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' COMBINED REPLY IN SUPPORT OF SUMMARY JUDGMENT, OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, AND RESPONSE TO AMICI CURIAE

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INTRODUCTION

The NIH Guidelines for funding human embryonic stem cell research are invalid both because they violate the Congressional prohibition on funding "research in which" embryos are destroyed or knowingly placed at risk, and because they were not promulgated in accordance with the requirements of the Administrative Procedure Act ("APA"). The Court was correct in preliminarily enjoining Defendants' implementation of the Guidelines. And for the same reasons the Court articulated, as well as additional grounds that the Court has not yet addressed, the Court should grant summary judgment for Plaintiffs and deny Defendants' motion for summary judgment.

Defendants argue that the Guidelines do not violate the Dickey-Wicker Amendment because the Amendment's ban on funding "research" can be limited to "pieces of research," and that the Court should defer to Defendants' supposed interpretation of that term. But Defendants are incorrect, because Dickey-Wicker clearly prohibits funding of embryonic stem cell research that depends on or incentivizes the destruction of embryos. And Defendants' interpretation, offered for the first time in legal briefs in this litigation, would not be entitled to deference under *Chevron* in any event, because the law is clear that an agency must interpret a statute through official agency action in order to be entitled to such deference. Moreover, even now Defendants do not interpret the statute based on any expertise, but rather based on their lawyers' selection of one dictionary's secondary definition of the term. The law is clear that no deference is due under these circumstances.

The Guidelines are also invalid under the APA. Defendants, by their own admission, failed to consider thousands of relevant comments explaining the scientific shortcomings and ethical concerns that human embryonic stem cell research entails. Defendants argue that the President *required* them to fund human embryonic stem cell research as contemplated in the

Guidelines, but the President's Executive Order did no such thing. The President ordered that NIH "*may*" fund "*responsible, scientifically worthy*" embryonic stem cell research "*to the extent permitted by law*," not that NIH "shall" fund human embryonic stem cell research. And Defendants' legal argument is incorrect in any event—an agency is not immune from review under the APA simply because it followed a presidential directive. Defendants' argument amounts to an unprecedented and shocking claim of unfettered Executive power to trump an act of Congress at whim, and it should be summarily rejected.

For these reasons, and for the reasons set forth in the Court's preliminary injunction order, summary judgment is appropriate to declare the Guidelines invalid and to permanently enjoin any further implementation of the Guidelines by Defendants.

ARGUMENT

I. The Standard of Review.

"Summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review." *Alliance to Save the Mattaponi v. U.S. Army Corps of Engineers*, 606 F. Supp. 2d 121, 127 (D.D.C. 2009). To be sure, "judicial review of agency action is normally to be confined to the administrative record." *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989). But where, as here, "the procedural validity of the Department's action also remains in serious question . . . , it may sometimes be appropriate to resort to extra-record information to enable judicial review to become effective." *Id.*; *see also Nehemiah Corp. of Am. v. Jackson*, 546 F. Supp. 2d 830, 848 (E.D. Cal. 2008) ("Although the court's review [of agency action] is generally limited to the record, extra-record evidence is admissible subject to certain narrow exceptions . . . . ").

Defendants urge the Court to confine its review of the Guidelines to the administrative record, but their counsel have repeatedly introduced new material outside the administrative record in an attempt to bolster their factual assertions about the scientific merits of human embryonic stem cell research and to obscure the ethical and scientific bases for Defendants' promulgation of the Guidelines.[1] (*See* Defs.' Mem. & Opp. at 2–7 [Dkt. #57-58]; Landis Decl. ¶¶ 13–21.) Defendants cannot have it both ways. Plaintiffs fully agree that the Court must evaluate the bulk of Plaintiffs' APA challenges to the NIH Guidelines on the basis of the administrative record alone; indeed, Plaintiffs have argued from the beginning that it is plainly inappropriate for Defendants' counsel to offer *post hoc* factual assertions in a belated attempt to fabricate ethical and scientific bases for Defendants' decision to fund embryonic stem cell

