ORAL ARGUMENT NOT YET SCHEDULED
No. 10-5287

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DR. JAMES L. SHERLEY, et al.,

Plaintiffs-Appellees,

v.

KATHLEEN SEBELIUS, et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Columbia
1:09-cv-01575-RCL

BRIEF FOR APPELLEES

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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. Except for the following, all parties, intervenors, and amici appearing before the district court and in this Court are listed in the Brief for Appellants: The State of Wisconsin is an amicus in this Court, and the Coalition for the Advancement of Medical Research and the Genetics Policy Institute, Inc. have moved to be amici in this Court.

B. Rulings Under Review. References to the rulings at issue appear in the Brief for Appellants.

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 aware of no other related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

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GLOSSARY

APA	Administrative Procedure Act
hESC	Human Embryonic Stem Cells
HHS	U.S. Department of Health and Human Services
NIH	National Institutes of Health
NOPR	Notice of Proposed Rulemaking
PI	Principal Investigator
UC	University of California

STATEMENT OF THE ISSUE

Whether the district court properly enjoined Defendants from implementing or taking action pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009).

STATUTES AND REGULATIONS

Except for the relevant statutes and regulations that are reproduced in the Addendum to this brief, all applicable statutes and regulations are contained in the Brief for Appellants.

STATEMENT OF FACTS

Dr. James L. Sherley and Dr. Theresa Deisher ("Plaintiffs"), among others, brought this action alleging that the National Institutes of Health's ("NIH") Guidelines for Human Stem Cell Research ("Guidelines")—which authorize federal funding of research involving human embryonic stem cells—are not in accordance with law, are arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A), and were promulgated without observing procedures required by law, *id.* § 706(2)(D). Accordingly, Plaintiffs moved for a preliminary injunction restraining Defendants from implementing, applying, or taking any action pursuant to the Guidelines.

Defendants opposed Plaintiffs' motion and filed a motion to dismiss. The district court granted Defendants' motion to dismiss on the ground that, in its view,

Plaintiffs lacked standing. JA177. The district court then denied as moot Plaintiffs' motion for a preliminary injunction. JA188.

On appeal, this Court held that Drs. Sherley and Deisher have standing under the competitor-standing doctrine. JA222–23 (*Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010) ("*Sherley I*")). The Court also reinstated Plaintiffs' motion for a preliminary injunction. JA224. On remand, the district court granted Plaintiffs' motion for a preliminary injunction. JA226. That order is the subject of this appeal.

A. The Dickey-Wicker Amendment

Federal law bans federal funding of research in which human embryos are destroyed or knowingly subjected to harm. An appropriations rider, commonly known as the Dickey-Wicker Amendment, states: "(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 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, § 509(a)(2), 123 Stat. 3034, 3280–81. Congress has included the Dickey-Wicker Amendment in

every Health and Human Services ("HHS") appropriations bill since 1996 and has not altered the Amendment in any material respect. JA54–55.

B. History Of Governmental Policy Relating To Human Embryonic Stem Cell Research

Shortly after Dickey-Wicker's initial enactment, NIH took the position that the statute prohibited federal support for DNA research on material derived from embryos (even though the embryos were not necessarily destroyed). In a 1996 letter to Georgetown University researchers who were using federally funded equipment to conduct tests on DNA derived from embryos, NIH "clarif[ied] . . . the NIH position on embryo research." JA283. The agency explained that "analysis from DNA derived from a human embryo" violated the federal prohibition on research involving embryos and that NIH equipment "may not be used for embryo work of any kind." *Id.*

Four years later, NIH altered its position and issued Guidelines authorizing the funding of human embryonic stem cell research. *See* 65 Fed. Reg. 51,976 (Aug. 25, 2000). Before the 2000 Guidelines were published, then-HHS General Counsel Harriet Rabb concluded that human embryonic stem cells are not "embryos" under Dickey-Wicker, and therefore that NIH could legally fund experiments on the stem cells after those cells had been derived with private funds. JA161. The Rabb Memorandum, however, addressed only the definition of "embryos" and said nothing about the scope of the word "research." The 2000

Guidelines were never implemented because NIH formally withdrew them, *see* 66 Fed. Reg. 57,107 (Nov. 14, 2001), to allow for the implementation of President Bush's new policy.[1]

In 2001, President Bush announced a policy confining federal funding of human embryonic stem cell research to research on existing cell lines derived from "embryos that ha[d] already been destroyed" prior to the policy's announcement. *Address to the Nation on Stem Cell Research From Crawford, Texas*, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001); *see also* Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007). From 2002 through 2009, Defendants took the position that this "moral line," 37 Weekly Comp. Pres. Doc. 1149, was also a decisive legal line drawn by Dickey-Wicker. In 2002, then-HHS General Counsel Alex Azar II articulated the agency's legal justification for the Bush policy, concluding that the Bush policy complied with Dickey-Wicker in part because it "provide[d] no incentives for the destruction of additional embryos." JA123; *see also* JA120–26.

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[1] *See* Nat'l Inst. of Health, Office of the Dir., *Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry* NOT-OD-02-005 (Nov. 7, 2001), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.

C. Promulgation Of The 2009 Guidelines

In 2009, President Obama signed Executive Order 13,505, which "revoked" the Bush Administration's policy on human embryonic stem cell research and stated 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." JA278–79 (74 Fed. Reg. 10,667 (Mar. 11, 2009)). The Order required that HHS and NIH "issue new NIH guidance on [human stem cell] research that is consistent with [the] order." *Id.*

Six weeks later, Defendants issued a notice of proposed rulemaking ("NOPR") containing draft Guidelines for human stem cell research ("Draft Guidelines"). JA280 (74 Fed. Reg. 18,578 (Apr. 23, 2009)). According to the NOPR, the Guidelines' purpose would be to "ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law." *Id*. The NOPR proposed the authorization of federal funding of human embryonic stem cell research and invited public comment on the Draft Guidelines. *Id*.

NIH received approximately 49,000 comments, JA42, most of which opposed human embryonic stem cell research funding, *see* Jeffrey Young, *Administration Unveils Stem Cell Rules*, The Hill, July 6, 2009, *available at* http://thehill.com/homenews/administration/49462-administration-unveils-stem-

cell-rules; *cf.* Declaration of Story Landis ¶ 9 ("Landis Decl.") [Dkt. #58-1] ("[m]any comments opposed hESC research"). Numerous comments addressed scientific and ethical flaws in federally funding such research and documented superior alternatives. JA56–60, 127–38, 142–45; *see also, e.g.*, Administrative Record 016673–77, 002965, 009191 [Dkt. #66]. The comments identified serious risks associated with human embryonic stem cell treatments, as well as inherent limitations on those cells' therapeutic potential. JA58–60, 127, 134, 142–45. The comments also detailed the substantial and verifiable medical results already delivered by adult stem cells and other characteristics that render adult stem cells a superior scientific and ethical alternative. JA48, 56–57, 61, 127–34, 155–57. Defendants admittedly disregarded these comments, because in Defendants' view they "did not ask the public whether [NIH] should fund research on human embryonic cells," but rather "how [NIH] should fund human embryonic stem cell research." Young, *supra*; *cf.* Landis Decl. ¶¶ 11-13.

On July 7, 2009, Defendants issued the final Guidelines, JA42–47, which purport to implement the Executive Order by authorizing the federal funding of human embryonic stem cell research utilizing live human embryos that were "created . . . for reproductive purposes" but are "no longer needed for [that] purpose." JA46. The Guidelines set forth the procedures by which live embryos must be selected for destruction if they are to be used in government-funded

research. *Id*. The Guidelines also assert that Dickey-Wicker applies only to the act of deriving stem cells from human embryos, not to subsequent experiments on those cells, because human embryonic stem cells "are not embryos as defined by Section 509." JA45.

D. Advances In Stem Cell Research

Stem cell research has the potential to treat diseases that have long resisted traditional methods. JA49, 56–60. Indeed, numerous *adult* stem cell therapies already exist. JA56, 127–34. But, both scientifically and ethically, all stem cells are not created equal. There are three general types of stem cells: embryonic, adult, and induced pluripotent. JA56–60. Although human embryonic stem cells have received much of the public and media attention, no actual medical treatments have been approved using these cells. JA127. By contrast, scientists have made dramatic breakthroughs in the use of adult stem cells, and these ethically unobjectionable research methods have generated the vast majority of scientific advances and all of the actual medical success stories involving stem cells. JA49–50, 56–60, 127–34.

Human embryonic stem cells are developed from the cells that compose the inner cell mass of a living human embryo. JA43, 112. The removal of the inner cell mass is necessary to develop the human embryonic stem cell, but in order to extract the cells, the human embryo must be destroyed. JA 43, 52, 112; *see also*

Defs.' Br. 41, *Sherley I*. Although many researchers predicted that human embryonic stem cell research would yield cures for numerous serious diseases, those predictions have not come to pass. JA68. In fact, research shows that human embryonic stem cells would likely form tumors when injected into a patient's body or be rejected by the patient's immune system. JA134, 143–44.

Adult stem cells are cells found in the body and in tissues normally discarded after birth (such as umbilical cord blood and the placenta), and as a group adult stem cells are responsible for generating and renewing all of the different tissues in the human body. JA56, 127. Unlike human embryonic stem cells, adult stem cells have already shown documented clinical success as well as great therapeutic promise. JA49, 56, 127, 130–34. Adult stem cells have verifiably treated countless individuals suffering from a wide variety of diseases, without posing many of the risks associated with human embryonic stem cells. JA49, 130–34.

Induced pluripotent stem cells are produced by genetically reprogramming mature cells such that they are virtually indistinguishable from human embryonic stem cells. JA135–36. Induced pluripotent cells "meet the defining criteria [that were] originally proposed for human [embryonic stem] cells, with the significant exception that the [induced pluripotent stem] cells are not derived from embryos." JA137. And NIH has recognized that, unlike human embryonic stem cells, "tissues

derived from [induced pluripotent stem cells] will be a nearly identical match to the cell donor and thus probably avoid rejection by the immune system." Nat'l Inst. of Health, *Stem Cell Basics* 14 (2009), *available at* http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf.

