

[ORAL ARGUMENT SCHEDULED FOR DECEMBER 6, 2010]

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

REPLY BRIEF FOR APPELLANTS

TONY WEST

Assistant Attorney General

RONALD C. MACHEN, JR.

United States Attorney

BETH S. BRINKMANN

Deputy Assistant Attorney General

MARK B. STERN

STEPHANIE R. MARCUS

ABBY C. WRIGHT

(202) 514-0664

Attorneys, Appellate Staff

Civil Division, Room 7252

U.S. Department of Justice

950 Pennsylvania Ave., N.W.

Washington, DC 20530-0001

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GLOSSARY

Term	Definition
APA	Administrative Procedure Act
HHS	Department of Health and Human Services
IVF	<i>In Vitro</i> Fertilization
JA	Joint Appendix
NIH	National Institutes of Health
Pl. Br.	Plaintiffs' Brief
UC Br.	University of California's Amicus Brief
WI Br.	Wisconsin's Amicus Brief

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INTRODUCTION AND SUMMARY

1. Plaintiffs, like the district court, misconstrue the language of the Dickey-Wicker amendment. Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81. Plaintiffs also ignore a decade of congressional approval for the National Institutes of Health (“NIH”) interpretation of the amendment. Plaintiffs claim that the NIH interpretation has been inconsistent, but that is not so. NIH has consistently interpreted the Dickey-Wicker amendment to allow federal funding for research using

human embryonic stem cells, with different presidential administrations having adopted different policy views on the scope of eligibility of particular embryonic stem cell lines.

Congress enacted the Dickey-Wicker amendment in 1996 in reaction to an NIH panel report that recommended federal funding of research on human embryos to improve *in vitro* fertilization techniques and to screen embryos for genetic defects, among other things. Congress rejected that recommendation and drafted the amendment to prohibit federal funding of that research by barring 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.

Two years later, in 1998, for the first time, human embryonic stem cell lines were established, which made possible the use of stem cells in research to study and develop treatments for conditions such as diabetes, Parkinson’s disease, and spinal cord injury. NIH published guidelines in 2000 to make clear that the Dickey-Wicker amendment does not apply to such research using embryonic stem cells because stem cells are not embryos, and thus research that uses such cells and does not use embryos in any way is not research in which an embryo is endangered or destroyed. 65 Fed. Reg. 51,976 (Aug. 25, 2000).

That NIH interpretation has remained in place through the subsequent decade, and is the basis for the 2009 NIH Guidelines challenged in this case. JA 42 (74 Fed. Reg. 32,170). Congress, fully aware of NIH's interpretation, has repeatedly enacted the amendment each year in substantially identical form. Indeed, when Congress most recently enacted the amendment in the FY 2010 Appropriations Act, Congress expounded on the amendment's scope, making plain that it allows federal funding for human embryonic stem cell research, and certainly does not unambiguously prohibit funding for such research, as plaintiffs argue and the district court concluded. *See* H.R. Rep. No. 111-220, at 273 (July 22, 2009); *see also* S. Rep. No. 111-66, at 121 (Aug. 4, 2009); Conf. Rep. No. 111-366, at 982 (Dec. 8, 2009).

NIH's interpretation is compelled by the language of the amendment. The term "research" as used in the Dickey-Wicker amendment does not include all acts antecedent to the research funded by NIH. In particular, "research in which a human embryo or embryos are destroyed" does not include research that uses embryonic stem cells where the cells come from a registered stem cell line. Research using such stem cells is not part of the process of the creation of the stem cell line from an embryo, which indeed is a process that may have occurred years earlier and may already have provided stem cells to hundreds of other research projects. At the very least, the agency's interpretation is "based on a permissible construction of the statute," and

should therefore be upheld. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

2. The balance of harms does not weigh in favor of an injunction. As the basis for establishing their alleged irreparable harm, plaintiffs rely on this Court's decision on standing in *Sherley v. Sebelius*, No. 09-5374. JA220. But it is one thing to conclude that Dr. Deisher and Dr. Sherley demonstrated standing to survive the government's motion to dismiss, and quite another to conclude that they have also demonstrated the irreparable harm necessary to support a preliminary injunction.

