

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. JAMES L. SHERLEY, et al.,

Plaintiffs,

v.

KATHLEEN SEBELIUS, et al.,

Defendants.

Civil Action
No. 09-CV-01575-RCL

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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Plaintiffs, through undersigned counsel, respectfully move this Court for summary judgment pursuant to Fed. R. Civ. P. 56 vacating and declaring invalid the National Institutes of Health's Guidelines for Human Stem Cell Research ("Guidelines") and permanently enjoining further implementation of the Guidelines. A Memorandum of Points and Authorities, Plaintiffs' Statement of Material Facts As To Which There Is No Genuine Dispute, and a Proposed Order are submitted herewith pursuant to LCvR 7(h) and 56.1.

In view of the fact that the issues were addressed in the oral argument on Plaintiffs' Motion for Preliminary Injunction, the Court may conclude that further oral argument is not necessary on this motion, but Plaintiffs would be pleased to participate in oral argument if it would be of assistance to the Court.

Dated: September 9, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of September, 2010, I electronically filed the foregoing Motion for Summary Judgment, and accompanying Memorandum of Law in Support, Statement of Material Facts, and related exhibits, with the Clerk of the United States District Court for the District of Columbia by using the CM/ECF system.

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**MEMORANDUM OF LAW IN SUPPORT OF
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INTRODUCTION

In the wake of this Court’s recent opinion and Order issuing a preliminary injunction in this matter, the time is right for this Court to grant summary judgment in favor of the Plaintiffs’ claim that the National Institutes of Health Guidelines for Human Stem Cell Research (“NIH Guidelines”) are invalid as a matter of law. The NIH Guidelines violate federal law, which prohibits funding “research in which” a human embryo is “destroyed, discarded, or knowingly subjected to risk of injury or death.” Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, § 509(a)(2), 123 Stat. 3034, 3280–81 (the “Dickey-Wicker Amendment”). Moreover, in promulgating the Guidelines, NIH failed to explain how the funding of embryonic stem cell research will fulfill the Guidelines’ stated purpose to support “ethically responsible” and “scientifically worthy” research, and failed to address substantial evidence in the administrative record showing that federal funding of such research will in fact have the opposite effect. *See* 74 Fed. Reg. 32,170 (July 7, 2009) (attached as Declaration of Steven H. Aden in Support of Pls.’ Mot. for Summary Judgment (“Aden Decl.”), Ex. C). Plaintiffs’ claims for declaratory and injunctive relief can be resolved based on the undisputed facts and therefore are ready for summary adjudication.

As this Court has already concluded, Plaintiffs’ claim under the Dickey-Wicker Amendment presents a straightforward question of statutory interpretation—namely, whether human embryonic stem cell research is “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death.” The Dickey-Wicker Amendment unambiguously precludes the funding of embryonic stem cell research under the NIH Guidelines, because such research necessarily and inevitably involves the destruction of human embryos. Plaintiffs’ Administrative Procedure Act (“APA”) claims are similarly straightforward and ready for resolution. With respect to those claims, this Court must simply

decide whether NIH failed to offer a reasoned explanation for its *sub silentio* rejection of the public comments and substantial evidence in the administrative record showing that the Guidelines are categorically inconsistent with the agency’s stated goals and criteria.

BACKGROUND

I. The Dickey-Wicker Amendment

For more than a decade, Congress has explicitly banned federal funding of research in which human embryos are destroyed or knowingly subjected to harm. In 1996, Congress first enacted an appropriations rider that prohibits federal funding of research in which human embryos are harmed or destroyed. That rider, commonly known as the Dickey-Wicker Amendment, provides that: “(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” § 509(a)(2), 123 Stat. at 3280–81.

Congress has included the Dickey-Wicker Amendment in every Health and Human Services (“HHS”) appropriations bill since 1996, and has not altered the Amendment in any material respect. (SOF ¶ 17.) Congress thus continues to prohibit federal funding for “research in which” an embryo is “destroyed, discarded, or knowingly subjected to risk of injury or death.” And since Congress first enacted the Dickey-Wicker Amendment, no federal money had been spent on research that entailed and encouraged the further destruction of human embryos—until now.¹

¹ NIH attempted to fund human embryonic stem cell research in 2000 when it finalized and made effective “Guidelines for Research Using Human Pluripotent Stem Cells” (“2000

[Footnote continued on next page]

II. The Promulgation of the Guidelines

On March 9, 2009, President Obama signed Executive Order 13,505, which authorized NIH to “support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.” 74 Fed. Reg. 10,667 (Mar. 11, 2009) (attached as Aden. Decl., Ex. A); SOF ¶ 20. To that end, the Order provided that “[w]ithin 120 days . . . [HHS and NIH] shall 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.” 74 Fed. Reg. 10,667; SOF ¶ 20.

Six weeks later, Defendants issued a notice of proposed rulemaking (“NOPR”) containing a proposed draft of the current Guidelines for human stem cell research (“Draft Guidelines”). 74 Fed. Reg. 18,578 (Apr. 23, 2009) (attached as Aden Decl., Ex. B); SOF ¶ 22. According to the NOPR, the Guidelines’ purpose would be to “ensure that NIH-funded research [involving human embryonic stem cells] is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.” 74 Fed. Reg. 18,578; SOF ¶ 23. The NOPR

[Footnote continued from previous page]

Guidelines”), 65 Fed. Reg. 51,976 (Aug. 25, 2000). (SOF ¶ 18.) Then-HHS General Counsel Harriet S. Rabb concluded in a memorandum (“Rabb Memorandum”), that embryonic stem cells are not “embryos” under the Dickey-Wicker Amendment, and therefore that NIH could legally fund experiments on the stem cells after those cells had been derived with private funds. (Aden Decl., Ex. E [Rabb Memorandum].) The Rabb Memorandum opined only on the definition of “embryos,” and said nothing about the scope of the word “research.” The 2000 Guidelines were never implemented, however, because in 2001 NIH formally withdrew those guidelines, *see* 66 Fed. Reg. 57,107 (Nov. 14, 2001); SOF ¶ 19, and issued new guidelines that allowed funding only for research involving already-derived stem cell lines derived no later than the August 9, 2001 date set by President Bush in the announcement of his policy regarding the funding of embryonic stem cell research. (Aden Decl., Ex. D at E-2 to E-3.) *See also* Nat’l Institutes of Health, Office of the Director, *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 (Aug. 9, 2001), available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>.

proposed the authorization of federal funding of human embryonic stem cell research. 74 Fed. Reg. 18,578; SOF ¶ 24. Defendants also invited public comment on the Draft Guidelines. 74 Fed. Reg. 18,578; SOF ¶ 22. It is undisputed that the notice-and-comment procedures set forth in 5 U.S.C. § 553(c) governed Defendants' promulgation of the Guidelines.

Defendants received 49,015 public comments (SOF ¶ 37; *see* Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm?), most of which opposed federal funding of human embryonic stem cell research. (*See* SOF ¶ 38; Aden Decl., Ex. F [Jeffrey Young, *Administration Unveils Stem Cell Rules*, The Hill, July 6, 2009, *available at* <http://thehill.com/homenews/administration/49462-administration-unveils-stem-cell-rules>].) Some of the comments addressed the numerous scientific and ethical flaws in federally funding such research and documented the superior alternatives to it. (*See* SOF ¶¶ 26–28, 30–32; *e.g.*, Aden Decl., Ex. D.) The comments also identified the serious risks associated with human embryonic stem cell treatments, as well as the inherent limitations on those cells' therapeutic potential. (*See* SOF ¶ 28(y)–(ff); Aden Decl., Ex. D at I-1 to I-3.) The comments also detailed the substantial and verifiable medical results already delivered by adult stem cells, and other characteristics that render adult stem cells a superior scientific and ethical alternative. (*See* SOF ¶¶ 28(b)–(l), 32(d)–(g), 32(m)–(n); *e.g.*, Aden Decl., Ex. D at G-2, G-6.) Defendants disregarded these comments, however, because in Defendants' view they “did not ask the public whether [NIH] should fund research on human embryonic cells,” but rather “*how* [NIH] should fund human embryonic stem cell research.” (SOF ¶ 38; Aden Decl., Ex. F (emphasis added).)

On July 7, 2009—only six weeks after the comment period closed—Defendants issued the final Guidelines. 74 Fed. Reg. 32,170 (attached as Aden Decl., Ex. C); SOF ¶ 40. The

Guidelines purport to implement the President's Executive Order by authorizing the federal funding of embryonic stem cell research utilizing live human embryos that were "created . . . for reproductive purposes" but are "no longer needed for [that] purpose." 74 Fed. Reg. at 32,170, 32,174; SOF ¶ 40. The Guidelines set forth the procedures by which live embryos must be selected for destruction if they are to be used in government-funded research. *See, e.g.*, 74 Fed. Reg. at 32,174; SOF ¶¶ 41, 45.

III. Advances in Non-Embryonic Stem Cell Research

As noted above, many of the commenters on the Draft Guidelines explained that stem cell research has the potential to treat a number of diseases that have long resisted traditional methods. (*See* SOF ¶¶ 28(b); Aden Decl., Ex. D at 9–10.) Indeed, numerous *adult* stem cell therapies already exist (*e.g.*, bone marrow transplants used to treat leukemia). (*See* SOF ¶ 28(c); Aden Decl., Ex. D at 9, G-1, G-4.) But, both scientifically and ethically, all stem cells are not created equal. There are three general types of stem cells: embryonic, adult, and induced pluripotent. (SOF ¶ 28(a).) Although embryonic stem cells have received much of the public and media attention, no actual medical treatments have been approved using these cells. (*See* SOF ¶¶ 28(z), 51; Aden Decl., Ex. D at G-1; *id.* at Ex. G [Bernadine Healy, M.D., *Why Embryonic Stem Cells Are Obsolete*, U.S. News & World Report, Mar. 4, 2009, *available at* <http://health.usnews.com/blogs/heart-to-heart/2009/03/04/why-embryonic-stem-cells-are-obsolete.html>].) In contrast, scientists have made dramatic breakthroughs in the use of adult and induced pluripotent stem cells, and these ethically unobjectionable research methods have generated the vast majority of scientific progress, and all of the actual medical success stories involving stem cells. (*See* SOF ¶ 28(c), (z); Aden Decl., Ex. D at G-1 to G-8, H-1 to H-4.)

A. Embryonic Stem Cell Research

Human embryonic stem cells are found in the inner cell mass of a living human embryo. (See SOF ¶ 50; see Aden Decl., Ex. D at E-3.) The removal of the inner cell mass generates the embryonic stem cell, but in order to extract the stem cell, the human embryo must be destroyed. (SOF ¶ 50; Aden Decl., Ex. D at 5, E-3.) Although many researchers predicted that embryonic stem cell research would lead to the cure of diseases such as Parkinson's, Alzheimer's, and diabetes, those predictions have not come to pass. (SOF ¶ 54; Aden Decl., Ex. G; see also Aden Decl., Ex. D at A-2.) Indeed, far from the miracle-working potential that some had forecasted, research shows that embryonic stem cells would likely form tumors when injected into a patient's body. (SOF ¶ 28(aa)–(cc); Aden Decl., Ex. D at I-2 to I-3.) And because the cells do not come from the patient, they would likely be rejected by a patient's immune system. (See SOF ¶ 28(ee); Aden Decl., Ex. D at G-8.)

B. Adult Stem Cell Research

Adult stem cells are cells found in the body and in tissues normally discarded after birth (such as umbilical cord blood and the placenta) that have the potential to generate most or all of the different tissues in the human body. (SOF ¶ 28(d); Aden Decl., Ex. D at 9.) And—unlike embryonic stem cells—adult stem cells have demonstrated great therapeutic promise. (SOF ¶ 28(b)–(c); Aden Decl., Ex. D at G-1.) As former NIH head Dr. Bernadine Healy observed early last year, adult stem cells “have become stars,” representing “most of the stem cell triumphs that the public hears about.” (Aden Decl., Ex. G. at 2.) In fact, adult stem cells have verifiably treated countless individuals suffering from a wide variety of diseases, including ovarian cancer, retinoblastoma, brain tumors, testicular cancer, chronic and acute leukemias, breast cancer, renal cell carcinoma, anemias, Crohn's disease, rheumatoid arthritis, and juvenile diabetes. (SOF ¶ 28(c); Aden Decl., Ex. D at G-4 to G-6.) Adult stem cells also have shown an

ability to home in on damaged tissue, allowing the development of minimally invasive administration techniques. (SOF ¶ 28(j); Aden Decl., Ex. D at G-8.) And whereas embryonic stem cells pose serious risks of tumor formation and immune-rejection by the patient's body, adult stem cells present neither of these problems. (SOF ¶ 28(k); Aden Decl., Ex. D at G-8.)