E. The Present Action

Drs. Sherley and Deisher, among others, brought this action challenging the Guidelines. Dr. Sherley is an adult stem cell researcher who works at the Boston Biomedical Research Institute. JA166, ¶ 2. Dr. Sherley does not conduct research on human embryos or use human embryonic stem cells. *Id.* He relies exclusively on research grants for funding, and most of the grants he receives are from NIH. JA167, ¶ 3. Dr. Sherley will continue to apply for NIH grants in the future, without which he would be unlikely to be able to continue his research. *Id.*, ¶ 4. Dr. Deisher is an adult stem cell researcher and is the founder, managing member, and research and development director of AVM Biotechnology. JA168–69, ¶¶ 2–3. Dr. Deisher does not conduct research on human embryos or use human embryonic stem cells. *Id.*

In the first appeal in this case, this Court held that Drs. Sherley and Deisher have standing under the competitor-standing doctrine. JA215. The Court reasoned that "[t]here can be no doubt the Guidelines will elicit an increase in the number of grant applications involving [human embryonic stem cells] . . . . Because the

Guidelines have intensified the competition for a share in a fixed amount of money, the plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury." JA222–23.[2] The Court further explained that Plaintiffs "will suffer an additional injury whenever a project involving [human embryonic stem cells] receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs." JA223.

On remand, the district court granted Plaintiffs' motion for a preliminary injunction, ordering "that defendants and their officers, employees, and agents are enjoined from implementing, applying, or taking any action whatsoever pursuant to the National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human

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[2] Applicants for NIH research funding undergo a competitive two-tier peer review process. JA220; *see also* JA172–73, ¶¶ 8–12. At the first stage, "a peer-review committee assigns a preliminary score to each grant application." JA220; *see also* JA172. An application that scores above the median "then goes to one or more of the 24 Institutes and Centers (ICs) at the NIH." JA220; *see also* JA172. At the second stage, "each IC decides which grant applications to fund." JA221; *see also* JA172. Each IC "has its own budget and awards grants to projects that address its particular mission," JA220–21, including both adult and human embryonic stem cell research. JA174–75.

embryonic stem cells as contemplated in the Guidelines."[3] JA226. In response, NIH instructed researchers to halt so-called "intramural" (internal) NIH experiments on human embryonic stem cells and also directed that "[p]rocedures that will conserve and protect the research resources should be followed."[4] This directive was consistent with the standard scientific technique of cell cryopreservation, which researchers routinely use to maintain cell cultures and cell lines in the laboratory. JA267–68, ¶ 19.

This Court administratively stayed the preliminary injunction on September 9, 2010. JA274. Within hours of that stay order, NIH issued a directive to employees who review grant applicants to "give[] priority" to previously delayed human embryonic stem cell research applications and awards[5] and ordered the immediate resumption of intramural human embryonic stem cell research

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[3] Before dismissing Plaintiffs' claims on standing grounds, the district court held an oral argument on Plaintiffs' preliminary injunction motion and Defendants' motion to dismiss, *see* JA9, during which Plaintiffs' claims based on Dickey-Wicker and the APA were addressed.

[4] Jocelyn Kaiser, *NIH Orders Immediate Shutdown of Intramural Human Embryonic Stem Cell Research*, Science Insider (Aug. 30, 2010), *available at* http://news.sciencemag.org/scienceinsider/2010/08/nih-orders-immediate-shutdown.html.

[5] Gretchen Vogel & Jocelyn Kaiser, *NIH Rushes to Hand Out Stem Cell Grants During Temporary Stay*, Science Insider (Sept. 10, 2010), *available at* http://news.sciencemag.org/scienceinsider/2010/09/nih-rushes-to-hand-out-stem-cell.html.

activities.[6] On September 28, this Court granted Defendants' motion for a stay pending appeal of the preliminary injunction. JA275.

SUMMARY OF ARGUMENT

1. Plaintiffs are likely to succeed on the merits of their claims. The Dickey-Wicker Amendment precludes funding of "research in which a human embryo or embryos are destroyed [or] discarded." § 509(a)(2), 123 Stat. at 3280–81. It is undisputed that "all embryonic stem cell research involves the destruction of embryos at some point," Defs.' Br. 41, *Sherley I*, and so NIH cannot plausibly contend that the human embryonic stem cell research it funds is not "research in which . . . embryos are destroyed." Dickey-Wicker also prohibits NIH from funding "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death." § 509(a)(2), 123 Stat. at 3280–81. It is untenable to suggest that the Guidelines, and the research that they contemplate, do not knowingly subject embryos to risk of injury or death. They create demand for human embryonic stem cells and dictate how that demand shall be met through the destruction of particular categories of human embryos.

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[6] Meredith Wadman, *NIH Tells Researchers to Recommence Stem Cell Work*, The Great Beyond, nature.com (Sept. 9, 2010), *available at* http://blogs.nature.com/news/thegreatbeyond/2010/09/nih_tells_its_campus_research.html.

What is more, although Defendants claimed only to intend to authorize funding for "ethically responsible, scientifically worthy" research "conducted in accordance with applicable law," JA42, they ignored many comments explaining why human embryonic stem cell research was neither ethically responsible nor scientifically worthy. And they failed to examine the relevant data and articulate a satisfactory explanation for their actions.

2. Each of the additional aspects of the standard for a preliminary injunction—irreparable harm, injury to other interested parties, and the public interest—weighs strongly in favor of an injunction here. Plaintiffs are suffering irreparable injury from illegal competition and the permanent loss of federal funds to illegal human embryonic stem cell research. This illegal diversion of taxpayer money also impairs the pursuit of other research that could otherwise lead to potential cures and other medical and scientific breakthroughs. Finally, it is clearly in the public interest for the courts to carry out the will of Congress.

STANDARD OF REVIEW

This Court "review[s] a district court decision regarding a preliminary injunction for abuse of discretion, and any underlying legal conclusions *de novo*." *Mills v. Dist. of Columbia*, 571 F.3d 1304, 1308 (D.C. Cir. 2009) (citations omitted). The Court "will overturn any of the district court's factual findings only upon a finding of clear error." *Id.*

ARGUMENT

This Court should affirm the preliminary injunction entered by the district court because Plaintiffs have "show[n] '1) a substantial likelihood of success on the merits, 2) that [they] would suffer irreparable injury if the injunction is not [affirmed], 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by the injunction.'" *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998).

I. PLAINTIFFS ARE LIKELY TO PREVAIL ON THE MERITS OF THEIR CLAIMS.

Plaintiffs are likely to succeed on the merits of their claims because the Guidelines plainly violate both the Dickey-Wicker Amendment and the APA. Because "Plaintiffs assert two independent arguments as to why they are likely to succeed on the merits," JA235, they may establish their likelihood of success based on either their Dickey-Wicker arguments or their APA arguments.

A. The Guidelines Violate The Dickey-Wicker Amendment By Funding Research In Which An Embryo Is Destroyed Or Knowingly Subjected To Risk Of Injury Or Death.

The Dickey-Wicker Amendment provides that "[n]one 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 C.F.R. 46.204(b)

and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." § 509(a)(2), 123 Stat. at 3280–81. "Congress says in a statute what it means and means in a statute what it says there," *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (internal quotation marks omitted), and Dickey-Wicker plainly prohibits research—such as human embryonic stem cell research—that depends upon and induces the destruction of human embryos. Moreover, neither indeterminate legislative history nor implied congressional ratification can override the statute's unambiguous text, and NIH is entitled to no deference here.

1. The Guidelines Violate Dickey-Wicker's Unambiguous Prohibitions.

The Guidelines violate the statute in two independent ways. *First*, the Guidelines authorize the funding of "research in which a human embryo or embryos are destroyed [or] discarded." § 509(a)(2), 123 Stat. at 3280–81. *Second*, the Guidelines unlawfully authorize funding of "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." § 509(a)(2), 123 Stat. at 3280–81.

(a) The Guidelines Unlawfully Authorize Funding For "Research In Which" A Human Embryo Is Destroyed.

The Guidelines violate Dickey-Wicker's unambiguous prohibition on federal funding of "research in which a human embryo or embryos are destroyed [or] discarded." § 509(a)(2), 123 Stat. at 3280–81. The ban on research that involves the destruction of embryos is broad; funding is prohibited for any "research in which . . . embryos are destroyed." *Id.* Importantly, it is undisputed that "all embryonic stem cell research involves the destruction of embryos at some point." Defs.' Br. 41, *Sherley I*. Thus, NIH cannot plausibly contend that the human embryonic stem cell research it funds is separate and distinct from the destruction of human embryos.

Yet that is just what NIH contends. NIH asserted in the Guidelines that Dickey-Wicker applies only to the act of deriving stem cells from embryos, not to subsequent experiments on those cells, because human embryonic stem cells "are not embryos as defined by Section 509." JA45. But Defendants' distinction between the derivation and use of human embryonic stem cells is completely unmoored from the statutory text, and the conclusion that human embryonic stem cells are not embryos does not even address the relevant interpretive questions. Dickey-Wicker prohibits not only the specific acts that destroy human embryos, but also all "*research in which*" an embryo is "destroyed, discarded, or knowingly

subjected to risk of injury or death." § 509(a)(2), 123 Stat. at 3280–81 (emphasis added). Accordingly, the relevant interpretive questions are whether the derivation of human embryonic stem cells occurs as part of "research" that receives federal funding, and (even if not) whether NIH "knowingly subject[s]" embryos to risk of destruction by funding human embryonic stem cell research.

Defendant's derivation/use distinction is belied by Defendants' own understanding of the statute. Specifically, Defendants' pronouncement that Dickey-Wicker precludes funding for derivation of human embryonic stem cells undermines their argument that Dickey-Wicker permits funding for research using those cells. The Guidelines state that "NIH funding of the derivation of stem cells from human embryos is prohibited *by the annual appropriations ban on funding of human embryo research* . . . , otherwise known as the Dickey Amendment." JA47 (emphasis added). Since Dickey-Wicker refers to "research" in which an embryo is destroyed, the Guidelines' prohibition against funding of derivation confirms that, according to Defendants' own interpretation, derivation is part of "research." Indeed, the section of the Guidelines stating that derivation is ineligible for funding is entitled "Other *Research* Not Eligible for NIH Funding." *Id.* (emphasis added). In other words, derivation is not merely a preparatory step before commencing research; it is itself part of the research. And the statute's text leaves no room for Defendants' attempt to bifurcate a research project by allowing funding for one

aspect of the research (experimentation) but not for another aspect of the research (derivation performed for the sole purpose of experimentation).

