies should be guided by the language and instructions set forth in House Report 111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293.").

III. Prior Proceedings

Plaintiffs filed suit on August 19, 2009, arguing that the 2009 Guidelines promulgated by NIH violate the federal prohibition against federal funding for "research in which a human embryo or embryos are destroyed." Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81; JA 37 (Complaint ¶¶ 66-68). Plaintiffs also argued that the Guidelines were promulgated in violation of the Administrative Procedure Act's procedural requirements, JA 37-38 (Complaint ¶¶ 69-72), and that the Guidelines constitute arbitrary and capricious agency action, JA 38 (Complaint ¶¶ 73-75).

The plaintiffs included Dr. James L. Sherley and Dr. Theresa Deisher, two scientists who perform research using adult stem cells. JA 16-18 (Complaint ¶¶ 6, 7). The original plaintiffs also included Nightlight Christian Adoptions, an agency facilitating the adoption of frozen embryos, and its clients Shayne Nelson, Tina Nelson, William Flynn, and Patricia Flynn, JA 18-20 (Complaint ¶¶ 8, 10, 11); Christian Medical Association, a non-profit association "dedicated to improving the ethical standards of health care in the United States and abroad," JA 20 (Complaint ¶

12); and all embryos created using *in vitro* fertilization and no longer needed for reproduction, JA 19(Complaint ¶ 9). Those plaintiffs have been dismissed for lack of standing.

Plaintiffs filed a motion for a preliminary injunction and a motion to appoint a guardian ad litem for the plaintiff embryos. They argued that if an injunction were not granted, the plaintiff embryos might be destroyed and the two plaintiff research scientists would suffer injury because their grant proposals to NIH would be in competition with those of embryonic stem cell researchers.

The government opposed the preliminary injunction and filed a motion to dismiss for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim. The district court granted the government's motion and dismissed the complaint on October 27, 2009, on the ground that plaintiffs lacked standing. JA 177. The district court rejected the scientists' claim that increased competition resulted in their injury in fact and their invocation of the "competitor standing doctrine." JA 185.

Plaintiffs appealed the ruling with respect to the standing of the two plaintiff scientists. This Court reversed, holding that the two plaintiff scientists have standing according to the "competitor standing" doctrine, under which "plaintiffs may 'establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to

compete with [their] own sales.'" JA 220. The Court reasoned that the increase in grant applications for embryonic stem cell research resulting from the Guidelines would "intensif[y] the competition for a share in a fixed amount of money." JA 222-23. The Court declined plaintiffs' invitation to reach the merits of their claims and remanded to the district court. JA 225.

On August 23, 2010, within days of the issuance of the mandate and without any further briefing or factual submissions by the parties to address developments that had taken place during the preceding ten months during which the Guidelines had been implemented and no stay had been in effect, the district court issued a preliminary injunction. The order enjoins defendants from "implementing, applying, or taking any action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." JA 226.

The government moved for a stay in the district court, which was denied. JA 271. The government then moved for a stay pending appeal in this Court. On September 9, this Court entered an administrative stay. JA 274. After argument on the government's motion for a stay pending appeal, this Court granted the government's motion for stay pending appeal on September 28. JA 275.

SUMMARY OF ARGUMENT

I. A. Congress enacted the Dickey-Wicker amendment in 1996 in reaction to an NIH panel report that had recommended federal funding of research on human embryos to improve *in vitro* fertilization techniques and to screen embryos for genetic defects, among other things. In order to address this type of research, in which an embryo is destroyed or endangered, Congress barred funding for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death . . . ."

Two years later, in 1998, human embryonic stem cells were isolated for the first time, which made possible the derivation of stem cell lines that can be used in research to study and develop treatments for conditions such as diabetes, Parkinson's disease, and spinal muscular dystrophy. NIH published guidelines in 2000 to address the application of the Dickey-Wicker amendment to research using embryonic stem cells. NIH explained that stem cells are not embryos, and research using embryonic stem cells is not research in which an embryo is endangered or destroyed.