[1] Defendants' objections to Plaintiffs' Statement of Material Facts are similarly misplaced. (Defs.' Resp. to Pls.' Stmt. of Material Facts at 1 [Docket ("Dkt.") #59].) First, as set forth below, Plaintiffs' claims under the Dickey-Wicker Amendment need not be evaluated on the basis of the administrative record alone. Second, Plaintiffs' claim that NIH Acting Director Kington approached the rulemaking with an unalterably closed mind is not limited to the administrative record. Third, Defendants have continued to challenge Plaintiffs' standing, despite the D.C. Circuit's unanimous holding that Plaintiffs have established their standing to bring this action. This is therefore not a case in which only the administrative record is at issue, and accordingly Plaintiffs' statement of undisputed facts is procedurally proper. *Cf.* LCvR 7(h); Comment to LCvR 7(h). Moreover, as set forth in text, Defendants' counsel have repeatedly tried to establish the purported scientific merits of human embryonic stem cell research and the alleged limits of adult stem cell research, notwithstanding the total lack of evidence or analysis to that effect in the administrative record. (*See, e.g.*, Defs.' Mem. in Support of Defs.' Mot. for Summary Judgment & in Opp'n to Pls.' Mot. for Summary Judgment ("Defs.' Mem. & Opp.") at 2–7 [Dkt. #57-58]; Decl. of Francis S. Collins ("Collins Decl.") ¶¶ 5–7; Decl. of Story Landis ("Landis Decl.") ¶¶ 13–21.) Plaintiffs have responded accordingly, to correct Defendants' misstatements and mischaracterizations of fact. (*See* Decl. of Dr. Theresa Deisher in Support of Pls.' Opp'n to a Stay of Prelim. Inj. ("Deisher Decl.") ¶¶ 7–18; Decl. of Dr. James Sherley in Support of Pls.' Combined Reply, Opp'n, & Response ("Sherley Decl.") ¶¶ 5–12.) Plaintiffs maintain, however, that Defendants' attempts to offer after-the-fact evidence on these points are impermissible, because the question whether Defendants adequately addressed the concerns raised in the comments must be assessed on the basis of the administrative record alone.

research. But Defendants cannot complain when Plaintiffs respond to erroneous, improper, and legally irrelevant factual assertions that Defendants' own declarations injected into the case. (*See, e.g.*, Defs.' Mem. & Opp. at 2–7 [Dkt. #57-58]; Collins Decl. ¶¶ 5–7; Landis Decl. ¶¶ 13–21.)

Moreover, with respect to Plaintiffs' claim that Defendants impermissibly prejudged the outcome of the rulemaking, the Court may properly consider evidence outside the record where, as here, "serious question[s]" about the "procedural validity" of agency action have been raised. *Esch*, 876 F.2d at 991. *See infra* Section IV.D. The undisputed evidence of this prejudgment exists only outside the administrative record, and it is therefore proper for consideration here. *See Nehemiah Corp.*, 546 F. Supp. 2d at 848.

II. Plaintiffs Have Standing Due to the Increased Competition They Face from Defendants' Funding of Embryonic Stem Cell Research.

Defendants press the same standing arguments that they made unsuccessfully before the D.C. Circuit, and they are wrong for the same reasons articulated in the Court of Appeals' decision. Defendants continue to argue that, in order to establish standing, Plaintiffs are required to show not only that they face increased competition, but also that they have suffered or will suffer further specific injuries (such as a particular loss of funding) as a result of that competition. (*See, e.g.*, Defs.' Mem. & Opp. at 14 ("all that Sherley alleges is that the guidelines 'will result in increased competition,'" and he "still does not allege that he has expended any extra effort or lost any funding *as a result of* this supposed competition" (emphasis added)) [Dkt. #57-58].) The D.C. Circuit squarely rejected this argument, holding that the undisputed increased competition that Plaintiffs face as a result of the Guidelines—and not any loss of funding or injury *resulting* from the increased competition—is sufficient in and of itself to confer Article III standing. *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010). To be sure, the Court

noted that Plaintiffs "will suffer an *additional* injury whenever a project involving ESCs receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs." *Id*. (emphasis added). As an example of such "additional" injury, the D.C. Circuit referenced the competition Dr. Sherley faced with respect to a then-pending grant application. *Id*.[2] But the injury from increased competition alone, completely apart from any resulting loss of funding, "is an actual, here-and-now injury," which itself gives Plaintiffs standing. *Id*.

As the Court of Appeals held, the increased competition that Plaintiffs face as a result of the Guidelines was present when they filed their Complaint, and there has been no subsequent change in circumstances that could somehow negate Plaintiffs' standing. The only relevant difference between the motion to dismiss and summary judgment stage for purposes of Plaintiffs' standing is the quantum of proof Plaintiffs must adduce to establish the facts necessary for standing; there is no qualitatively different proof that Plaintiffs must establish. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (standing must be established "with the manner and degree of evidence required at the successive stages of the litigation"). Defendants attempt to create factual disputes regarding the resulting effects of the increased competition that Plaintiffs face, but these disputes could not affect Plaintiffs' standing, because the facts regarding the increased competition that Plaintiffs face remain *undisputed*. As the D.C. Circuit held, "[t]here can be no doubt the Guidelines will elicit an increase in the number of grant applications

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[2] Plaintiffs continue to face such additional injury resulting from the increased competition. For example, Dr. Sherley has "had four adult stem cell research grant applications go unscored since the Guidelines were implemented." He declares that since the implementation of the Guidelines, his "success rate was significantly lower than [his] earlier above-average success rate." (Sherley Decl. ¶ 3.)

involving ESCs; indeed, *the Government never suggests otherwise*." *Sherley*, 610 F.3d at 74 (emphasis added). That statement remains true today. Indeed, the chairman of NIH's Working Group for Human Embryonic Stem Cell Eligibility Review has admitted that "given the large amount of research funding provided by the federal government, the new guidelines will permit a significant increase in the number of projects using embryonic stem cells."[3] The only disputes that Defendants raise relate to the existence *vel non* of *further* injuries resulting from the increased competition, but as set forth above, such additional injuries need not be shown in order to establish Plaintiffs' standing.