Dickey-Wicker's structure leaves no doubt as to its meaning. Dickey-Wicker contains two subsections: Subsection (1) precludes funding for the *specific act* of creating a human embryo or embryos for research purposes, while subsection (2) broadly prohibits *all* "research in which" a human embryo or embryos are destroyed, discarded, or knowingly threatened. NIH's interpretation renders this two-section format nonsensical: If Congress intended to forbid only the use of federal funds for specific acts that destroy human embryos, it could have done so in a far simpler and more straightforward way by utilizing the format of subsection (1) to prohibit funding for specific acts that destroy human embryos. *See Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227 (2008).

Congress instead chose to protect human embryos by enacting a much broader ban. Rather than banning funding only for specific acts that destroy human embryos, Congress banned funding for any "*research in which* a human embryo or embryos are destroyed." § 509(a)(2), 123 Stat. at 3280–81 (emphasis added). This Court should give effect to the difference in language between subsections (1) and (2). *See Russello v. United States*, 464 U.S. 16, 23 (1983); *Harbor Gateway Commercial Prop. Owners' Ass'n v. EPA*, 167 F.3d 602, 606 (D.C. Cir. 1999). And the text clearly indicates that subsection (2)'s broader

language was chosen to ensure that embryos are not destroyed to support federally funded experiments.

Defendants' counsel argued below that "research" can mean "a piece of research," and thus claimed that Dickey-Wicker permits funding for "pieces" of human embryonic stem cell research so long as the funding is not used for actual embryo destruction. Mem. in Supp. of Defs.' Mot. to Dismiss ("Mot. to Dismiss") at 31 [Dkt. #22-1]. On appeal, Defendants' counsel has seemingly backed away from this tautological interpretation—under which "research" means "research"—but the fundamental substance of counsel's argument is similar. *See* Defs.' Br. 30. In any event, the statutory prohibition against funding any "research in which" embryos are destroyed necessarily encompasses *all* of the research project at issue, not merely a selected task, phase, or "piece" of the research.

Indeed, NIH and HHS have recognized that "research" encompasses the entire research process and cannot be narrowed to include only individual tasks within a research project. In the Human Subject Protection Regulations—incorporated by Congress in Dickey-Wicker—NIH defined "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d); *see also* § 509(a)(2)(b), 123 Stat. at 3281. Additionally, HHS has stated that, under these regulations, an institution that receives federal funding is

generally engaged in human subjects research "*even where all activities involving human subjects are carried out by employees or agents of another institution*." Dep't of Health & Human Servs., *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html (emphasis added).

Defendants assert that "[t]he mere fact that certain research that is funded by NIH is 'systematic' does not mean that it includes acts or processes that predated the federally funded research." Defs.' Br. 29–30. But derivation is clearly part of the same "systematic investigation" (including "research development") as the research phase that utilizes the derived cells, because human embryonic stem cells are derived solely for use in the experimentation phase of human embryonic stem cell research.[7]

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[7] Defendants suggest that Dickey-Wicker "does not incorporate the definition of 'research' contained in the Human Subject Protection regulations." Defs.' Br. 29. But Dickey-Wicker expressly incorporates a portion of the Human Subject Protection Regulations by forbidding any risk to embryos "greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.204(b)." § 509(a)(2), 123 Stat. at 3280–81. And, by incorporating Section 46.204(b)'s standard of risk for "*research* on fetuses in utero," *id.* (emphasis added), the statute necessarily incorporates the definition of "research" used in that regulatory provision.

NIH's unduly narrow interpretation of "research" is also inconsistent with courts' use of that term. For instance, in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), the Supreme Court, in analyzing the scope of the research exemption under the patent statute, acknowledged that "research" is a multi-phase process rather than a single experiment: "There is simply no room in the statute for excluding certain information from the exemption on the basis of *the phase of research* in which it is developed or the particular submission in which it could be included." *Id.* at 202 (emphasis added); *see also Nat'l Ctr. for Mfg. Sciences, Inc. v. City of Ann Arbor*, 563 N.W.2d 65, 68 (Mich. Ct. App. 1997) ("research is not limited to a specific experiment" but includes "other critical steps in the research process").

Moreover, Defendants gain nothing by retreating to the argument that Congress's use of the present tense in banning funding for "research in which a human embryo or embryos are destroyed" restricts the statute to the specific act a researcher is performing at a given moment in time. *See* Defs.' Br. 30–31. This argument rests on the false premise that the derivation of human embryonic stem cells occurs *prior to* commencing "research." But, as described above, Defendants' own construction of Dickey-Wicker demonstrates that derivation is itself "research," which means that human embryos "are" destroyed as part of the "research." Moreover, the implications of Defendants' arguments are absurd: If

the funding ban encompassed only the destruction of human embryos where the destruction occurs during the period of funding, then NIH could fund the already-completed act of destroying embryos.

Finally, Defendants' attempt to portray the derivation of stem cells as a remote antecedent task is unavailing for several additional reasons. *First*, the Guidelines themselves regulate the process by which embryos are selected and ultimately destroyed for purposes of federally funded research. JA42. The Guidelines also require that NIH-funded researchers delve into the matter of derivation to ensure that the process by which the embryos were selected for destruction complied with the Guidelines. *See* JA46. Defendants cannot plausibly contend that the human embryonic stem cell research they propose to fund is wholly separate from the destruction of human embryos, while at the same time regulating the process by which embryos are acquired for destruction.

Second, the Guidelines permit the *same researcher* both to derive stem cells from an embryo *and* to receive federal funding for all research activities involving those cells. JA45; JA46 ("[t]he attending physician responsible for reproductive clinical care and *the researcher deriving and/or proposing to utilize [human embryonic stem cells]* should not have been the same person *unless separation was not practicable*" (emphases added)). It defies common sense and the statutory text to suggest that a federal grant recipient is not engaged in "research in which" an

embryo is destroyed when the researcher is conducting a multi-phase study of stem cells and he derives the stem cells—and thereby destroys an embryo—at phase one of the research effort. *See Harbor Gateway*, 167 F.3d at 606 (rejecting EPA's interpretation of an appropriations rider because "there [was] no reason to mistrust the common sense understanding of the statutory language" (internal quotation marks omitted)).

Third, the Defendants' derivation/use distinction is undermined by their repeated concession that federal funds are often used to pay the researcher who destroyed the embryo by deriving the stem cells. When the government was recently asked whether "grant money [is] ever used to pay for the [stem cell] line from the extractor," it answered "[y]es." *Sherley v. Sebelius*, No. 10-5287 (D.C. Cir.), Sept. 27, 2010 Oral Arg. Tr. at 15. Indeed, the government's brief emphasizes this point, noting that the "provider of the stem cell line . . . . 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." Defs.' Br. 7. Simply put, the government's derivation/use distinction collapses in practice because, among other reasons, it is *undisputed* that (1) the same person can derive the stem cells and use them for later stages of the research process and (2) federal funds are often paid to the provider of the stem cell line.

(b) The Guidelines Impermissibly Fund "Research In Which" A Human Embryo Is Knowingly Subjected To Risk Of Injury Or Death.

The Guidelines also violate Dickey-Wicker for a second, independent reason: They impermissibly fund "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." *See* § 509(a)(2), 123 Stat. at 3280–81. Even if this Court were to endorse Defendants' strained interpretation of "research," the Guidelines plainly contravene Dickey-Wicker's "knowingly subjected to risk" prong, as Plaintiffs specifically argued below. *See, e.g.*, Mem. in Supp. of Pls.' Mot. for Preliminary Injunction at 15–16 [Dkt. #3-1].

A person does not need to *intend* a consequence in order to act "knowingly"; instead, "the word knowingly . . . means that the defendant realized what she was doing and was aware of the nature of her conduct and did not act through ignorance, mistake or accident." *United States v. Alston-Graves*, 435 F.3d 331, 337 (D.C. Cir. 2006) (internal quotation marks omitted). The Guidelines, and the research that they contemplate, knowingly subject embryos to risk of injury or death because they *necessitate* the destruction of embryos by using, and creating demand for, human embryonic stem cells. In fact, the Guidelines dictate how that demand shall be met: Part II.A of the Guidelines details the procedures for

identifying and acquiring additional embryos to be destroyed for research purposes "on or after the effective date of the[] Guidelines." JA46–47. What is more, NIH has *already* approved for use under the Guidelines at least two stem cell lines derived from embryos that were donated and destroyed after promulgation of the Guidelines. *See* Mem. in Supp. of Defs.' Mot. for Summ. J. ("Defs.' Mot. Summ. J.") at 26 [Dkt. # 57–58]. Moreover, multiple embryos must be destroyed to obtain a single human embryonic stem cell line for continued research purposes. *See* David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1068 (May 2003).

Defendants argue below that the Guidelines do not violate the "risk of injury or death" prong because they pose no *known increased risk* to embryos. That is purportedly so because "the same 'risk of harm' to spare embryos in IVF clinics exists whether or not the guidelines are in effect, as third-party donors may be just as likely in the absence of the guidelines to discard their unused embryos." *See* Defs.' Mot. Summ. J. at 27. If an embryo is intended to be discarded anyway, Defendants' argument goes, the destruction of the living embryo in research does not increase the *relative probability* of harm to the embryo.

As an initial matter, the assertion that every embryo being destroyed for federally funded research would otherwise have been discarded is mere speculation. Embryos can be and are stored for years, even decades, before being

implanted and carried to term. Donna Dowling-Lacey et al., *Live Birth from a Frozen-Thawed Pronuclear Stage Embryo Almost 20 Years After Its Cryopreservation*, Article in Press—Corrected Proof, 94 FERTILITY & STERILITY 4 (Sept. 30, 2010). Misled by the Guidelines' imprimatur on human embryonic stem cell research, some parents will inevitably view donation for research as a worthy cause even though they would be unwilling simply to discard living embryos. The Guidelines unquestionably place such embryos at risk.