C. Induced Pluripotent Stem Cell Research

Induced pluripotent stem cells are produced by genetically reprogramming mature cells such that they are virtually indistinguishable from embryonic stem cells. (SOF ¶ 28(o); Aden Decl., Ex. D at H-1 to H-2; *see also* SOF ¶ 63.) The process of producing human induced pluripotent stem cells was invented just two years ago. (SOF ¶ 28(p); Aden Decl., Ex. D at H-1.) This marked a dramatic leap forward in developmental biology, and was hailed by the journal *Science* as the leading scientific breakthrough in any field in 2008. (Aden Decl., Ex. H [Gretchen Vogel, *Breakthrough of the Year: Reprogramming Cells*, 322 *Science* 1766 (2008)].) Induced pluripotent cells “meet the defining criteria [that were] originally proposed for human [embryonic stem] cells, with the significant exception that the [induced pluripotent stem] cells are not derived from embryos.” (SOF ¶ 28(w); Aden Decl., Ex. D at H-3.) And NIH has recognized that, unlike embryonic stem cells, “tissues derived from [induced pluripotent stem cells] will be a nearly identical match to the cell donor and thus probably avoid rejection by the immune system.” Nat'l Institutes of Health, *Stem Cell Basics* 14 (2009), *available at* <http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf>; *see* SOF ¶ 64. Induced pluripotent cells thus offer the same benefits as embryonic stem cells without the immune-rejection risks to patients or, what is more, the ethical problems entailed in destroying human embryos in order to obtain embryonic stem cells for research or therapeutic purposes. (SOF ¶¶ 28(m)–(n), (w); Aden Decl., Ex. D at 10, H-4.)

IV. NIH's Funding Process

Applicants for NIH research funding undergo a competitive two-tier peer review process. *Sherley v. Sebelius*, 610 F.3d 69, 73 (D.C. Cir. 2010) (attached as Aden. Decl., Ex. N); SOF ¶¶ 3, 9; *see also* Aden Decl., Ex. J [Decl. of Sarah Jean Rockey, Ph.D., in Support of Defs.' Opp'n to Pls.' Mot. for Prelim. Inj.] ¶¶ 8–12.² At the first stage, “a peer-review committee assigns a preliminary score to each grant application.” *Sherley*, 610 F.3d at 73; *see also* SOF ¶ 6; Aden Decl., Ex. J ¶ 11. An application that scores above the median “then goes to one or more of the 24 Institutes and Centers (ICs) at the NIH.” *Sherley*, 610 F.3d at 73; *see also* SOF ¶ 6; Aden Decl., Ex. J ¶ 9. At the second stage of the grant application process, “each IC decides which grant applications to fund.” *Sherley*, 610 F.3d at 73; *see also* SOF ¶ 7.

Embryonic and adult stem cell researchers compete for the same funding. Each IC “has its own budget and awards grants to projects that address its particular mission,” *id.*; *see also* SOF ¶ 5; Aden Decl., Ex. J ¶ 5, including both adult and embryonic stem cell research (*see* SOF ¶ 5(c); Aden Decl., Ex. J ¶¶ 16–18). NIH funding is a zero-sum game. “[T]he amount of money [presently] available from NIH for research grants is fixed notwithstanding the greater range of stem cell research projects made eligible for funding by the Guidelines.” *Sherley*, 610 F.3d at 73. And because the Guidelines “will elicit an increase in the number of grant applications involving” human embryonic stem cells, the Guidelines have thus “intensified the competition for a share in a fixed amount of money.” *Id.* at 74; SOF ¶ 10.

² In addition to accepting grant applications, NIH “encourages research in areas of top priority (such as stem cell research) by publishing [Program Announcements], [Requests for Applications], and [Requests for Proposals].” Nat’l Institutes of Health, Funding for Research, <http://stemcells.nih.gov/research/funding/defaultpage.asp> (last visited Aug. 28, 2010). These “targeted” announcements are used “to stimulate research in particular areas of science.” (SOF ¶ 8; Aden Decl., Ex. J ¶ 6.)

V. The Present Action

Dr. James L. Sherley³ and Dr. Theresa Deisher⁴ (“Plaintiffs”), among others, brought this action against Defendants alleging that the Guidelines are not in accordance with law and are arbitrary and capricious within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). Plaintiffs also allege that Defendants promulgated the Guidelines without observing procedures required by law within the meaning of 5 U.S.C. § 706(2)(D). Plaintiffs moved for a preliminary injunction restraining Defendants from implementing, applying, or taking any action pursuant to the Guidelines. (Pls.’ Mot. for Prelim. Inj., Aug. 19, 2009 [Docket (“Dkt.”) #3].)

Defendants opposed Plaintiffs’ motions and filed a motion to dismiss, which this Court granted on the ground that, in its view, Plaintiffs lacked standing. *Sherley v. Sebelius*, 686 F. Supp. 2d 1, 3 (D.D.C. 2009). The Court then denied as moot Plaintiffs’ motion for a preliminary injunction. (Order of Oct. 27, 2009 [Dkt. #37].)

³ Dr. Sherley is an adult stem cell researcher who currently works at the Boston Biomedical Research Institute. (SOF ¶¶ 1 & 1(a); Declaration of Dr. James L. Sherley in Support of Pls.’ Mot. for Summary Judgment (“Sherley Decl.”) ¶ 2.) Dr. Sherley does not conduct research on human embryos or use human embryonic stem cells. (SOF ¶ 1(b); Sherley Decl. ¶ 2) He relies exclusively on research grants for funding, and most of the grants he receives are from NIH. (SOF ¶ 1(c); Sherley Decl. ¶ 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. (SOF ¶ 1(i)-(j); Sherley Decl. ¶ 5.)

⁴ Dr. Deisher is an adult stem cell researcher and is the founder, managing member, and research and development director of AVM Biotechnology. (SOF ¶ 2 & 2(a); Declaration of Dr. Theresa Deisher in Support of Pls.’ Mot. for Summary Judgment (“Deisher Decl.”) ¶¶ 2-3.) Dr. Deisher does not conduct research on embryos or use embryonic stem cells. (SOF ¶ 2(c); Deisher Decl. ¶ 2.) She can continue her research only if she obtains funding from NIH, for which she is in the process of applying and which she will continue to seek. (SOF ¶ 2(d)-(e); Deisher Decl. ¶ 3.)

Plaintiffs appealed, and prevailed on the issue of whether they have standing to bring this action. The D.C. Circuit held that Plaintiffs have standing under the competitor-standing doctrine. *Sherley*, 610 F.3d at 70. The Court of Appeals’s reasoning was not premised on any disputed facts, but rather flowed logically from its explication of the competitor-standing doctrine and the basic laws of economics. The Court explained that “the basic requirement common to all [the court’s] cases is that the complainant [must] show an actual or imminent increase in *competition*, which increase [the court] recognize[s] will almost certainly cause an injury in fact.” *Id.* at 73 (emphasis added). The Court continued, “[t]here can be no doubt that the Guidelines will elicit an increase in the number of grant applications involving [embryonic stem cells] Because the Guidelines have intensified the competition for a share in a fixed amount of money, the plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury.” *Id.* at 74. The Court further explained that Plaintiffs “will suffer an additional injury whenever a project involving [embryonic stem cells] receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs Although no one can say exactly how likely the [Plaintiffs] are to lose funding to projects involving [embryonic stem cells], having been put into competition with those projects, the [Plaintiffs] face a substantial enough probability to deem the injury to them imminent.” *Id.*

Having determined that Plaintiffs have standing, the D.C. Circuit also reversed this Court’s order dismissing as moot Plaintiffs’ motion for a preliminary injunction, and ordered that motion reinstated. *Id.* at 75. On remand, this Court granted Plaintiffs’ motion for a preliminary injunction, ordering “that defendants and their officers, employees, and agents are enjoined from implementing, applying, or taking any action whatsoever pursuant to the National Institutes of

Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), or otherwise funding research involving human embryonic stem cells as contemplated in the Guidelines.” Order of Aug. 23, 2010 [Dkt. #45]. Defendants moved to stay the Court’s order [Dkt. #48], but the Court denied that motion, Order of Sept. 7, 2010 [Dkt. #53]. In the interests of judicial economy and a swift final resolution of this case, and because no genuine issue of material fact exists and Plaintiffs are entitled to judgment as a matter of law on their claims under both the Dickey-Wicker Amendment and the APA, Plaintiffs now move for summary judgment on their claims for declaratory and injunctive relief.

ARGUMENT

I. Standard of Review

Either party may move for summary judgment at any time, even as early as the commencement of the action and before the defendant has answered the complaint. Fed. R. Civ. P. 56(a), (c)(1)(A), advisory committee’s note. *See also First Am. Bank, N.A. v. United Equity Corp.*, 89 F.R.D. 81, 87 (D.D.C. 1981) (“[A]n answer to the complaint is not a prerequisite to the consideration of a motion for summary judgment.”). Summary judgment is proper “if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c)(2); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). “By its very terms, [Rule 56(c)] provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for

summary judgment; the requirement is that there be no *genuine* issue of *material* fact.”

Anderson, 477 U.S. at 247–48.⁵

II. Standing

The question of Plaintiffs’ standing has been resolved by the D.C. Circuit’s opinion. *See Sherley*, 610 F.3d 69 (attached as Aden. Decl., Ex. N). As Plaintiffs reaffirmed in their recent declarations, the facts in the case have not changed. (*Compare* *Sherley* Decl., *Deisher* Decl. with *Aden* Decl., Exs. L–N.) Plaintiffs continue to work primarily with adult stem cells, and continue to seek research funding from NIH. (SOF ¶¶ 1 & 1(b), 2(b); *Sherley* Decl. ¶¶ 2, 5; *Deisher* Decl. ¶¶ 2–3.) And it remains “uncontested that, at least in the short run, the amount of money available from NIH for research grants is fixed notwithstanding the greater range of stem cell research projects made eligible for funding by the Guidelines.” *Sherley*, 610 F.3d at 73; SOF ¶ 5(d). As a result, Plaintiffs continue to suffer the “actual, here-and-now injury” of “intensified competition for a share in a fixed amount of money,” and continue to face the “additional,” “imminent” injury of losing funding when grants are awarded to human embryonic stem cell researchers that, but for the Guidelines, would have been awarded to Plaintiffs. *Sherley*, 610 F.3d at 74. These facts are not in dispute, and the Court of Appeals has clearly held that they are sufficient to confer both Article III and prudential standing on Plaintiffs. *Id.* at 74–75.

⁵ Plaintiffs are entitled to both declaratory and injunctive relief. Plaintiffs have clearly satisfied the requirements of 28 U.S.C. § 2201 that (1) “a case of actual controversy” exists, and (2) that case comes within the court’s jurisdiction. *Id.* § 2201(a); *see also Tierney v. Schweiker*, 718 F.2d 449, 456-57 (D.C. Cir. 1983). And as set forth in Section V below, Plaintiffs have shown they are entitled to a permanent injunction.

III. The Guidelines Violate the Dickey-Wicker Amendment, and Summary Judgment Therefore Should be Entered for Plaintiffs

As the Court has already explained (Dkt. #44, at 10), the NIH Guidelines violate the unambiguous terms of the Dickey-Wicker Amendment, which forbids federal funding of “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death.” § 509(a)(2), 123 Stat. at 3280–81. Human embryonic stem cell research necessarily entails the destruction of human embryos. (SOF ¶¶ 45(c), 50; Aden Decl., Ex. D at E-3; Dkt. #44, at 12 (“To conduct ESC research, ESCs must be derived from an embryo. The process of deriving ESCs from an embryo results in the destruction of the embryo.”).) This fact cannot be disputed, and indeed is recognized in the text of the Guidelines: They set forth the very procedures by which live embryos must be selected for destruction for purposes of government-funded research. *See* 74 Fed. Reg. at 32,170, 32,174; SOF ¶¶ 41, 45. In the face of these regulations, NIH cannot plausibly contend that the embryonic stem cell research that it funds is separate and distinct from the destruction of human embryos. Because it is undisputed that human embryonic stem cell research causes injury to and the destruction of human embryos, the Guidelines plainly violate the statute by authorizing the funding of such research.

A. The Dickey-Wicker Amendment Plainly Prohibits Federal Funding of All Research in Which Human Embryos Are Destroyed

The Dickey-Wicker Amendment provides that “[n]one of the funds made available in this Act may be used for—(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. § 289g(b)).” § 509(a)(2), 123 Stat. at 3280–81. “Congress says in a statute what it means and

means in a statute what it says there,” *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (internal quotation marks omitted), and Dickey-Wicker unambiguously prohibits the federal funding of research—such as embryonic stem cell research—that requires and induces the destruction of human embryos. Despite their best efforts, Defendants cannot reconcile the Guidelines with Dickey-Wicker’s unambiguous command. Summary judgment must therefore be entered for Plaintiffs.