Dr. Deisher has never applied for an NIH grant, and four of Dr. Sherley's recent applications for NIH funding were not scored in the peer review process – meaning that they did not pass the first level of scientific peer review and thus were not given further consideration for funding. Dr. Sherley's applications were therefore not funded because of lack of scientific merit, not because of any alleged competition from human embryonic stem cell projects. *See* Sherley Declaration, ¶ 3, Dkt #70, No. 1:09-cv-01575-RCL.

Plaintiffs' claims that other parties and the public interest will not be harmed by an injunction are equally without merit. Dr. Collins' declaration and the amicus briefs filed in this Court by the University of California and the State of Wisconsin demonstrate the direct and immediate harm to NIH-funded research that will follow from a preliminary injunction. In contrast to plaintiffs' unsubstantiated harms, the

public interest will undoubtedly suffer from a delay in the pursuit of lifesaving medical advances.

ARGUMENT

THIS COURT SHOULD VACATE THE PRELIMINARY INJUNCTION BECAUSE IT 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.

For plaintiffs to prevail, they must demonstrate that the language of the Dickey-Wicker amendment *unambiguously* supports their interpretation of the amendment, which is impossible for them to do in light of the clear statements of Congress and the statutory text.

A. NIH's Interpretation Of The Dickey-Wicker Amendment Is Longstanding And Has Been Repeatedly Ratified By Congress.

As explained in our opening brief, Congress has repeatedly enacted the Dickey-Wicker amendment with full knowledge of NIH's interpretation of the amendment. And these enactments have been accompanied by statements that the Dickey-Wicker amendment does not bar federal funding for research using human 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.”); 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 . . .”); H.R. Rep. No. 110-231, at 288 (July 13, 2007); H.R. Rep. No. 108-636, at 199 (Sept. 7, 2004).

Indeed, Congress newly enacted the Dickey-Wicker amendment in the FY 2010 Appropriations Act after the Guidelines were issued, and the relevant Committee Report again declared that the amendment’s “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. 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.”).¹

¹Plaintiffs note, *see* Pl. Br. 33, that the continuing resolution that extends NIH funding to December 2010 contains no legislative history concerning the Dickey-

Plaintiffs argue that this Court should ignore this clear intent of Congress, however, because – they claim – NIH’s interpretation of the Dickey-Wicker amendment is not longstanding. Pl. Br. 30.² That claim is baseless. NIH has maintained the same interpretation of the Dickey-Wicker amendment for over a decade. And that consistent interpretation has been the premise of the policies of both the Bush Administration and the Obama Administration, policies that differ in the scope of the embryonic stem cell lines that are eligible to be used in federally funded research but agree on the necessary underlying principle that the amendment does not prohibit federally funded research using embryonic stem cells.

In the face of this history, plaintiffs argue that a 1996 letter from NIH to a federally funded researcher demonstrates inconsistency in NIH’s interpretation of the Dickey-Wicker amendment. JA283. Plaintiffs suggest that NIH’s concerns were with tests performed by the researcher with DNA removed from an embryo, rather than with experimentation on human embryos, and plaintiffs cite for support a

Wicker amendment. *See* Pub. L. No. 111-242, 124 Stat. 2607. Of course, it also does not contain the language of the Dickey-Wicker amendment.

²Plaintiffs also suggest that a past unsuccessful proposal to amend the Dickey-Wicker amendment supports their position, but the Supreme Court has repeatedly cautioned that “[c]ongressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.” *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.* 511 U.S. 164, 187 (1994) (citation omitted).

congressional hearing that was held following the discovery that the researcher was using federal funds for prohibited research. Pl. Br. 31 & n.10. But the testimony throughout the hearing makes plain that the researcher in question, along with his research assistants, performed pre-implantation genetic diagnosis on embryos, which requires the removal of a cell from an embryo to test that embryo for genetic abnormalities and thereby subjects the embryo to a risk of harm. This research was the focus of Congress's concern. *See Management Concerns at the National Institutes of Health*, House Subcomm. on Oversight and Investigations of the House Comm. on Commerce, at 29 (June 19, 1997) (“Rep. Barton: Well, can you do preimplantation genetic diagnosis without doing human embryo research? Dr. Varmus [then Director of NIH]: Pre-implantation genetic diagnosis, no.”); *id.* at 2-3 (stating that the prohibited research “at the NIH campus involved a misdiagnosis that resulted in the birth of an infant with cystic fibrosis”). We explained in our opening brief that in 1996, as today, the Dickey-Wicker amendment precludes federal funding for such research because it is research in which an embryo is subject to a risk of injury or death.