More fundamentally, Defendants' argument grossly distorts and misapplies the risk standard set forth in Dickey-Wicker. That provision makes clear that NIH cannot excuse fatal research risks to an embryo due to the expectation that the embryo will be destroyed anyway. Specifically, Dickey-Wicker states that the risk of injury or death cannot be "greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." § 509(a)(2), 123 Stat. at 3280–81. The first reference is to a provision in the Human Subject Regulations that states that "the risk to the fetus" can be *no* "*greater than minimal*" when the research does not "hold out the prospect of" directly benefiting the mother or fetus. 45 C.F.R. § 46.204(b) (emphasis added). Significantly, the second reference is to a statutory provision that requires that the "[r]isk standard for fetuses intended to be aborted and fetuses intended to be carried to term" must be the "same." 42 U.S.C. § 289g(b). In other

words, the baseline risk is set by the "fetus[] intended to be carried to term," even when the fetus is intended to be destroyed. By applying Section 289g(b) to embryos, Dickey-Wicker makes clear that embryos intended to be discarded can be exposed to no greater risk than embryos intended to be implanted—the "[r]isk standard" for both must be the "same." Consequently, NIH cannot claim that the risk of destruction-by-derivation is offset by the alleged risk that the embryo would otherwise have been discarded by third parties.[8]

The Guidelines demonstrate NIH's knowledge that future derivation of human embryonic stem cells for federally funded research purposes was inevitable. NIH stated that one of its goals was "ensuring that the greatest number of ethically

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[8] This protection for embryos is not diminished by the fact that the Human Subject Regulations permit research on material derived from an aborted fetus under some circumstances. 45 C.F.R. § 46.206(a); 45 C.F.R. § 46.204. Abortions are performed for reasons totally unrelated to research, and the Human Subject Regulations create a firewall between fetal research and the decision to abort by mandating that "[i]ndividuals engaged in the research will have *no part* in any decisions as to the timing, method, or procedures used to terminate a pregnancy." 45 C.F.R. § 46.204(i) (emphasis added). The regulations thus assure that abortion decisions and procedures are strictly separate from considerations of fetal tissue procurement. The Guidelines do just the opposite. An embryo is destroyed in human embryonic stem cell research for the sole purpose of experimenting on material derived from the dead embryo. This is not a situation where a parent destroys the embryo and then a researcher later derives stem cells from the embryo. Furthermore, the Guidelines permit the federally funded researcher to perform the destructive act, as long as that act is privately funded. JA45. And the Guidelines specify in detail how embryos are to be identified for destruction. JA46.

derived hESCs are available for Federal funding," and the Guidelines specifically "articulate . . . requirements" to govern all "*future* embryo donations in the United States." JA44 (emphasis added).

Finally, the Guidelines explicitly authorize researchers to apply for and receive human embryonic stem cell grants *without* first identifying (or even necessarily deriving) the stem cell lines they intend to use.[9] As the Guidelines make clear, it is entirely permissible for the *same* researcher to derive human embryonic stem cells and then, using federal funds, experiment on those very cells. *See* JA45. Considering that derivation of one stem cell line can destroy as many as 40 embryos, *see* Hoffman, *supra*, at 1068, the decision by even one researcher to develop a new line for use in federally funded human embryonic stem cell research poses a "greater than minimal" risk to embryos. *See* 45 C.F.R. § 46.204(b).

2. Neither The Implied Ratification Theory Nor Indeterminate Legislative History Can Override The Plain Meaning Of The Dickey-Wicker Amendment.

Because Defendants cannot reconcile the Guidelines with Dickey-Wicker's unambiguous text, they rely on two non-textual theories of interpretation. *See, e.g.*, Defs.' Br. 21–27. *First*, Defendants argue that by failing to alter Dickey-

[9] The Guidelines require only that grantees provide assurances that the stem cell lines they are using were listed on the NIH registry "[p]rior to the *use* of NIH funds" for research on those human embryonic stem cells. JA47 (emphasis added).

Wicker, Congress has impliedly ratified NIH's current policy. *Second*, Defendants attempt to elevate committee reports over the plain language of the statute. Both arguments fail.

(a) The Implied Ratification Theory Fails.

Defendants claim that the Court should deem Congress's failure to change Dickey-Wicker over the years as a tacit approval of the Guidelines, but the "congressional ratification" doctrine they rely on is inapposite here. Most importantly, Congress's reenactment of Dickey-Wicker after NIH's promulgation of the current Guidelines does not constitute an implied ratification of the Guidelines' purported interpretation of Dickey-Wicker, for "'where the law is plain'"—as it is here—"'subsequent reenactment does not constitute an adoption of a previous administrative construction.'" *Brown v. Gardner*, 513 U.S. 115, 121 (1994).

The Supreme Court has sometimes recognized congressional ratification of an agency interpretation based on affirmative legislative action, but only when the interpretation is "longstanding." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 846 (1986); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 155–56 (2000). But the routine reenactment of Dickey-Wicker without alteration is not the kind of "positive legislation" that signals congressional ratification of an agency interpretation. *Schor*, 478 U.S. at 846 (finding

congressional ratification where Congress affirmatively amended the statute to recognize the agency's jurisdiction); *see also Brown & Williamson*, 529 U.S. at 155–56 (holding that Congress ratified the agency's position that it lacked jurisdiction over tobacco by enacting distinct regulatory schemes for tobacco products, and explaining that the Court did not "rely on Congress' failure to act").

Moreover, ratification applies only to "*longstanding* administrative interpretation[s]." *Schor*, 478 U.S. at 846 (emphasis added). For example, in *Brown & Williamson*, the FDA's ratified position was over 75 years old. 529 U.S. at 156. The Guidelines were promulgated a little over a year ago.

Nor can Defendants establish that the Guidelines embody a longstanding administrative interpretation. Administrative interpretations and policies pertaining to human embryonic stem cell research have fluctuated during the period in which Dickey-Wicker has been reenacted. In 1996, an NIH letter to Georgetown University researchers explained that using federal support to perform "analysis from DNA derived from a human embryo" violated Dickey-Wicker and that NIH equipment "may not be used for embryo work of any kind." JA283. This conclusion—that research on materials *derived from* a human embryo violates Dickey-Wicker—cannot be squared with Defendants' litigation position that NIH

has always interpreted Dickey-Wicker to permit funding of human embryonic stem cell research.[10]

President Bush later announced a policy that, unlike the Guidelines, did not encourage embryo destruction and could not have been challenged under Dickey-Wicker's "risk of injury or death" prong. The Bush policy confined federal funding to research on existing cell lines derived from "embryos that ha[d] already been destroyed" prior to the policy's announcement. 37 Weekly Comp. Pres. Doc. 1149; *see also* Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007). Additionally, in a 2002 memorandum, agency counsel explicitly justified the Bush policy under Dickey-Wicker on the ground that the "policy provides no incentives for the destruction of additional embryos." JA123. Far from continuing a longstanding administrative interpretation, the 2009 Guidelines were designed precisely to "remove these limitations." JA278–79 (Executive Order revoking the Bush policy).

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[10] This illegal research, led by Dr. Mark Hughes, was the subject of a 1997 congressional subcommittee hearing. *See Continued Management Concerns At The NIH: Hearing Before the Subcomm. On Oversight & Investigations of the H. Comm. on Commerce*, 105th Cong. 26 (1997). According to NIH, Dr. Hughes' offense was use of NIH-funded single-cell genetic analysis equipment to analyze DNA of cells that had been removed from an embryo. *Id.* at 13–15 (Statement of Dr. Harold E. Varmus, then-NIH Director). NIH did *not* allege that Hughes directly experimented with or destroyed embryos.

Based on a new, unarticulated *reinterpretation* of Dickey-Wicker, the Guidelines opened the door to research on *newly* derived human embryonic stem cells and specified how additional embryos are to be identified for destruction. This major shift undermines any argument that NIH's interpretation is "longstanding." *See Schor*, 478 U.S. at 846.

(b) Ambiguous Legislative History Cannot Trump Unambiguous Statutory Text.

"Legislative history is irrelevant to the interpretation of an unambiguous statute." *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 494 (D.C. Cir. 2004) (internal quotation marks omitted); *see also Dep't of Hous. & Urban Dev. v. Rucker*, 535 U.S. 125, 132 (2002). "[I]t is the statute, and not the Committee Report, which is the authoritative expression of the law . . . ." *City of Chicago v. Envtl. Def. Fund*, 511 U.S. 328, 337 (1994); *see also Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 570 (2005).

Defendants cite committee reports stating that Dickey-Wicker 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. 107-229, at 180 (Oct. 9, 2001); *see also* H.R. Rep. No. 111-220, at 227 (July 22, 2009). But that statement has been repeated without change in multiple committee reports since 2001, and, until recently, the President's policy was to *prohibit* stem cell research that incentivized embryo destruction. Furthermore, the

most recent reenactment of Dickey-Wicker was accompanied by no legislative history on this issue. *See* Continuing Appropriations Act, 2011, Pub. L. No. 111-242, § 101, 124 Stat. 2607.

Other legislative history pertaining to Dickey-Wicker is also indeterminate, as it includes statements supporting both parties' positions. For example, the Amendment's author, Congressman Jay Dickey, explained that federal funding of human embryonic stem cell experiments that incentivizes the destruction of human embryos "undermines the spirit and letter of the law." Special Hearing on Stem Cell Research: Hearing Before the Subcommittee on Labor, Health, and Education of the S. Comm. on Appropriations, 106th Cong. 9–10 (Nov. 4, 1999). Other legislators have expressed similar views that Dickey-Wicker precludes Defendants' funding for human embryonic stem cell research.[11] Even the members of Congress who support human embryonic stem cell research have recognized that federal funding thereof does not comport with Dickey-Wicker; for this reason, an additional subsection was introduced in the 2001 Senate version of

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[11] *See, e.g.*, Statement of Representative Schaffer, 145 Cong. Rec. E1696-02, 1696–97 (July 30, 1999) ("[T]axpayer funding of research which relies on the intentional killing of human beings would violate the law."); Statement of Senator Brownback, 147 Cong. Rec. S6393-01, 6394 (June 19, 2001) ("[I]f a research project requires the destruction of human embryos no federal funds should be used for that project.").

Dickey-Wicker that would have allowed funding of all "stem cell research, on embryos that have been created in excess of clinical need and will be discarded, and donated with the written consent of the progenitors." S. 1536, 107th Cong. § 510(c) (2001). Thus, even if it were appropriate to use legislative history to interpret Dickey-Wicker, it would be unhelpful here because it "supports conflicting inferences and provides scant illumination." *Carter v. United States*, 530 U.S. 255, 271 n.9 (2000); *see also Lamie v. U.S. Trustee*, 540 U.S. 526, 539–42 (2004).