That interpretation has remained in place through the subsequent decade, and is the basis for the 2009 NIH Guidelines challenged in this case. That interpretation was also the premise for the embryonic stem cell research that was authorized by President Bush. At no point has NIH concluded that the Dickey-Wicker amendment precludes

funding for research that uses embryonic stem cells. Congress, fully aware of that interpretation, has repeatedly reenacted the amendment in substantially identical form. Indeed, when Congress reenacted the provision for FY 2010, both the House and Senate reports declared that the 2009 Guidelines are consistent with the funding restriction.

B. The district court failed to address this repeated statutory reenactment against this regulatory history, and accorded no deference to NIH's consistent and longstanding interpretation of the statute not to prohibit federal funding of research that uses embryonic stem cells. The district court mistakenly concluded that the statute is unambiguous and that "Congress has 'directly spoken to the precise question at issue[.]'" JA 235 (quoting *Chevron U.S.A., Inc.,* v. *Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 843 (1984)).

Congress has never purported to ban federal funding for research that uses embryonic stem cells. The statutory text does not address the "precise question at issue," nor could it, because when the text was first enacted the precise question did not yet exist; it arose only when later developments made human embryonic stem cell lines available to researchers for the first time. Insofar as Congress has addressed the "precise question at issue," it has done so by repeatedly reenacting the statutory language and expressing approval of the agency's interpretation.

The statutory text is in no way an unambiguous ban on research using embryonic stem cells. Research that makes use of embryonic stem cells that come from a registered stem cell line – a line which may have been in existence for a decade and may already have provided stem cells to hundreds of other researchers – is not "research in which a human embryo or embryos are destroyed[.]" The agency's interpretation is certainly "based on a permissible construction of the statute," and should therefore be upheld. *Chevron*, 467 U.S. at 843.

II. The district court committed a clear abuse of discretion in its evaluation of the impact of its injunction. The two plaintiffs have demonstrated no imminent, irreparable harm. Indeed, Dr. Deisher does not even claim to have applied for an NIH grant, and Dr. Sherley received $425,000 in NIH grant funds under the current Guidelines. In contrast, the injury to NIH by the cut-off of federal funding to its own intramural research that uses human embryonic stem cells and the injury to research conducted by NIH grantees, detailed in the declaration of NIH Director Dr. Francis S. Collins, is real, immediate, and irreparable.

STANDARD OF REVIEW

This Court "review[s] the district court's weighing of the preliminary injunction factors under the abuse of discretion standard, and its findings of fact under the clearly erroneous standard. To the extent the district court's decision hinges on

questions of law, however, this court's review is essentially *de novo*." *Arkansas Dairy Coop. Ass'n* v. *U.S. Dep't of Agriculture*, 573 F.3d 815, 821 (D.C. Cir. 2009) (quoting *Serono Labs., Inc.* v. *Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998)).

ARGUMENT

THE COURT SHOULD VACATE THE PRELIMINARY INJUNCTION, WHICH IS BASED ON LEGAL ERROR AND AN ERRONEOUS ASSESSMENT OF INJURIES.

I. Plaintiffs Have Demonstrated No Likelihood Of Success On The Merits Because The NIH Guidelines Do Not Violate The Dickey-Wicker Amendment.

A. NIH Has Consistently Interpreted The Dickey-Wicker Amendment to Permit Federal Funding of Research That Uses Embryonic Stem Cells, And Congress Has Repeatedly Ratified That Interpretation.

1. Congress first enacted the Dickey-Wicker amendment in 1996, in reaction to a 1994 NIH panel report that had advocated federal funding of research that would have involved the use of human embryos. The research was designed to improve the process of *in vitro* fertilization, to determine whether embryos carried genetic abnormalities, and to isolate embryonic stem cells, and the embryos would have been destroyed or subject to risk of being destroyed during the research. *See* NIH, Report of the Human Embryonic Research Panel 75-76, *available at* http://www.bioethics.gov/commissions/.

The Dickey-Wicker amendment created a ban on federal funding of this type of research, specifically prohibiting federal funding of "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death. . . ." Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81. A 1996 letter from NIH to researchers at Georgetown University, cited by plaintiffs in opposing a stay, illustrates the nature of the research to which the statute was directed. *See* JA 283. The research at issue involved pre-implantation genetic diagnosis, which is research using human embryos to detect genetic abnormalities in the embryos. NIH explained to the researchers that federal dollars could not be used to fund the project. In 1996, as today, federal funding for such research was unavailable.[2]

When funding for research using human embryonic stem cells first became an issue in 1999, the General Counsel of HHS issued an opinion letter that concluded that research using embryonic stem cells is not prohibited by the amendment because embryonic stem cells are not an "embryo" and are not capable of developing into a human being. *See* JA 161 (Rabb Memorandum).