1. The Guidelines Authorize Funding for “Research in Which” Embryos Will Be Destroyed or Knowingly Subjected to Risk of Injury or Death

(a) Defendants’ Derivation/Use Distinction Has No Basis in the Text or Structure of the Dickey-Wicker Amendment

As an initial matter, NIH asserted in the Guidelines that Dickey-Wicker’s funding ban applies only to the act of deriving stem cells from embryos, not to subsequent experiments on those cells, because embryonic stem cells “are not embryos as defined by Section 509.” 74 Fed. Reg. at 32,173 (attached as Aden Decl., Ex. C). But that proposition does not resolve the statutory issue, because the statute’s text prohibits funding not only for discrete acts that destroy human embryos, but also for all “*research in which*” an embryo is “destroyed, discarded, or knowingly subjected to risk of injury or death.” § 509(a)(2), 123 Stat. at 3280 (emphasis added).

Indeed, Dickey-Wicker’s structure confirms that Defendants’ purported distinction between derivation of stem cells from embryos (in which the embryo is destroyed) and the experimentation on the stem cells harvested from the destroyed embryos is their own creation, not a feature of the statute. Congress structured the Dickey-Wicker Amendment such that it contains two subsections: Subsection (1) prohibits the *specific act* of using federal funds for the creation of 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. As this Court has explained, “[h]ad Congress intended to limit the

Dickey-Wicker to only those discrete acts that result in the destruction of an embryo, like the derivation of ESCs, or to research on the embryo itself, Congress could have written the statute that way.” (Dkt. #44, at 11.)

Congress is presumed not to enact Rube Goldberg-style statutes. *See, e.g., Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227 (2008) (rejecting petitioner’s interpretation of a statute, in part because “[h]ad Congress intended to limit [the statute’s] reach as petitioner contends, it easily could have written [it that way]”). Dickey-Wicker is no exception: Congress’s choice to prohibit broadly the funding of “research in which” embryos are destroyed plainly rejects the distinction pressed by Defendants. *See Russello v. United States*, 464 U.S. 16, 23 (1983) (“Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”).

(b) Defendants’ Counsel’s “Piece of Research” Interpretation Defies the Statutory Text, Conflicts with Defendants’ Interpretation Outside This Litigation, and Ignores the Context in Which Dickey-Wicker Was Enacted

In an effort to circumvent the structure and plain language of the statute, Defendants’ counsel has argued that “research” can mean “a piece of research,” and has therefore claimed that Dickey-Wicker does not preclude Defendants from funding “piece[s]” of embryonic stem cell research so long as the funding is not used for the actual destruction of human embryos—even though the funded research *necessarily requires* such destruction. (Mem. in Support of Defs.’ Mot. to Dismiss, and in Opp’n to Pls.’ Mot. for Prelim. Inj. at 31 [Dkt. #23].) This Court has already rejected this argument (Dkt #44, at 11), and for good reason—Defendants’ proposed interpretation does violence to the statutory text, conflicts with Defendants’ interpretation of

“research” outside the context of this litigation, and ignores the circumstances surrounding Dickey-Wicker’s enactment.

The statutory prohibition against funding any “research in which” embryos are destroyed necessarily encompasses *all* of the research project at issue, not merely a selected “phase” or “piece” of the research. Indeed, outside of this litigation, NIH and HHS have recognized that “research” encompasses the entire research process, and cannot be narrowed to include only individual tasks within a research project. For instance, in the Human Subject Protection Regulations—incorporated by Congress in the Dickey-Wicker Amendment—NIH defined “research” as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (SOF ¶ 46; 45 C.F.R. § 46.102(d); *see also* § 509(a)(2)(b), 123 Stat. at 3281.) And 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.*” (SOF ¶ 47; Dep’t of Health & Human Servs., *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html> (emphasis added).) What other view of “research” could HHS have had when it instructed that an institution that receives a grant for non-exempt human subjects research is still engaged in research involving human subjects *even if it does not directly interact with human subjects?*

Interpreting “research” to include only a portion of a research project is also inconsistent with courts’ use of that term. For instance, in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), the Supreme Court, in analyzing the scope of the research exemption under the patent statute, acknowledged that “research” is a multi-phase process rather than a single

experiment: “There is simply no room in the statute for excluding certain information from the exemption on the basis of *the phase of research* in which it is developed or the particular submission in which it could be included.” *Id.* at 202 (emphasis added); *see also Nat’l Ctr. for Mfg. Scis., Inc. v. City of Ann Arbor*, 563 N.W.2d 65, 68 (Mich. Ct. App. 1997) (agreeing that “research is not limited to a specific experiment” but includes “other critical steps in the research process [such as] the definition of the research agenda, raising the money to perform the necessary experiments, and the monitoring and evaluation of the results”). Thus, Defendants’ counsel’s “piece of research” argument is without merit.

Defendants’ “piece of research” argument is further belied by the fact that Congress prohibited funding not only for research in which embryos are “destroyed,” but also research in which embryos are “discarded.” § 509(a)(2), 123 Stat. at 3280. Plainly, therefore, Congress understood that the term “research” as used in Dickey-Wicker extends broadly to include the act of discarding an embryo as part of a research project, and Congress undoubtedly intended to ban federal funding of any projects that entailed such action. Defendants’ interpretation, by contrast, would render this prohibition meaningless, because the funding prohibition would apply only to the mere act of discarding the embryo; the remainder of the research project could be funded, an absurd result that Congress could not possibly have intended when it enacted Dickey-Wicker.

Indeed, the Guidelines themselves acknowledge that the act of destroying embryos is integral to, and inextricable from, “research” involving embryonic stem cells, because the Guidelines regulate the process by which embryos are selected and ultimately destroyed for purposes of federally-funded research. *See Fed. Reg.* 32,170 (noting that “the Guidelines pertain primarily to the donation of embryos for the derivation of [human embryonic stem cells]”). The Guidelines require that NIH-funded researchers delve into the matter of derivation to ensure that

the process by which the embryos were selected for destruction was in accordance with the Guidelines. *See* 74 Fed. Reg. at 32,174 § II(A) (providing that applicant institutions “proposing research” using human embryonic stem cells may either use human embryonic stem cell lines posted on the NIH registry or “establish eligibility” for funding by “submitting an assurance of compliance” with § II(A) of the Guidelines and setting forth the criteria for how “[human embryonic stem cells] should have been derived from human embryos”). Defendants cannot plausibly contend that the embryonic stem cell research that they propose to fund is wholly separate and distinct from the destruction of human embryos while at the same time regulating the process by which embryos are destroyed, and requiring that NIH-funded researchers investigate the same.

Defendants’ interpretation also defies common sense. 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. 74 Fed. Reg. at 32,173 (“[it] is not always possible, nor is it required” that the in vitro fertilization “doctor and the researcher seeking donation . . . be different individuals”); *id.* at 32,174 (“[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*” (emphasis added)); SOF ¶ 42. To suggest that a federal grant recipient is not engaged in “research in which” a human embryo is destroyed when the researcher conducts a study that entails derivation of the stem cells—and hence destruction of an embryo—as the essential initial step of the research effort barely passes the straight-face test. *See Harbor Gateway Commercial Prop. Owners Ass’n v. EPA*, 167 F.3d 602, 606 (D.C. Cir. 1999) (rejecting the EPA’s interpretation of

an appropriations rider because “there [was] no reason to mistrust the common sense understanding of the statutory language” (internal quotation omitted)).

(c) The Guidelines Violate Dickey-Wicker Because They Knowingly Subject Human Embryos to Risk of Death or Injury by Incentivizing the Destruction of Additional Embryos

Even assuming that the word “research” could be limited to a specific “piece” of that research, the Guidelines would still violate Dickey-Wicker. Defendants’ interpretation also ignores the statutory prohibition against funding “research in which” embryos are “knowingly subjected to risk of injury or death.” § 509(a)(2), 123 Stat. at 3280. It cannot be denied that the Guidelines, and the federally funded research that they contemplate, have created a need for additional, newly derived human embryonic stem cells, and thus for the destruction of additional human embryos. As a consequence, it is incontrovertible that by funding embryonic stem cell research, Defendants (and the researchers they fund) are knowingly subjecting additional embryos to risk of death.

A person does not need to *intend* a consequence in order to act “knowingly”—he need only set in motion a chain of events that ultimately leads to a foreseeable result. *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)). Under NIH’s Guidelines, grant-awarding officials and federally funded researchers will “knowingly subject” human embryos “to risk of injury or death” by funding and conducting embryonic stem cell research that inevitably creates a substantial risk—indeed, a virtual certainty—that more human embryos will be destroyed in order to derive more embryonic stem cells for research purposes. Whenever a privately funded researcher destroys an embryo in order to satisfy a request for embryonic stem cells from a federally funded scientist—a practice allowed under NIH’s

Guidelines—the public scientist knows that his request, which is an integral part of his research, will subject living human embryos “to risk of injury or death.” Similarly, by awarding new grants for such research, NIH officials inevitably create demand for additional, newly derived stem cells. Thus, there can be no question that NIH officials are knowingly subjecting human embryos to risk of death. Indeed, the Guidelines—by regulating the process by which those embryos are selected for destruction—explicitly contemplate the destruction of additional embryos for purposes of federally funded research. *See* 74 Fed. Reg. at 32,174. The Guidelines therefore violate the Dickey-Wicker Amendment even under NIH’s interpretation of the statutory language.

(d) Dickey-Wicker’s Ambiguous Legislative History Cannot Eclipse the Unambiguous Statutory Text

Unable to reconcile the Guidelines with Dickey-Wicker’s plain language, Defendants have previously relied on bits of legislative history in an effort to shift focus away from the statutory text. But reference to legislative history is inappropriate when—as here—the text of a statute is unambiguous. *Dep’t of Hous. & Urban Dev. v. Rucker*, 535 U.S. 125, 132 (2002); *see also United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 494 (D.C. Cir. 2004) (Roberts, J.) (stating that “[l]egislative history is irrelevant to the interpretation of an unambiguous statute” (quoting *Davis v. Mich. Dep’t of Treasury*, 489 U.S. 803, 808–09 n.3 (1989))).

There are, to be sure, statements in the legislative history supporting Defendants’ interpretation. *See, e.g.*, Statement of Sen. Specter, 145 Cong. Rec. S11585-07, *S11586 (Sept. 29, 1999). But numerous statements support Plaintiffs’ interpretation as well. For example, the Amendment’s co-author, Congressman Jay Dickey, has explained that federal funding of embryonic stem cell experiments that incentivizes the destruction of human embryos

“undermines the spirit and letter of the law.” Special Hearing on Stem Cell Research: Hearing before the Subcommittee on Labor, Health, and Education of the S. Comm. on Appropriations, 106 Cong. 9–10 (Nov. 4, 1999).⁶ Legislative history is therefore unhelpful because it “supports conflicting inferences and provides scant illumination.” *Carter v. United States*, 530 U.S. 255, 271 n.9 (2000); *see also Lamie v. U.S. Trustee*, 540 U.S. 526, 539–42 (2004) (resting holding on the statutory text because the statute’s legislative history “create[d] more confusion than clarity about the congressional intent”). This only “further confirms the wisdom of relying on the *legislative text* to determine the purpose of [the statute].” *Nat’l Ass’n of Mfrs. v. Taylor*, 582 F.3d 1, 13 (D.C. Cir. 2009) (emphasis added).

In any event, as Justice Scalia has explained, statements in House committee reports “tell us nothing about what [a] statute means, since (1) we do not know that the members of the Committee read the Report, (2) it is almost certain that they did not vote on the Report . . . , and (3) even if they did read and vote on it, they were not, after all, those who made th[e] law. The statute . . . is a law because its text was approved by a majority vote of [Congress], and was signed by the President.” *Milavetz, Gallop & Milavetz v. United States*, 130 S. Ct. 1324, 1341–42 (2010) (Scalia., J., concurring in part). Defendants cannot evade the unambiguous meaning

⁶ *See also, e.g.*, Statement of Rep. Schaffer, 145 Cong. Rec. E1696-02, 1696-97 (July 30, 1999) (“While HHS has tried to rewrite the current law on embryo research, it is clear that Congress has prohibited all funding of ‘research in which’ embryos are destroyed or discarded. Simply stated, the taxpayer funding of research which relies on the intentional killing of human beings would violate the law.”); Statement of Sen. Brownback, 147 Cong. Rec. S6393-01, 6394 (July 19, 2004) (expressing same view); *id.* (placing in the record a letter from twenty Senators to NIH urging the agency to withdraw the “Clinton-era guidelines which call for the destruction of human embryos for the purpose of subsequent Federal funding for the cells that have been derived from the process of embryo destruction” because they were “contrary to the law and Congressional intent,” and stating that “[c]learly, the destruction of human embryos is an integral part of the contemplated research, in violation of the law”).

of the statute based on snippets or inferences drawn from legislative history. “If Congress wished to achieve that result, it needed to enact different statutory language. It c[an]not achieve that result, in the face of the statutory language it enacted, simply by inserting a passage in a committee report.” *Penn. Protection & Advocacy, Inc. v. Houston*, 228 F.3d 423, 427–28 (3d Cir. 2000) (Alito, J.).