NIH's interpretation is not inconsistent with a 2002 memorandum from the Department of Health and Human Services (“HHS”) General Counsel to the Acting Director of NIH addressing the Dickey-Wicker amendment, as plaintiffs suggest. Pl. Br. 31; JA 120. That internal memorandum evaluated whether President Bush's policy

on stem cell research was lawful, and its findings on that score are consistent with NIH's interpretation of the amendment. The memorandum rejects a broad interpretation of the language of the amendment, describing the common usage and definitions of the words "in" and "which" and how those definitions imply a narrow connotation to the phrase "research in which"; and the memorandum recognized that federal funding was not available for the derivation of stem cells from embryos.

JA123-24. The memorandum also noted that "[t]he President's policy provides no incentives for the destruction of additional embryos," but did not suggest that the statute imposed such a requirement and did not suggest that the policy in place before President Bush's announcement was infirm. JA123.³

Congress was fully aware of NIH's interpretation of the Dickey-Wicker amendment when it enacted the amendment anew in 2009 following the issuance of the Guidelines. Thus even if NIH's interpretation had not been longstanding, this is not a case where a court must use the length of time an agency has held a particular

³In any event, as described *infra* pages 16-17, the Guidelines are structured to avoid any incentive for the destruction of additional embryos: The Guidelines make federal funding available for embryonic stem cell research 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" (*i.e.*, not created for research purposes), that "were no longer needed for this purpose," and that "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, including donation to others. *Ibid.*

interpretation to infer that Congress knew of the agency's interpretation. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 157 (2000) (“Although not crucial, the consistency of the FDA’s prior position bolsters the conclusion that when Congress created a distinct regulatory scheme addressing the subject of tobacco and health, it understood that the FDA is without jurisdiction to regulate tobacco products and ratified that position.”); *Isaacs v. Bowen*, 865 F.2d 468, 475 (2d Cir. 1989) (“Duration is particularly helpful when Congress is silent, because the passage of time may elevate congressional inaction into approval. In other words, longevity merely has evidentiary significance for discerning Congress’ appreciation of the agency’s actions.”).

B. The Dickey-Wicker Amendment Does Not Unambiguously Prohibit NIH’s Reasonable And Consistent Interpretation Of The Statutory Text.

1. Plaintiffs maintain that the language of the Dickey-Wicker amendment unambiguously supports their reading, but the text does not support that argument. Indeed, NIH’s interpretation is compelled by the language of the amendment. The term “research” as used in the Dickey-Wicker amendment does not include all acts antecedent to the research funded by NIH. In particular, “research in which a human embryo or embryos are destroyed” does not include research that uses embryonic stem cells where the cells come from a registered stem cell line. Such research is not part of the process of the creation of the stem cell line from an embryo, which indeed is a

process that may have occurred years earlier and may already have provided stem cells to hundreds of other research projects.

a. Plaintiffs argue that the structure of the Dickey-Wicker amendment suggests that section (1) is designed to prohibit funding for a specific act (“the creation of a human embryo or embryos for research purposes”), while section (2) is meant to prohibit funding for a broad range of research, not just research that necessarily destroys embryos. Plaintiffs suggest that Congress could have expressly worded the second clause of the amendment to prohibit funding for “specific acts” that destroy embryos, if that was all that was meant to be covered. Pl. Br. 18.

Defendants agree that Congress intended that section (2) prohibit funding of more than just research that destroys embryos; it also precludes funding of research in which “a human embryo . . . is discarded, or knowingly subjected to risk of injury or death.” Pub. L. No. 111-117, Div. D, § 509(a), 123 Stat. 3034, 3280-81. Thus, section (2) prohibits federal funding of research that uses embryos to attempt to improve *in vitro* fertilization techniques and research involving pre-implantation genetic diagnosis because embryos are threatened with destruction or subjected to risk of injury as part of that research.