In any event, Dr. Sherley has in fact been forced to adjust his grant application methods as a result of the increased competition from embryonic stem cell research applicants produced by the Guidelines. He has had to submit more applications for funding than ever before in his career, as a result of the lower success rate he has experienced since the implementation of the Guidelines. (Sherley Decl. ¶¶ 2–4.)

III. The Dickey-Wicker Amendment Bars Funding Under the Guidelines.

A. The Guidelines Violate the Amendment's Unambiguous Prohibition

As this Court has already explained, Defendants' counsel's contrived interpretation of the term "research" cannot efface the plain text of the Dickey-Wicker Amendment. *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70–71 (D.D.C. 2010). The expenditure of federal funds is forbidden for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." Consolidated Appropriations Act, 2010, Pub. L.

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[3] Press Release, University of Utah, *Utah Ethicist Heads Stem Cell Panel* (Sept. 22, 2009) (quoting Dr. Jeffrey R. Botkin, Chairman, Working Group for Human Embryonic Stem Cell Eligibility Review) (Included in Sherley Decl., Ex. B).

No. 111-117, § 509(a)(2), 123 Stat. 3034, 3280–81. Living human embryos are the sole source of human embryonic stem cells, and harvesting stem cells from an embryo necessarily causes its death and destruction; indeed, *multiple* embryos must be destroyed to yield a single stem cell line for research purposes.[4] The Guidelines, by authorizing funding of research on hESCs and devising the procedure by which embryos will be acquired to satisfy this new research demand, therefore fund "research in which" human embryos are destroyed and knowingly subjected to risk of injury and death.

1. The Guidelines Unlawfully Fund "Research In Which" A Human Embryo Is Destroyed

It is undisputed in this case that "all embryonic stem cell research involves the destruction of embryos at some point." Brief for Appellees at 41, *Sherley v. Sebelius*, 610 F.3d 69 (D.C. Cir. 2010) (No. 09-5374). Defendants nonetheless press several arguments in an attempt to separate the derivation of an embryo from the experimentation for which the embryo was derived. But this Court was correct in previously concluding that the Guidelines "unambiguously" violate Dickey-Wicker by funding research in which embryo destruction is an "integral step." *Sherley*, 704 F. Supp. 2d at 71. Summary judgment is warranted for the same reason.

Defendants' counsel first argue that derivation of an hESC is not part of the "research" for which the hESC is used, but rather more like the "production of [a] tool used in scientific research." (Defs.' Mem. & Opp. at 18 [Dkt. #57-58].) Defendants' counsel would liken harvesting hESCs to manufacturing a Petri dish; neither activity is part of the research that

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[4] David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1068 (2003).

follows. But this nonsensical view contradicts both common sense and NIH's own views. The Guidelines state that "NIH funding of the derivation of stem cells from human embryos is prohibited *by the annual appropriations ban on funding of human embryo research*." NIH Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,175 (July 7, 2009) (Aden Decl., Ex. C) (emphasis added). Dickey-Wicker refers only to "*research*" in which an embryo is destroyed, so the prohibition against funding of derivation confirms that hESC derivation is "research." Derivation is not merely a preparatory step in anticipation of research; it is itself research.

Defendants' counsel next argue that derivation of hESCs is somehow disconnected from the experiment for which the hESCs are prepared. They claim that "research" as used in Dickey-Wicker does not really mean "research" but rather "a piece of research" or a "particular research project." (Defs.' Mem. & Opp. at 18 [Dkt. #57-58].) On that theory, as long as NIH does not pay for the destructive act itself, it can fund the other "pieces of research" that comprise hESC research.

But as this Court explained in ordering the preliminary injunction, this strained interpretation is wholly incompatible with the text and structure of Dickey-Wicker, the Government's own regulatory definition of research, and "the most common" meaning of the term. *Sherley*, 704 F. Supp. 2d at 70–71. Defendants' own Human Subject regulations define "research" not as a particular task, but as a "a systematic investigation, including research *development*, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d) (emphasis added). Defendants question the relevance of this definition, arguing that it is "not in any way incorporated into the Dickey-Wicker Amendment" and is not supported by any common "dictionary definition." (Defs.' Mem. & Opp. at 17, 18

[Dkt. #57-58].) Defendants are incorrect on both counts. That definition in fact mirrors the *first* entry in the same dictionary that Defendants rely upon, as this Court recognized. *Sherley*, 704 F. Supp. 2d at 70 (quoting the "first definition of research" in Random House Dictionary). Moreover, Dickey-Wicker expressly incorporates a portion of the Human Subject regulations by forbidding any risk to embryos "greater than that allowed for research on fetuses in utero under 45 C.F.R. § 46.204(b)." § 509(a)(2), 123 Stat. at 3280–81. By incorporating Section 46.204(b)'s standard of risk for "research on fetuses in utero," the statute necessarily incorporates the definition of "research" used in that regulatory provision, which is the definition set forth above. Defendants' own regulations and sources therefore make clear that "research" is not a discrete act or experiment, but rather encompasses the broader process of development and testing.