3. NIH Is Not Entitled To *Chevron* Deference.

Defendants contend that their purported interpretation of Dickey-Wicker is entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). Not so. Because "Congress has directly spoken to the precise question at issue," "that is the end of the matter," and no deference is due. *Id.* at 842–43. Moreover, Defendants have never provided an interpretation of "research" that this Court could assess for reasonableness under *Chevron*.

Defendants assert that Congress could not have addressed "the precise question at issue" when it first enacted Dickey-Wicker in 1996 because "scientists first isolated human embryonic stem cells" in 1998. *See* Defs.' Br. 28. This argument fails. *First*, it "'is ultimately the provisions of our laws rather than the

principal concerns of our legislators by which we are governed.'" *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 167–168 (2004). Thus, at least where the statutory text is clear, the assessment of whether Congress addressed the "precise question at issue" focuses on the text, not whether the legislators had a specific factual scenario in mind. *Second*, Defendants' assertion that "scientists first isolated human embryonic stem cells" two years after Dickey-Wicker's initial enactment, *see* Defs.' Br. 28, is inaccurate. Human embryonic stem cells were first isolated in 1994—two years *before* Dickey-Wicker's initial enactment. *See* JA260.

Even if there were some ambiguity in the statute, Defendants would deserve no deference because they have never proffered an interpretation of "research" that this Court could analyze for reasonableness under *Chevron*. To receive deference, an agency must in fact interpret the statutory provision in question, *Pub. Citizen, Inc. v. Dep't of Health & Human Servs.*, 332 F.3d 654, 661 (D.C. Cir. 2003), and must do so in a rule "carrying the force of law," *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Although an agency need not define every word in a statute to receive *Chevron* deference, there must be evidence that the agency *in fact* considered the critical statutory terms in proffering its interpretation. *See Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 420 (1992). But, instead of interpreting "research," the Guidelines state only that funding of human embryonic stem cell research does not violate Dickey-Wicker because human

embryonic stem cells are not embryos. JA45. This ignores a central question: whether deriving stem cells occurs as part of "research" under Dickey-Wicker. Because the agencies have never answered *that* question in a rule carrying the force of law, there is no interpretation to which this Court can defer. *See, e.g.*, *Pub. Citizen*, 332 F.3d at 661.

It is only in this litigation that Defendants' *counsel* attempted to articulate why human embryonic stem cell research that depends upon embryo destruction purportedly complies with Dickey-Wicker. But counsel's "piece of research" interpretation has *never* been offered in any official agency statement promulgated through notice-and-comment procedures, and agencies are not entitled to deference for interpretations offered by their counsel in legal briefs. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988).

In any event, counsel's "interpretation" would not merit any deference here because it is not based on an exercise of agency expertise, but rather on a definition cribbed from a dictionary. *See, e.g.*, Mot. to Dismiss at 31. An agency cannot "rest simply on its parsing of the statutory language—it must bring its experience and expertise to bear in light of competing interests at stake." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (internal quotation marks and alteration omitted); *see also Crowley v. Fed. Bureau of Prisons*, 312 F. Supp. 2d 453, 459 (S.D.N.Y. 2004). Defendants have

utilized no such experience or expertise here. *See Alarm Indus. Commc'n Comm. v. FCC*, 131 F.3d 1066, 1069 (D.C. Cir. 1997) (an agency is afforded no deference when it attempts to give "meaning to the provision on the basis of a dictionary"). Consequently, counsel's interpretation deserves no deference (*Chevron*, *Skidmore*, or otherwise).

B. Defendants Promulgated The Guidelines In Violation Of The Administrative Procedure Act.

Under the APA, Defendants were required to examine the relevant data, consider the important issues, respond to relevant comments, and articulate a sufficient explanation for their decision to fund human embryonic stem cell research. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Instead, Defendants rammed their predetermined outcome through an inadequate notice-and-comment process that flouted the most fundamental requirements of the APA. In an attempt to excuse their actions, Defendants argued below that the Executive Order commanded them to ignore important data and disregard significant comments. It is ironic that Defendants use an Executive Order that authorized NIH to fund only scientifically worthy and ethically responsible research to excuse their utter disregard for comments that went to those precise issues.

1. Defendants' Promulgation Of The Guidelines Was Arbitrary And Capricious.

The President ordered Defendants to fund only stem cell research that is "responsible" and "scientifically worthy," JA278, and the stated purpose of the Guidelines is likewise to ensure that NIH funding is "ethically responsible, scientifically worthy, and conducted in accordance with applicable law," JA42. Defendants therefore received comments detailing the *scientific* problems with human embryonic stem cell research. JA58–60, 134, 142–52. For example, human embryonic stem cells form tumors. JA143–44. Moreover, they do not differentiate into the type of cells needed for therapeutic treatments because they differentiate only into fetal or immature cell types, rather than into fully functioning adult cells. JA142–43. These scientific flaws are absent from adult stem cells. *See* JA56–57.

Additionally, induced pluripotent lines can be created from a specific individual, allowing creation of patient-specific cell lines. JA138. And, as NIH itself has recognized, "tissues derived from [induced pluripotent stem cells] will be a nearly identical match to the cell donor and thus probably avoid rejection by the immune system." JA34. Moreover, because induced pluripotent stem cells are created from adult cells yet are essentially indistinguishable from human embryonic stem cells for research purposes (except for the foregoing advantages),

they offer the purported benefits of human embryonic stem cell research (and more) without creating the same ethical problems. JA57–58.

The comments also established the myriad *ethical* problems posed by human embryonic stem cell research, which necessarily involves killing human embryos. JA52, 56. For example, it was noted that the National Bioethics Advisory Commission concluded that "derivation of stem cells from embryos remaining following infertility treatments is justifiable *only* if no less morally problematic alternatives are available for advancing the research." Nat'l Bioethics Advisory Comm'n, 1 *Ethical Issues in Human Stem Cell Research* 53 (Sept. 1999); *see* JA60; Administrative Record 015834. Because adult and induced pluripotent stem cell research do not require the destruction of human embryos and offer all the purported benefits of human embryonic stem cell research, they are ethically superior forms of research. *See* JA56.

It was arbitrary and capricious for the agency to decide to fund human embryonic stem cell research, given the more ethical and scientifically worthy alternatives. NIH failed to "'examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *U.S. Telecom Ass'n v. FCC*, 227 F.3d 450, 461 (D.C. Cir. 2000); *see also Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992). Accordingly,

they acted arbitrarily and capriciously within the meaning of 5 U.S.C. § 706(2)(A), and the Guidelines must therefore be "set aside," *id.*

2. Defendants Promulgated The Guidelines Without Following Procedures Required By Law.

NIH was required to "respond in a reasoned manner to those [comments] that raise[d] significant problems." *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006). Because Defendants admittedly failed to respond, the Guidelines were promulgated "without observance of procedure required by law," 5 U.S.C. § 706(2)(D), and must be set aside. *See Am. Mining Congress v. EPA*, 907 F.2d 1179, 1190–91 (D.C. Cir. 1990).

By their own admission, Defendants failed to consider approximately 30,000 comments that opposed federal funding for human embryonic stem cell research on scientific and ethical grounds. Defendants received "approximately 49,000 comments" on the Guidelines, JA42, including "[a]bout 30,000" comments "debat[ing] *whether* the NIH should be funding embryonic stem cell research" at all. Young, *supra* (emphasis added); *cf.* Landis Decl. ¶ 9 ("[m]any comments opposed hESC research"); *see generally* JA48–160; Administrative Record 016673–77, 002965, 009191. But Defendants admitted that they "disregarded all such comments," instead branding such comments "unresponsive," because, as NIH's then-Director explained, "[NIH] actually did not ask the public *whether* we should fund research on human embryonic stem cells. [NIH] asked the public *how*

we should fund human embryonic stem cell research." Young, *supra* (emphases added and internal quotation marks omitted); *see also* Landis Decl. ¶¶ 11–13; *see also id.* ¶ 13 ("NIH did not address comments that . . . sought a blanket ban on federal funding for research involving hESCs."). In other words, comments opposing such research as a categorical matter were simply ignored.

Defendants argued in the district court that the question of which human embryonic stem cell research grants were scientifically worthy and ethical is left to the grant application process, and that they were not required to determine whether, *as a categorical matter*, human embryonic stem cell research was scientifically worthy and ethically responsible. *Cf.* Landis Decl. ¶¶ 11–13, 16. Not so. A categorical approach to ethical issues is sensible and, in fact, NIH expressly *rejected* a case-by-case approach in favor of a *categorical* resolution of ethical concerns. The preamble to the Guidelines considered but rejected a proposal that ethical issues be left for case-by-case decision on the ground that NIH needed to provide a blanket rule so as to facilitate use of the Registry. *See* JA43. NIH thus made the categorical determination that any human embryonic stem cell line meeting the standards set forth in the Guidelines and listed on the Registry would be automatically eligible for use in federally funded research. *See* JA47 (§ II.D). In addition, the Guidelines established, as a categorical matter, the manner in

which human embryos must (on a going-forward basis) be selected for destruction in order to qualify for federal funding. JA46 (§ II.A).

The Guidelines also made numerous other categorical judgments. For example, the Guidelines categorically prohibit the use of funds for cloning or breeding of animals, JA47 (§§ IV, V), presumably for ethical reasons. And they mandate that "[n]o payments, cash or in kind [may be] offered for the donated embryos," JA46 (§ II.A.3.b), seemingly also for ethical reasons.

In sum, Defendants disregarded many comments received during the notice-and-comment process, and it is pure sophistry for them to assert that they eschewed all categorical determinations. This is a quintessential APA violation. *See, e.g.*, *Am. Mining Congress*, 907 F.2d at 1191 ("'the points raised in the comments were sufficiently central that agency silence . . . demonstrate[s] the rulemaking to be arbitrary and capricious'").

3. NIH Did Not Even Attempt To Satisfy Its Own Stated Criteria For The Rulemaking.

The Draft Guidelines stated that the purpose of the Guidelines would be to "ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law." JA280. NIH reiterated those criteria in promulgating the final Guidelines. JA42. As discussed above, however, Defendants deemed irrelevant numerous comments addressed to these very issues, completely ignoring *their own* stated criteria in issuing the Guidelines.