[2] For the same reasons, NIH does not fund work designed to improve fertilization techniques or otherwise improve IVF success rates, when it involves research using human embryos and destroys an embryo or subjects an embryo to a risk of harm.

NIH set forth this interpretation again in guidelines issued in 2000 after notice and comment. 65 Fed. Reg. 51,976 (Aug. 25, 2000). The 2000 guidelines explained that research using embryonic stem cells is not "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death."

2. NIH has never departed from its interpretation of the Dickey-Wicker amendment set out in the 2000 guidelines to not bar research using human embryonic stem cells. In the subsequent decade, that understanding has been the premise of the policies of both the Bush Administration and the Obama Administration, policies that differ in the scope of embryonic stem cell lines that can be used in federally funded research but that do not differ on the necessary underlying principle that the amendment does not prohibit research using embryonic stem cells.

President Bush limited federal funding to research that used stem cells obtained from lines that had been created before the announcement of his policy. His authorization to use stem cells from earlier lines necessarily rested on the premise that research using embryonic stem cells is not "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." President Bush emphasized that research using embryonic stem cells that is funded by federal dollars, as opposed to only privately funded research, is particularly important because federal funding of research "ensure[s] new discoveries are widely shared at the

largest number of research facilities and that the research is directed toward the greatest public good." Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001).

When Congress reenacted the Dickey-Wicker language for FY 2002, it recognized that the Bush policy was consistent with the amendment, which does not prohibit federal funding of research because it uses embryonic stem cells. *See* H.R. Rep. No. 107-229, at 180 (Oct. 9, 2001) ("The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President."); *see also* S. Rep. No. 107-84, at 18 (Oct. 11, 2001) ("The Committee urges the NIH to move quickly to support all types of stem cell research, including embryonic [and] adult . . .."). Congress continued to express this view throughout the Bush administration. *See* H.R. Rep. No. 110-231, at 288 (July 13, 2007); H.R. Rep. No. 108-636, at 199 (Sept. 7, 2004).

In an Executive Order issued on March 9, 2009, President Obama "expand[ed] NIH support for the exploration of human stem cell research," to allow "human embryonic stem cell research, to the extent permitted by law." JA 278, §§ 1-2 (Executive Order No. 13,505). The President directed NIH to issue new guidance on

such research. JA 278, § 3. NIH again engaged in notice-and-comment rulemaking. NIH promulgated the final Guidelines challenged here on July 7, 2009. JA 42 (74 Fed. Reg. 32,170).[3]

Under the NIH 2009 Guidelines, research using human embryonic stem cells is eligible for federal funding only if the cells are from stem cell lines that were derived from human embryos that "were created using *in vitro* fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by individuals . . . who gave voluntary consent for the human embryos to be used for research purposes." JA 46. For stem cell lines derived from embryos donated after the Guidelines, the donor must also have been informed of all options available at the facility for the disposition of embryos. JA 46.

When Congress included the Dickey-Wicker amendment in the FY 2010 appropriations bill, it was fully aware of the NIH Guidelines that had been promulgated to govern funding of research grants. The relevant Committee Report, like Committee Reports issued during the Bush administration, declared that the amendment's "language should not be construed to limit Federal support for research

[3] Plaintiffs' suit claims that promulgation of the Guidelines violated the APA. The district court did not rule on this issue, *see* JA 235, and did not rely on it as a basis for the preliminary injunction. The plaintiffs' APA claims are currently the subject of summary judgment briefing in district court.

involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 111-220, at 273 (July 22, 2009); *see also* S. Rep. No. 111-66, at 121 (Aug. 4, 2009) ("The Committee is pleased that stem cell research was included as a special emphasis area in the NIH Challenge Grant program . . . . The Committee also welcomes the recent release of guidelines for the use of human embryonic stem cells [hESC] with NIH funds . . . ."); Conf. Rep. No. 111-366, at 982 (Dec. 8, 2009) ("In implementing this conference agreement, the Departments and agencies should be guided by the language and instructions set forth in House Report 111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293.").