Derivation is clearly part of the same "systematic investigation" (including "research development") as the experimentation phase involving the derived cells, because hESCs are derived solely and specifically for use in the experimentation phase of hESC research. Defendants's counsel dispute this because, they claim, the word "systematic" means "having, showing, or involving a system, method, or plan," and therefore a research project does not need to "include within its scope all steps . . . that made the research possible." (Defs.' Mem. & Opp. at 17–18 [Dkt. #57-58].) But as this Court correctly recognized, "[s]imply because ESC research involves multiple steps does not mean that each step is a separate 'piece of research' that may be federally funded, provided the step does not result in the destruction of an embryo." *Sherley*, 704 F. Supp. 2d at 71. Derivation of hESCs is not simply any kind of research; it is an unavoidable step in *human embryonic stem cell research*—the very research that the Guidelines

fund. And derivation is performed for the singular purpose of producing hESCs in advance of experimentation. It is manifestly part of any hESC researcher's "system, method, or plan."[5]

It therefore blinks reality to claim that derivation of stem cells is a remote, "antecedent . . . development" in relation to experimentation on the very cells being derived. (Defs.' Mem. & Opp. at 18 [Dkt. #57-58].) This position is especially untenable in light of the fact that HHS has concluded that a federal grantee is generally engaged in human subjects "research" even when unfunded *third parties* conduct all the interaction involving human subjects. (Pls.' Mem. in Support of Mot. for Summary Judgment ("Pls. Mem.") at 16 (quoting Pls.' Stmt. of Undisputed Facts ("SOF") ¶ 46) [Dkt. #55].) On this point, Defendants offer no response. Indeed, the Guidelines authorize NIH funding of hESC research conducted by the *same individual researcher* who destroys the embryo for the purpose of experimenting on hESCs derived from it. 74 Fed. Reg. at 32,173.

Defendants' counsel opine that "science is a continuum," and that "it is hard to see where the dividing line might be" between prohibited and permitted funding under the definition of research recognized by this Court. (Defs.' Mem. & Opp. at 22 [Dkt. #57-58].)[6] This claim is

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[5] Amicus Genetics Policy Institute ("GPI") asserts that this Court's earlier opinion was "based on a mistaken understanding of what the government's definition means." (GPI Am. Br. at 2 [Dkt. #63].) But it is GPI that is confused. According to GPI, the government meant to say that "research" means a "particular instance of research," and "instance" means "an example or single occurrence of something." (*Id.* at 4–5 (quoting Random House Dictionary).) But even accepting this string of tautologies, the fact remains that the *occurrence of research* means the occurrence of a "systematic investigation, including research development, testing and evaluation." *Sherley*, 704 F. Supp. 2d at 70–71. As this Court observed, that definition of "research" is required by both the common dictionary meaning and the Defendants' own regulatory definition. *Id.*

[6] Defendants' counsel also claim that the words "in which" and "are destroyed" limit Dickey-Wicker's scope to that part of the research process that involves the *specific act*

[Footnote continued on next page]

dubious coming from litigation counsel for the federal agencies that *adopted* and *apply* that same definition of "research" in the analogous context of Human Subject regulations. In any event, Defendants' counsel's position would empty the term "research" of any independent meaning. If "research" means simply the "research project for which federal funding is sought" (*id.*), then the term assumes whatever meaning a particular NIH grant application gives it. Under this endlessly manipulable definition, the "dividing line" is entirely rubbed out.

Defendants' counsel have not yet come to grips with the implications of their own litigating position. Under their proffered approach, there is no reason why NIH could not, for example, fund a preimplantation genetic diagnosis "research project" that will inevitably result in discarding of embryos, as long as private donors pay for the follow-up "research project" of discarding the embryos found to be genetically defective.[7]

Defendants also have no coherent response to Plaintiffs' argument that not only the text but the structure of Dickey-Wicker precludes the interpretation that Congress meant only to withhold funds for the *specific act* that destroys the embryo. (Defs.' Mem. & Opp. at 20 [Dkt. #57-58].) The first paragraph of the ban prohibits the *specific act* of using federal funds for "the creation of a human embryo or embryos," while the second paragraph broadly prohibits *all*

[Footnote continued from previous page]

of embryo destruction. Defendants' counsel are correct, of course, when they assert that the words "in which" are necessarily limiting. Without a subordinate clause, the statute would prohibit *all* NIH funding. This tells us nothing, however, about *what* the statute prohibits.

[7] Defendants' counsel's interpretation of the phrase "research in which" also puts a surprising twist on the Guidelines' ban on funding for "[r]esearch in which hESCs . . . are introduced into non-human primate blastocysts." 74 Fed. Reg. at 32,175. By Defendants' counsel's logic, an NIH researcher can experiment with chimpanzee blastocysts that have been united with human ESCs, as long as the researcher uses private funds to for the discrete act of "introduc[tion]."