2. No Deference Is Due Defendants’ Interpretation of Dickey-Wicker’s Unambiguous Terms

Defendants also have claimed previously that their interpretation of Dickey-Wicker is entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984). (Mem. in Support of Defs.’ Mot. to Dismiss, and in Opp’n to Pls.’ Mot. for Prelim. Inj. at 30 [Dkt. #23].) As this Court has already stated, no such deference is due.

First, the statute plainly prohibits the funding of “research in which” embryos are destroyed or knowingly threatened. Because “Congress has directly spoken to the precise question at issue,” “that is the end of the matter,” and no deference is due to Defendants’ contrary interpretation. *Chevron*, 467 U.S. at 842–43; *see also Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) (“Even for an agency able to claim all the authority possible under *Chevron*, deference to its statutory interpretation is called for *only* when the devices of judicial construction have been tried and found to yield no clear sense of congressional intent.” (emphasis added)); Dkt. #44, at 10 (“Congress has spoken to the precise question here—whether federal funds may be used for research in which an embryo is destroyed.”).

Second, even if there were some ambiguity in the statute (which there is not), Defendants would plainly deserve no such deference here, because neither NIH nor HHS has ever proffered an authoritative interpretation of “research” that this Court could analyze for reasonableness under *Chevron*. (See SOF ¶ 49.) To receive deference, an agency must in fact interpret the

statutory provision in question, *Pub. Citizen, Inc. v. Dep't of Health & Human Servs.*, 332 F.3d 654, 661 (D.C. Cir. 2003), and must do so in a rule “carrying the force of law,” *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). But instead of setting forth an interpretation of “research,” the Defendants contend in the Guidelines that their funding of embryonic stem cell research does not violate Dickey-Wicker because “[human embryonic stem cells] are not embryos as defined by Section 509.” 74 Fed. Reg. at 32,173. The relevant question is not whether embryonic stem cells are embryos, however, but whether the derivation of those cells occurs as part of “research” that receives funding. Because the agencies have never answered *that* question in a rule carrying the force of law (*see* SOF ¶ 49), there is no interpretation to which this Court can defer. *Chevron* deference does not operate in a vacuum. *See, e.g., Pub. Citizen*, 332 F.3d at 661 (holding that *Chevron* was “inapplicable”—even though the agency’s guidance “does contain a reference” to the statute at issue—because “there is no place in the manual where the agency explains *why* it believes that [its conclusion] satisfies the statut[e]”).⁷

⁷ 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; *Chevron* does not authorize courts to guess at what an agency had in mind. *See Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 420 (1992) (deferring to the ICC’s interpretation of the word “required” because it “was a necessary presupposition of the ICC’s decision” and “the only reasonable reading of the Commission’s opinion,” and noting that “neither party contend[ed] that the ICC’s decision was not informed and governed by th[e] statutory interpretation”). Here, Defendants have given no indication that they ever considered whether the derivation of embryonic stem cells occurs as part of federally funded “research” that destroys or knowingly subjects human embryos to the risk of injury or death, or whether Defendants’ funding of embryonic stem cell research “knowingly subject[s]” embryos to risk of harm. *Cf. Pub. Citizen*, 332 F.3d at 661 (holding that *Chevron* was “inapplicable”—even though the agency’s guidance “does contain a reference” to the statute at issue—because “there is no place in the manual where the agency explains *why* it believes that [its conclusion] satisfies the statut[e]”).

It is only in this litigation that Defendants' *counsel* for the first time have attempted to articulate why embryonic stem cell research that depends on the further destruction of human embryos is consistent with Dickey-Wicker—because, according to counsel, “research” can mean a “piece of research.” But that interpretation has *never* been offered in any official agency statement promulgated through notice-and-comment procedures (*see* SOF ¶ 49(a)), and the law is clear that agencies are not entitled to deference for interpretations offered by their counsel in legal briefs. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) (“[W]e have declined to give deference to an agency counsel’s interpretation of a statute where the agency itself has articulated no position on the question, on the ground that Congress has delegated to the administrative official and not to appellate counsel the responsibility for elaborating and enforcing statutory commands.” (internal quotation omitted)); *City of Kansas City v. Dep’t of Hous. & Urban Dev.*, 923 F.2d 188, 192 (D.C. Cir. 1991) (refusing to award *Chevron* deference to a “*post hoc* rationale developed as part of a litigation strategy”); *Pub. Citizen*, 332 F.3d at 661.

Finally, even if post-hoc explanations in legal briefs could receive deference, Defendants’ counsel’s “interpretation” would not merit any here because it is not based on an exercise of the agencies’ expertise, but rather on a definition cribbed from a dictionary. (Defs’ Mot. to Dismiss at 31 [Dkt. #23].) An agency cannot “rest simply on its parsing of the statutory language—it must bring its experience and expertise to bear in light of competing interests at stake.” *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (internal quotation and alteration omitted); *see also Crowley v. Fed. Bureau of Prisons*, 312 F. Supp. 2d 453, 459 (S.D.N.Y. 2004) (“*Mead* and *Chevron* explain . . . a key rationale behind affording deference to agencies is that their interpretations are properly informed by their experience and their expertise.”).

Defendants have utilized no such experience or expertise here. The only explanation Defendants have offered for their counsel’s interpretation of “research” is their counsel’s dictionary definition of that term—that “research” can mean a “piece of research.” Putting aside the tautological nature of that definition—under which “research” means “research”—Defendants’ counsel’s simple parsing of the statute is not the kind of application of agency expertise that merits judicial deference. *See Alarm Indus. Commc’ns Comm. v. F.C.C.*, 131 F.3d 1066, 1069 (D.C. Cir. 1997) (holding that an agency is afforded no deference when it attempts to give “its meaning to the provision on the basis of a dictionary”). Any party can consult a dictionary; an agency must bring its particular expertise to bear. Because Defendants have not done so here, they are not due any deference (*Chevron*, *Skidmore*, or otherwise).⁸

IV. Defendants Promulgated the Guidelines in Violation of the Administrative Procedure Act

In response to the Draft Guidelines, Defendants received almost 50,000 public comments on various aspects of the proposed decision to fund embryonic stem cell research and the manner in which to fund such research. (See SOF ¶ 37; Nat’l Institutes of Health, *Listing of Comments on Draft NIH Human Stem Cell Guidelines*, http://grants.nih.gov/stem_cells/web_listing.htm? (last visited Aug. 16, 2010).) It is incontrovertible that Defendants were required to consider and respond to these comments and to “examine the relevant data and articulate a satisfactory explanation for [their] action including a ‘rational connection between the facts found and the

⁸ In *Mead*, the Supreme Court noted that even where an agency’s interpretation is not entitled to *Chevron* deference, that interpretation may still be entitled to some “respect proportional to its ‘power to persuade’” where the agency “bring[s] the benefit of specialized experience to bear on the subtle questions in th[e] case.” *Mead*, 533 U.S. at 235 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Because NIH has not brought its “specialized experience to bear,” however, its interpretation is not entitled even to *Skidmore* deference.

choice made.”” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 158 (1962)).

Defendants plainly did not satisfy these requirements in promulgating the Guidelines. The President ordered Defendants to fund only stem cell research that is “responsible” and “scientifically worthy,” 74 Fed. Reg. 10,667 (attached as Aden Decl., Ex. A), and Defendants received numerous public comments explaining why *human* embryonic stem cell research is neither ethically responsible nor scientifically worthy. (SOF ¶¶ 28(x)–(hh), 32(d)–(g), 32(m); *see, e.g.*, Aden Decl., Ex. D; *see also* Aden Decl., Ex. F at 1–2.) Those comments explained that scientifically valid alternatives to embryonic stem cell research exist that present far greater promise for success and that do not raise the same serious ethical problems. (*See, e.g.*, Aden Decl., Ex. D at 9–10, 18, G-4 to G-8, H-1 to H-4.) But Defendants ignored the comments in the administrative record and failed to articulate any reasoned basis for funding embryonic stem cell research instead of these scientifically and ethically superior alternatives. In doing so, Defendants acted arbitrarily and capriciously and failed to follow procedures prescribed by law. Summary judgment should therefore be entered in favor of the Plaintiffs.

A. Defendants’ Promulgation of the Guidelines Was Arbitrary and Capricious and Violated Procedures Required by Law

An agency acts arbitrarily and capriciously and violates procedures required by the APA when it fails to respond to relevant and “significant” public comments. *See Am. Mining Cong. v. EPA*, 907 F.2d 1179, 1190–91 (D.C. Cir. 1990). Defendants completely ignored every public comment categorically objecting to funding of embryonic stem cell research, despite the fact that those comments plainly were relevant to the proposed rulemaking and raised significant questions about the ethical and scientific problems with such research. *See infra* note 9. If Defendants had considered the comments, they would have been exposed to a wealth of

literature and information demonstrating that non-embryonic stem cell research programs are ethically and scientifically superior to embryonic stem cell research as a categorical matter. Because Defendants failed to examine the relevant data and articulate a satisfactory explanation for the decision to fund embryonic stem cell research, they acted arbitrarily and capriciously within the meaning of 5 U.S.C. § 706(2)(A), and violated procedures required by law. Accordingly, the Guidelines must be set aside.

NIH's stated purpose in promulgating the Guidelines was to ensure that NIH funding is "ethically responsible, scientifically worthy, and conducted in accordance with applicable law," 74 Fed. Reg. at 32,170, which echoes the President's salutary goal of ensuring that "scientific data is never distorted or concealed to serve a political agenda—and that we make scientific decisions based on facts, not ideology," President Barack Obama, Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum (attached as Aden Decl., Ex. O). Yet Defendants allowed ideology, not facts, to drive their decision to fund research that is ethically objectionable and scientifically dubious.

During the public comment period, Defendants received numerous comments detailing the many *scientific* problems with human embryonic stem cell research. (*E.g.*, SOF ¶ 28(y)–(ff); Aden Decl., Ex. D at 11–13, G-1, G-8, I-1 to I-11.) For example, embryonic stem cells form tumors (SOF ¶ 28(aa)–(cc); Aden Decl., Ex. D at I-2 to I-3), and they do not differentiate into the type of cells needed for therapeutic treatments (SOF ¶ 28(y); Aden Decl., Ex. D at I-1). As a result, they are biologically inadequate replacements for lost adult cells. (SOF ¶ 28(ff); Aden Decl., Ex. D at I-1.)

As the comments in the record before the agency demonstrate, these serious problems simply do not plague the use of adult stem cells, which “provide or promise to provide actual cell-based therapies that will lead to beneficial results for patients” (SOF ¶ 28(b); Aden Decl., Ex. D at 2.) Importantly, adult stem cells do not cause tumors when used in treatment. (SOF ¶ 28(k); Aden Decl., Ex. D at G-8.) Accordingly, adult stem cell research is an ethically superior alternative and “worthy scientific priority meriting federal funding” (SOF ¶ 32(n); Aden Decl., Ex. D at 9.)

The NIH also received comments regarding recent breakthroughs with respect to induced pluripotent stem cell lines that obviate any alleged need for ethically problematic research using human embryonic stem cells. The comments explained that induced pluripotent stem cells are produced by genetically reprogramming mature cells yet are essentially indistinguishable from embryonic stem cells for research purposes, and so they offer all the purported benefits of embryonic stem cell research (and more) without creating the same ethical problems. (SOF ¶ 28(m)–(p), (v)–(w); Aden Decl., Ex. D at 10–11; *see also* SOF ¶ 63.)

Notwithstanding the extensive comments in the administrative record demonstrating these glaring weaknesses of embryonic stem cell research and the categorical superiority of adult stem cell research and induced pluripotent stem cell research, NIH failed to offer any explanation for its decision to devote limited federal research funds to embryonic stem cell research. The agency thus failed to justify its decision in light of its own stated criterion that the Guidelines would fund only “scientifically worthy” research.