3. NIH's interpretation of the statute, set out in 2000 and reaffirmed in 2009, is plainly entitled to judicial deference. Congress's reenactment of the statute with knowledge of the existing Executive Branch interpretation counsels special hesitation in setting that longstanding agency interpretation aside. The Supreme Court explained in *N.L.R.B.* v. *Bell Aerospace Co.*, 416 U.S. 267, 274-75 (1974), that "a court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration. This is especially so where Congress has re-enacted the statute without pertinent change." *See also Lorillard* v. *Pons*, 434 U.S. 575, 580-81 (1978) ("Congress is presumed to be aware of an administrative or judicial

interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.").

Indeed, the express declarations in the House and Senate reports approving the agency's interpretation demonstrate that Congress has ratified NIH's interpretation. Where Congress repeatedly reenacts an appropriations restriction accompanied by clear expressions of legislative intent, those statements are "worthy of considerable respect from the coordinate branches," and this Court has made clear that consideration should be given to such statements in interpreting the language of the appropriations restriction. *National Senior Citizens Law Center* v. *Legal Servs. Corp.*, 751 F.2d 1391, 1393 (D.C. Cir. 1985) (R.B. Ginsburg, J.); *see also Brooks* v. *Dewar*, 313 U.S. 354, 360-61 (1941) (Congress's "repeated appropriations" with knowledge of the agency's practice "not only confirms the departmental construction of the statute, but constitutes a ratification of the action of the Secretary as the agent of Congress in the administration of the act"); *FDIC v. Philadelphia Gear Co.,* 476 U.S. 426, 437-38 (1986) (citing reports of both Houses as evidence that Congress "has expressly incorporated [agency regulations] into the statutory scheme").

B. The District Court Erred In Setting Aside The Agency's Reasonable And Longstanding Interpretation Of The Dickey-Wicker Amendment Not To Preclude Funding For Research Using Embryonic Stem Cells.

1. The district court refused to defer to the longstanding and consistent NIH interpretation of the funding restriction, because, in the court's view, "Congress has 'directly spoken to the precise question at issue[.]'" JA 235 (quoting *Chevron*, 467 U.S. at 843). That reasoning is not sustainable.

Congress certainly did not address "the precise question at issue" when it first enacted the Dickey-Wicker amendment in 1996, nor could it have because it was not until two years later that scientists first isolated human embryonic stem cells. If Congress has directly addressed the precise question at issue, it has done so by repeatedly reenacting the amendment against the backdrop of NIH's regulatory history and expressing approval of the agency's interpretation of the statute. Because the district court did not address this history and the repeated reenactment, it did not reconcile its own understanding of the statute with the congressional view signaled by the reenactment and the legislative history.

Although the district court referred to "the unambiguously expressed intent of Congress," JA 235 (quoting *Chevron*, 467 U.S. at 843), it did not identify any unambiguous statutory text. Instead, it invoked the Human Subject Protection Regulations, which are cited in the Dickey-Wicker amendment as a reference point for

degree of risk, and which also include a definition of "research" covered by those regulations.[4] Citing the regulations, the district court declared that "the term 'research' as used in the Dickey-Wicker Amendment has only one meaning, *i.e.*, 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.'" JA 236 (quoting 45 C.F.R. § 46.102(d)). In the court's view, this definition compels the conclusion that "[d]espite defendants' attempt to separate the derivation of [embryonic stem cells] from research on the [embryonic stem cells], the two cannot be separated." JA 238.

But the Dickey-Wicker amendment does not incorporate the definition of "research" contained in the Human Subject Protection regulations. Rather, the amendment cites the regulation only as a reference point for degree of risk and it forbids funding for research in which embryos are subjected to risk greater than that allowed under 45 C.F.R. § 46.204(b), a regulation that describes the risk allowed for research involving pregnant women or fetuses. Moreover, even if the Dickey-Wicker amendment did incorporate that definition of "research," that regulatory definition provides no support for the district court's reading. The mere fact that certain

[4] The Dickey-Wicker amendment prohibits funding of research in which embryos are 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))."

research that is funded by NIH is "systematic" does not mean that it includes acts or processes that predated the federally funded research. Indeed, a different NIH regulation that governs the extramural grant process defines "research" as "a systematic investigation, study or experiment designed to contribute to general knowledge relating broadly to public health." 42 C.F.R. § 52.2. That regulation thus makes clear that "research" can consist of a single study or a single experiment. The regulation does not make all the activity predating a study or an experiment part of the study or experiment itself and, indeed, makes plain that a single study or experiment may itself be "systematic."