Here by contrast, the research for which federal funding is sought does not subject embryos to a risk of harm because the research does not involve the use of any embryos. This research uses human embryonic stem cells: cells that are the result of

cell division from lines of cells that often exist for years. If Congress had meant to ban funding for any research using embryonic stem cells it would have said so rather than adopting language pointing to a very different conclusion.

b. NIH adopted certain requirements, described above, to limit the particular stem cell lines from which cells can be used for federally funded research. NIH did so to ensure that federal funding provides no chance of an incentive for the creation or destruction of embryos for research purposes. President Bush's policy similarly limited the lines that could be used to avoid any such incentive, but whereas his policy did so in a temporal way, the current guidelines do so in a manner that is limited to the already existing consequences of IVF processes. These requirements on what lines can be used in federally funded research are not mandated by the terms of the Dickey-Wicker amendment, and they do not imply that the creation of a stem cell line is part of all later research that NIH may fund that may use stem cells from that line. Nor does the fact that NIH funds awarded for research may be used to pay a licensing or other fee to obtain stem cells from an established stem cell line create such an inference. NIH funds are used to obtain a variety of materials for NIH-funded research, but the production of those materials does not therefore become part of the research that is funded by NIH (and any issue posed by such a payment certainly could not justify the district court's preliminary injunction). Again, plaintiffs' argument

would mean that the same was true under President Bush's policy, where researchers were also able to use NIH funds to obtain stem cells from established stem cell lines.

Also, NIH's interpretation of the amendment to allow federal funding of research that uses embryonic stem cells, but precludes federal funding for the activities that derive stem cells from embryos, is consistent with the statutory text and not somehow impermissible as plaintiffs suggest. Indeed, as plaintiffs acknowledge, Congress has elsewhere drawn a similar distinction, permitting federal funding of research on material derived from an aborted fetus, but prohibiting federal funding of abortion. *See* Pl. Br. 27 n.8; 42 U.S.C. § 289g-1. Plaintiffs attempt to distinguish this situation, arguing that the regulations that govern fetal tissue research ensure that the decision to abort remains separate from the research. But the Guidelines accomplish this same goal. *See* JA46 (specifying that, with respect to the stem cell lines from which cells can be used for federally funded research, “[d]ecisions related to the creation of human embryos for reproductive purposes should have been made free from the influence of researchers proposing to derive or utilize [human embryonic stem cells] in research”).

c. Seeking to manufacture an internal inconsistency in NIH's interpretation of the Dickey-Wicker amendment, plaintiffs argue that NIH's interpretation of the amendment to preclude funding of the derivation of stem cells from an embryo indicates agreement with plaintiffs' argument that the creation of a stem cell line must

be regarded as part of all future research projects that use any stem cells that have resulted from the division of cells at any point in that line. Pl. Br. 17. But that does not follow. NIH interprets the amendment to prohibit the funding of derivation of stem cells from embryos because the amendment prohibits federal funding of research in which embryos are discarded or destroyed or otherwise put at risk. NIH thus also does not fund research that is designed to improve the efficiency of the derivation of stem cell lines from embryos (that is, to increase the success rate in deriving stem cell lines from embryos). *See, e.g.,* Stephenson and Braud, 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>. That NIH will not fund research involving derivation of a stem cell line does not suggest that this research therefore becomes part of the hundreds of other research projects that may use stem cells obtained from the stem cell line over the course of many years.

2. As an alternative argument, plaintiffs now assert that Congress did not intend to fund research that may create an incentive to destroy additional embryos. Pl. Br. 24. Plaintiffs argue that, by funding research that uses embryonic stem cells, NIH will “knowingly subject” human embryos “to risk of injury or death” because the Guidelines create demand for human embryonic stem cells. *Ibid.* The statutory text does not support such an incentive argument, however, as it clearly precludes 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. That statutory language plainly requires that the research for which federal funding is barred be research that involves embryos, and plaintiffs do not dispute that embryonic stem cells are not embryos. *See* JA 161 (Rabb Memorandum).

Indeed, the district court did not rely on the argument that federal funding of research using embryonic stem cells violated the amendment by creating an incentive for private researchers to derive stem cell lines. Nor could it, as the district court purported to rely on the unambiguous text of the amendment.

