ORAL ARGUMENT SCHEDULED FOR APRIL 23, 2012

Case No. 11-5241

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

DR. JAMES L. SHERLEY, et al.,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, et al.,

Defendants-Appellees.

On Appeal From The United States District Court
For The District Of Columbia
1:09-cv-01575-RCL

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties and Amici. Plaintiffs in the district court, and Appellants in this appeal, are Dr. James L. Sherley and Dr. Theresa Deisher.[1]

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

An *ad hoc* coalition of scholars, whose initial members are Professor Robert P. George and Mr. Yuval Levin, is an amicus curiae supporting Plaintiffs-Appellants in this appeal. The Coalition for the Advancement of Medical Research, the Genetics Policy Institute, Inc., and the State of Wisconsin were amici in the district court.

There are no intervenors.

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[1] Nightlight Christian Adoptions, Shayne Nelson, Tina Nelson, William Flynn, Patricia Flynn, Christian Medical Association, and Embryos were Plaintiffs in the district court, but have been dismissed for lack of standing.

B. Rulings Under Review. This appeal is from the final Order and Judgment and Memorandum Opinion of the United States District Court for the District of Columbia, entered on July 27, 2011, which entered judgment for Defendants, granted Defendants' Motion for Summary Judgment, denied Plaintiffs' Motion for Summary Judgment, and dismissed all claims, J.A.655-93; and all other orders and rulings adverse to Plaintiffs in *Sherley v. Sebelius*, No. 09-cv-01575 (D.D.C.) (Lamberth, J.). The Memorandum Opinion is published at 776 F. Supp. 2d 1 (D.D.C. 2011). J.A.655-92.

C. Related Cases. The present case was previously before this Court in *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010) (Case No. 09-5374) (J.A.216-27), and *Sherley v. Sebelius*, 644 F.3d 388 (D.C. Cir. 2011) (Case No. 10-5287) (J.A.508-28). Counsel is not aware of any related case that is currently pending in this Court or any other court.

Dated: January 12, 2012

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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
SOF	Plaintiffs' Statement of Material Facts as to Which There Is No Genuine Dispute

JURISDICTIONAL STATEMENT

Pursuant to 28 U.S.C. § 1331, the district court possessed jurisdiction over this federal-question action arising under the Administrative Procedure Act ("APA") and the congressional ban on funding "research in which" a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death." Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, div. F, § 508, 125 Stat. 786, 1112 (2011) (the "Dickey-Wicker Amendment"). On July 27, 2011, the district court granted Defendants' motion for summary judgment, denied Plaintiffs' motion for summary judgment, and entered final judgment rejecting all claims. J.A.693. Dr. James L. Sherley and Dr. Theresa Deisher ("Plaintiffs") timely filed a notice of appeal on September 19, 2011. Fed. R. App. P. 4(a)(1)(B); J.A.694. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATUTES AND REGULATIONS

Relevant statutes and regulations are reproduced in the Addendum to this brief.

STATEMENT OF ISSUES PRESENTED FOR REVIEW

I. Whether the district court erred in granting Defendants' motion for summary judgment and denying Plaintiffs' motion for summary judgment, because the National Institutes of Health ("NIH") promulgated the "Guidelines For Human Stem Cell Research," 74 Fed. Reg. 32,170 (July 7, 2009) (the "Guidelines")

(J.A.44-49) in violation of the Dickey-Wicker Amendment's ban on funding "research in which" a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death."

II. Whether the district court erred in granting Defendants' motion for summary judgment and denying Plaintiffs' motion for summary judgment, because NIH promulgated the Guidelines in violation of the APA, 5 U.S.C. §§ 553, 706(2)(A), (D), by ignoring relevant comments, failing to address whether or how the funding of human embryonic stem-cell research will fulfill the Guidelines' stated purpose to support "ethically responsible" and "scientifically worthy" research, failing to address substantial evidence in the administrative record showing that federal funding of such research will in fact have the opposite effect, and otherwise failing to comply with the APA.

STATEMENT OF FACTS

A. The Dickey-Wicker Amendment

For fifteen years, federal law has banned federal funding of research in which human embryos are destroyed or knowingly subjected to harm. J.A.232-33 (*Sherley v. Sebelius*, 704 F. Supp. 2d 63, 67 (D.D.C. 2010)). An appropriations rider, known as the Dickey-Wicker Amendment, prohibits the use of federal funds for "(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or

knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Pub. L. No. 112-74, § 508.

"Congress enacted the Amendment 'in reaction to a 1994 NIH panel report,'" which "advocated federal funding of research 'designed to improve the process of *in vitro* fertilization, to determine whether embryos carried genetic abnormalities, *and to isolate embryonic stem cells*.'" J.A.530 (*Sherley v. Sebelius*, 644 F.3d 388, 400 (D.C. Cir. 2011) (Henderson, J., dissenting) ("*Sherley II*")). The Dickey-Wicker Amendment has been included in every Health and Human Services ("HHS") appropriations bill since 1996, and has not been altered in any material respect. J.A.233. Thus, Congress continues to prohibit federal funding for "research in which" an embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death."

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 researchers who were using federally funded equipment to conduct tests on DNA derived from embryos, NIH "clarif[ied]" the "NIH position on embryo research." J.A.507. The agency explained that "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." *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 that NIH could legally fund experiments on the stem cells after those cells had been derived with private funds. J.A.163. 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), in favor of President Bush's stem-cell 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, 1151 (Aug. 9, 2001); *see also* Exec. Order No. 13,435, 72

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[1] *See* NIH, 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.

Fed. Reg. 34,591 (June 20, 2007). From 2002 through 2009, Defendants took the position that this "moral line," 37 Weekly Comp. Pres. Doc. at 1151, 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." J.A.125; *see also* J.A.122-28.

C. Promulgation Of The 2009 Guidelines

In March 2009, President Obama signed Executive Order 13,505, which provided that NIH "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." J.A.493, § 2 (74 Fed. Reg. 10,667 (Mar. 11, 2009)). The Order required HHS and NIH to "review existing NIH guidance and other widely recognized guidelines on human stem cell research" and "issue new NIH guidance on such research that is consistent with [the] order" within 120 days. *Id.*, § 3.

Defendants then issued a notice of proposed rulemaking ("NOPR") containing draft Guidelines for human stem-cell research ("Draft Guidelines"). J.A.495 (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*. In the notice, Defendants proposed to authorize federal funding of human embryonic stem-cell research and invited public comment on the Draft Guidelines. *Id*.

NIH received 49,015 public comments (J.A.29), more than 60 percent of which opposed federal funding of human embryonic stem-cell research. J.A.303-04; *cf.* J.A.462. The comments addressed numerous scientific and ethical problems that funding such research would entail and documented superior alternatives to it. J.A.58-62, 129-40, 144-47; *see also, e.g.*, Administrative Record 016673-77, 002965, 009191, Dkt. #66. The comments also identified serious medical risks associated with human embryonic stem-cell treatments, as well as the inherent limitations on those cells' therapeutic potential. J.A.60-62, 129, 136, 144-47. Additionally, the comments detailed the substantial and verifiable medical results already achieved by adult stem-cell research, along with other characteristics that render adult stem cells a superior scientific and ethical alternative. J.A.51-52, 58-59, 63, 129-36, 157-59. Defendants admit that they disregarded these comments, however, because in Defendants' view the NOPR "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." J.A.303-04; *cf.* J.A.463-64 (Landis Decl. ¶¶11-13).

On July 7, 2009, Defendants issued the final Guidelines. J.A.44-49. The Guidelines 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." J.A.45. They also 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 thus mark the first use of federal funds to incentivize the destruction of live human embryos.

D. Advances In Stem-Cell Research

Stem-cell research has the potential to treat diseases that have long resisted traditional methods. J.A.51, 58-62. But, both scientifically and ethically, not all stem cells are created equal. There are three general types of stem cells: embryonic, adult, and induced pluripotent. J.A.58-62. Although human embryonic stem cells have received much of the public and media attention, no successful medical treatments (as opposed to mere clinical trials) have been approved using these cells. J.A.129. In 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 successful medical treatments involving stem cells. J.A.51-52, 58-62, 129-36. Moreover, as of September 3, 2010, more than 1,900 adult stem-cell interventional

trials were listed on an NIH-maintained website, but zero interventional clinical trials with human embryonic stem cells were listed (and, since that date, one company that attempted a trial involving human embryonic stem cells has abandoned the effort). *See* J.A.485 (Defs.' Resp. to Pls.' Statement of Facts ("SOF") ¶¶57-58) (describing the number of trials listed as of September 3, 2010).