The comments also establish the myriad *ethical* problems posed by human embryonic stem cell research. Such research necessarily involves the killing of the human embryo from which the embryonic stem cells are harvested. (*See* SOF ¶¶ 45(c), 50; Aden Decl., Ex. D at 5.)

For this reason, as the National Bioethics Advisory Commission—created by President Clinton and whose members the President appointed (*see* Executive Order 12,975, 60 Fed. Reg. 52,063 (Oct. 5, 1995)—explained, “derivation of stem cells from embryos remaining following infertility treatments is justifiable *only* if no less morally problematic alternatives are available for advancing the research.” Nat’l Bioethics Advisory Comm’n, 1 *Ethical Issues in Human Stem Cell Research* 53 (Sept. 1999) (attached as Aden Decl., Ex. P). Adult and induced pluripotent stem cell research, by contrast, do not require this destruction of human embryos, and are therefore ethically superior forms of research. (*See* SOF ¶¶ 28(d), 28(m), 28(o), 28(w), 32(n); *see, e.g.*, Aden Decl., Ex. D at 9–10, H-3.)

Under the APA, NIH was required to “respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments, and to show how that resolution led the agency to the ultimate rule.” *Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216 (D.C. Cir. 1983) (internal quotation marks omitted). Despite that requirement, Defendants ignored all comments objecting categorically to embryonic stem cell research.⁹ Defendants thus failed to “examine the relevant data and

⁹ Defendants received “approximately 49,000 comments” on the Guidelines, 74 Fed. Reg. at 32,170; *see* SOF ¶ 37, including “[a]bout 30,000” comments “debat[ing] *whether* the NIH should be funding embryonic stem cell research” at all (Aden Decl., Ex. F (emphasis added); SOF ¶ 38). But Defendants admitted that they “disregarded all such comments” (60 percent of the total comments), instead branding such comments “unresponsive,” because, as NIH’s then-Director explained, “[NIH] actually did not ask the public *whether* we should fund research on human embryonic stem cells. [NIH] asked the public *how* we should fund human embryonic stem cell research.” (SOF ¶¶ 38 & 38(a); Aden Decl., Ex. F (emphases added and internal quotation marks omitted).) Indeed, Defendants argued before this Court that NIH “properly ignored . . . the relative merits” of human embryonic stem cell research (Defs.’ Memo. in Support of Mot. to Dismiss at 44 [Dkt. #23]; SOF ¶ 39), and that “NIH responded appropriately to comments that were relevant to the formulation of the Guidelines, namely, comments that addressed the

[Footnote continued on next page]

articulate a satisfactory explanation for its action, including a rational connection between the facts and the choice made,” *U.S. Telecom Ass’n v. FCC*, 227 F.3d 450, 461 (D.C. Cir. 2000) (internal quotation marks omitted), with respect to their decision to use limited funding for embryonic stem cell research.

In fact, although the record before the agency establishes as a categorical matter that adult and induced pluripotent stem cell research are scientifically and ethically superior alternatives, Defendants did not even acknowledge—much less explain away—the important scientific and ethical problems with embryonic stem cell research. Because Defendants have not proffered any valid reason for failing to “respond[] to significant points raised by the public,” *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35–36 (D.C. Cir. 1977), the Guidelines were promulgated arbitrarily and capriciously and “without observance of procedure required by law,” 5 U.S.C. § 706(2)(D); *Am. Mining Cong.*, 907 F.2d at 1190–91 (“[T]he agency’s failure to respond to . . . specific challenges in the record is fatal here, since ‘the points raised in the comments were sufficiently central that agency silence . . . demonstrate[s] the rulemaking to be arbitrary and capricious.’”); *see also Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992) (citing *State Farm*, 463 U.S. at 43). Indeed, NIH’s disregard of its own stated criteria—namely, its goals of funding only “scientifically worthy” and “ethically responsible” research—is the *essence* of arbitrary and capricious decision-making. *See, e.g., Am. Equity Inv. Life Ins. Co. v. SEC*, 572 F.3d 923, 934 (D.C. Cir. 2009) (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 (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87

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substance of the informed consent procedures that NIH proposed to establish” (Defs.’ Reply in Support of Mot. to Dismiss at 20 [Dkt. #32]; SOF ¶ 39).

(1943)); *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 815 (D.C. Cir. 1983).

Any post-hoc justification Defendants might now offer is plainly insufficient under the APA. *See, e.g., Bowen*, 488 U.S. at 212; *Chenery Corp.*, 318 U.S. at 87 (“The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based.”); *Fort Stewart Schs. v. Fed. Labor Relations Auth.*, 495 U.S. 641, 651–52 (1990) (“[I]t is elementary that if an agency’s decision is to be sustained in the courts on any rationale under which the agency’s factual or legal determinations are entitled to deference, it must be upheld on the rationale set forth by the agency itself.”). Even if there were good scientific and ethical reasons to authorize funding of embryonic stem cell research (and there are not), Defendants were required to *explain* such reasons in response to the numerous comments in the administrative record that establish the categorically unethical and scientifically unworthy nature of human embryonic stem cell research. Because Defendants offered no such explanation or justification, the Guidelines must be set aside.

B. Defendants Entered the Comment Period with an Unalterably Closed Mind

The Guidelines are invalid for the additional reason that Defendants, by their own admission, entered the rulemaking period having already made the decision to fund embryonic stem cell research. Agencies cannot fulfill their duty to consider important comments, *see* 5 U.S.C. § 553(c), when the key agency decision maker “has an unalterably closed mind on matters critical to the disposition of the proceeding.” *Ass’n of Nat’l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979). Defendants in this case have admitted their minds were closed with respect to the question whether to fund embryonic stem cell research, and the Guidelines should therefore be invalidated.

Even before the comment period began, Acting NIH Director Raynard Kington¹⁰ 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.” (SOF ¶ 25; Aden Decl., Ex. I [Gautam Naik, *NIH Offers Rules for Embryonic Stem Cell Research*, Wall St. J., Apr. 17, 2009] (emphasis added)). And, as noted, Kington admitted after the Guidelines had been promulgated that he and the agency had ignored all public comments that addressed the question whether to fund embryonic stem cell research. (See SOF ¶ 38; Aden Decl., Ex. F at 1–2.) Kington claimed that NIH “did not ask the public” for input on that question. (SOF ¶ 38(a); Aden Decl., Ex. F at 2.)

This closed-minded approach plainly violated Defendants’ duty under the APA. See 5 U.S.C. § 553(c). In *Nehemiah Corp. of America v. Jackson*, 546 F. Supp. 2d 830, 847–48 (E.D. Cal. 2008), the court determined that Housing and Urban Development Secretary Jackson had entered a rulemaking proceeding with an “unalterably closed mind” about the merits of a proposed rule. During the comment period, a Bloomberg News report quoted Secretary Jackson as stating his views on the proposed rule and claiming that the agency “intend[ed] to approve the new rule by the end of the year even if the agency receive[d] critical comments.” *Id.* at 847. Based on these statements, the court ordered that Secretary Jackson be excluded from the decision-making process on remand to the agency. *Id.* at 849.

Kington’s actions in this case are far more egregious than those in *Nehemiah*. Indeed, Defendants have never disputed that they entered the rulemaking process already set on funding embryonic stem cell research—the only open question was *how* they would achieve that pre-

¹⁰ Kington served as the Acting Director of NIH from October 31, 2008 to August 7, 2009, when the Senate confirmed Dr. Francis Collins as the new Director of NIH.

determined goal. (See SOF ¶ 38(a); Aden Decl., Ex. F (“[NIH] actually did not ask the public whether we *should* fund research on human embryonic stem cells. We asked the public *how* we should fund human embryonic stem cell research.” (emphasis added))). This plainly violated the APA, and the Guidelines must therefore be set aside.

C. The Executive Order Did Not and Could Not Exempt Defendants from the Requirements of the APA

Defendants have not even suggested that they considered the comments they received that explain why human embryonic stem cell research is, as a categorical matter, neither ethically responsible nor scientifically worthy. Instead, Defendants have claimed, both before this Court and on appeal, that President Obama’s order did not leave them discretion to consider whether to fund embryonic stem cell research. (See Defs.’ Memo. in Support of Mot. to Dismiss at 43 [Dkt. #23]; Defs.’ Br. on Appeal at 15, 29–30.) But Defendants are incorrect, both factually and legally. The President’s Executive Order did *not* remove Defendants’ discretion to decide whether to fund embryonic stem cell research; and even if it had purported to do so, the President could not free Defendants of their obligations under the APA.

1. The President Did Not Direct Defendants to Fund Embryonic Stem Cell Research and Therefore Defendants Violated the APA by Failing to Explain Why They Rejected Comments with Categorical Objections to Such Funding

The Executive Order contained no directive to fund human embryonic stem cell research. The Order speaks in explicitly non-mandatory terms, stating that NIH “*may*” support “responsible, scientifically worthy” stem cell research (SOF ¶ 20; 74 Fed Reg. 10,667 § 2 (attached as Aden Decl., Ex. A)); it did not state NIH *shall* support *all* forms of such research. See *United States v. Rodgers*, 461 U.S. 677, 706 (1983) (the term “*may*” is usually discretionary). Moreover, the Order directs Defendants to issue guidance on “*human stem cell*

research,” not specifically on human *embryonic* stem cell research. (SOF ¶ 20; 74 Fed. Reg. 10,667 § 3.)

In short, the Order states that Defendants may support “*responsible, scientifically worthy* human stem cell research, including human embryonic stem cell research.” (SOF ¶ 20; 74 Fed. Reg. 10,667 § 2.) NIH was therefore free, within the framework of the APA and in light of the comments received, to determine whether embryonic stem cell research is “responsible” and “scientifically worthy,” but the Order did not purport to absolve Defendants of the task of determining whether embryonic stem cell research satisfies these criteria. It was incumbent on Defendants to determine whether embryonic stem cell research ever meets the criteria required by the President, and to bring their “experience and expertise to bear in light of competing interests at stake.” *Peter Pan Bus Lines, Inc.*, 471 F.3d at 1354. They plainly failed to do so.

To comply with the requirements of the APA, the Defendants needed to confront whether, *as a categorical matter*, embryonic stem cell research was both scientifically worthy and ethically responsible. There were numerous public comments arguing that embryonic stem cell research is not scientifically worthy or ethically responsible *as a categorical matter*. (See, e.g., SOF ¶¶ 28(hh), 32(m); Aden Decl., Ex. D at 11, 18, J-3 to J-5.) By determining, in the Guidelines, that such research is at least *sometimes* scientifically worthy and ethically responsible, Defendants rejected these comments.

Defendants have argued previously that the Guidelines simply postponed all categorical decisions on research until the application stage, but that is simply not true. As promulgated, the Guidelines contain several categorical limitations. For example, the Guidelines categorically prohibit the use of any funds for cloning or breeding of animals (SOF ¶ 43; 74 Fed. Reg. at 32,175, §§ IV, V), presumably for ethical reasons. And they mandate that “[n]o payments, cash

or in kind [may be] offered for the donated embryos” (SOF ¶ 44; 74 Fed. Reg. at 32,175, § II.A.3.b), also for ethical reasons, it would appear. Thus, Defendants adopted those categorical limitations with which they agreed. By the same token, they necessarily rejected those comments arguing that human embryonic stem cell research is, as a categorical matter, scientifically unworthy and ethically irresponsible—yet they have offered no explanation for doing so. This is a plain violation of the APA.

Finally, the President’s Order states that Defendants may fund stem cell research only “*to the extent permitted by law,*” and the Order makes crystal clear that it “shall be implemented *consistent with applicable law.*” (SOF ¶ 20; 74 Fed Reg. 10,667 §§ 2, 4 (emphases added).) The Order therefore explicitly requires that Defendants follow all applicable law—including the APA—when deciding whether to make such research eligible for funding. *See Natural Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 765 (3d Cir. 1982) (“[Executive Order] 12291 says nothing about the notice and comment requirements of the APA, and does not attempt to authorize an agency to act without complying with those requirements. Rather, [Executive Order] 12291 specifically states that any action taken pursuant to it must be in compliance with applicable law.”). Defendants thus had no purported Presidential mandate to ignore the APA.

2. The President Cannot Authorize Agencies to Disregard the Requirements of the APA

Even if the President had directed Defendants to fund embryonic stem cell research without regard to the merits of such research, without engaging in reasoned decision-making, and without responding to significant public comments, such a directive would not insulate the Guidelines from review under the APA. To the contrary, the fact that the Guidelines “are based on the President’s Executive Order hardly seems to insulate them from judicial review under the APA, even if the validity of the Order were thereby drawn into question.” *Chamber of*

Commerce of the U.S. v. Reich, 74 F.3d 1322, 1327 (1996), *modified on other grounds*, 83 F.3d 439 (D.C. Cir. 1996).