After establishing these criteria for the notice-and-comment process, Defendants were not free to ignore them. An agency cannot "arbitrarily and narrowly circumscrib[e] the scope of relevant factors" by deeming comments "irrelevant." *Ad Hoc Telecommc'ns Users Comm. v. FCC*, 680 F.2d 790, 798 (D.C. Cir. 1982) (MacKinnon, J., concurring). And, most importantly, an agency "must defend its analysis before the court upon the basis it employed in adopting that analysis"—even if "the [agency] was not required" by statute to base its decision on those grounds. *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177 (D.C. Cir. 2010); *see Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 814–15 (D.C. Cir. 1983). In short, Defendants acted inconsistently with the APA and settled administrative law by completely ignoring relevant comments and their own rulemaking criteria in issuing the Guidelines.

4. Defendants Entered The Comment Period With An Unalterably Closed Mind.

The Guidelines are invalid because Defendants, by their own admission, entered the rulemaking period having conclusively decided to fund human embryonic stem cell research. Agencies cannot fulfill their duty to consider important comments, *see* 5 U.S.C. § 553(c), when the key agency decision-maker "has an unalterably closed mind on matters critical to the disposition of the proceeding." *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979). Defendants were required to show a "flexible and open-minded

attitude" toward the rulemaking. *Fed. Express Corp. v. Mineta*, 373 F.3d 112, 120 (D.C. Cir. 2004) (internal quotation marks omitted).

Even before the comment period began, then-Acting NIH Director Raynard Kington announced the predetermined result of the rulemaking. On April 17, 2009, Kington reported to the press that NIH "*will* expand greatly the number of cell lines eligible for funding." Gautam Naik, *NIH Offers Rules for Embryonic Stem Cell Research*, Wall St. J., Apr. 17, 2009, *available at* http://online.wsj.com/article/SB123999343505429693.html (emphasis added). And, as noted above, Kington admitted after the Guidelines had been promulgated that he and the agency had ignored all public comments that addressed the question whether to fund human embryonic stem cell research. *See* Young, *supra*.

This closed-minded approach plainly violated Defendants' duty under the APA. In *Nehemiah Corp. of America v. Jackson*, 546 F. Supp. 2d 830, 847–48 (E.D. Cal. 2008), the court determined that HUD Secretary Jackson had entered a rulemaking proceeding with an "unalterably closed mind" about the merits of a proposed rule. During the comment period, a *Bloomberg News* report quoted Secretary Jackson as stating his views on the proposed rule and claiming that the agency "intend[ed] to approve the new rule by the end of the year even if the agency receive[d] critical comments." *Id.* at 847. Based on these statements, the court ordered that Secretary Jackson be excluded from the decisionmaking process

on remand to the agency. *Id.* at 848. Kington's actions in this case are far more egregious than those in *Nehemiah*. Indeed, Defendants do not dispute that they entered the rulemaking process already determined to fund human embryonic stem cell research.

5. The Executive Order Did Not And Could Not Exempt Defendants From The Requirements Of The APA.

(a) The President Did Not Direct Defendants To Fund Human Embryonic Stem Cell Research.

According to Defendants, the Executive Order limited the scope of the rulemaking to the question of *how* human embryonic stem cell research should be funded, not *whether* such research should be funded. Defendants argued below that the President "directed" them to fund human embryonic stem cell research, and that they "would have acted inconsistently with the Order if [they] had refused" to do so. Mot. to Dismiss at 43–44. But Defendants misread the President's Order.

The Order speaks in explicitly non-mandatory terms, stating that NIH "*may*" support "responsible, scientifically worthy" stem cell research. JA278 (emphasis added); *see also United States v. Rodgers*, 461 U.S. 677, 706 (1983) ("may" is usually discretionary). In addition, the Order states that Defendants may support "*responsible*, *scientifically worthy* human stem cell research, including human embryonic stem cell research." JA278 (emphasis added). NIH was therefore free,

within the framework of the APA, to determine whether human embryonic stem cell research is "responsible" and "scientifically worthy," but the Order did not purport to absolve Defendants of the task of determining whether human embryonic stem cell research satisfies these criteria. It was incumbent on Defendants to determine whether human embryonic stem cell research ever meets the criteria required by the President, and to bring their "experience and expertise to bear in light of competing interests at stake." *Peter Pan Bus Lines*, 471 F.3d at 1354.

Finally, the Order states that Defendants may fund stem cell research only "*to the extent permitted by law*," and the Order makes crystal clear that it "shall be implemented *consistent with applicable law*." JA278 (emphases added). The Order therefore explicitly requires that Defendants follow all applicable law—including the APA—when deciding whether to make such research eligible for funding. *See Natural Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 765 (3d Cir. 1982). Defendants thus had no purported presidential mandate to ignore the APA.

(b) The President Cannot Authorize Agencies To Disregard The APA's Requirements.

Even if the President had directed Defendants to fund human embryonic stem cell research without regard to the APA's requirements, such a directive would not insulate the Guidelines from APA review. On the contrary, the fact that the Guidelines "are based on the President's Executive Order hardly seems to

insulate them from judicial review under the APA, even if the validity of the Order were thereby drawn into question." *Chamber of Commerce of the U.S. v. Reich*, 74 F.3d 1322, 1327 (D.C. Cir. 1996), *modified on other grounds*, 83 F.3d 439.

It is undisputed that the notice-and-comment-rulemaking requirements of 5 U.S.C. § 553(c) govern Defendants' decision to issue the Guidelines here. Nothing in the APA authorizes the President to direct an agency to violate the APA by ignoring relevant public comments during the rulemaking process, or in any way exempts an agency's actions from APA review even if the policy was dictated by the President. *See Reich*, 74 F.3d at 1328. Accordingly, even if the President had ordered Defendants to fund human embryonic stem cell research without regard to whether such research is ethically and scientifically unworthy of funding, Defendants would still be bound by the procedural requirements of the APA.

II. ABSENT A PRELIMINARY INJUNCTION, PLAINTIFFS WOULD SUFFER IRREPARABLE HARM.

Each day that the Court's stay pending appeal remains in effect, Plaintiffs are forced to compete with illegal grant applications, and more tax dollars that could be spent to fund adult stem cell (and other) research projects are illegally diverted to human embryonic stem cell research. Moreover, Defendants' insistence that Plaintiffs' harms are based on "bare allegations" and mere "possibilit[ies]," Defs.' Br. 34, is flatly inconsistent with this Court's holding in *Sherley I*. Under the law of this case and this Circuit, Plaintiffs are currently

suffering irreparable injury from illegal competition for, and the permanent loss of, limited federal research funds.

In *Sherley I*, this Court recognized that Drs. Sherley and Deisher suffer an "actual," "imminent" injury from being forced to compete with illegal grant applications for a limited pool of federal money. JA223. As this Court held, "[b]ecause the Guidelines have intensified the competition for a share in a fixed amount of money, the plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury." *Id*.

Plaintiffs have no after-the-fact remedy for the irreparable harm of being forced to face illegal competition for federal funding. That injury is ongoing and increases with each additional round of grant competitions, and there is no way to undo the harm once a given round is over. Even re-running an already-completed grant competition (which is impracticable in any event) could not remedy the competitive harm already suffered. In the absence of an adequate remedy, Plaintiffs' "here-and-now injury," JA223, is irreparable. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28–29 (D.D.C. 1997). Simply put, there is "'no adequate compensatory or other corrective relief' that can be provided at a later date" to compensate or correct Plaintiffs' injury of having to face illegal competition. *Id.* at 29 (quoting *Hoffman-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978)).

In addition, the Court in *Sherley I* explained that Plaintiffs "will suffer an additional injury whenever a project involving [human embryonic stem cells] receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs." JA223. Once dollars from NIH's limited annual appropriations are expended for human embryonic stem cell research, they cannot be recouped. As potential grantees, Plaintiffs therefore suffer irreparable competitive injury from the loss of federal dollars to other grantees.[12] *See Population Inst. v. McPherson*, 797 F.2d 1062, 1074–82 (D.C. Cir. 1986); *see also Ambach v. Bell*, 686 F.2d 974, 986 (D.C. Cir. 1982).[13]

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[12] Thus, Defendants' observations that NIH allocated more money to adult stem cell research in 2010 than human embryonic stem cell research, Defs.' Br. 35, or that NIH has allocated a multi-million dollar budget to intramural human embryonic stem cell research, *id.* at 38–39, do not defeat Plaintiffs' claims of irreparable injury. It is sufficient for Plaintiffs to establish irreparable competitive harm that federal dollars that could be awarded to adult stem cell research will instead be spent on human embryonic stem cell research, with the opportunity for other uses of that money forever lost.

[13] Defendants' reliance on Dr. Sherley's receipt of federal funding under the Guidelines as a reason to deny a preliminary injunction, *see* Defs.' Br. 35, is a non sequitur. Dr. Sherley's receipt of particular NIH dollars does nothing to vindicate his right to seek additional federal funding free from illegal competition. For example, Dr. Sherley currently has four NIH grant applications pending, Decl. of Dr. James Sherley ¶ 4 [Dkt. #70-1], and absent an injunction, will have to compete with illegal human embryonic stem cell research applications for approval.

NIH's response to this Court's grant of an administrative stay and a stay pending appeal simply reinforces one way in which Plaintiffs will suffer irreparable injury absent a preliminary injunction. Directly on the heels of the administrative stay order, NIH issued a blunt and unqualified directive for its employees who review grant applicants to "give[] priority" to previously delayed human embryonic stem cell research applications and awards. Vogel & Kaiser, *supra*. NIH likewise ordered the immediate resumption of funding for so-called intramural (internal) NIH human embryonic stem cell research projects. Wadman, *supra*. NIH's actions during this temporary stay period demonstrate that the increased competition from, and potential loss of federal dollars to, human embryonic stem cell research is much more than a mere "possibility"—it is an ongoing reality. This competitive injury will continue unabated—and, indeed, exacerbated—absent a preliminary injunction.

III. A PRELIMINARY INJUNCTION WOULD NOT SUBSTANTIALLY INJURE OTHER INTERESTED PARTIES.

A preliminary injunction would not cause substantial injury to other interested parties—and Defendants' arguments to the contrary do not change the calculus. In fact, most of Defendants' arguments address the *scope* of injunctive relief, rather than whether the harm caused by the injunction would be substantial and irreparable. *First*, Defendants complain that the scope of the district court's order would prevent human embryonic stem cell research under the Bush

Administration's policy. Defs.' Br. 37. But the Bush policy has been revoked and is no longer in effect. The district court's order did not (and cannot) address the legality of a policy that is not before it and is no longer the law. *See generally* JA271.