Human embryonic stem cells are found in the inner cell mass of a living human embryo. J.A.45, 114. "[I]solating an [embryonic stem cell] requires removing the 'inner cell mass' of the embryo, a process that destroys the embryo." J.A.510; *see also* J.A.530 (Henderson, J., dissenting). Although researchers widely predicted that human embryonic stem-cell research would yield cures for numerous diseases, those predictions have not come to pass. J.A.70. In fact, research shows that human embryonic stem cells would likely form tumors when injected into a patient's body and could be rejected by the patient's immune system. J.A.136, 145-46.

Adult stem cells are cells found in the body and in tissues normally discarded after birth (such as umbilical cord blood and the placenta). Unlike human embryonic stem cells, adult stem cells have already shown both clinical success and great therapeutic promise. J.A.51, 58, 129, 132-36. In fact, 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. J.A.51, 132-36.

Induced pluripotent stem cells are produced by genetically reprogramming mature cells such that they are virtually indistinguishable from human embryonic stem cells. J.A.137-38. The process of producing induced pluripotent stem cells was invented approximately four years ago, and was hailed by the journal *Science* as the leading scientific breakthrough in any field in 2008. Gretchen Vogel, *Breakthrough of the Year: Reprogramming Cells*, 322 Science 1766 (2008). 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." NIH, *Stem Cell Basics* 14 (2009), *available at* http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf. Induced pluripotent cells thus offer the same potential as embryonic stem cells without the immune-rejection risks to patients or the ethical problems entailed in destroying human embryos for research or therapeutic purposes.

E. The Present Action

Dr. James L. Sherley and Dr. Theresa Deisher, among others, brought this lawsuit in 2009 alleging that the Guidelines violate the Dickey-Wicker Amendment and the APA. Dr. Sherley is an adult-stem-cell researcher who does

not conduct research on human embryos or use human embryonic stem cells. J.A.289, ¶2. He relies exclusively on research grants for funding, and most of the grants he receives are from NIH. J.A.290, ¶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.*, ¶5. Dr. Deisher is also an adult-stem-cell researcher and is the founder, managing member, and research-and-development director of AVM Biotechnology. J.A.296-97, ¶¶2-3. Dr. Deisher, who does not conduct research on human embryos or use human embryonic stem cells, intends to seek NIH grants to fund her research. *Id.*

After Plaintiffs moved for a preliminary injunction, the district court granted Defendants' motion to dismiss for lack of standing. J.A.180 (*Sherley v. Sebelius*, 686 F. Supp. 2d 1, 3 (D.D.C. 2009)). On appeal, this Court held that Drs. Sherley and Deisher have standing under the competitor-standing doctrine. J.A.216, 224 (*Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010) ("*Sherley I*")).

On remand, the district court granted Plaintiffs' motion for a preliminary injunction. J.A.229. The court concluded that the Guidelines violate Dickey-Wicker by allowing federal funding of research in which an embryo is destroyed. J.A.240.

In April 2011, a divided panel of this Court vacated the preliminary injunction. J.A.509-10. The majority expressly limited its analysis of Plaintiffs'

likelihood of success to their claim that the Guidelines violate Dickey-Wicker's ban on funding "research in which a human embryo or embryos are destroyed." J.A.525-26. Acknowledging that Plaintiffs had "raised a 'serious legal question' on the merits" (J.A.526), the majority nonetheless accorded *Chevron* deference to Defendants' view of the term "research" and held that Plaintiffs were not likely to succeed on that claim (J.A.509-10, 517-23). The Court declined to address Plaintiffs' separate claim that the Guidelines violate Dickey-Wicker's prohibition on funding "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death," because that argument had not yet been addressed by the district court. J.A.525. For the same reason, this Court did not rule on Plaintiffs' claim that NIH violated the APA by promulgating the Guidelines "through an inadequate notice-and-comment process." J.A.525-26. Judge Henderson dissented, concluding that because Defendants' "reading of the [Dickey-Wicker] Amendment contravenes the Amendment's plain meaning," Plaintiffs were likely to prevail on the merits. J.A.538 (Henderson, J., dissenting).

On remand, the district court denied Plaintiffs' motion for summary judgment, granted Defendants' motion for summary judgment, and entered final judgment for Defendants. Plaintiffs appealed.

SUMMARY OF ARGUMENT

The NIH Guidelines for funding human embryonic stem-cell research are invalid because they violate the Dickey-Wicker Amendment and because they were promulgated in violation of the APA. Accordingly, Plaintiffs—not Defendants—are entitled to summary judgment.

The Guidelines violate Dickey-Wicker in two independent ways. *First*, the Guidelines authorize the funding of "research in which a human embryo or embryos are destroyed [or] discarded." § 508(a)(2). *Second*, by promulgating the Guidelines, and by supporting or engaging in human embryonic stem-cell research, Defendants and federally funded scientists "knowingly subject" human embryos "to risk of injury or death," in violation of Dickey-Wicker. *Id.* Moreover, this Court's divided opinion vacating the preliminary injunction in this case does not preclude the present panel from holding that the Guidelines violate Dickey-Wicker.

Even if the Guidelines could be squared with Dickey-Wicker (which they cannot), they nevertheless must be vacated because they were promulgated in violation of the APA. Defendants concededly turned a blind eye to tens of thousands of comments challenging the ethical and scientific merits of human embryonic stem-cell research. Although the district court excused NIH's admitted failure to address these comments because NIH's Draft Guidelines purportedly "did not invite" comments on whether to fund human embryonic stem-cell research

and because the Executive Order supposedly took that threshold issue off the table (J.A.687), neither rationale justifies NIH's actions here. Indeed, it was Defendants—not the Executive Order—that took the key question off the table by short-circuiting the public-comment process and refusing to consider contrary views.

STANDARD OF REVIEW

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). This Court reviews the district court's decision to grant or deny summary judgment *de novo*. *Calhoun v. Johnson*, 632 F.3d 1259, 1261 (D.C. Cir. 2011); *Capitol Sprinkler Inspection, Inc. v. Guest Servs., Inc.*, 630 F.3d 217, 223 (D.C. Cir. 2011).

ARGUMENT

I. 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 . . . 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))."

§ 508(a)(2). "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) (citation omitted). Dickey-Wicker plainly prohibits research—such as human embryonic stem-cell research—that depends upon and induces the destruction of human embryos.

A. This Panel Is Not Bound By *Sherley II*'s Preliminary Assessment Of Plaintiffs' Claims.

As an initial matter, nothing in the divided *Sherley II* ruling, which vacated the preliminary injunction, prevents this Court from holding that the Guidelines violate Dickey-Wicker. Indeed, this Court's assessment at a preliminary stage that Plaintiffs had not shown a likelihood of success on the merits is not binding in future phases of the case. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) ("[C]onclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits."). And this should be especially true where, as here, the majority's preliminary assessment was that Plaintiffs had "raised a 'serious legal question' on the merits" (J.A.526), and the dissent concluded that the statutory text unambiguously bars Defendants' interpretation (J.A.529-33 (Henderson, J., dissenting)).

Declining to follow *Camenisch*, the district court mistakenly concluded that the "mandate rule" compelled it to accept as binding the *Sherley II* majority's tentative assessment of Plaintiffs' likelihood of success. J.A.673-75 (*Sherley*, 776

F. Supp. 2d 1, 15 (D.D.C. 2011) (citing *Ins. Grp. Comm. v. Denver & Rio Grande W. R.R. Co.*, 329 U.S. 607, 612 (1947))).[2] The "mandate rule," however, applies only when an appellate court "dispose[s] of [an issue] by its decree" such that the issue may be considered "*finally settled*." *In re Sanford Fork & Tool Co*., 160 U.S. 247, 255 (1895) (emphasis added); *accord United States v. Thrasher*, 483 F.3d 977, 981 (9th Cir. 2007); *United States v. Bell*, 5 F.3d 64, 66 (4th Cir. 1993). Courts repeatedly have emphasized that a decision regarding likelihood of success at the preliminary injunction stage is neither "final" nor binding on subsequent proceedings in the case. *See, e.g.*, *Camenisch*, 451 U.S. at 395; *Homans v. City of Albuquerque*, 366 F.3d 900, 904-05 (10th Cir. 2004). Such a decision rests on a tentative assessment of the probable result on the merits, but generally is not law of the case. *Wilcox v. United States*, 888 F.2d 1111, 1114 (6th Cir. 1989); *accord Southco, Inc. v. Kanebridge Corp*., 324 F.3d 190, 194-95 (3d Cir. 2003); *Bordelon v. Chicago Sch. Reform Bd. of Trustees*, 233 F.3d 524, 528 n.4 (7th Cir. 2000) ("[A] court's findings and conclusions at the preliminary injunction stage are by nature preliminary. . . . and therefore are not binding [in subsequent proceedings].").