Furthermore, the language of the Dickey-Wicker amendment precludes the district court's extension of the statute to encompass matters that occurred prior to the research being funded. The amendment clearly speaks in the present tense. It specifically prohibits funding of "research *in which* a human embryo or embryos *are* destroyed, discarded, or knowingly subjected to risk of injury or death[.]" (emphasis added). The amendment does not bar funding for research that uses embryonic stem cells from a stem cell line that may have been derived a dozen years earlier and used in hundreds of other types of research, as is the case with the H9 stem cell line. The Supreme Court has recently observed that the use of present tense, rather than past or present perfect, "reinforces the conclusion" that the plain language of an act does not

include past actions. *Carr* v. *United States*, 130 S. Ct. 2229, 2236 (2010); *see also Sutton* v. *United Air Lines*, 527 U.S. 471, 482 (1999) ("Because the phrase 'substantially limits' appears in the Act in the present indicative verb form, we think the language is properly read as requiring that a person be presently - not potentially or hypothetically - substantially limited in order to demonstrate a disability."), *superseded by* Pub. L. No. 110-325 (2009).

Although the Dickey-Wicker amendment is written in present tense and is not directed at past research, the Guidelines impose requirements on the stem cell lines that can be used in federally funded research. *See* JA 46-47. These requirements are not required by the terms of the Dickey-Wicker amendment, but NIH adopted them to ensure that federal funding provides no chance of an incentive for the creation or destruction of embryos for research purposes. NIH did so by limiting the NIH registry to stem cell lines derived from embryos created through IVF and donated by IVF patients who have determined that such embryos are no longer necessary for meeting their reproductive goals.

2. NIH's longstanding interpretation of the Dickey-Wicker amendment to allow federal funding of research that uses embryonic stem cells, unlike the district court opinion, reflects an understanding of the use of stem cells in federally funded research. A researcher who applies for NIH funding identifies the stem cell line to be

used in the research that is described in the application. Thus, at the time of the expenditure of federal funds, the stem cell line has already been derived and approved for inclusion in the NIH registry. The process of obtaining NIH approval to list a stem cell line on the registry may itself take over a year.

These stem cell lines are generally managed by a university or associated research institute, or a private entity, which typically provides cells to non-commercial researchers for relatively modest fees, such as the $1,000 per line charged by the University of Wisconsin. The NIH registry, as of the time of this filing, includes 76 stem cell lines available for use in federally funded research. These lines are controlled by 13 organizations, including the research institute associated with the University of Wisconsin, which manages the H9 line created in 1998 as well as the H1 and H7 lines. *See* Stem Cell Registry, http://grants.nih.gov/stem_cells/registry/current.htm. In FY 2010, NIH provided funding for 223 grants using these stem cell lines controlled by 13 organizations. JA 251-52, Decl. ¶ 14. NIH acted lawfully because it relied on an interpretation of the Dickey-Wicker amendment that is, at a minimum, a reasonable interpretation, if not the only logical interpretation in light of the statutory text and history.

As noted previously, NIH does not fund research in which embryos are discarded or destroyed or otherwise put at risk. NIH thus does not fund research that

is designed to improve the efficiency of the derivation of stem cell lines from embryos (that is, to increase success rates in attempting to derive stem cell lines from embryos). *See*, *e.g.*, Stephenson and Braud, *Derivation of the King's College London Human Embryonic Stem Cell Lines, available at* http://www.springerlink.com/content/w401g674327n2l57/fulltext.html; O'Leary et al., *Stem Cells and Development: The Influence Of Early Embryo Traits On Human Embryonic Stem Cell Derivation Efficiency, available at* http://www.liebertonline.com/doi/abs/10.1089/scd.2010.0338. Unlike the work funded by NIH, this is research in which an embryo is destroyed or put at risk, and NIH Guidelines have consistently precluded funding of such work.