"research in which" an embryo is destroyed, discarded or knowingly threatened. § 509(a), 123 Stat. at 3280–81; Pls.' Mem. at 14 [Dkt. #55]. If Congress had meant what Defendants' counsel claim it meant, there would have been no reason to use the "research in which" language rather than the formulation used in the first paragraph. Defendants' proffered interpretation therefore violates the canon of construction that "[w]here 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." *Duncan v. Walker*, 533 U.S. 167, 173–74 (2001) (internal quotation marks omitted).

Defendants' entire argument, therefore, rests on the slender reed of Congress's use of the present tense in describing embryos that "*are* destroyed." In Defendants' view, this restricts the statute to the specific act a researcher is performing at a given moment in time or, as one amicus brief puts it, "the risk of harm must be contemporaneous" with the funded research. (CAMR Am. Br. at 19 [Dkt. #61].) But if "research" includes the derivation of hESCs in advance of experimentation—as this Court already concluded—then the embryos *are* destroyed as part of the research. *Sherley*, 704 F. Supp. 2d at 71–72. Moreover, the implications of Defendants' arguments are absurd. If the Dickey-Wicker Amendment prohibited only the funding of present destruction of human embryos, as Defendants now argue, then NIH could fund even the already-completed act of destroying human embryos to produce stem cell lines for which researchers "are" now seeking NIH approval. Not even Defendants take that position, instead conceding that they cannot fund such destruction after the fact, even though it has by definition already occurred with respect to any NIH-approved stem cell lines. In short, Defendants' argument based on verb tense must be rejected as inconsistent with NIH's own interpretation of the statute.

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

Even under Defendants' counsel's construction of the term "research," the Guidelines still violate Dickey-Wicker's separate prohibition on funding for research in which embryos are "knowingly subjected to risk of injury or death." § 509(a)(2), 123 Stat. at 3280–81. The Guidelines, and the hESC research that they contemplate, *necessitate* the destruction of human embryos by using and creating demand for hESCs. The Guidelines even dictate how that demand shall be met. Part II.A of the Guidelines spells out in detail the procedures for identifying and acquiring embryos to be destroyed for research purposes "on or after the effective date of the[] Guidelines." 74 Fed. Reg. at 32,174. It therefore cannot seriously be doubted that Defendants and the researchers they fund are fully aware that hESC research under the Guidelines incentivizes and requires destruction of human embryos. Indeed, Defendants admit that NIH has *already* approved for use under the Guidelines (and thus for federal funding of hESC research) at least two cell lines derived from embryos that were selected and destroyed after promulgation of, and in accordance with, the Guidelines. (Defs.' Mem. & Opp. at 26 [Dkt. #57-58].) And it is well established that multiple embryos must be destroyed to obtain a single ESC line for continued research purposes. *See supra* note 4. Thus, Defendants cannot deny that the Guidelines and federally funded hESC research are knowingly subjecting human embryos to risk, and indeed to actual destruction.

Against this, Defendants offer two objections. First, they argue that embryos are not "knowingly subject[ed] to risk of injury or death" if they are not "involved" in the research. (Defs.' Mem. & Opp. at 26 [Dkt. #57-58].) The text of the statute says nothing of the kind. By the statute's plain terms, any federally funded research that subjects embryos to more than minimal risk violates the funding ban, regardless of the manner in which that risk is created. Indeed, the very notion of creating a *risk* suggests that the threatening act may occur at some

point removed from the threatened person or object. *Cf. Palsgraf v. Long Island R.R. Co*., 248 N.Y. 339, 344–45 (1928) ("[R]isk imports relation; it is risk to another or to others within the *range of apprehension*.") (emphasis added). Only a *risk* is required, not the actual realization of that risk (although both are present here).

Second, Defendants contend that the Guidelines do not violate the "risk of injury or death" prong of Dickey-Wicker because they pose no *known increased risk* to embryos. That is purportedly so because "the same 'risk of harm' to spare embryos in IVF clinics exists whether or not the guidelines are in effect, as third-party donors may be just as likely in the absence of the guidelines to discard their unused embryos." (Defs.' Mem. & Opp. at 27 [Dkt. #57-58].) If an embryo is intended to be discarded anyway, Defendants' argument goes, its destruction in research does not increase the *relative probability* of harm to the embryo. Amicus Genetic Policy Institute repeats this argument, claiming that the government would have to "quantify the *incremental* risk created by hESC research" over other risks to that particular embryo. (GPI Am. Br. at 23 [Dkt. #63].)