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[2] In *Insurance Group*, the petitioner urged lower federal courts to reexamine a *final ruling* from the Supreme Court *on the merits* of petitioner's case—not a preliminary assessment of the petitioner's likelihood of success on the merits. 329 U.S. at 611.

If *Sherley II*'s tentative legal conclusions were binding here, "an unacceptable conflation of the merits decision and the preliminary inquiry would result." *Homans*, 366 F.3d at 905. The district court's approach effectively transformed *Sherley II* into a final judgment on the merits. *See* J.A.677. That is plainly inconsistent with the "limited purpose" of a preliminary injunction proceeding. *See Camenisch*, 451 U.S. 395.

Sherley II's tentative assessment of Plaintiffs' claims was made for the limited purpose of determining whether Plaintiffs were entitled to a preliminary injunction (*see* J.A.528)—not to resolve the merits of Plaintiffs' claims. Accordingly, this Court is not bound by *Sherley II*'s preliminary assessment of Plaintiffs' likelihood of success.

B. 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." § 508(a)(2). The ban on research that involves the destruction of embryos is broad; funding is prohibited for any "research in which . . . embryos are destroyed." *Id.* 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." J.A.47. But Defendants' distinction between the derivation and use of human embryonic stem cells has no basis in the statutory text, and the conclusion that human embryonic stem cells are not embryos does not address the relevant interpretive questions, which are (1) whether the derivation of human embryonic stem cells occurs as part of "research" that receives federal funding, and (2) even if not, whether NIH "knowingly subject[s]" embryos to risk of destruction by funding human embryonic stem-cell research.

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," *i.e.*, "the Dickey Amendment." J.A.49. As the *Sherley II* majority recognized, since Dickey-Wicker refers only to "research" funding, the Guidelines' prohibition against funding of derivation necessarily confirms that, according to Defendants' interpretation, derivation is part of "research." J.A.521 ("it is clear the NIH treats the act of derivation as 'research'"). Indeed, the section of the Guidelines stating

that derivation is ineligible for funding is entitled "Other *Research* Not Eligible for NIH Funding." J.A.49 (emphasis added). Thus, 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 "research" 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). *See* J.A.531-33 (Henderson, J., dissenting).

In addition, 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 more straightforward way by utilizing the format of subsection (1) to prohibit funding for only those specific acts. *See Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227 (2008). Instead, Congress chose to protect human embryos by enacting a much broader ban on funding for any "*research in which* a human embryo or embryos are destroyed." § 508(a)(2) (emphasis added); *see also* J.A.532-33 (Henderson, J., dissenting). The *Sherley II* majority disagreed with this

argument because, in its view, "[t]he definition of research is flexible enough to describe either a discrete project or an extended process." J.A.519. But the majority's analysis misses the critical point that, read in the context of subsection (1)'s language, which is aimed at the *specific act* of creating a human embryo for research purposes, it is clear that the term "research" in subsection (2) must be broadly construed so as to encompass derivation. *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).

At times, Defendants have argued that "research" can mean "a piece of research," and 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. *See, e.g.*, Mem. in Supp. of Mot. to Dismiss at 31, Dkt. #22-1. The statutory prohibition against funding any "research in which" embryos are destroyed, however, necessarily encompasses the *entire* research project at issue, not merely a selected task, phase, or "piece" of the research. J.A.533-35 (Henderson, J., dissenting).

Indeed, NIH and HHS have recognized that "research" encompasses the full research process and cannot be narrowed to include only certain tasks within a research project. In the Human Subject Protection Regulations, which are incorporated into Dickey-Wicker, "research" is defined 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). Thus, "research" includes the "development" phase as well as subsequent "testing and evaluation," and the development phase of stem-cell research—derivation of the stem cells—is part and parcel of the "research" project.

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." HHS, *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), *available at* http://www.hhs.gov/ohrp/policy/engage08.html. Thus, the fact that derivation may be performed by a different institution from that performing the "testing and evaluation" does not detract from the conclusion that the latter institution is engaged in "research in which" human embryos are destroyed.[3]

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[3] NIH's unduly narrow interpretation of "research" is also inconsistent with courts' use of that term. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *Nat'l Ctr. for Mfg. Sciences, Inc. v. City of Ann Arbor*, 563 N.W.2d 65, 68 (Mich. Ct. App. 1997). Although *Merck* may not have "depend[ed] upon an interpretation of the term 'research,'" as the *Sherley II* majority stated (J.A.519 n.*), its acknowledgment that "research" is a multi-phase process rather than a single experiment supports Plaintiffs' interpretation here.

Defendants previously insisted that Dickey-Wicker "does not incorporate the definition of 'research' contained in the Human Subject Protection regulations." Defs.' Br. 29, *Sherley II*. 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)." § 508(a)(2). 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. The *Sherley II* majority did not resolve this issue (*see* J.A.518 n.*), but the dissent concluded that Dickey-Wicker's incorporation of the definition of "research" in the Human Subject Protection Regulations in one part of the statute required that the term "research" be interpreted the same throughout. J.A.533-34 & n.1 (Henderson, J., dissenting) (quoting *Brown v. Gardner*, 513 U.S. 115, 118 (1994)).

Moreover, contrary to the *Sherley II* majority's assumption (J.A.518-19), Congress's use of the present tense in banning funding for "research in which a human embryo or embryos are destroyed" does not restrict the statute to the specific act a researcher is performing at a given moment in time. 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 regulations, combined with their construction of Dickey-Wicker, demonstrate that

derivation (the "development" phase) is itself part of the same "research" as the later "testing and evaluation," which means that human embryos "are" destroyed as part of the "research." Here, the context indicates that the present tense encompasses the derivation of human embryonic stem cells. *See* 1 U.S.C. § 1 (providing that, "*unless the context indicates otherwise* . . . words used in the present tense include the future as well as the present") (emphasis added); J.A.535-37 (Henderson, J., dissenting).

Additionally, the implications of Defendants' present-tense argument are absurd: If Dickey-Wicker encompassed only the destruction of human embryos where the destruction occurs during the period of funding, then NIH could retroactively fund the already-completed act of destroying embryos. The *Sherley II* majority failed to address this argument, which has been bolstered by subsequent Supreme Court precedent. *See McNeill v. United States*, 131 S. Ct. 2218, 2221-24 (2011) (holding that a present-tense verb referred to the law applicable at a *previous* point in time, due partly to "absurd results that would follow" from interpreting the present-tense verb as a reference to *current* law).

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. J.A.48-49. The

Guidelines also require that NIH-funded researchers delve into the manner of derivation to ensure that the process by which the embryos were selected for destruction complied with the Guidelines. *See* J.A.48.

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. J.A.47; *see also* J.A.48 ("[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 agency's interpretation of appropriations rider because there was "no 'reason to mistrust the common sense understanding of the statutory language'").

Third, Defendants' derivation/use distinction is undermined by their concession that federal funds are often used to pay the researcher who destroyed the embryo by deriving the stem cells. When the government was asked whether "grant money [is] ever used to pay for the [stem cell] line from the extractor," it

answered "[y]es." *Sherley II*, Oral Arg. Tr. at 15, Sept. 27, 2010; *see generally* Defs.' Br. 7, *Sherley II*. Simply put, the government's derivation/use distinction collapses in practice because, among other reasons, it is uncontested 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.