The district court declared that if Congress had meant to enact the distinctions reflected in the NIH Guidelines, "Congress could have written the statute that way." JA 237. More pertinently, however, if Congress had meant to ban all federal funding for "research involving human embryonic stem cells," JA 226, as the district court held, Congress could certainly "have written the statute that way" on any of the many occasions on which it has reenacted the same language with full knowledge that federal funds were being used to support research using embryonic stem cells. The district court erred in setting aside a longstanding and plainly reasonable agency interpretation that has been repeatedly confirmed by Congress.

II. The Balance Of Harms Does Not Permit The Grant Of A Preliminary Injunction.

A. Plaintiffs Have Failed To Demonstrate That A Preliminary Injunction Is Required To Avoid Imminent, Irreparable Injury.

"Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter* v. *Natural Resources Defense Council, Inc.*, 129 S. Ct. 365, 375 (2008). "Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* at 375-76.

This Court has similarly made clear that "[b]are allegations of what is likely to occur are of no value since the court must decide whether the harm will in fact occur[.]" *Reynolds Metals Co.* v. *F.E.R.C.* 777 F.2d 760, 763 (D.C. Cir. 1985) (Scalia, J.). Thus, to obtain a preliminary injunction, "[t]he moving party must show the injury complained of is of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm," and that "the injury must be beyond remediation." *Chaplaincy of Full Gospel Churches* v. *England*, 454 F.3d 290, 297-98 (D.C. Cir. 2006) (internal quotations omitted).

Plaintiffs have not come close to making the requisite showing. The district court accepted uncritically plaintiffs' assertion "'that obtaining NIH funding is *necessary* for their continued research.'" JA 239 (citing plaintiffs' opposition to the motion to dismiss at 44.). To demonstrate irreparable harm, the court found it sufficient that the plaintiffs might suffer some competitive injury if research funds were awarded to other scientists whose research involves embryonic stem cell lines. It was irrelevant to the court's analysis that Dr. Deisher has *never* applied for research funding from NIH and states only that she is "in the process of applying" for funding. JA 259, ¶ 4. Dr. Sherley's declaration states only that he has in the past received NIH grants and now has two grants pending. JA 257. His experience under the current Guidelines, under which he has received $425,500 in NIH grant funds, does not suggest imminent injury of the type necessary to justify preliminary relief. JA 254-55, ¶ 23.

Indeed, NIH funding for adult stem cell research and induced pluripotent stem cell research far exceeds funding for embryonic stem cell research. In FY 2010, NIH provided approximately $380 million in funding to human non-embryonic stem cell research and approximately $200 million in funding to human embryonic stem cell research. The $380 million provided during FY 2010 is also far greater than the $297 million for human non-embryonic stem cell research provided in FY 2008. JA 174-75, ¶ 18 (Decl. of Sarah Jean Rockey); JA 254, ¶ 22.

There is, moreover, no reason to conclude that an immediate halt of federal funding of embryonic stem cell research would result in a reallocation of funds in a way that would have any short-term impact whatsoever on Dr. Sherley's applications. It is one thing to conclude that Dr. Deisher and Dr. Sherley demonstrated standing to survive the government's motion to dismiss. It is quite another to conclude that they also demonstrated entitlement to a preliminary injunction.

B. The Injunction Would Result In Irreparable Injury To NIH Research, Research Funded By NIH, And The Public Interest.

The preliminary injunction would result in direct and immediate harm to ongoing NIH intramural research that uses embryonic stem cells and to research funded by NIH that uses such cells, much of which is in pursuit of potentially lifesaving medical advances and furthers the public interest.

1. The district court barred all such federally funded research. It nevertheless declared that its injunction somehow "would not seriously harm [embryonic stem cell] researchers" because it "would not interfere with their ability to obtain private funding for their research." JA 240. The court did not explain why the federal funding that it deemed "necessary for [plaintiffs'] continued research," JA 239 (quoting plaintiffs' opposition at 44), is not similarly necessary to the research of the scientists who would be wholly ineligible for federal funding of their research, including those with ongoing federally funded research with significant investment over the past several

years that would be abruptly cut off. *See* JA 259, ¶ 4 (Decl. of Dr. Deisher) (stressing that "private funding is scarce").