Plaintiffs attempt to rely on the regulatory and statutory provisions that are referenced in the amendment, but that reasoning also fails. The amendment does not prohibit federal funding of all research whatsoever that could possibly increase to any degree the risk of injury or death to which an embryo might be subject. Rather, the amendment specifies that it prohibits federal funding of research where there is a “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. The referenced provisions allow research involving fetuses when the “risk to the fetus is

caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.” 45 C.F.R. 46.204(b); *see also* 42 U.S.C. 289g(b). Nothing in the provisions suggests the kind of causal analysis plaintiffs argue is required by the Dickey-Wicker amendment. Rather the provisions make plain that in enacting the Dickey-Wicker amendment, Congress sought to prohibit federal funding for research using embryos that directly subjected the embryos to a particular level of harm, research for which federal funding had been proposed in 1994 and then rejected by Congress. *See* NIH, Report of the Human Embryonic Research Panel 75-76, *available at* http://bioethics.georgetown.edu/pcbe/reports/past_commissions/index.html.

In any event, plaintiffs’ argument that the Guidelines will create incentives for the destruction of additional embryos lacks any basis in the record supporting the district court’s preliminary injunction. The Guidelines make federal funding available for stem cell research 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. These requirements thus focus donation on embryos that are no longer necessary for reproductive purposes, and plaintiffs' assertion that the Guidelines will somehow cause "additional destruction of embryos" is highly implausible on its face. Plaintiffs present no evidence that destruction of embryos through the decision of IVF patients to discard their embryos would be altered in any manner by the Guidelines. Plaintiffs also present no evidence that embryos donated for stem cell derivation would somehow be embryos that would otherwise have been implanted, which is the only means ultimately to avoid harm to the embryo.

To bolster their incentive argument, plaintiffs rely on the fact that there are new stem cell lines available to researchers due to the lifting of the restriction imposed by President Bush. This does not show that these lines were created from embryos destroyed *due to* the availability of federal funding for embryonic stem cell research, however. In fact, as plaintiffs note, almost all the stem cell lines on the NIH registry were created from embryos donated prior to the Guidelines, when federal funding for research on new lines was *not* available. Human embryonic stem cells have been, and would continue to be, derived from human embryos even in the absence of federal funding for embryonic stem cell research. Thus, plaintiffs' assertion that the Guidelines somehow create a "known risk" to embryos is meritless when the Guidelines do nothing to change the private sources of funding for the process of

derivation. In addition, plaintiffs' argument would not support the broad preliminary injunction issued by the district court, because, as noted, almost all the stem cell lines on the registry were created from embryos donated before the Guidelines.

C. Plaintiffs' APA Claims Did Not And Could Not Support The District Court's Preliminary Injunction.

Plaintiffs further argue that NIH's promulgation of the Guidelines violated the Administrative Procedure Act ("APA"). As an initial matter, the district court did not reach plaintiffs' claims under the APA, and such claims thus were not a basis for the entry of the preliminary injunction. Nor could they be. Indeed, the administrative record was not filed in this case until after the preliminary injunction was appealed.

Even if this Court were to address such claims, however, they lack merit. Plaintiffs reason that NIH should have used the Guidelines as a vehicle to declare that it would reject all applications for federal funding for human embryonic stem cell research, in advance of a review of the actual content of any such application. Executive Order No. 13,505 revoked the prior limitations on federal funding for human embryonic stem cell research, and restored the evaluation of the scientific worth of that research to the proper forum, *i.e.*, NIH's statutorily-mandated two-tier system of expert peer review. NIH was not free to disregard the Executive Order and to reimpose the limitations that the President had withdrawn. At the same time, the Guidelines abided by the Executive Order's requirement to fund "responsible" human

embryonic stem cell research, limiting such federal funding to research using embryonic stem cells from embryonic stem cell lines derived from embryos created for reproductive purposes, but no longer necessary for those purposes. Commenters who sought to replace case-by-case peer review with a categorical declaration that human embryonic stem cell research lacks any scientific merit, did not speak to any matter that was at issue in formulating the Guidelines.

Moreover, even if such claims had merit, an injunction would not be the proper remedy for any alleged violations of the APA; rather, a remand to the agency is the appropriate remedy in such cases. *See Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761 (2010) (“If a less drastic remedy (such as partial or complete vacatur of [the] deregulation decision) was sufficient to redress respondents’ injury, no recourse to the additional and extraordinary relief of an injunction was warranted.”); *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm’n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993).