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

Even assuming that the word "research," contrary to its plain meaning and the meaning assigned to it in the Human Subject Protection Regulations, could be limited to a specific "piece" of research, the Guidelines would still violate Dickey-Wicker for an independent reason: Human embryonic stem-cell research is "research in which" embryos are "knowingly subjected to risk of injury or death." In *Sherley II*, this Court reserved the question whether the Guidelines violate the third, "'knowingly subjected to,'" prong of Dickey-Wicker, but acknowledged Plaintiffs' argument that human embryonic stem-cell "research 'creat[es] demand for[ ] human embryonic stem cells,' which '*necessitate[s]* the destruction of embryos.'" J.A.525. The district court erred on remand in concluding that Dickey-Wicker permits Defendants to knowingly fund research and thereby incentivize and facilitate the ongoing destruction of embryos.

Dickey-Wicker's third prong prohibits federal 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))." § 508(a)(2). This language is intentionally broader than the first two prongs of Dickey-Wicker: It extends to research that knowingly places embryos at risk of harm, even if an embryo is not physically destroyed or discarded as part of that research.

A person does not need to *intend* a particular consequence, or even to personally bring it about, to act with knowledge that an increased risk is the foreseeable result of his actions. Rather, to act "knowingly" merely "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). Thus, to satisfy prong three of Dickey-Wicker, it is enough that Defendants or researchers understand that their actions will result in an increased risk of harm to embryos. *See, e.g.*, *H.A.L. v. Foltz*, 551 F.3d 1227, 1230 (11th Cir. 2008) (holding that a state employee "*knowingly subjected* [foster children] to a substantial risk of victimization" by placing another child with a history of aggressive sexual behavior in the same home (emphasis added)).

Dickey-Wicker's own definition of "risk," derived from the Human Subject Protection Regulations, confirms that result. Under those regulations, which concern research on fetuses in utero, the "risk of injury or death" occasioned by the research may "not [be] greater than minimal," unless the research "hold[s] out the prospect of direct benefit for the woman or the fetus." 45 C.F.R. § 46.204(b). Applying that standard here, it is obvious that experimentation on stem cells derived by *destroying* embryos does not *benefit* those embryos. Thus, the "minimal" risk standard governs.[4]

The regulations define "minimal risk" as a "probability and magnitude of harm or discomfort *anticipated in* the research . . . 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." 45 C.F.R. § 46.102(i) (emphasis added); *see also id.* § 46.202 (applying above definition to Section 46.204, which is cited in Dickey-Wicker).

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[4] The regulations further require that the government show that "the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means." 45 C.F.R. § 46.204(b). Defendants do not even attempt to meet this standard, and on the administrative record in this case, they cannot. *See infra* pp. 7-9. Nor do the Guidelines require such a showing as a prerequisite to the funding of human embryonic stem-cell research.

Under this framework, it is plain that Defendants, by promulgating the Guidelines and funding human embryonic stem-cell research, "knowingly subject[ ]" embryos to more than a "minimal" risk of harm. That is because Defendants and their federally funded researchers are well aware that federally funded research requires the destruction of embryos and creates demand for the destruction of more embryos. Indeed, in promulgating the Guidelines, NIH stated that one of its goals was "ensuring that the greatest number of ethically derived hESCs are available for Federal funding"; the Guidelines accordingly "articulate . . . requirements" to govern all "*future* embryo donations [for research] in the United States." J.A.46 (emphasis added); *see* J.A.482 (Defs.' Resp. to SOF ¶45a) (conceding that the Guidelines address criteria governing "voluntary and informed donation of embryos from which hESCs are derived"); J.A.286 (SOF ¶45).

The availability of federal funding unquestionably provides a strong incentive for researchers to develop additional human embryonic stem-cell lines. NIH has already approved for use under the Guidelines at least two stem cell lines derived from embryos that were donated and destroyed after the Guidelines were promulgated. Defs.' Mot. Summ. J. 26, Dkt. #57. More lines will inevitably follow. Indeed, University of Michigan researchers intend to develop additional lines and "to submit the lines to [NIH] for inclusion in the national registry of human embryonic stem cell lines that are eligible for federal research funding."

J.A.545-46. This is direct evidence that federal funding under the Guidelines incentivizes researchers to develop new stem-cell lines in order to obtain NIH grants.

Further proof that researchers will derive additional stem-cell lines for NIH approval lies in the fact that existing lines created prior to the Guidelines are subject to narrow use restrictions or contain unique genetic properties of interest to only certain researchers. J.A.543-44. Those restrictions and properties are listed on NIH's website. J.A.543. For example, research on one Rockefeller University line may not be conducted for "diagnostic or therapeutic use," and research with a particular New York University line may not involve "transplantation into humans." *Id.* Other lines were derived from embryos with diagnosed congenital diseases such as Marfan Syndrome. J.A.544. Further embryo destruction is necessary to create lines tailored specifically to satisfy the diverse research demands of federally funded human embryonic stem-cell researchers.

As NIH's Director has explained, "[e]mbryonic stem-cell lines that carry the recipe for an inherited disease are valued by researchers." J.A.544.[5] For example, scientists created line SIVFO17, which is in the process of being added to the NIH registry, to research a specific genetic condition (Huntington's Disease). *Id.* The

[5] Disease-specific lines using induced pluripotent stem cells are also available. J.A.140, 141-43.

organization associated with this line plans to derive more disease-specific human embryonic stem-cell lines from embryos with genetic diseases. J.A.544-45. Other researchers plan to derive new lines that reflect ethnic diversity. J.A.546-47. Although Plaintiffs doubt that these new research projects will yield any medically valuable information, the funding provided under the Guidelines plainly encourages researchers to develop and utilize these new lines.

Moreover, for each new human embryonic stem-cell line developed for research purposes, multiple embryos *must* be destroyed. *See* David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 Fertility & Sterility 1063, 1068 (May 2003). Thus, it is incontrovertible that Defendants (and the researchers they fund) have "knowingly subjected" embryos to at least "minimal," if not certain, "risk of injury or death." That is, Defendants and their grant recipients "anticipated" that federally-funded "research" under the Guidelines would have the natural, foreseeable consequence of encouraging the destruction of embryos. § 508(a)(2); 45 C.F.R. § 46.204(b); *id.* § 46.102(i).

Defendants' previous attempts to resist this common-sense reading are unpersuasive. For example, Defendants previously argued that Dickey-Wicker's risk-of-injury prong applies only to embryos physically "involved" in federally

funded research that subjects them to an increased risk of harm. Defs.' Mot. Summ. J. at 26.

This argument, however, requires a wholesale rewriting of the statute. Defendants' argument would insert the term "involved" into Dickey-Wicker as a limitation on the types of embryos that are protected from risk of injury or death. But no such limitation appears in the statute. Nothing in the statute specifies that the embryo placed at risk must be physically "involved" in the federally funded project. Rather, the statute bans *any* federally funded research that knowingly subjects *any* "embryo or embryos" to risk of harm. Indeed, the regulations incorporated by reference into Dickey-Wicker confirm that a researcher need only "anticipate[ ]" that his research will create a "minimal" risk of harm to an embryo. 45 C.F.R. § 46.102(i).

To place a limitation in a statute that is "conspicuously absent more closely resembles inventing a statute rather than interpreting one." *Hardt v. Reliance Standard Life Ins. Co.*, 130 S. Ct. 2149, 2156 (2010) (internal alterations and quotation marks omitted). Where Congress has intentionally chosen to use broad, inclusive language, courts must honor that choice and apply the statute as enacted. *See H. J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 244-46 (1989). Nothing in Dickey-Wicker limits the third prong to cover only the specific embryo that was

destroyed to derive the stem cell used in the research. This Court should not manufacture that limitation by writing the term "involved" into the statute.

The district court attempted to solve this problem by interpreting the words "in which," which modify each prong of Dickey-Wicker, to impose a durational requirement—namely, that an embryo must be physically exposed to risk of harm *during* a human embryonic stem-cell research experiment. But the ordinary meaning of the phrase "knowingly subjected to risk" does not impose a physical-presence requirement. The only definitions of the term "subjected" that make sense in context are "to make liable," "predispose," "cause to undergo or submit to," or "expose." *Merriam-Webster's Third International Dictionary* 2275 (3d ed. 1976) (definitions 2a and 4). It is possible for federally funded research to make embryos liable, predisposed, exposed, or caused to undergo "risk of injury or death" without those embryos being the specific subject of the research. In this case, it is enough that Defendants and federally funded researchers know at the time they are funding and performing "research" authorized by the Guidelines that the very existence of the federally funded "research" incentivizes the further destruction of embryos and the creation and sale of additional stem-cell lines derived from such embryo destruction.