In the first instance, Defendants and their amici offer no basis other than sheer speculation for their assertion that every embryo being destroyed for federally funded research would otherwise have been discarded. Embryos can be and are stored for years, even decades, before being implanted and carried to term (by either their biological mothers or adoptive mothers). Indeed, earlier this year a baby was born after the embryo had been stored for nearly 20 years. Donna Dowling-Lacey et al., *Live Birth from a Frozen-Thawed Pronuclear Stage Embryo Almost 20 Years After Its Cryopreservation Corrected Proof*, 94 FERTILITY & STERILITY 4 (Sept. 30, 2010). Misled by NIH's imprimatur on hESC research and by inaccurate media portrayals of promised dramatic cures, some parents will inevitably view donation for research as

a worthy cause even though they would be unwilling simply to discard living embryos, and the Guidelines unquestionably place such embryos at risk.

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

By applying Section 289g(b) to embryos, Dickey-Wicker makes clear that embryos intended to be discarded can be exposed to no greater risk than embryos intended to be implanted—the "[r]isk standard" for both must be the "same." Consequently, in assessing whether hESC research poses a "greater than minimal" risk to embryos, NIH cannot claim that the risk of destruction-by-derivation is *offset* or *canceled out* by the alleged risk that "the embryo would otherwise have been discarded due to the discretionary decision of third part[ies]." (Defs.' Mem. & Opp. at 27 [Dkt. #57-58].) By spurring demand for embryo destruction, and by specifying the precise means by which embryos must be destroyed in order to qualify for federal

funding, Defendants (and the hESC researchers they fund) inevitably and knowingly subject embryos to a "greater than minimal" risk of injury or death.[8]

Finally, Defendants falsely suggest that hESC research under the Guidelines only draws on the existing inventory of hESC lines. (Defs.' Mem. & Opp. at 27 & n.12 [Dkt. #57-58].) To the contrary, the Guidelines themselves explicitly demonstrate NIH's knowledge and expectation that future derivation of hESCs for federally funded research purposes was inevitable. NIH stated that among its goals were "ensuring that the greatest number of ethically derived hESCs are available for Federal funding," and the Guidelines specifically "articulate[d] one set of procedural requirements" to govern all "future embryo donations in the United States." 74 Fed. Reg. at 32,172; *see id.* (discussing "the only way to establish eligibility" for federal funding "for embryos donated in the U.S. on or after the effective date of the Guidelines"). Similarly, the Chairman of NIH's Working Group for Human Embryonic Stem Cell Eligibility Review, Dr. Jeffrey R. Botkin, recently noted that access to new stem cell lines is necessary to meet the demands of the "many investigators who want to pursue this research," which the "small number

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[8] This protection for embryos is in no way diminished by the fact that the Human Subject Regulations permit research on material derived from an aborted fetus under some circumstances. 45 C.F.R. § 46.206(a); 45 C.F.R. § 46.204. An embryo is destroyed in hESC research for the sole purpose of experimenting on material derived from the dead embryo. By contrast, abortions are performed for reasons totally unrelated to research—and HHS regulations guarantee that is the case. The Human Subject Regulations create a firewall between fetal research and the decision to abort by mandating that "[i]ndividuals engaged in the research will have *no part* in any decisions as to the timing, method, or procedures used to terminate a pregnancy." 45 C.F.R. § 46.204(i) (emphasis added). The regulations thus assure that abortion decisions and procedures are strictly separate from considerations of fetal tissue procurement. The Guidelines do just the opposite. They not only permit the federally funded researcher to be involved in timing, method, or procedures used to destroy an embryo—they allow the researcher to *perform* the destructive act, as long as that piece of research is privately funded. 74 Fed. Reg. at 32,173. And the Guidelines specify in detail how embryos are to be identified for destruction, so that they can be used in federally funded research. 74 Fed. Reg. at 32,174.

of available lines [under the Bush policy] did not support."[9]

Moreover, the Guidelines explicitly authorize researchers to apply for and receive hESC grants *without* first identifying (or even necessarily deriving) the stem cell lines they intend to use.[10] As the Guidelines make clear, it is entirely permissible for the *same* researcher to derive hESCs and then, using federal funds, experiment on those very cells. 74 Fed. Reg. at 32,173. Considering that derivation of one single stem cell line can destroy as many as 40 embryos,[11] the decision by even one researcher to develop a new line for use in federally-funded hESC research doubtless poses a "greater than minimal" risk to embryos. 45 C.F.R. § 46.204(b).

B. The Indeterminate Legislative History Cannot Vary the Plain Meaning of the Dickey-Wicker Amendment

Because Defendants cannot square the Guidelines with the unambiguous text of Dickey-Wicker, they instead argue that Congress has effectively amended that statute not by changing its words, but by printing committee reports. But "[l]egislative history is irrelevant to the

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9 Press Release, University of Utah, *supra* note 3.

10 The Guidelines require only that grantees provide assurances that the stem cell lines they are using were listed on the NIH registory "[p]rior to the use of NIH funds" for research on those hESCs. 74 Fed. Reg. at 32,175. Similarly, the relevant grant application form states: "[I]f research using human embryonic stem cells is proposed, the applicant organization will identify hESCs to be used from the NIH Registry (http://stemcells.nih.gov/research/registry/), *or*, if a specific cell line cannot be referenced at the time of application, *certify that one from the NIH Registry will be used*, in accord with the NIH Guidelines on Human Stem Cell Research." U.S. Dep't of Health & Human Services, Public Health Service Grant Application (PHS 398), available at http://grants.nih.gov/grants/funding/phs398/phs398.html (emphases added).