It is undisputed that the notice-and-comment rulemaking requirements of 5 U.S.C. § 553(c) govern Defendants' decision to issue the Guidelines here. Nothing in the APA authorizes the President to direct an agency to violate the APA by ignoring relevant public comments during the rulemaking process, or in any way exempts an agency's actions from APA review even if the policy was dictated by the President. *See Reich*, 74 F.3d at 1328 ("Even if [an agency] 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.'" (quoting *Soucie v. David*, 448 F.2d 1067, 1072 n.12 (D.C. Cir. 1971))). Accordingly, even if the President had ordered Defendants to fund embryonic stem cell research without regard to whether such research is ethically and scientifically unworthy of funding (which he clearly did not), Defendants would still be bound by the procedural requirements of the APA, including the requirement that they articulate a reason for rejecting the numerous comments establishing that such funding is inappropriate under Defendants' own criteria.

There are no disputed facts that are material to resolution of this issue—it is undisputed that Defendants received the comments and that they failed to respond. Defendants' only purported explanation for failing to respond is that they thought the President directed them to fund embryonic stem cell research. But as set forth above, that excuse is neither correct nor a sufficient justification for Defendants' actions, and summary judgment in favor of Plaintiffs is therefore required.

V. Permanent Injunctive Relief Is Necessary and Appropriate

Because the NIH Guidelines violate federal law, Plaintiffs respectfully request that this Court issue a permanent injunction to restrain Defendants' ongoing legal violations and halt the serious harm now being suffered by Plaintiffs. In granting Plaintiffs' motion for a preliminary injunction, this Court has already thoroughly addressed the requirements for granting such equitable relief. *Sherley v. Sebelius*, No. 1:09-cv-1575 (RCL), 2010 U.S. Dist. LEXIS 86441, at *20–23 (D.D.C. Aug. 23, 2010). In the short period of time since this Court issued its preliminary injunction, nothing has changed that would require a different result. Further, just two days ago, this Court denied Defendants' motion to stay the preliminary injunction. (Order of Sept. 7, 2010 [Dkt. #53].) In issuing a preliminary injunction, the Court found that “a stay would flout the will of Congress, as this Court understands what Congress has enacted in the Dickey-Wicker Amendment.” *Id.* at *1. Plaintiffs' present submission shows definitively that the NIH Guidelines violate both the Dickey-Wicker Amendment, as this Court has already indicated, and the Administrative Procedure Act. There is no genuine question of fact as to the illegality of the NIH Guidelines. As a result, upon declaring the Guidelines invalid, this Court should also grant permanent injunctive relief.

When deciding whether to issue a permanent injunction, a district court must consider the following factors: (1) success on the merits; (2) whether the plaintiff will suffer irreparable injury absent an injunction; (3) the balance of the hardships (including harm to defendant and other interested parties); and (4) the public interest. *ACLU v. Mineta*, 319 F. Supp. 2d 69, 87 (D.D.C. 2004) (“In determining whether to enter a permanent injunction, the Court considers a modified iteration of the factors it utilizes in assessing preliminary injunctions: [listing factors above].”); *see Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 44 (D.D.C. 2002). The court should apply essentially the same standard when granting *permanent* injunctive relief as

when granting *preliminary* injunctive relief, except that a plaintiff must show actual success on the merits, as opposed to a likelihood of success. *Mineta*, 319 F. Supp. 2d at 87; *see Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n.12 (1987) (“The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success.”); *Nat’l Mining Ass’n v. U.S. Army Corps of Eng’rs*, 145 F.3d 1399, 1408–09 (D.C. Cir. 1998). Accordingly, after declaring its conclusion that the Guidelines are invalid, this Court should also grant permanent injunctive relief. This Court has already considered the requirements for preliminary injunctive relief, after full briefing and oral argument, and those same considerations support Plaintiffs’ request for permanent relief.

A. Plaintiffs Can Show Actual Success on the Merits

For the reasons set forth in sections II–IV above, Plaintiffs are entitled to a declaratory judgment that the Guidelines are invalid under the Dickey-Wicker Amendment and/or were not promulgated in accordance with the Administrative Procedure Act. Obviously, such a declaration would constitute actual success on the merits for Plaintiffs. And when plaintiffs “prevail[] on the merits, permanent injunctive relief is the appropriate remedy” *Mineta*, 319 F. Supp. 2d at 87.

B. Equitable Considerations Support Permanent Injunctive Relief

The equitable considerations for granting injunctive relief continue to support Plaintiffs’ request for a permanent injunction. Absent a permanent injunction, Drs. Sherley and Deisher will continue to suffer irreparable harm. (*See* SOF ¶¶ 10–11.) Further, because the NIH Guidelines are illegal, the balance of hardships and the public interest weigh heavily in favor of granting Plaintiffs’ request for permanent injunctive relief. Only two weeks have passed since this Court issued its preliminary injunction to prohibit Defendants’ ongoing violations of federal

law and the equitable considerations have not changed in that short time. (*See* Pls.’ Memo. in Opp’n to Defs.’ Mot. to Stay Order Pending Appeal, at 12–20 (discussing the factors supporting a preliminary injunction which also counsel in favor of permanent injunctive relief) [Dkt. #51].) In denying Defendants’ motion for a stay of the preliminary injunction, this Court made clear that “Defendants are incorrect about much of their ‘parade of horrors’ that will supposedly result from this Court’s preliminary injunction.” (Order of Sept. 7, 2010, at *1 [Dkt. #53].) Twice this Court has examined the equitable considerations regarding injunctive relief, and both times the Court has found that they favor Plaintiffs’ request for injunctive relief.

1. Plaintiffs Would Suffer Irreparable Harm Absent a Permanent Injunction

Drs. Sherley and Deisher would suffer irreparable injury absent a permanent injunction. The NIH has a limited budget for funding scientific research that could lead to potentially life-saving medical breakthroughs (*see* SOF ¶¶ 5, 10), and Plaintiffs—as well as other adult stem cell researchers and the scientific community as a whole—must compete for those federal dollars (*see* SOF ¶¶ 9–11). As the D.C. Circuit has recognized, Plaintiffs suffer immediate and legally cognizable injury from being forced to compete with illegal grant applications, *see Sherley*, 610 F.3d at 70, 74, and they and other applicants should not have to face such illegal competition for a single additional day. As this Court found in its August 23 decision, the Guidelines, “by allowing federal funding of ESC research, increase[] competition for NIH’s limited resources.” *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *21. Therefore, adult stem cell researchers, such as Drs. Sherley and Deisher, would suffer “actual, imminent injury” if federal dollars continued to be diverted to embryonic stem cell research. *Id.* In addition, without a permanent injunction, “[t]here is no after-the-fact remedy for this injury because the Court cannot compensate plaintiffs for their lost opportunity to receive funds.” *Id.*; *see also Indep. Bankers Ass’n of Am. v. Smith*,

534 F.2d 921, 951 (D.C. Cir. 1976) (“[w]ithout the prophylactic effect of the district court’s injunction, each day [plaintiffs] would have suffered further economic and competitive injury . . .”).

The harm that will result absent a preliminary injunction is not merely pecuniary and is not limited to the Plaintiffs that appear before the Court. To the contrary, if Defendants are permitted to continue their illegal funding of human embryonic stem cell research under the invalid Guidelines, all adult and induced pluripotent stem cell researchers and all other lawful grant applicants for NIH research funding will continue to be forced to compete against illegal research applications and will continue to be denied funding for their own research projects that would otherwise have been funded—projects that could lead to potential cures and other medical and scientific breakthroughs. (*See* SOF ¶¶ 10–11, 28(b), 28(n).) Failure to grant a permanent injunction would also cause irreparable harm to American taxpayers, who would be forced to continue funding research projects for which the people’s elected representatives have barred federal funding in the Dickey-Wicker Amendment. Victims of disease and illness will continue to suffer because they will be denied the results of the beneficial research that would have been funded but for Defendants’ insistence on wasting federal tax dollars on speculative human embryonic stem cell research that is highly unlikely to produce actual cures. (*See* SOF ¶¶ 28(b)–(c), (e)–(f), (j)–(l), (n), (u)–(v), (y)–(ff).) Finally, the harm to the living human embryos that could be destroyed absent a permanent injunction—precisely the harm that the Dickey-Wicker Amendment was enacted to prevent—would be irreversible.

“Where [an] injury is both ‘threatened’ and ‘occurring’ at the time of the motion [for injunctive relief] and plaintiff is successful on the merits,” the court should issue permanent injunctive relief. *Mineta*, 319 F. Supp. 2d at 87. The actual and imminent injury suffered by

Plaintiffs due to the continued illegal federal funding of embryonic stem cell research, along with certain future injury absent an injunction, supports issuance of a permanent injunction.

2. The Balance of the Hardships Supports Permanent Injunctive Relief

As this Court previously found, the balance of the hardships also supports Plaintiffs' request for injunctive relief. On the one hand, Drs. Sherley and Deisher (and all other adult and induced pluripotent stem cell researchers and lawful NIH grant applicants) face a concrete and significant competitive injury due to Defendants' continued illegal funding of embryonic stem cell research. On the other hand, Defendants can only allege highly "speculative" and uncertain claims that individuals will be deprived of potential treatments developed through embryonic stem cell research at some unarticulated time in the future, or that embryonic stem cell researchers will seek other opportunities outside the United States. *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *21–22; *see also* Collins Decl. ¶¶ 5, 7, 12, 14.

Moreover, Defendants' claims of harm to third parties (embryonic stem cell researchers and persons seeking medical cures) rest on an utterly false dichotomy, namely the assumption that there is no alternative to funding embryonic stem cell research. As the administrative record in this case makes clear, however, there are such alternatives, including both adult and induced pluripotent stem cell research, and those alternatives are *more* likely to result in cures for debilitating diseases, and thus *more* likely to benefit patients. (SOF ¶¶ 28(b)–(l), 28(n), 28(q)–(v), 28(y)–(ff), 54–59, 68–69.) Defendants cannot invoke such speculative, unlikely, and contingent harms in opposition to Plaintiffs' request for a permanent injunction.

In short, nothing has changed in the two weeks since this Court previously held that the "balance of the hardships weighs in favor of an injunction." *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *21. And just two days ago, this Court reaffirmed that "Defendants are incorrect about much of their 'parade of horrors' that will supposedly result" (Order of Sept. 7, 2010, at

*1 [Dkt. #53].) Defendants have again failed to assert any concrete, tangible, or even likely harms to tilt the balance of hardships in their favor, and thus permanent injunctive relief is appropriate.

3. Permanent Injunctive Relief Would Serve the Public Interest

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

As this Court held in granting Plaintiffs’ motion for a preliminary injunction, the Dickey-Wicker Amendment clearly expresses Congress’ will to “prohibit federal funding of research in which human embryos are destroyed.” *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *17–19. In denying Plaintiffs motion for a stay of the preliminary injunction, this Court held that allowing the NIH Guidelines to continue in operation would “flout the will of Congress.” (Order of Sept. 7, 2010, at *1 [Dkt. #53].) “Congress has mandated that the public interest is served by preventing taxpayer funding of research that entails the destruction of human embryos,” and although Congress remains free to revise or amend the Dickey-Wicker Amendment, “[t]his

Court is not free to do so.” (*Id.*) An injunction that permanently prohibits Defendants from funding such research will “carry out the will of Congress” and thereby serve the public interest.

CONCLUSION

For the foregoing reasons, Plaintiffs’ motion for summary judgment should be granted, and the Court should enter judgment (1) declaring that the Guidelines are vacated and invalid because they are contrary to law, were promulgated without observing the procedures required by law, and constitute arbitrary and capricious agency action, and (2) enjoining any further implementation of the Guidelines.

Dated: September 9, 2010

Respectfully Submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

DR. JAMES L. SHERLEY, et al.,)	
)	
	Plaintiffs,)
)	
)	
)	
v.)	
)	Civil Action
)	No. 09-CV-01575-RCL
)	
)	
KATHLEEN SEBELIUS, et al.,)	
)	
	Defendants.)
)	
)	
)	

**PLAINTIFFS’ STATEMENT OF MATERIAL FACTS AS TO WHICH
THERE IS NO GENUINE DISPUTE**

1. Plaintiff Dr. James L. Sherley is an adult stem cell researcher. (Declaration of Dr. James L. Sherley in Support of Pls.’ Mot. for Summary Judgment (“Sherley Decl.”) ¶ 2.)
 - a. Dr. Sherley currently works at the Boston Biomedical Research Institute. (Sherley Decl. ¶ 2.)
 - b. Dr. Sherley does not conduct research on embryos or human embryonic stem cells. (Sherley Decl. ¶ 2.)
 - c. Dr. Sherley relies exclusively on research grants for funding. (Sherley Decl. ¶ 3.) The “vast majority” of grants he receives are from NIH. (*Id.*)
 - d. Since 1999, Dr. Sherley has applied for NIH funding approximately 42 times. (Sherley Decl. ¶ 3.)
 - e. Fourteen of Dr. Sherley’s research proposals have received NIH funding. (Sherley Decl. ¶ 3.)
 - f. Two of Dr. Sherley’s research proposals in which he is a principal investigator are currently pending. (Sherley Decl. ¶¶ 3, 4.)
 - g. Since 1999, Dr. Sherley has received only one significant private research award. (Sherley Decl. ¶ 3.)