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

1. Plaintiffs cannot demonstrate the requisite irreparable harm to support the district court's injunction. As explained in our previous filings, Dr. Deisher does not even claim to have applied for an NIH grant and cannot therefore demonstrate any injury. Dr. Sherley fares no better. Plaintiffs point to Dr. Sherley's declaration, submitted in the district court summary judgment proceedings, but that document only underscores the lack of irreparable injury. Dr. Sherley claims as "concrete harm" that four of his recent applications went unscored during the peer review process. *See* Sherley Declaration, ¶ 3, Dkt #70, No. 1:09-cv-01575-RCL. But an unscored application is one that does not pass the first level of scientific peer review, and Dr. Sherley's applications thus were not given further consideration for funding. Dr. Sherley's applications were therefore denied not because of competition from human embryonic stem cell research, but because they lacked scientific merit.

In response to Amicus University of California's argument that plaintiffs have not demonstrated standing, plaintiffs recognize that there is a difference in the "quantum of proof" required at successive stages of litigation. Pl. Br. 58 n.18. As explained, however, Dr. Deisher and Dr. Sherley's claims of injury are even weaker here than they were on the previous appeal, which was an appeal from a motion to dismiss.

Moreover, as noted in our opening brief, there is no reason to assume as a general matter that money that would have supported embryonic stem cell research would be reallocated to adult stem cell or induced pluripotent stem cell research. Dr. Sherley now claims that human embryonic stem cell research is “a uniquely substantial competitor” for his work because his work has the same goals as some embryonic stem cell research. *See* Sherley Declaration, ¶ 2, Dkt #70, No. 1:09-cv-01575-RCL. But there is no reason to assume NIH would not fund the research of both a researcher using human embryonic stem cells and Dr. Sherley, if both proposed scientifically meritorious research. NIH has consistently funded adult stem cell research at a high level. 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; *see also* UC Br. 10 (university grantees seek funding for all types of stem cell research).

Plaintiffs persist in asserting that NIH acted improperly in the wake of the administrative stay and that this demonstrates their irreparable harm. *See* Pl. Br. 50. But, as made clear in the government’s reply in the stay proceedings, NIH merely resumed the activities that the preliminary injunction had prohibited. *See* Amended

Status of Applications and Awards Involving Human Embryonic Stem Cells, and Submissions of Stem Cell Lines for Eligibility Consideration,

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-136.html>. The

preliminary injunction caused the delay of embryonic stem cell research funding that would otherwise have been awarded prior to the end of FY 2010. NIH directed its institutes and centers to process those funds as necessary to meet the applicable end-of-fiscal-year deadlines. NIH also directed its institutes to commence with the peer review of applications that were *delayed by the preliminary injunction*. NIH in no sense provided those applications with more favorable treatment than other applications.

2. Plaintiffs attempt to cast doubt on the severity of the impact of the preliminary injunction, asserting without support that all embryonic stem cell research funded by NIH could be easily resumed after being halted. That NIH began the process of resuming its normal activities following this Court's administrative stay is not surprising – indeed, it is unclear what purpose plaintiffs believe the administrative stay should have served – and demonstrates nothing about the effect a preliminary injunction would have on NIH-funded research. Indeed, Wisconsin notes in its amicus brief that even during the very brief period of time in which the preliminary injunction was in effect, researchers experienced serious negative effects on their research. *See WI*

Br. 18 & n.26. And the longer the research is halted, the more difficult it will be to restart.

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 further 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. The University of California has also set forth serious concrete harms that its researchers and students will suffer if funding for human embryonic stem cell research is halted. UC Br. 17-19. That Dr. Collins' declaration could not state with absolute precision what ill effects each NIH-funded project would suffer is of no moment. Dr. Collins' declaration addressed the risks that stopping experiments mid-stream has on the materials created in the experiment, the animals used in the experiment, and the researchers whose livelihood is threatened. If this research is halted, research materials

and products that require constant monitoring and maintenance may be irrevocably lost.