In denying the government's motion for a stay, the district court stated that "[p]laintiffs agree that this Court's order does not even address the Bush administration guidelines." JA 271. But plaintiffs have not indicated agreement. And, as explained above, the district court's reasoning precludes all research using embryonic stem cells, including research that was funded under the Bush Administration policy. The court's injunction does not address the Bush Administration policy because it no longer exists and cannot be the basis for new funding decisions, but the injunction clearly bars all new grants for research using embryonic stem cells.

2. The injunction would bar federal funding for new grants that have successfully completed NIH's rigorous peer review process. JA 252, Decl. ¶ 15. The injunction would also halt NIH consideration of all pending applications for funding of research using human embryonic stem cells and would require NIH to cease peer review activities of all embryonic stem cell research applications. NIH estimates that, once stopped for a significant period of time, it would take as long as six to eight months for the process to fully resume. JA 253, ¶ 18. The injunction would also

require that NIH cease reviewing stem cell lines to determine whether they are eligible for placement on the NIH Human Embryonic Stem Cell Registry. JA 253, ¶¶ 19, 20.

When the district court denied the government's motion for a stay, it stated that plaintiffs, in their opposition to the government's district court stay motion, "question whether this Court's order prevents NIH from doing peer review of applications." JA 272. But the injunction specifically enjoins NIH "from implementing, applying, or taking any action whatsoever pursuant to the" challenged Guidelines "or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines." JA 226. The court did not explain how that language of the injunction could be construed to authorize a continuation of the application review process. Indeed, plaintiffs did *not* question whether the injunction applies to the peer review process, but argued instead that "the processing of additional Registry and grant applications contributes directly to the competitive injuries to Plaintiffs (and other scientists) that the preliminary injunction was designed to prevent, and was properly enjoined." Docket No. 51, at 6.

Dr. Collins' declaration also explains that the injunction would cripple NIH's internal research program. NIH currently is engaged in eight intramural research projects that use human embryonic stem cells; those eight projects are staffed by approximately 45 scientists and other personnel, with a combined budget of

approximately $9.5 million for 2009. JA 252-53, ¶ 17. The longer that NIH might be prevented from conducting its intramural research, the more likely there will be loss of unique biological materials that have taken years to develop and that require ongoing maintenance and attention. JA 251, ¶ 12. Although the district court stated that "Plaintiffs question whether this Court's order exempts so-called 'intramural' NIH projects—that is, research carried out onsite by NIH researchers," JA 272, plaintiffs did not, in fact, question the injunction's applicability to NIH researchers. Docket No. 51, at 6.

3. The district court erroneously dismissed the effect of its ruling on the public interest, and summarily declared that "the harm to individuals who suffer from diseases that one day may be treatable as a result of" research using embryonic stem cell lines "is speculative." JA 240. "It is not certain," the court declared, whether such "research will result in new and successful treatments for diseases such as Alzheimer's and Parkinson's disease." JA 240.

It is quite true that the path to a cure for any disease is fraught with uncertainties. It is quite another thing to describe as "speculative" the importance of one of the most vital areas of research into the origins and treatments of human disease. *See* JA 245-48, ¶¶ 5-7. The progress made by scientists using embryonic stem

cells is real. The district court's willingness to substitute its scientific judgment for that of NIH does not protect the substantial public interest at stake.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and the preliminary injunction vacated.

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OCTOBER 2010

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I hereby certify that this brief complies with the type-volume limitation in Rule 32(a)(7)(B). The foregoing brief is presented in proportionally-spaced font typeface using Corel WordPerfect X4 in 14-point Garamond font. The brief, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), contains 9,084 words, as counted by Corel WordPerfect X4.

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CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2010, I filed and served the foregoing Brief for Appellants with the Clerk of the Court by causing a copy to be electronically filed via the appellate CM/ECF system. I also hereby certify that I hand delivered 8 copies.

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ADDENDUM

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Dickey-Wicker Amendment
Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81

SEC. 509.

(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 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Executive Order No. 13, 505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds. For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, 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.

Sec. 2. Research. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

Sec. 3. Guidance. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall 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 this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

Sec. 4. General Provisions. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
(b) Nothing in this order shall be construed to impair or otherwise affect:
(I) authority granted by law to an executive department, agency, or the head thereof; or
(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. Revocations. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.
(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.
THE WHITE HOUSE,
March 9, 2009.