- c. “[S]tem cell research . . . is included within the overall payline and funded . . . according to the particular proposals received and the funding available to the particular IC.” (Aden Decl., Ex. J ¶ 16.)
 - d. “[I]n the short run, the amount of money available from NIH for research grants is fixed notwithstanding the greater range of stem cell projects made eligible for funding by the Guidelines.” *Sherley*, 610 F.3d at 73(attached as Aden Decl., Ex. N); *see also* Aden Decl., Ex. J at ¶¶ 15-16.
6. Each application receives a preliminary score; in general, only the applications in the top half of all preliminary scores are discussed at the first level of peer review. (Aden Decl., Ex. J ¶ 11.)
 7. An application that is considered receives an actual score. (Aden Decl., Ex. J ¶ 11.) Based on this score “and the needs and mission of the particular funding component . . . , the Council or Board then recommends certain applications for funding.” (*Id.* ¶ 12.)
 8. NIH “uses specific funding or ‘targeted’ announcements to stimulate research in particular areas of science through use of an announcement called a ‘Request for Applications’ (RFA).” (Aden Decl., Ex. J ¶ 6.)
 9. The grant-application process is competitive, such that “[o]nly about 20 percent of applicants are successful in having their research proposals funded by NIH.” (Aden Decl., Ex. J ¶ 14.)
 10. The NIH Guidelines for Human Stem Cell Research (“Guidelines”) “have intensified the competition for a share in a fixed amount of money.” *Sherley*, 610 F.3d at 74 (attached as Aden Decl., Ex. N); *see also* *Sherley* Decl. ¶ 5; *Deisher* Decl. ¶ 4.
 11. As a result of the intensified competition caused by the Guidelines, “the plaintiffs will have to invest more time and resources to craft a successful grant application.” *Sherley*, 610 F.3d at 74 (attached as Aden Decl., Ex. N); *see also* *Sherley* Decl. ¶ 5; *Deisher* Decl. ¶ 4.
 12. “[Adult stem cells] and [embryonic stem cells] are substitutes in some uses.” *Sherley*, 610 F.3d at 74 (attached as Aden Decl., Ex. N); *see generally* Aden Decl., Ex. D at 9-10.
 13. The Dickey-Wicker Amendment provides that: “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)).” Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, 123 Stat. 3034, 3280-81, § 509(a).
 14. The Dickey-Wicker Amendment was enacted in direct response to efforts on the part of the National Institutes of Health (NIH) to begin funding research entailing the destruction of or undue risk to human embryos. (Aden Decl., Ex. D at 7.)

15. In early 1993, NIH Director Harold Varmus convened the Human Embryo Research Panel, which recommended that NIH fund research entailing risks to human embryos. (*See* Aden Decl., Ex. D at 6.)
16. Before NIH could approve any grants for human embryonic stem cell research, Congress passed the Dickey-Wicker Amendment for the first time. (Aden Decl., Ex. D at E-6.)
17. Congress has included the Dickey-Wicker Amendment without material change in every Health and Human Services (“HHS”) appropriations bill since 1996. (*See* Aden Decl., Ex. D at 7-8; *see also* Defs.’ Memo. in Support of Mot. to Dismiss at 37 [Dkt. #23].)
18. NIH attempted to fund embryonic stem cell research in 2000, when it finalized and made effective “Guidelines for Research Using Human Pluripotent Stem Cells” (“2000 Guidelines”). 65 Fed. Reg. 51,976 (Aug. 25, 2000).
19. In 2001, NIH formally withdrew the 2000 Guidelines, which had never been implemented. 66 Fed. Reg. 57,107 (Nov. 14, 2001); Aden Decl., Ex. D at E-2.
20. Executive Order 13,505 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,” and that “[w]ithin 120 days . . . [HHS and NIH] shall 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 this order.” 74 Fed. Reg. 10,667 (Mar. 11, 2009) (attached as Aden Decl., Ex. A).
21. The Executive Order also required that it “be implemented consistent with applicable law.” 74 Fed. Reg. 10,667 (Mar. 11, 2009) (attached as Aden Decl., Ex. A).
22. On April 23, 2009, NIH issued and requested comment on draft guidelines (“Draft Guidelines”) for human stem cell research. 74 Fed. Reg. 18,578 (Apr. 23, 2009) (attached as Aden Decl., Ex. B).
23. The Draft Guidelines’ stated purpose was “to help ensure that NIH-funded research [involving human embryonic stem cells] is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.” 74 Fed. Reg. 18,578.
24. The Draft Guidelines proposed the authorization of federal funding of human embryonic stem cell research. 74 Fed. Reg. 18,578.
25. In a telephone briefing with reporters after the Draft Guidelines were issued, Acting NIH Director Raynard Kington stated: “We will expand greatly the number of cell lines eligible for funding We know of several hundred cell lines that will meet the guideline standards.” (Aden Decl., Ex. I [Gautam Naik, *NIH Offers Rules for Embryonic Stem Cell Research*, Wall St. J., Apr. 17, 2009].)
26. In response to the Draft Guidelines, Do No Harm, et al., submitted Comments that detailed numerous scientific flaws associated with human embryonic stem cell research. (Aden Decl., Ex. D.)

27. Defendants received the Comments submitted by Do No Harm, et al., detailing the scientific problems associated with human embryonic stem cell research, and they are part of the administrative record. (Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm?StartID=47017 (last visited Aug. 16, 2010).)
28. The administrative record establishes the following scientific facts, as shown by the Do No Harm Comments:
- a. There are three general types of stem cells: embryonic, adult, and induced pluripotent. (*See* Aden Decl., Ex. D at 9-13.)
 - b. Adult stem cells “provide or promise to provide actual cell-based therapies that will lead to beneficial results for patients” (Aden Decl., Ex. D at 2.)
 - c. Adult stem cells have verifiably treated individuals suffering from a variety of diseases, including ovarian cancer, retinoblastoma, brain tumors, testicular cancer, chronic and acute leukemias, breast cancer, renal cell carcinoma, anemias, Crohn’s disease, rheumatoid arthritis, and juvenile diabetes. (Aden Decl., Ex. D at 9, G-4 to G-6)
 - d. Adult stem cells are found in the body and in tissues normally discarded after birth (such as umbilical cord blood and the placenta) that have the potential to generate most or all of the different tissues in the human body. (Aden Decl., Ex. D at 9.)
 - e. Adult stem cells can be harvested and grown in numbers sufficient for patient treatments. (Aden Decl., Ex. D at 9.)
 - f. Adult stem cells can provide matched tissue transplants, especially in the majority of cases where the patient’s own cells are used, and also in donor transplants. (Aden Decl., Ex. D at 9.)
 - g. “Some adult stem cells . . . show pluripotent flexibility in generation of tissues, meaning that they can generate most or all of the different tissues of the body.” (Aden Decl., Ex. D at G-1.)
 - h. Adult stem cells showing pluripotent flexibility have come from various sources, including bone marrow, peripheral blood, inner ear, umbilical cord blood, nasal mucosa, placental amniotic membrane, and testicular tissue. (Aden Decl., Ex. D at G-1 to G-2.)
 - i. “The true test of usefulness of any stem cell is not its pluripotency, but rather its ability for use in regenerative medicine, repairing damaged and diseased tissue and improving health.” (Aden Decl., Ex. D at G-2.)

- j. Adult stem cells show an ability to home in on damaged tissue, allowing development of minimally invasive administration techniques. (Aden Decl., Ex. D at G-8.)
- k. Adult stem cells present no risk of tumor formation or immune-rejection. (Aden Decl., Ex. D at G-8.)
- l. Adult stem cells have shown efficacy at repairing damaged and diseased tissue in numerous animal models of disease and injury. (Aden Decl., Ex. D at 10.)
- m. Induced pluripotent stem cells provide an ethical alternative to human embryonic stem cells. (Aden Decl., Ex. D at 10.)
- n. The exceptional promise of induced pluripotent stem cell research is well documented. (Aden Decl., Ex. D at H-1 to H-4.)
- o. Induced pluripotent stem cells are produced by genetically reprogramming mature cells such that they are virtually indistinguishable from embryonic stem cells. (Aden Decl., Ex. D at H-1 to H-2.)
- p. The process of producing human induced pluripotent stem cells was invented in November 2007. (Aden Decl., Ex. D at H-1.)
- q. Induced pluripotent stem “cells from mice have already been used in proof-of-principle experiments to ameliorate disease in mouse models of sickle cell anemia, Parkinson’s disease, and murine hemophilia.” (Aden Decl., Ex. D at H-3.)
- r. Induced pluripotent stem cells “can be created from virtually any cell type,” including “common fibroblast cells,” “plucked human hair,” and “human blood cells.” (Aden Decl., Ex. D at H-3.)
- s. Induced pluripotent stem cells can be created more easily and less expensively than human embryonic stem cell lines. (Aden Decl., Ex. D at 10.)
- t. Within a year after the announcement of the first human induced pluripotent stem cell lines, at least 315 human induced pluripotent stem cell lines were generated; over 500 induced pluripotent stem cell lines have now been reported. (Aden Decl., Ex.D at H-4.)
- u. Induced pluripotent stem “cell lines from patients suffering from various diseases have been created, covering 13 different diseases.” (Aden Decl., Ex. D at H-4.)
- v. Induced pluripotent stem cells can be created from a specific individual, allowing creation of patient-specific cell lines. (Aden Decl., Ex. D at 10.)

- w. Induced pluripotent stem cells “meet the defining criteria . . . originally proposed for human [embryonic stem] cells, with the significant exception that the [induced pluripotent stem] cells are not derived from embryos.” (Aden Decl., Ex. D at H-3.)
 - x. Human embryonic stem cells must be extracted from living human embryos. (See Aden Decl., Ex. D at E-3.)
 - y. Human embryonic stem cells will not lead to safe therapeutics because: they are not normal cells; they do not differentiate into desired adult phenotype cells, but to fetal, immature phenotype cells; they are not required for research using other pluripotent cells; and they will not cure the targeted diseases listed in the Draft Guidelines. (Aden Decl., Ex. D at 11-13.)
 - z. Embryonic stem cells have shown no success in therapeutic applications. (Aden Decl., Ex. D at G-1.)
 - aa. Tumor- or teratoma-formation is a “universal” and “innate” characteristic of human embryonic stem cells, and thus presents an “insurmountable hurdle” to therapeutic application. (Aden Decl., Ex. D at I-2.)
 - bb. Embryonic stem cells may form tumors when injected into a patient’s body. (Aden Decl., Ex. D at I-2 to I-3; *see also* Defs.’ Memo. in Support of Mot. to Dismiss at 3 [Dkt. #23].)
 - cc. Despite claims that differentiating embryonic stem cells prevents tumor-formation upon implantation, “[c]areful assessment of differentiated hESCs demonstrates . . . that even differentiated hESCs rapidly formed teratomas.” (Aden. Decl., Ex. D at I-2.)
 - dd. Several other therapeutic problems have been routinely observed with the use of differentiated embryonic stem cells for *in vivo* therapy. (Aden Decl., Ex. D at I-2 to I-3.)
 - ee. Embryonic stem cells may be rejected by a patient’s immune system. (See Aden Decl., Ex. D at G-8.)
 - ff. Embryonic stem cells are biologically inadequate replacements for lost adult stem cells. (See Aden Decl., Ex. D at I-1.)
 - gg. Embryonic stem cells “are neither useful nor required for research using other pluripotent stem cells.” (Aden Decl., Ex. D at 12.)
 - hh. Human embryonic stem cell research is scientifically unnecessary. (Aden Decl., Ex. D at 11, 18.)
29. In promulgating the Guidelines, Defendants failed to address or respond to the scientific problems identified in the Comments of Do No Harm, et al., and failed to explain

30. In response to the Draft Guidelines, Do No Harm, et al., submitted Comments that detailed numerous ethical flaws associated with human embryonic stem cell research. (Aden Decl., Ex. D.)
31. Defendants received the Comments of Do No Harm, et al., detailing the ethical flaws associated with human embryonic stem cell research, and they are part of the administrative record. (Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm?StartID=47017 (last visited Aug. 16, 2010).)
32. The administrative record establishes the following ethical flaws with the Guidelines, as shown by the Do No Harm Comments:
 - a. The Guidelines do not prevent conflicts of interest between the reproductive facility and the research facility. (Aden Decl., Ex. D at 13.)
 - b. By limiting federal funding to cell lines derived from embryos that are “no longer needed” for reproductive purposes, the Guidelines set the stage for abuse by infertility clinics. (Aden Decl., Ex. D at 13-14.)
 - c. The Guidelines completely disregard the unique status, worth, and life of human embryos, and unethically accord less protection to “unwanted” embryos. (Aden Decl., Ex. D at 14.)
 - d. Human embryos are living human beings and therefore deserve treatment commensurate with their status. (Aden Decl., Ex. D at 14, J-4.)
 - e. An international consensus recognizes that human embryos are biologically living human beings beginning at fertilization, and that human growth and development is a continuous physical process from the one-cell stage forward. (Aden Decl., Ex. D at J-4.)
 - f. Both the Human Embryo Research Panel and the National Bioethics Advisory Commission describe the human embryo from its earliest stages as a living organism and a “developing form of human life.” (Aden Decl., Ex. D at 14, J-4.)
 - g. In 1995, the historic and well-respected Ramsey Colloquium statement on embryo research acknowledges that “[t]he [embryo] is human; it will not articulate itself into some other kind of animal. Any being that is human is a human being.” (Aden Decl., Ex. D at J-4.)
 - h. Twenty-one states have fetal homicide statutes that apply without regard to gestational age. (Aden Decl., Ex. D at 8, B-1 to B-2.)