11 Hoffman, *supra* note 4. This study estimates that if all of the approximately 11,000 embryos designated for research in the United States were used for hESC research, those embryos would yield approximately 275 stem cell lines. *Id.* at 1068. That translates to 40 embryos destroyed per stem cell line derived.

interpretation of an unambiguous statute." *United States ex rel. Totten v. Bombardier Corp*., 380 F.3d 488, 494 (D.C. Cir. 2004) (Roberts, J.) (internal quotations omitted); (Pls.' Mem. at 20 (citing cases) [Dkt. #55]). And even if Dickey-Wicker were ambiguous, as set forth below, the legislative history cited by Defendants is indeterminate and unreliable.

No matter how often Defendants claim that "*Congress* could not have been more clear" about how to construe Dickey-Wicker (Defs.' Mem. & Opp. at 22 [Dkt. #57-58]), the fact remains that *Congress* did not say anything in reports approved only by "unelected congressional staff" or "a legislative subgroup." *Sharp v. United States*, 27 Fed. Cl. 52, 62 (Fed. Cl. 1992). Citing decades-old case law, Defendants argue that the Supreme Court has "consistently relied" on committee reports. (Defs.' Mem. & Opp. at 24 [Dkt. #57-58].) But more recently, the Court has made clear that "it is the statute, and not the Committee Report, which is the authoritative expression of the law." *City of Chicago v. Envtl. Def. Fund*, 511 U.S. 328, 337 (1994); *see also Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 570 (2005) (Kennedy, J.) ("One need not subscribe to the wholesale condemnation of legislative history to refuse to give any effect to such a deliberate effort to amend a statute through a committee report."). Indeed, as the D.C. Circuit has held, "it [is] plainly wrong as a general matter . . . to regard committee reports . . . as reflecting the congressional will more accurately than the statutory text itself. Committee reports, we remind, do not embody the law." *Abourezk v. Reagan*, 785 F.2d 1043, 1054–55 & n.11 (D.C. Cir. 1986).

The legislative history Defendants rely on is also indeterminate, as it includes statements supporting both parties' positions. (*See* Pls.' Mem. at 20–21 & n.6 [Dkt. #55].) And although Defendants claim that the legislative history to the *more recent* reenactment of Dickey-Wicker is the most relevant, the most recent reenactment of Dickey-Wicker was accompanied by no

legislative history at all on this issue. *See* Continuing Appropriation Act, 2011, § 101, Pub. L. 111-242 (appropriating "[s]uch amounts as may be necessary, at a rate for operations as provided in the applicable appropriations Acts for fiscal year 2010 and under the authority *and conditions* provided in such Acts") (emphasis added).

Defendants also claim that the Court should deem Congress's failure to change Dickey-Wicker over the years as a tacit approval of the Guidelines (Defs.' Mem. & Opp. at 23 [Dkt. #57-58]), but the "congressional ratification" doctrine they rely on is inapposite here. The Supreme Court has recognized congressional ratification of an agency interpretation based only on *affirmative* legislative action and only when the interpretation is "longstanding." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 846 (1986); *see also FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 155–56 (2000). The routine reenactment of Dickey-Wicker without alteration is not the kind of "positive legislation" that signals congressional ratification of an agency interpretation. *Schor*, 478 U.S. at 846. In *Schor*, for example, the Court held that Congress had ratified an agency's authority to adjudicate counterclaims by *affirmatively amending* the Commodity Exchange Act to recognize the agency's jurisdiction over counterclaims. *Id.* ("[W]e need not, as the Court of Appeals argued, rely simply on congressional 'silence' to find approval of the [agency's] position . . . ."). Likewise, in *Brown & Williamson*, the Court held that Congress had ratified the Food and Drug Administration's position that it lacked jurisdiction over tobacco by enacting distinct regulatory schemes for tobacco products, premised on the limits of the FDA's authority. 529 U.S. at 155–56 ("[W]e do not rely on Congress' failure to act . . . ."). By contrast, Congress's *failure* to amend Dickey-Wicker—a perennial appropriations rider—cannot ratify NIH's warped interpretation.

Moreover, ratification applies only to "*longstanding* administrative interpretation[s] *without pertinent change*." *Schor*, 478 U.S. at 846 (emphasis added). For example, in *Brown & Williamson*, the FDA's ratified position was over 75 years old. 529 U.S. at 156. The Guidelines—and the unstated, unreasoned interpretation they purportedly embody—were promulgated a little over a year ago. The short life of the Guidelines forecloses the ratification argument.