The district court speculated that, absent a physical-presence requirement, Dickey-Wicker would produce absurd results, such as prohibiting a "research

project involving dangerous chemicals or explosive gasses . . . in the vicinity of an embryo storage facility." J.A.684. "A tank of propane in an adjacent laboratory would be enough," the court reasoned. *Id.* But again, the district court's conclusion follows only if one ignores statutory text. Dickey-Wicker does not prohibit *all* risk, and in particular it permits risks that are "not greater in and of themselves than those ordinarily encountered in daily life." 45 C.F.R. § 46.102(i). And even greater risks are not prohibited if the persons creating those risks have no knowledge of them. A person does not act *knowingly* if a consequence results out of "ignorance, mistake or accident." *Alston-Graves*, 435 F.3d at 337. Propane tanks are ordinarily encountered in daily life, and presumably NIH is not in the business of knowingly funding research with a greater than minimal risk of producing violent explosions that destroy neighboring facilities.

By contrast, it is the *necessary consequence* of the research authorized and implemented by the Guidelines that embryos *must* be destroyed to create human embryonic stem-cell lines, and that the availability of federal funding for such research creates enhanced incentives for creation of further such lines—*as explicitly contemplated by the Guidelines themselves*. The interpretations advanced by Defendants and the district court to avoid this common-sense conclusion conflict with the plain language of Dickey-Wicker and cannot withstand scrutiny.

D. 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 have previously relied on two non-textual theories of interpretation. *See, e.g.*, Defs.' Br. 21-27, *Sherley II*. *First*, Defendants have argued that by failing to alter Dickey-Wicker, Congress has impliedly ratified NIH's current policy. *Second*, Defendants have attempted to elevate committee reports over the plain language of the statute. Both arguments fail.

1. The Implied-Ratification Theory Fails.

Despite the *Sherley II* majority's tentative agreement with Defendants' argument that Congress's failure to change Dickey-Wicker over the years should be treated as tacit approval of the Guidelines (*see* J.A.523-24 & n.*), the "congressional ratification" doctrine is inapposite here. 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.'" *Gardner*, 513 U.S. at 121 (citation omitted); *see also* J.A.538 (Henderson, J., dissenting).

Moreover, the administrative interpretations of Dickey-Wicker that are entitled to the greatest deference are the Human Subject Protection Regulations, which are incorporated into the statute itself. Because the regulatory definitions of "research" and "risk" unambiguously preclude funding of research on stem cells derived from embryos, *see supra* pp. 19-21, 26-27, any contrary interpretations contained in guidance documents, opinion letters, and the like are entitled to no weight. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997) (deference does not extend to administrative interpretations that are "plainly erroneous or inconsistent with . . . regulation[s]" (internal quotation marks omitted)).

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); *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).

Moreover, ratification applies only to "longstanding administrative interpretation[s]." *Schor*, 478 U.S. at 846. In *Brown & Williamson*, for example, the FDA's ratified position was over 75 years old. 529 U.S. at 156. Because the Guidelines were promulgated less than three years ago, however, "congressional reenactment of the Amendment in the years *predating* 2009 signifies nothing in relation to the Guidelines." J.A.538 n.6 (Henderson, J., dissenting).

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 expressed NIH's position 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." J.A.535 n.2 (Henderson, J., dissenting); J.A.507. 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.[6]

President Bush later announced a policy that, unlike the Guidelines, did not incentivize 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. at 1151; *see also* J.A.512; 72 Fed. Reg. at 34,591. 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." J.A.125. Far from continuing that longstanding administrative interpretation, the 2009 Guidelines were designed precisely to "remove these limitations." J.A.493.

Based on a new, unarticulated *reinterpretation* of Dickey-Wicker, and for the first time ever, the Guidelines provided funding for research on *newly* derived

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[6] This illegal Georgetown research, led by Dr. Mark Hughes, was the subject of a 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, 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.

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.

2. 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) (citation omitted). "[I]t is the statute, and not the Committee Report, which is . . . authoritative." *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). Because Dickey-Wicker unambiguously prohibits human embryonic stem-cell research, it is not necessary to consult legislative history here.

In any event, there are numerous indications in the legislative history that Dickey-Wicker was intended to prevent federal funding for human embryonic stem-cell research. For example, the Amendment's author, Congressman Jay Dickey, explained that federal funding of human embryonic stem-cell experiments that incentivize embryo destruction "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.

See, e.g., Statement of Representative Schaffer, 145 Cong. Rec. E1696-02, 1696-97 (July 30, 1999); Statement of Senator Brownback, 147 Cong. Rec. S6393-01, 6394 (June 19, 2001). 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 Dickey-Wicker (but never enacted) 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).

Defendants' previous citation of committee reports is unpersuasive. The reports state 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 273 (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.

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

Finally, contrary to the *Sherley II* majority's conclusion (J.A.517-23), Defendants' purported interpretation of Dickey-Wicker is not entitled to deference

under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). 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; *see also* J.A.531 (Henderson, J., dissenting) ("we need go no further than *Chevron* step one here"). Moreover, Defendants have never provided an interpretation of the relevant statutory terms that this Court could assess for reasonableness under *Chevron*.

Defendants previously asserted 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, e.g.*, Defs.' Br. 28, *Sherley II*. 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, 167-68 (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, *Sherley II*, is inaccurate. Human embryonic stem cells were first isolated in 1994—two years *before* Dickey-Wicker's initial enactment. *See*

J.A.358, 360. Thus, "[t]here is no reason to assume . . . the Congress did not consider hESC research when it first enacted the Dickey-Wicker Amendment." J.A.530 (Henderson, J., dissenting).

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. HHS*, 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). As the *Sherley II* majority expressly acknowledged, however, "the Guidelines do not define the term 'research.'" J.A.520. Instead, 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. J.A.47.

To be sure, the *Sherley II* majority tentatively concluded that Defendants' "use" of the term "research" in the Guidelines implicitly reflects the agency's narrow understanding of the term "research." *See* J.A.520-21. But, even if one

could hazard a guess as to NIH's understanding of the term "research" based on the agency's "use" of that term, the Guidelines do not meaningfully address (explicitly or implicitly) the key questions (1) whether deriving stem cells occurs as part of "research" under Dickey-Wicker and (2) whether federal funding of research that incentivizes further embryo destruction violates the "knowingly subject[s]" prong of Dickey-Wicker. Because the agencies have never answered *those* questions 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.

Nor does the *post hoc* interpretation offered by Defendants' counsel salvage Defendants' claim for deference. That after-the-fact interpretation—offered in legal briefs, not in official agency statements promulgated through notice-and-comment procedures—is entitled to no deference. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988). Moreover, 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'—'[i]t 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); *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). Consequently, counsel's interpretation deserves no deference (*Chevron*, *Skidmore*, or otherwise).

Finally, even if NIH's reading of Dickey-Wicker deserved *some* deference, NIH cannot claim *Chevron* deference because it is not the only agency charged with administering the statute. *See Collins v. NTSB*, 351 F.3d 1246, 1253 (D.C. Cir. 2003). Dickey-Wicker restricts expenditures not only by NIH, but also by the Departments of Labor and Education as well as other agencies within HHS. *See* Pub. L. No. 112-74, § 508, 125 Stat. at 1112, 1116 (limiting use of "funds made available in this Act," *i.e.*, Division F of the Consolidated Appropriations Act, which funds all of these agencies). NIH thus has no unique insight or expertise that entitles its view to special respect, nor will deferring to its reading of Dickey-Wicker even yield uniformity, since other agencies may interpret the statute differently. *Cf. Collins*, 351 F.3d at 1252-53.

II. NIH PROMULGATED THE GUIDELINES IN VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT.

Even if NIH's Guidelines could be squared with the Dickey-Wicker Amendment, they must nevertheless be vacated because they were promulgated in violation of the APA. Under the APA, NIH was required to consider and respond to relevant comments, including 30,000 comments addressing whether human embryonic stem-cell research meets the criteria for federal funding. The agency,

however, admittedly disregarded those comments, writing them off as irrelevant. The district court erred in excusing the agency's failure.

A. NIH Flouted Its Undisputed Duty To Address Relevant Comments.

The APA requires an agency promulgating a rule to consider and respond to public comments it receives that are relevant to the rulemaking. *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 & n.58 (D.C. Cir. 1977). Failure to do so contravenes the APA in two related ways.