- i. Eight states have wrongful death statutes that apply regardless of gestational age. (Aden Decl., Ex. D at 8, B-3.)
 - j. In states that acknowledge and protect life from the moment of fertilization or conception, “donation” of human embryos for the purpose of destruction is viewed as a state criminal violation. (Aden Decl., Ex. D at 9; *see generally id.* at C-1 to C-18.)
 - k. The Guidelines wrongly assume that the biological parents of human embryos are legally and morally empowered to substitute their judgment for that of the human embryo in consenting to its destruction. (Aden Decl., Ex. D at 15-16.)
 - l. The Guidelines fail to require that parents receive sufficient information to be able to give truly informed consent. (Aden Decl., Ex. D at 16.)
 - m. Human embryonic stem cell research is categorically unethical. (Aden Decl., Ex. D at J-3 to J-5.)
 - n. Adult stem cell research is an ethically superior alternative to human embryonic stem cell research and a “worthy scientific priority meriting federal funding.” (Aden Decl., Ex. D at 9.)
33. In promulgating the Guidelines, Defendants failed to address or respond to the ethical concerns raised in the Comments of Do No Harm, et al., and failed to explain Defendants’ decision to authorize the federal funding of embryonic stem cell research in view of the ethical flaws Do No Harm identified. *See* 74 Fed. Reg. 32,170 (attached as Aden Decl. Ex. C).
34. The Do No Harm Comments also expressed concern that NIH Acting Director Raynard Kington had entered the rulemaking proceeding with “an unalterably closed mind” regarding the merits of the Guidelines and urged that he be excluded from the decisionmaking process. (Aden Decl., Ex. D at 19.)
35. Defendants received the comment referenced in ¶ 34, which is part of the administrative record. (Nat’l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm?StartID=47017 (last visited Aug. 16, 2010).)
36. Defendants ignored the comment referenced in ¶ 34 and failed to explain their decision to permit Acting Director Kington to participate in the decisionmaking process despite his professed bias and unalterably closed mind. *See* 74 Fed. Reg. 32,170.
37. NIH received 49,015 public comments on the Guidelines. (*See* Nat’l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm? (last visited Aug. 16, 2010).)
38. NIH disregarded as “unresponsive” about 30,000 such comments, which opposed federal funding for embryonic stem cell research on ethical and scientific grounds. (Aden. Decl.,

- a. Explaining NIH's decision to disregard these comments, Acting NIH Director Raynard Kington stated, "We actually did not ask the public whether we should fund research on human embryonic stem cells. We asked the public how we should fund human embryonic stem cell research." (Aden Decl., Ex. F at 2.)
 - b. Kington also stated, "We clearly predict that the opportunities for research will greatly expand" with respect to human embryonic stem cell research. (Aden Decl., Ex. F at 2.)
 - c. Kington's statements regarding NIH's decision to disregard comments opposed to embryonic stem cell funding were accurately reported in the article referenced in ¶ 38.
39. Defendants ignored comments addressing the merits of human embryonic stem cell research. (*See* Defs.' Memo. in Support of Mot. to Dismiss at 44 [Dkt. #23] (NIH "properly ignored . . . the relative merits" of embryonic stem cell research); *see also* Defs.' Reply in Support of Mot. to Dismiss at 20 [Dkt. #32] ("NIH responded appropriately to comments that were relevant to the formulation of the Guidelines, namely, comments that addressed the substance of the informed consent procedures that NIH proposed to establish.").)
40. On July 7, 2009, NIH issued "Guidelines for Human Stem Cell Research," which authorized federal funding of embryonic stem cell research utilizing live human embryos that were "created . . . for reproductive purposes" but are "no longer needed for [that] purpose." 74 Fed. Reg. at 32,170, 32,174 (attached as Aden Decl., Ex. C).
41. The Guidelines require applicant institutions proposing research using human embryonic stem cells to ensure that the process by which the embryonic stem cells were derived from human embryos was in accordance with the Guidelines. 74 Fed. Reg. at 32,174-75 (attached as Aden Decl., Ex. C).
42. 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. 74 Fed. Reg. at 32,174 ("The 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") (attached as Aden Decl., Ex. C).
43. The Guidelines categorically prohibit the use of any funds for cloning or breeding of animals. 74 Fed. Reg. at 32,175 §§ IV, V (attached as Aden Decl., Ex. C).
44. The Guidelines categorically prohibit the offering of "payments, cash or in kind," for "donated embryos." 74 Fed. Reg. at 32,174 § II.A.3.b (attached as Aden Decl., Ex. C).

45. The Guidelines regulate the process by which embryos must be obtained if they are to be used in government-funded research. 74 Fed. Reg. at 32,174-32,175 (attached as Aden Decl., Ex. C).
- a. “[T]he Guidelines pertain primarily to the donation of embryos for the derivation of [human embryonic stem cells].” 74 Fed. Reg. 32,170 (attached as Aden Decl., Ex. C).
 - b. The Guidelines require that individuals donating “human embryos for research purposes” be informed of “[w]hat would happen to the embryos in the derivation of [the stem cells].” 74 Fed. Reg. at 32,174 (attached as Aden Decl., Ex. C).
 - c. “To conduct [embryonic stem cell] research, [embryonic stem cells] must be derived from an embryo. The process of deriving [embryonic stem cells] from an embryo results in the destruction of the embryo.” (Order of Aug. 23, 2010, at 12 [Dkt. #44]; *see also* Aden Decl., Ex. D at 5, E-3.)
46. In the Human Subject Protection Regulations, incorporated in the Dickey-Wicker Amendment, NIH defined “research” as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45 C.F.R. § 46.102(d); *see also* § 509(a)(2)(b), 123 Stat. at 3281.
47. HHS guidance documents on the Human Subject Protection Regulations state that an institution that receives federal funding is generally engaged in human subjects research “even where all activities involving human subjects are carried out by employees or agents of another institution.” (Dep’t of Health & Human Servs., *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>.)
48. The Guidelines do not prohibit a privately funded researcher from destroying an embryo at a publicly funded researcher’s behest. *See* 74 Fed. Reg. at 32,174 (discussing limitations on eligibility for embryonic stem cell funding) (attached as Aden Decl., Ex. C).
49. Defendants never have set forth an interpretation of the word “research” as used in the Dickey-Wicker Amendment.
- a. Defendants never have interpreted “research” to mean a “piece of research” in an official agency statement promulgated through notice-and-comment procedures.
50. The removal of the inner cell mass of a human embryo generates the embryonic stem cell, but in order to extract the stem cell, the human embryo must be destroyed. *See* 74 Fed. Reg. at 32,171 (defining human embryonic stem cells as “cells that are derived from the inner cell mass of blastocyst stage human embryos”) (attached as Aden Decl., Ex. C); Aden Decl., Ex. D at E-3 (“[t]he process by which human embryonic stem cells are extracted from human embryos necessarily destroys the human embryos”).

51. Mouse embryonic stem cells were first isolated and successfully grown in the laboratory in 1981, while the first mouse adult stem cell was successfully isolated and purified in the laboratory in 1988. (Aden Decl., Ex. Q [Declaration of Dr. Theresa Deisher in Support of Pls.' Opp'n to a Stay of the Prelim. Inj.] ¶ 7.)
52. Human embryonic stem cells were first isolated and grown briefly in the laboratory in 1994, and were first successfully maintained long-term in the laboratory in 1998. (Aden Decl., Ex. Q ¶ 7.)
53. The first human adult stem cell was first isolated in the laboratory in 1992. (Aden Decl., Ex. Q. ¶ 7.)
54. Although many researchers predicted that embryonic stem cell research would lead to the cure of diseases such as Parkinson's, Alzheimer's, and diabetes, those predictions have not come to pass. (Aden Decl., Ex. G [Bernadine Healy, M.D., *Why Embryonic Stem Cells Are Obsolete*, U.S. News & World Report, Mar. 4, 2009, <http://health.usnews.com/blogs/heart-to-heart/2009/03/04/why-embryonic-stem-cells-are-obsolete.html>]; *see also* Aden. Decl., Ex. D at A-2.)
55. No patients have been injected with human embryonic stem cells. (Aden Decl., Ex. Q. ¶ 11.)
56. Even many human embryonic stem cell research proponents are concerned that a clinical trial of a human embryonic stem cell-derived therapy is not safe to proceed despite having received FDA approval to begin enrolling certain patients. (Aden Decl., Ex. Q ¶ 11.)
57. As of September 3, 2010, 1,973 adult stem cell interventional trials were listed at ClinicalTrials.gov, a website developed and maintained by NIH. (Aden Decl., Ex. Q ¶ 12.)
58. As of September 3, 2010, zero interventional clinical trials with embryonic stem cells were listed on ClinicalTrials.gov. (Aden Decl., Ex. Q ¶ 12.)
59. The published literature contains . . . examples of adult stem cells that can differentiate into cell types different from their tissue of origin, including recently-discovered very small embryonic-like ('VSEL') cells from adult bone marrow, and demonstrates that these bone marrow-derived cells can repair cardiac damage. (Aden Decl., Ex. Q ¶ 14.)
60. Bone marrow stem cells can form neurons, as even NIH as noted. (Aden Decl., Ex. Q ¶ 15.)
61. Adult neural stem cells can be obtained from the post-mortem human brain and yield nerve cells. (Aden Decl., Ex. Q ¶ 16.)
62. The technique used to generate induced pluripotent stem cells was originally discovered using knowledge from mouse embryonic stem cells; that same technique was used to create the first human induced pluripotent stem cell. (Aden Decl., Ex. Q ¶ 17.)

63. Recently published literature confirms that human embryonic stem cells and induced pluripotent stem cells are “virtually identical.” (Aden Decl., Ex. Q ¶ 18 & n.21.)
64. Induced pluripotent stem cells probably avoid rejection by the immune system. (Nat’l Institutes of Health, *Stem Cell Basics* 14 (2009), available at <http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf>; see also Aden Decl., Ex. D at 10.)
65. Standard cell culture technique involves freezing (cryopreservation) of cell stocks from the very inception of a cell culture and cell line. (Aden Decl., Ex. Q. ¶ 19.)
66. Cryopreserved cells are stored in liquid nitrogen at -196° C, at which temperature they can be maintained indefinitely; methods have been refined specifically for human embryonic stem cells. (Aden Decl., Ex. Q ¶ 19.)
67. In 2006, a total of 50,417 transplants were performed worldwide using hematopoietic (blood-forming) adult stem cells. (Aden Decl., Ex. Q ¶ 20.)
 - a. Almost half (48%) of such transplants took place in Europe. (Aden Decl., Ex. Q ¶ 20.)
 - b. Only 36% took place in all of the Americas. (Aden Decl., Ex. Q ¶ 20.)
68. Adult stem cell transplants have become the standard of care for many patients with blood disorders and malignancies, though they are starting to be used for other conditions including autoimmune disorders and heart disease. (Aden Decl., Ex. Q ¶ 20.)
69. Adult stem cell therapy is an accepted therapy worldwide. (Aden Decl., Ex. Q ¶ 20.)

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Respectfully Submitted,

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