Second, Defendants claim irreparable harm because the injunction would prevent NIH from engaging in "peer review" of human embryonic stem cell grant applications. Dr. Collins previously speculated that it would take six to eight months to restart this process—which involves expert review of potential grant applications—once stopped. Defs.' Br. 37; JA253, ¶ 18. But after the preliminary injunction halted peer review, the NIH ordered the process restarted—and in certain cases *expedited*—immediately after this Court ordered an administrative stay. *See* Vogel & Kaiser, *supra*. There is no reason to believe that the NIH would be unable to resume the process again if the district court denies permanent injunctive relief. Moreover, any harm that NIH has suffered in this regard has been substantially mitigated by the fact that the peer review process has since resumed and is prioritizing processing of human embryonic stem cell applications.

Third, Defendants cannot claim harm from a temporary delay in funding for intramural research projects. Defs.' Br. 38–39. As is true in the "peer review" context, recent actions have belied Defendants' claim that a halt to human embryonic stem cell research would result in the destruction of lab cultures or a

delay in experiments. *See id.* at 39; JA251, ¶ 12. To the contrary, when NIH instructed researchers to halt "intramural" experiments on human embryonic stem cells in response to the preliminary injunction order, it also directed that "[p]rocedures that will conserve and protect the research resources should be followed." Kaiser, *supra*. Consistent with this instruction, when this Court granted an administrative stay, NIH ordered the process immediately resumed. *See* Wadman, *supra*.

NIH's ability to play "Red Light, Green Light" with intramural research is unsurprising in light of the fact that Director Collins's declaration hedges his conclusions at every turn on the harm a delay in research would cause the agency. The declaration cites purely speculative injuries that may (or may not) occur at some point in the future, such as the possible death of lab animals or the loss of researchers to opportunities in other countries. *See* JA251–52, ¶¶ 12, 14. Defendants rely on Director Collins's assertions that biological resources would be lost if research were temporarily halted, Defs.' Br. 38–39, but Dr. Collins equivocates on that point throughout his affidavit, stating in general and cryptic terms that "it *may* take months or years to recreate" undefined "biological materials" and "reagents" used in current experiments. JA251, ¶ 12 (emphasis

added).[14] Defendants cannot have it both ways—either it takes months to restart paused human embryonic stem cell experiments (in which case an instruction to restart those experiments for the duration of this appeal would be futile) or Defendants would suffer no harm from a brief lapse in funding.

Nor will a preliminary injunction result in a loss of federal dollars. Although Defendants protest that NIH has allocated $9.5 million to intramural human embryonic stem cell experiments (using numbers from fiscal year 2009), Defs.' Br. 38–39, NIH would certainly reallocate that money if this Court determined that human embryonic stem cell research funding violated federal law. Moreover, *McPherson* counsels that a court must assume that such reallocation is possible in determining the balance of equities for purposes of ordering injunctive relief. NIH will spend the same amount on research in any event; the only question is whether millions will be wasted on human embryonic stem cell

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[14] The harms alleged in the University of California's ("UC") amicus brief fare no better. As an initial matter, the amicus improperly relies on new "facts" contained in affidavits attached to an untimely motion to intervene on appeal, which was denied. UC also asks this Court to consider third-party harms based on highly attenuated chains of reasoning, such as the suggestion that faculty members who do human embryonic stem cell research will be unable to continue to act as student mentors, which would endanger student training grants. UC Br. 19.

research instead of being devoted to more scientifically and ethically worthy causes.

In any event, Defendants *never* briefed the "peer review" or "intramural" research issues in opposition to Appellees' motion for a preliminary injunction, nor did they move to clarify the scope of the district court's order below. Defendants' failure to raise these issues in a timely manner in the district court should certainly not redound to their advantage in this Court; litigants should not be permitted to sit on their hands and then complain that their own inaction has compounded the impact of an adverse ruling.[15]

Fourth, Defendants' claim that a brief interruption in research could delay scientific discoveries that could benefit people with debilitating illnesses is, as the district court held, purely "speculative." JA240. Although Dr. Collins refers often to the promise of human embryonic stem cell research in his declaration, he concedes that the discovery of cures through such research is a mere possibility. *See* JA245–47, ¶¶ 5, 7. Indeed, Defendants admit that human embryonic stem cell research is "fraught with uncertainties," but nonetheless assert (without

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[15] Even if this Court determines to set aside some aspects of the preliminary injunction (*e.g.*, its application to intramural research) there is no basis for setting aside application of the injunction to third-party, extramural research.

substantiation) that such research is "vital" to our understanding and treatment of disease. Defs.' Br. 39.

Consideration of the harm to third parties favors affirmance of the injunction here.[16] As an initial matter, Defendants' claims of harm to third parties (such as persons seeking medical cures) rest on the utterly false dichotomy that there is no alternative to funding human embryonic stem cell research. As the Administrative Record makes clear, there are such alternatives, including both adult and induced pluripotent stem cell research. And whatever loss in research would occur from a delay in human embryonic stem cell research funding would be more than offset by allocating those funds to other research such as adult and induced pluripotent stem cell research, which the Administrative Record showed are superior therapeutic and ethical alternatives. *See* JA48–160.

Absent injunctive relief, adult stem cell researchers and other NIH grant applicants will be impaired in their ability to pursue their own research, which could otherwise lead to potential cures and other medical and scientific

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[16] In considering the propriety of injunctive relief, this Court may consider the injunction's effect on "other parties interested in the proceedings," *Washington Metro. Area Transit Comm'n v. Holiday Tours*, 559 F.2d 841, 843 (D.C. Cir. 1977) (internal citation omitted), which includes consideration of the "impact on third parties," *O'Donnell Constr. Co. v. Dist. of Columbia*, 963 F.2d 420, 429 (D.C. Cir. 1992).

breakthroughs. Thus, maintenance of the district court's preliminary injunction will actually *advance* scientific progress and *hasten* future medical cures by freeing up additional funds for more promising grant proposals.[17]

IV. THE PUBLIC INTEREST FAVORS DENIAL OF A STAY.

"It is in the public interest for courts to carry out the will of Congress and for an agency to implement properly the statute it administers." *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 45 (D.D.C. 2000). Indeed, "[e]very citizen of this country has an interest in seeing [the] government carry out its legal duties . . . ." *Cobell v. Kempthorne*, 455 F.3d 301, 315 (D.C. Cir. 2006) (internal quotation marks omitted). Under binding D.C. Circuit precedent, an administrative action violating the clear will of Congress cannot serve the public interest—"[s]uch a fait accompli is hardly in the public interest." *Indep. Bankers Ass'n of Am. v. Smith*, 534 F.2d 921, 951 (D.C. Cir. 1976). This factor carries considerable weight, because courts "must pay particular regard to whether such relief would further the public interest." *Cobell*, 455 F.3d at 315.

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[17] In addition, the harm to the embryos that would be destroyed if a preliminary injunction were lifted—precisely the harm that Dickey-Wicker was enacted to prevent—would be irreversible. "Simply put, absent some form of preliminary relief [the embryos] run[] the real risk of dying and in such circumstances money damages would be wholly useless . . . ." *DiDomenico v. Employers Coop. Indus. Trust*, 676 F. Supp. 903, 907 (N.D. Ind. 1987).

Moreover, denial of a stay will serve the public interest by preventing a wasteful diversion of public funds to needless and relatively unpromising research. As the Administrative Record makes plain, the Guidelines take funds away from more promising types of research and perpetuate popular misconceptions about the science of human embryonic stem cells. Therefore, a preliminary injunction will serve the public interest by ensuring that federal funding is not wasted on unethical research when more beneficial alternatives exist.

V. THE UNIVERSITY OF CALIFORNIA'S STANDING ARGUMENTS ARE BASELESS.

Although this Court squarely held in *Sherley I* that Drs. Sherley and Deisher have standing based on the undisputed "intensified . . . competition for a share in a fixed amount of money" created by the Guidelines, 610 F.3d at 74, amicus University of California ("UC") now seeks to challenge Plaintiffs' standing. UC's arguments are improper and baseless.

In the first place, an amicus cannot raise a new argument not pressed by a party, *Eldred v. Reno*, 239 F.3d 372, 378 (D.C. Cir. 2001), and Defendants do not question Plaintiffs' standing in this appeal. In addition, UC improperly relies on "evidence" that it submitted to this Court in support of its untimely post-injunction motion to intervene, *e.g.*, UC Br. 14, 18–19, which is not part of the record on appeal. *See* Fed. R. App. P. 10(a); *Weinstock v. Columbia Univ.*, 224 F.3d 33, 46 (2d Cir. 2000); *Frito-Lay, Inc. v. Willoughby*, 863 F.2d 1029, 1035–36 (D.C. Cir.

1988). And in dozens of places, UC simply asserts facts that supposedly affect Plaintiffs' standing, without citing any evidence inside or outside the record. *See, e.g.*, UC Br. 7, 10, 13–15. In its entire standing argument, UC does not cite a single competitive-injury standing case, with the exception of *Sherley I*. Based on these defects alone, the Court should disregard UC's amicus brief.[18]

UC claims that the harm caused by the Guidelines runs to Plaintiffs' *employers* rather than to Plaintiffs individually. UC Br. 9–10. The evidence in the record directly refutes this: Dr. Sherley has clearly alleged that research grants are his only source of research funding and that the "vast majority" of such grants are from NIH, JA167, ¶ 3; he receives no salary from his employer, Boston Biomedical Research Institute. Dr. Deisher is the founder, sole managing member, and research and development director of AVM Biotechnology, JA168–69, ¶ 3, and therefore benefits directly from any grant funding. Each Plaintiff declared

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[18] UC contends that this Court's holding in *Sherley I* "is not the 'law of the case,'" because there is supposedly a higher burden for establishing standing for a preliminary injunction. UC Br. 4. But the only relevant difference between successive stages of litigation for standing purposes is the quantum of proof Plaintiffs must adduce to establish the facts necessary for standing; there is no qualitatively different proof that Plaintiffs must establish. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). In any event, UC's argument is meritless given that this Court in *Sherley I* simultaneously held that Plaintiffs have standing and reinstated Plaintiffs' preliminary injunction motion. JA223–24.

under oath that the Guidelines "will result in increased competition for the limited resources that are available to fund human stem cell research, threatening *my* ability to obtain federal funding for *my* adult stem cell research." JA167, ¶ 4 (emphases added); JA169, ¶ 4 (emphases added). Additionally, the district court found that "the Guidelines threaten the very livelihood of plaintiffs Sherley and Deisher." JA240.