First, the public is entitled to an opportunity to comment on proposed rules. 5 U.S.C. § 553(b)-(c). But that right to offer input becomes "meaningless" if the agency fails to "respond[ ] to significant points raised by the public," *Home Box Office*, 567 F.2d at 35-36; *Ala. Power Co. v. Costle*, 636 F.2d 323, 384-85 (D.C. Cir. 1979), or approaches the points raised with an "unalterably closed mind," *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979); *see Fed. Express Co. v. Mineta*, 373 F.3d 112, 120 (D.C. Cir. 2004).

Second, in light of the APA's ban on arbitrary and capricious action, 5 U.S.C. § 706(2)(A), the agency must "examine the relevant data and articulate a satisfactory explanation for its action," and it cannot "entirely fail[ ] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983); *see Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148 (D.C. Cir. 2011). An agency that refuses to confront commenters' objections

falls short of that standard. *Tesoro Alaska Petrol. Co. v. FERC*, 234 F.3d 1286, 1294 (D.C. Cir. 2000); *Canadian Ass'n of Petrol. Producers v. FERC*, 254 F.3d 289, 298-99 (D.C. Cir. 2001); *see also Costle*, 636 F.2d at 385.

In adopting the Guidelines, NIH flouted this statutory duty. It received approximately 30,000 comments regarding an issue directly relevant to the rulemaking: whether human embryonic stem-cell research satisfies the President's and the agency's own criteria for funding. J.A.479-80, ¶¶37-38; J.A.303-04. Yet NIH admittedly disregarded these comments, dismissing them without a word. This was a quintessential APA violation.

1. Comments Challenging Human Embryonic Stem-Cell Research Required A Response.

An agency's duty to address relevant comments encompasses all points commenters raise that, "if adopted, would require a change in [the] agency's proposed rule" or would "cast doubt on the reasonableness of" the agency's position. *Home Box Office*, 567 F.2d at 35 n.58. The agency therefore must rebut evidence and objections that, if credited, would undermine its conclusions. *See Tesoro*, 234 F.3d at 1294; *Petrol. Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1173 (D.C. Cir. 1994). Additionally, it must provide a reasoned explanation for rejecting commenters' proposed alternatives. *See Canadian Ass'n*, 254 F.3d at 298-99; *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 (D.C. Cir. 1987).

The 30,000 comments questioning the scientific and ethical merits of human embryonic stem-cell research were directly relevant to the issues before the agency. Indeed, the Executive Order that directed NIH to issue new rules put the merits of such research directly at issue. The Order authorized NIH to fund only "*responsible*, *scientifically worthy* human stem cell research, including human embryonic stem cell research, to the extent permitted by law," requiring NIH to issue new guidance "consistent with this order." J.A.493, §§ 2-3 (emphasis added). By making scientific worthiness and ethical responsibility prerequisites to federal funding, the Order required NIH to evaluate the approach taken in its Guidelines against those standards.

NIH's Draft Guidelines repeated the Order's requirement that only "responsible" and "scientifically worthy" research should be eligible for funding, and they stated their own "purpose" as "ensur[ing] that NIH-funded research in this area" meets those requirements. J.A.495. Moreover, the Draft Guidelines dealt *specifically* with the merits of human embryonic stem-cell research. The proposal recited several purported benefits of such research. *Id.* And it proposed exceptions forbidding funding in certain categories of cases based on ethical concerns—for example, research involving cloning or breeding animals, or projects where "inducements were offered for the donated embryos." J.A.496-97. In sum, if the Executive Order left any doubt that the scientific and ethical merits

of human embryonic stem-cell research were at issue, the agency itself eliminated it.

Unsurprisingly, the tens of thousands of comments the agency received opposing human embryonic stem-cell research addressed whether such research is scientifically worthy and ethically responsible. The comments identified an array of *scientific* shortcomings of human embryonic stem-cell research—including the propensity of human embryonic stem cells to form tumors, and their inability to differentiate into the type of cells necessary for therapeutic treatment. *See, e.g.*, J.A.60-62, 145-46. They also noted the serious *ethical* problems posed by such research, including the destruction of human embryos from which such cells are harvested. *See, e.g.*, J.A.62-65, 157-59. And the comments advocated an alternative: directing federal funding to research involving adult and induced pluripotent stem cells, which collectively yields all the benefits that human embryonic stem-cell research purports to provide, without the same scientific or ethical drawbacks. *See, e.g.*, J.A.58-60, 137-40.

These comments thus fell squarely within the scope of the rulemaking. They challenged the agency's assumptions regarding issues that NIH itself initially recognized as relevant, and they called for a different approach to the problem than that proposed by the agency. Because the comments "cast doubt on the

reasonableness of" NIH's proposed approach, NIH was obligated to confront them. *Home Box Office*, 567 F.2d at 35 n.58.

2. NIH Entirely Disregarded Relevant Comments.

The APA requires an agency to "'respond'" to relevant comments "'in a reasoned manner.'" *Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216 (D.C. Cir. 1983) (citation omitted). How extensive its response must be depends on the content of the comments. *See City of Waukesha v. EPA*, 320 F.3d 228, 258 (D.C. Cir. 2003); *Thompson v. Clark*, 741 F.2d 401, 408-10 (D.C. Cir. 1984). But where comments raise facially legitimate objections, the agency cannot "simply dismiss" them "in conclusory terms." *Canadian Ass'n*, 254 F.3d at 299. It must instead "'explain how [it] resolved any significant problems'" they raised, *Action on Smoking & Health*, 699 F.2d at 1216 (citation omitted), so that a court can determine whether the agency gave "due weight" to all relevant factors, *Petrol. Commc'ns*, 22 F.3d at 1173, and drew a rational conclusion from all the evidence, *see Bus. Roundtable*, 647 F.3d at 1148; *Canadian Ass'n*, 254 F.3d at 299.

NIH admittedly disregarded the comments opposing human embryonic stem-cell research in their entirety, making no effort to rebut the scientific evidence or ethical objections they presented. *See* J.A.44; *see also* J.A.464, ¶12 ("NIH did not respond to comments that . . . categorically opposed hESC research on . . .

ethical grounds."). In its own words, NIH "deemed them irrelevant" (J.A. 480, ¶39), and "ignored" the issues that they raised (Mem. in Supp. of Mot. to Dismiss 44).

NIH's decision to ignore these relevant comments would be inexplicable but for public statements by the agency's head explaining its preconceptions. 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." J.A.314 (emphasis added). This statement shows that NIH had an unalterably closed mind, and had decided from the outset to expand funding for human embryonic stem-cell research. *Id.*; J.A.477 ¶25, 479-80 ¶38. Having closed its mind before the rulemaking even began, the agency had no interest in contrary views. J.A.303-04. Thus, when it received tens of thousands of comments challenging its stance, NIH simply branded them "unresponsive." J.A.304; J.A.479-80, ¶38.

Whatever NIH's reasoning for ignoring thousands of comments challenging a key premise of its proposal, its complete refusal to consider and respond to those comments violated the APA. Accordingly, its decision was not "reasoned" and cannot stand. *Canadian Ass'n*, 254 F.3d at 299.

B. Neither The Draft Guidelines Nor The Executive Order Excused NIH's Deliberate Disregard Of Relevant Comments.

The district court excused NIH's admitted failure to address thousands of comments on two grounds: In the court's view, the Draft Guidelines "did not invite" comments on whether to fund human embryonic stem-cell research, and the Executive Order took that threshold issue off the table by requiring NIH to issue rules for funding such research. J.A.687. Neither excuse justifies NIH's actions.

To begin with, NIH did not assert either reason in the rulemaking proceedings. It thus cannot rely on them in defending its rules after the fact. *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943); *see Canadian Ass'n*, 254 F.3d at 299 (holding that agency could not assert reason why comments were irrelevant that was neither offered in the rulemaking nor established by agency precedent).

Even on the merits, however, both of the district court's excuses are inadequate to excuse NIH's deliberate disregard of comments challenging a central premise of its proposal. The district court's conclusion that NIH did not have to respond to such comments because it did not *invite* them is factually false and legally incorrect. And its determination that the Executive Order foreclosed further debate on the issue is belied by the Order's text and purpose.