3. It is unclear why plaintiffs characterize the government's argument as being concerned with the *scope* of the injunctive relief, rather than the harm the injunction would cause. *See* Pl. Br. 50. The district court's injunction is broad, enjoining 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. That 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.⁴

Plaintiffs also confuse the government's argument regarding research authorized under the Bush policy. Pl. Br. 50-51. Human embryonic stem cell research was permitted under the Bush administration policy, but was limited to a particular set of stem cell lines. Research using those stem cell lines – which remain among the most

⁴Plaintiffs again declare that "[d]efendants *never* briefed the 'peer review' or 'intramural' research issues in opposition to Appellees' motion for a preliminary injunction," Pl. Br. 54, again failing to recognize 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.

frequently used lines – is plainly prohibited under the district court’s injunction. That injunction bars defendants from “funding research involving human embryonic stem cells as contemplated in the Guidelines.” JA 226.

4. Plaintiffs once again invite this Court to adopt the view of the district court and reject the reasoned scientific judgment of NIH and the broader scientific community. *See* UC Br. 19. Although plaintiffs claim that the benefits of embryonic stem cell research are merely “speculative,” Pl. Br. 54, embryonic stem cell research 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); *see also* WI Br. 18-22 (describing advances in human embryonic stem cell research). And plaintiffs cannot dispute that embryonic stem cell research is a necessary tool in induced pluripotent stem cell research. JA 247-48, Decl ¶ 7; WI Br. 21; 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>. The public interest thus weighs against issuance of the preliminary injunction.

CONCLUSION

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

Respectfully submitted,

TONY WEST
Assistant Attorney General

RONALD C. MACHEN, JR.
United States Attorney

BETH S. BRINKMANN
Deputy Assistant Attorney General

MARK B. STERN
(202) 514-5089
STEPHANIE R. MARCUS
(202) 514-1633
ABBY C. WRIGHT /s/ Abby C. Wright
(202) 514-0664
Abby.Wright@usdoj.gov
Attorneys, Appellate Staff
Civil Division, Room 7252
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, DC 20530-0001

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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 5,992 words, as counted by Corel WordPerfect X4.

/s/ Abby C. Wright
Abby C. Wright
Abby.Wright@usdoj.gov
Attorney, Appellate Staff
Civil Division, Room 7252
U.S. Department of Justice
950 Pennsylvania Ave., N.W.
Washington, DC 20530-0001

CERTIFICATE OF SERVICE

I hereby certify that on November 4, 2010, I filed and served the foregoing Reply 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 7 copies.

Service was accomplished on the following by the CM/ECF system:

Thomas G. Hungar
Blaine Evanson
Ryan Watson
Gibson, Dunn & Crutcher LLP
1050 Connecticut Avenue, NW
Washington, DC 20036-5306
blingo@gibsondunn.com

Robert Charrow
Greenberg Traurig LLP
2101 L Street, NW
Washington, D.C. 20037
Charrowr@gtlaw.com

Samuel B. Casey
Advocates International
9691 Main Street, Suite D
Fairfax, VA 22031
sbcasey@advocatesinternational.org

Steven H. Aden
Alliance Defense Fund
801 G Street, NW, Suite 509
Washington, D.C. 20001
saden@telladf.org

Dorinda C. Bordlee, Esquire
Direct: 504-231-7234
Email: dbordlee@aol.com
Bioethics Defense Fund
Firm: 480-483-3597
6811 East Voltaire Avenue
Scottsdale, AZ 85254

Jon E. Pettibone

Direct: 602-230-5572
Email: jon.pettibone@quarles.com
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004

Andrew T. Karron
Direct: 202-942-5000
Email: andrew_karron@aporter.com
Arnold & Porter, LLP
Firm: 202-942-5000
555 12th Street, NW
Washington, DC 20004-1206

Neal Goldfarb
Direct: 202-454-2826
Email: ngoldfarb@butzeltp.com
Fax: 202-454-2805
Butzel Long Tighe Patton, PLLC
Firm: 202-454-2800
1747 Pennsylvania Avenue, NW
Suite 300
Washington, DC 20006-4606

/s/ Abby C. Wright
ABBY C. WRIGHT
(202) 514-0664
Abby.Wright@usdoj.gov
Attorney, Appellate Staff
Civil Division, Room 7252
Department of Justice
950 Pennsylvania Ave., N.W.
Washington, D.C. 20530