This Court has repeatedly recognized that employees at risk of losing their livelihood suffer injury-in-fact sufficient for Article III standing. *See, e.g., Dist. No. 1, Pac. Coast Dist., Marine Engineers' Beneficial Assoc. v. Maritime Admin.*, 215 F.3d 37, 40–41 (D.C. Cir. 2000); *Nat'l Fed'n of Fed. Employees v. United States*, 905 F.2d 400, 403 (D.C. Cir. 1990). And there is an established line of cases holding that competitive injuries are sufficient for Article III standing. *See, e.g.*, *Sherley I*, 610 F.3d at 74; *Shays v. FEC*, 414 F.3d 76, 83 (D.C. Cir. 2005); *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998). UC essentially ignores this authority.

UC's redressability and "relevant market" claims are both squarely foreclosed by *Sherley I*. With respect to redressability, the Court held in *Sherley I* that "it is clear the [Plaintiffs'] alleged injury is . . . redressable by the court." 610 F.3d at 72. Moreover, the authority UC relies on to support its "relevant market" argument is relevant only in the antitrust context. *See* UC Br. 12 (citing *Illinois*

Tool Works v. Indep. Ink, 547 U.S. 28, 31 (2006) (addressing market power "as a matter of antitrust law")); *United States v. Microsoft Corp.*, 253 F.3d 34, 81–82 (D.C. Cir. 2001).[19] This Court squarely rejected any limit on competitive injury standing to economic or commercial markets, *see Sherley I*, 610 F.3d at 72; *see also Shays*, 414 F.3d at 87, and the Court made clear that the "relevant market" here is the highly competitive market for NIH research grants, *see* 610 F.3d at 73; *see also* JA173, ¶ 14.[20]

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[19] *J.F. Shea Co., Inc. v. City of Chicago*, 992 F.2d 745, 749 (7th Cir. 1993), which UC cites, is inapposite because it involved prudential standing. *See AFGE, Local 2119 v. Cohen*, 171 F.3d 460, 467 (7th Cir. 1999) (discussing *J.F. Shea*).

[20] UC—whose motion to intervene on appeal as of right was denied by this Court—also contends that Plaintiffs failed to join as necessary parties all grantees receiving funding for human embryonic stem cell research. *See* UC Br. 20–21. This argument fails. *First*, this issue is waived, as it was not raised below. *See Elliott v. USDA*, 596 F.3d 842, 850 (D.C. Cir. 2010). *Second*, grantees are not necessary parties, because the government is adequately representing their interests. *See Ramah Navajo School Bd. v. Babbitt*, 87 F.3d 1338, 1351 (D.C. Cir. 1996) (holding that "the nonparties [would] not be considered 'necessary,'" because the nonparties' interests were adequately represented by the government); *see also Burka v. Aetna Life Ins. Co.*, 917 F. Supp. 8, 12 (D.D.C. 1996) (concluding that the interests of nonparties with a contractual right to use the property at issue were adequately represented by the property owner). *Third*, UC's argument would lead to the absurd result that all grantees must be joined as parties in any case challenging the legality of federal funding.

CONCLUSION

For the foregoing reasons, the preliminary injunction issued by the district court should be affirmed and the stay pending appeal should be dissolved.

Respectfully submitted,

Dated: October 28, 2010

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure because it contains 13,924 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and D.C. Circuit Rule 32(a)(1). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced font using Microsoft Word 2003 in 14-point Times New Roman type.

Dated: October 28, 2010

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ADDENDUM OF STATUTES AND REGULATIONS

STATUTES AND REGULATIONS

5 U.S.C. § 553

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After

consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title [5 USCS §§ 556 and 557] apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

> (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
>
> (2) interpretative rules and statements of policy; or
>
> (3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

5 U.S.C. § 706

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title [5 USCS §§ 556 and 557] or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

42 U.S.C. § 289g

§ 289g. Fetal research

(a) Conduct or support by Secretary; restrictions. The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be the same. In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

45 C.F.R. § 46.102

§ 46.102 Definitions.

(a) Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) Institution means any public or private entity or agency (including federal, state, and other agencies).

(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

45 C.F.R. § 46.204

§ 46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) 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;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in § 46.402(a) who are pregnant, assent and permission

are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

45 C.F.R. § 46.206

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

72 Fed. Reg. 34,591

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to provide leadership with respect to research on pluripotent stem cells derived by ethically responsible techniques so that the potential of pluripotent stem cells can be explored without violating human dignity or demeaning human life, it is hereby ordered as follows:

Section 1. *Research on Alternative Sources of Pluripotent Stem Cells*. (a) The Secretary of Health and Human Services (Secretary) shall conduct and support research on the isolation, derivation, production, and testing of stem cells that are capable of producing all or almost all of the cell types of the developing body and may result in improved understanding of or treatments for diseases and other adverse health conditions, but are derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus.

(b) Within 90 days of this order, the Secretary, after such consultation with the Director of the National Institutes of Health (Director), shall issue a plan, including such mechanisms as requests for proposals, requests for applications, program announcements and other appropriate means, to implement subsection (a) of this section, that:

> (i) specifies and reflects a determination of the extent to which specific techniques may require additional basic or animal research to ensure that any research involving human cells using these techniques is clearly consistent with the standards established under this order and applicable law;
>
> (ii) prioritizes research with the greatest potential for clinical benefit;
>
> (iii) takes into account techniques outlined by the President's Council on Bioethics, and any other appropriate techniques and research, provided they clearly meet the standard set forth in subsection (a) of this section;
>
> (iv) renames the "Human Embryonic Stem Cell Registry" the "Human Pluripotent Stem Cell Registry;" and
>
> (v) adds to the registry new human pluripotent stem cell lines that clearly meet the standard set forth in subsection (a) of this section.

(c) Not later than December 31 of each year, the Secretary shall report to the President on the activities carried out under this order during the past fiscal year, including a description of the research carried out or supported by the Department of Health and Human Services, including the National Institutes of Health, and other developments in the science of pluripotent stem cells not derived from human embryos.

Sec. 2. *Policy*. The activities undertaken and supported by and under the direction of the Secretary shall be clearly consistent with the following policies and principles:

(a) the purposes of this order are (i) to direct the Department of Health and Human Services, including the National Institutes of Health, to intensify peer reviewed research that may result in improved understanding of or treatments for diseases and other adverse health conditions, and (ii) to promote the derivation of human pluripotent stem cell lines from a variety of alternative sources while clearly meeting the standard set forth in section 1(a) of this order;

(b) it is critical to establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity;

(c) the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another;

(d) human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold; and

(e) the Federal Government has a duty to exercise responsible stewardship of taxpayer funds, both supporting important medical research and respecting ethical and moral boundaries.

Sec. 3. *Interpretation of this Order*. (a) For purposes of this order, the term "human embryo" shall mean any organism, not protected as a human subject under 45 CFR 46 as of the date of this order, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

(b) For purposes of this order, the term "subjecting to harm a human embryo" shall mean subjecting such an embryo 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)) as of the date of this order.

(c) Nothing in this order shall be construed to affect any policy, guideline, or regulation regarding embryonic stem cell research, human cloning by somatic cell nuclear transfer, or any other research not specifically authorized by this order, or to forbid the use of existing stem cell lines deemed eligible for other federally funded research in accordance with the presidential policy decision of August 9, 2001, for research specifically authorized by this order.

Sec. 4. *General Provisions*. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) This order is not intended to, and does not, create any right, benefit, or privilege, 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.

74 Fed. Reg. 10,667

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.

PUB. L. NO. 111-117, § 509(a)(2), 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.

PUB. L. NO. 111-242, § 101, 124 Stat. 2607

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the following sums are hereby appropriated, out of any money in the Treasury not otherwise appropriated, and out of applicable corporate or other revenues, receipts, and funds, for the several departments, agencies, corporations, and other organizational units of Government for fiscal year 2011, and for other purposes, namely:

Sec. 101. Such amounts as may be necessary, at a rate for operations as provided in the applicable appropriations Acts for fiscal year 2010 and under the authority and conditions provided in such Acts, for continuing projects or activities (including the costs of direct loans and loan guarantees) that are not otherwise specifically provided for in this Act, that were conducted in fiscal year 2010, and for which appropriations, funds, or other authority were made available in the following appropriations Acts:

(1) The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010 (Public Law 111-80).

(2) Division A of the Department of Defense Appropriations Act, 2010 (division A of Public Law 111-118).

(3) The Energy and Water Development and Related Agencies Appropriations Act, 2010 (Public Law 111-85).

(4) The Department of Homeland Security Appropriations Act, 2010 (Public Law 111-83) and section 601 of the Supplemental Appropriations Act, 2010 (Public Law 111-212).

(5) The Department of the Interior, Environment, and Related Agencies Appropriations Act, 2010 (division A of Public Law 111-88).

(6) The Legislative Branch Appropriations Act, 2010 (division A of Public Law 111-68).

(7) The Consolidated Appropriations Act, 2010 (Public Law 111-117).

(8) Chapter 3 of title I of the Supplemental Appropriations Act, 2010 (Public

Law 111-212), except for appropriations under the heading "Operation and Maintenance" relating to Haiti following the earthquake of January 12, 2010, or the Port of Guam: Provided, That the amount provided for the Department of Defense pursuant to this paragraph shall not exceed a rate for operations of $ 29,387,401,000: Provided further, That the Secretary of Defense shall allocate such amount to each appropriation account, budget activity, activity group, and subactivity group, and to each program, project, and activity within each appropriation account, in the same proportions as such appropriations for fiscal year 2010.

(9) Section 102(c) of chapter 1 of title I of the Supplemental Appropriations Act, 2010 (Public Law 111-212) that addresses guaranteed loans in the rural housing insurance fund.

(10) The appropriation under the heading "Department of Commerce--United States Patent and Trademark Office" in the United States Patent and Trademark Office Supplemental Appropriations Act, 2010 (Public Law 111-224).

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of October, 2010, I electronically filed the foregoing Brief For Appellees with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. I also hereby certify that I hand delivered 8 copies to the Clerk's Office.

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