1. NIH's Draft Guidelines Did Not—And Could Not—Override NIH's Statutory Duty To Respond To Relevant Comments.

The district court concluded that "the NIH wasn't obligated to respond to" comments challenging the scientific and ethical merits of human embryonic stem-cell research "because the NIH's notice of proposed rulemaking did not invite" such comments. J.A.687. That is wrong for two reasons.

First, the district court's factual premise is false: Far from taking off the table the scientific and ethical merits of such research, the Draft Guidelines confirmed the relevance of both issues. As discussed above, *see supra* p. 45, the Draft Guidelines reiterated the Executive Order's restriction allowing funding only for ethically "responsible" and "scientifically worthy" research, and they expressed NIH's initial views of the scientific benefits and ethical boundaries of human embryonic stem-cell research. *See* J.A.495-97.

Having put these points at issue, NIH "welcome[d] public comment" on its proposals without any qualification. J.A.495. It said nothing about narrowing the issues open to comment or indicating an intent to ignore all comments opposing human embryonic stem-cell research. *See* J.A.495-97. NIH did not close the door to debate; if anything, it opened the door wider. It thus "utterly distorts the record to suggest that" challenges to the merits of human embryonic stem-cell research

"somehow [were] not responsive to [NIH's] solicitation" of public comments. *Petrol. Commc'ns*, 22 F.3d at 1173.

Nor, tellingly, did the public interpret NIH's notice as foreclosing debate on the issue. To the contrary, some 30,000 comments—approximately 60% of all comments received—addressed whether human embryonic stem-cell research satisfies the Executive Order's and the agency's own standards. J.A.479-80, ¶¶37-38. That so many commenters read the agency's notice to invite such comments undercuts the conclusion that the agency had clearly closed the door to them.

Second, even if NIH had precluded comments opposing human embryonic stem-cell research, that would make no difference. The agency's duty to address relevant comments derives from the APA, not the agency's own invitation. Dealing with public input is a statutory duty, not an act of administrative grace.

Nor is the scope of that duty left to the agency's discretion. The APA requires an agency to answer all objections that, on their face, would require the agency to change course or would "cast doubt on the reasonableness of" its approach, *Home Box Office*, 567 F.2d at 35 n.58, and to explain why it rejected the alternatives proposed, *see Canadian Ass'n*, 254 F.3d at 298-99. NIH could not sidestep that statutory duty simply by declining to invite certain comments. *See Ad Hoc Telecomm. Users Comm. v. FCC*, 680 F.2d 790, 798 (D.C. Cir. 1982) (MacKinnon, J., concurring in the result). Otherwise, an agency could end-run the

APA and gerrymander the result by soliciting only comments regarding issues as to which the agency is undecided—or only comments that *support* its proposal. That would defeat the entire purpose of notice-and-comment procedures by allowing agencies to convert the notice-and-comment process into an echo chamber that inevitably confirms the agency's preferred result.

Once it invited comments on the scientific and ethical merits of human embryonic stem-cell research, NIH was bound to address them. Even if NIH *could* have adopted criteria different from those established by the Executive Order (and it could not), it did not do so. And once it adopted those criteria as the benchmark for stem-cell funding, it was bound to adhere to them, and it must now defend the Guidelines in this Court on that basis. *See Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177 (D.C. Cir. 2010) (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); *Ad Hoc Telecomm. Users Comm.*, 680 F.2d at 798 (MacKinnon, J., concurring in the result) (explaining that an agency cannot "arbitrarily and narrowly circumscrib[e] the scope of relevant factors" by deeming comments "irrelevant").

The district court thus missed the mark in concluding that NIH "rightly disregarded" comments opposing human embryonic stem-cell research because they "provided no assistance regarding the task at hand: to create guidelines *for*

funding embryonic stem cell research that would ensure that funded projects are ethically responsible and scientifically worthy." J.A.688 (emphasis added). That was the "task at hand" only in the sense that NIH had prejudged the central question. But that is precisely the problem: NIH could *not* narrow the range of relevant comments by prejudging the issue; it *had* to consider all relevant comments, including those that challenged its assumptions and advocated other approaches.

Nor is this a case, like *Cable & Wireless, PLC v. FCC*, 166 F.3d 1224 (D.C. Cir. 1999), where the agency declined to address comments dealing with a discrete topic it had declined to regulate. An agency with control over its own regulatory agenda can elect to regulate some issues but not others, and it need not address comments concerning issues that it has deferred to future rulemakings. *See Cable & Wireless*, 166 F.3d at 1235-36. That is not the case here. Comments opposing human embryonic stem-cell research raised concerns not about an *additional* issue left open for the future, but about a *predicate* question that NIH *necessarily* resolved in deciding to fund such research—namely, whether such research fails NIH's own stated criteria of ethical responsibility and scientific worthiness.

2. The Executive Order Did Not Render Comments Opposing Human Embryonic Stem-Cell Research Irrelevant.

The district court's second reason for excusing NIH's deliberate disregard of thousands of comments—that the Executive Order supposedly rendered comments

opposing human embryonic stem-cell research irrelevant—is equally incorrect. Far from forbidding NIH from considering such comments, the Order *required* NIH to do so, and it certainly did not preclude NIH from considering them. The district court's contrary conclusion rests on a misreading of the Order and an erroneous assumption that the agency's *post hoc*, countertextual interpretation deserves judicial deference.

a. The Executive Order Required, And At The Very Least Permitted, NIH To Address Shortcomings Of All Human Embryonic Stem-Cell Research.

In interpreting the Executive Order to foreclose NIH from considering comments addressing the shortcomings of human embryonic stem-cell research, the district court got things backward. Fairly read, the Order *required* NIH to address those issues. As explained above, the Order allowed NIH to fund only scientifically worthy and ethically responsible research and commanded it to issue new rules consistent with that limitation. J.A.493, §§ 2-3. Before authorizing the funding of any stem-cell research—embryonic or otherwise—NIH thus *had* to evaluate its ethical and scientific merits. The Order did not eliminate the need to determine whether human embryonic stem-cell research satisfied those criteria; it simply delegated the task of making that determination to NIH.

At a minimum, the Order certainly did not *prevent* NIH from considering comments addressing whether human embryonic stem-cell research met those

criteria. Indeed, the Order *could not* have done so. NIH's duty to address relevant comments derives from the APA, which the Order undisputedly could not and did not supersede. *See* Defs.' Mot. Summ. J. 36 ("defendants do not dispute" that "the Executive Order did not override the requirements of the APA"); *see Chamber of Commerce v. Reich*, 74 F.3d 1322, 1327-28 (D.C. Cir. 1996) ("Even if the Secretary were acting at the behest of the President, this 'does not leave the courts without power to review the legality [of the action], for courts have power to compel subordinate executive officials to disobey illegal Presidential commands.'" (citation omitted)).

In any event, the Order's text makes clear that NIH could decline to fund *any or all* human embryonic stem-cell research, and therefore *could* consider the scientific and ethical merits of such research (including the relative merits of such research as compared to other forms of stem-cell research). The Order states that NIH "*may* support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research," not that it *must* do so. J.A.493, § 2 (emphasis added). It explicitly gave NIH discretion to decide which categories of stem-cell research projects to fund. *See United States v. Rodgers*, 461 U.S. 677, 706 (1983) ("may" in statutes is usually discretionary).

The government, in fact, conceded this point below. It stressed that "defendants have *not* made" the argument "that the Executive order directly

mandated that funds be awarded for hESC research." Defs.' Mot. Summ. J. 36. And it "fully agree[d] that the Executive Order did not mandate that the NIH fund any particular hESC research proposal." *Id.*; *see also* Reply in Supp. of Defs.' Mot. Summ. J. 19-20, Dkt. #73.

Although the government disputes the effect of that concession, it follows from its admission—and from the Order's text—that NIH remained free not to fund any human embryonic stem-cell research. If the Order did not compel NIH to fund any *specific* human embryonic stem-cell research projects, which it undisputedly did not, then it did not bar NIH from deciding to fund *none*. Put differently, the Order limited only NIH's ability to *support* certain projects, not its discretion to withhold support.

The only ground the government asserted below for resisting this logical conclusion—which the district court did not adopt—is belied by the Executive Order and the Final Guidelines. The government argued that banning funding for human embryonic stem-cell research would contravene NIH's case-by-case peer-review process created by statute—a process that it said the Order "restored." Defs.' Mot. Summ. J. 35-36. The Order, however, said nothing regarding that process, let alone about requiring NIH to resolve all ethical and scientific-worthiness questions through that process.

In any event, there is no inconsistency between imposing across-the-board restrictions rendering some types of research ineligible and employing case-by-case review to select which research proposals to fund. Indeed, like the Draft Guidelines, the Final Guidelines *themselves* adopted ethics-based categorical limitations prohibiting certain research, regardless of whether a peer-review panel would agree. They forbid funding of research involving breeding or cloning of animals or stem cells for which "payments, cash or in kind, were offered," and they require that "[d]ecisions related to the creation of human embryos" be made "free from the influence of researchers" seeking to derive stem cells from those embryos. J.A.48-49. Such across-the-board restrictions belie NIH's assertion that the peer-review process precluded categorical limitations.

In fact, NIH explicitly *rejected* the suggestion that all ethical concerns should be left for case-by-case resolution in the grant process. J.A.45. Its contrary argument in litigation contradicts the Guidelines.

Besides overlooking the Order's text, the district court misunderstood its purpose. President Bush's policy imposed limitations on which research NIH could fund, reflecting certain views on the scientific and ethical issues at stake. *See* J.A.493, § 1. The Order's explicit aim was to remove such political constraints imposed on NIH by the President, *see id.*, thereby freeing the agency to make these determinations in the first instance. The Order's aim was to give the agency *more*

leeway, not less, and to remove the White House from the equation. Interpreting the Order to allow NIH to decide which research merits funding under the Order's criteria fits perfectly with that purpose. In contrast, it makes no sense to interpret the Order, as the district court did, to impose the very type of top-down, political constraints it was explicitly designed to eliminate.

b. NIH's *Post Hoc* Interpretation Of The Executive Order Deserves No Deference.

The district court disregarded the clear import of the Order's text and purpose based on its erroneous assumption that NIH's interpretation of it deserved "considerable deference" under *Udall v. Tallman*, 380 U.S. 1 (1965). J.A.688. Such deference—which the government itself had not sought and which the district court applied based on its one-sentence analysis—is unwarranted here for three reasons.

First, NIH's current view of the Order deserves no deference at all because it flatly contradicts the Order's text. Under any doctrine of deference—even the standard of *Bowles v. Seminole Rock*, 325 U.S. 410, 413-14 (1945), which *Tallman* applied, *see* 380 U.S. at 16-17—no deference is due if an agency's reading cannot be squared with the text being interpreted. *See id.* at 18 (deference due only if agency's "interpretation is not unreasonable" and "if the language of the orders bears [its] construction"); *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 131 S. Ct. 2254, 2263 (2011) (deference unwarranted to agency's reading of its own regulation that

is "'plainly erroneous or inconsistent with the regulation'" (citation omitted)). As explained above, *see supra* pp. 54-58, the reading of the Order that NIH's counsel now advocates—namely, that the Order prohibited NIH from declining to fund human embryonic stem-cell research—is foreclosed by the Order's text, which states that NIH "*may*" fund scientifically and ethically worthy stem-cell research, not that it *must* fund stem-cell research that is unworthy and unethical. J.A.493, § 2 (emphasis added).

Second, even if the reading now advanced by NIH's counsel could be squared with the Order's plain language, it still would not merit any deference because the agency did not assert this view until this litigation. *Seminole Rock* deference does not apply to *post hoc* rationalizations that do "not reflect the agency's fair and considered judgment on the matter." *Talk Am.*, 131 S. Ct. at 2263; *see also Alaniz v. OPM*, 728 F.2d 1460, 1465 (Fed. Cir. 1984). Indeed, *Tallman* itself stressed that the agency's interpretation "had, long prior to [the events at issue], been a matter of public record and discussion." 380 U.S. at 17. NIH, however, *never* articulated its countertextual interpretation of the Order until this lawsuit began. Nor has it ever articulated this interpretation in an agency statement carrying the force of law. *See Mead*, 533 U.S. at 226-27; *Gonzales*, 546 U.S. at 255-56. Accordingly, its now-favored reading deserves no deference.

Third, the doctrine of deference the district court employed is irrelevant to NIH's interpretation of the Executive Order. Although the district court did not spell out its theory of deference, it cited *Tallman*, which applied *Seminole Rock*. *See* 380 U.S. at 16-17; J.A.688. But the *Seminole Rock* standard—clarified by *Auer*, 519 U.S. at 461, and later cases—does not apply to an agency's reading of an order that the agency itself did not write and cannot alter.

Seminole Rock rests on the common-sense assumption that the agency that brought its own "expertise and experience" to bear "to formulate [the] regulation" is in the best position to resolve ambiguities in the regulation. *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006); *see Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). But where there is no basis to assume the agency has special insight, *Seminole Rock* does not apply. *See Gonzales*, 546 U.S. at 257. "'[D]eference is inappropriate,'" for example, "'when [an agency] interprets regulations promulgated by a *different* agency.'" *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1016 (D.C. Cir. 2002) (citation omitted; emphasis added). Likewise, an agency's reading of a rule that simply "restate[s] the terms of the statute" that the rule implements deserves no deference, because an agency that merely "parrot[s]" or "paraphrase[s]" a statute "does not acquire special authority to interpret" the words it copied. *Gonzales*, 546 U.S. at 257.

For the same reason, *Seminole Rock* deference would not extend to the interpretation NIH now advocates of Executive Order 13,505, which NIH did not draft and cannot modify. The Order does not reflect NIH's "expertise and experience," *Gonzales*, 546 U.S. at 257, or even the agency's own views, but instead a directive *to* the agency from the President. The deference due under *Seminole Rock* to an agency's reading of its own regulation is thus inapposite.

Tallman, the only binding authority the district court cited, did not establish a different rule. In *Tallman*, the President issued an Executive Order establishing a public-land policy, but he "soon delegated" to the agency full authority to alter the original Order. *See* 380 U.S. at 5, 17. Exercising that authority before the events giving rise to the case, the agency issued a directive modifying the original Order. *See id.* at 5-6, 17. The Court deferred to the agency's longstanding interpretation of its directive and the Order it altered. *See id.* at 16-23.

Contrary to the district court's apparent view, *Tallman* thus did not drastically expand *Seminole Rock* to new territory, but simply applied it to an exceptional circumstance. Although the agency there did not author the original Order, the Order had effectively become the agency's own by the time the Court ruled, because the agency had been given full authority to alter the Order. The agency's interpretation of the Order it had modified thus deserved the same respect a court would accord to an agency's reading of its own regulations. The same is

not true, however, of executive orders—like the Order at issue here—that the agency cannot change. NIH has no authority to alter or abrogate Executive Order 13,505, and thus the interpretation NIH now advocates deserves no deference under *Tallman*.[7]

* * *

The district court incorrectly concluded that the issue whether to fund human embryonic stem-cell research "was not a question left on the table for the NIH" by the Order. J.A.690. If the issue was closed to debate, it was because NIH—not the Executive Order—took it off the table by resolving the issue without confronting contrary views. That is precisely what the APA forbids. Accordingly, the district court's decision must be reversed and the case must be remanded with instructions to vacate the Guidelines. *See, e.g.*, *NetCoalition v. SEC*, 615 F.3d 525, 544 (D.C. Cir. 2010) (vacating an agency's order).

CONCLUSION

The Guidelines plainly violate the congressional ban on funding "research in which" a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death." Moreover, the Guidelines were promulgated in violation of the

[7] The only other authority the district court cited, *Kester v. Campbell*, 652 F.2d 13, 15-16 (9th Cir. 1981), was decided long before modern deference cases such as *Gonzales* and *Auer*, and it did not undertake the sophisticated deference analysis required by modern deference cases.

APA. Accordingly, this Court should reverse the district court's judgment in favor of Defendants, reverse the grant of Defendants' Motion for Summary Judgment and the denial of Plaintiffs' Motion for Summary Judgment, and remand with directions to enter summary judgment for Plaintiffs.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,885 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).

2. 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 this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman type.

Dated: January 12, 2012

/s/ Ryan J. Watson
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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.

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. § 46.202

§ 46.202 Definitions.

The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

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.

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. 112-74, div. F, § 508, 125 Stat. 786, 1112 (2011)

Sec. 508. (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.

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of January, 2012, I electronically filed the foregoing Brief for Appellant 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.

Service was accomplished on the following persons on this 12th day of January, 2012, by the appellate CM/ECF system:

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