Anticipating this difficulty, Defendants suggest that the Guidelines were, in all relevant respects, a mere continuation of the Bush Administration's 2001 policy on hESC research. (Defs.' Mem. & Opp. at 23 & n.11 [Dkt. #57-58].) Not so. Unlike the Guidelines, the Bush policy in no way encouraged the destruction of embryos and therefore could not be challenged under the "risk of injury or death" prong of Dickey-Wicker. The Bush policy confined federal funding to research on existing cell lines derived from "embryos that have already been destroyed" prior to the policy's announcement. *Address to the Nation on Stem Cell Research From Crawford, Texas*, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001) ("This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos . . . ."); *see also* Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (2007). In a 2002 memorandum, the General Counsel of HHS explicitly justified the Bush policy under Dickey-Wicker on the ground that the "policy provides no incentives for the destruction of additional embryos." (Aden Decl., Ex. D at F-5 [Azar Memorandum].) According to HHS, therefore, the Bush policy was consistent with Dickey-Wicker because it strictly limited funding to experimentation using "a discrete set" of existing stem cell lines for which the "life and death decision" had already been made prior to the promulgation of the Bush policy. (*Id.*)

The Guidelines were designed precisely to "remove these limitations." Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (2009) (revoking the Bush policy). Based on a new, unarticulated *reinterpretation* of Dickey-Wicker, the Guidelines opened the door to research on *newly* derived hESCs and specified in detail how embryos are to be identified for destruction so that they can be used in federally funded research. Because this major shift certainly represents a "pertinent change" from the Bush policy, the ratification defense is a nonstarter. *Schor*, 478 U.S. at 846.

C. NIH Is Not Entitled to *Chevron* Deference

Defendants claim that this Court "already" recognized that the proper mode of analysis is under *Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc.*, 467 U.S. 837 (1984). (Defs.' Mem. & Opp. at 16 [Dkt. #57-58].) In reality, however, this Court has correctly held that Defendants' position is *not* entitled to *Chevron* deference, because Congress has unambiguously expressed its intent to prohibit funding of "research in which" embryos are destroyed or knowingly threatened. *Sherley*, 704 F. Supp. 2d at 70–71. Defendants suggest that establishing clear intent under *Chevron* is a "daunting burden" (Defs.' Mem. & Opp. at 30 [Dkt. #57-58]), but *Chevron* does not create any presumption favoring the validity of a regulation. It is well-settled that when the "relevant statutory language is plain but is inconsistent with the [agency interpretation], [the court] must hold the regulations invalid." *Am. Fed'n of Gov't Employees, AFL-CIO v. Gates*, 486 F.3d 1316, 1321–22 (D.C. Cir. 2007). Because the language of Dickey-Wicker is clear, "that is the end of the matter" under *Chevron*. 467 U.S. at 842–43.

But even if Dickey-Wicker were ambiguous, Defendants would not be entitled to deference, because neither NIH nor HHS has ever proffered an interpretation of "research" that supports their litigating position and that this Court could analyze for reasonableness. *Chevron* deference does not apply unless (1) the agency has in fact interpreted the statutory term or provision in question, *Pub. Citizen, Inc. v. Dep't of Health and Human Servs.*, 332 F.3d 654, 661

(D.C. Cir. 2003), and (2) "the agency interpretation claiming deference was promulgated" in a rule "carrying the force of law," *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001).

Even amici supporting Defendants recognize that the "Guidelines do not define 'research.'" (CAMR Am. Br. at 19 n.56 [Dkt. #62].) In fact, as Plaintiffs noted, Defendants nowhere claim that they even considered whether hESC derivation occurs as part of hESC "research" in promulgating the Guidelines. (Pls.' Mem. at 23 n.7 [Dkt. #55].) Instead they claim that agencies do not have to define "every term of a statute." (Defs.' Mem. & Opp. at 31 [Dkt. #57-58].) But that is a red herring. *Chevron* analysis focuses on the agency's interpretation of the "*relevant* statutory terms" that justify its actions, *Verizon Tel. Cos. v. FCC*, 292 F.3d 903, 909 (D.C. Cir. 2002) (emphasis added), and at a minimum, *Chevron* requires an agency to define the *central term* that underlies the interpretation for which it seeks deference, *Pub. Citizen*, 332 F.3d at 661. Defendants' counsel have devoted dozens of briefing pages to their tortured reading of "research" under Dickey-Wicker—thus confirming its centrality to their position—but Defendants have not identified even a single sentence in a binding agency statement that sets forth that tortured reading. Consequently, there is no interpretation to which this Court can defer. *Pub. Citizen*, 332 F.3d at 661.

This Court should not defer to Defendants' counsel's *post hoc* litigation position for the additional reason that the proffered interpretation is not the product of any agency expertise in defining "research." To merit deference, 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). Defendants' counsel vaguely assert that the Guidelines "explain[] NIH's understanding of the scientific terminology"

in Dickey-Wicker, but they do not deny that the sole authority for their "piece of research" definition is a secondary entry listed in the Random House Dictionary. (Defs.' Mem. & Opp. at 18, 31 [Dkt. #57-58].) No deference is due where, as here, agency counsel have merely "relied on the dictionary definition" of the critical term that supports their disputed interpretation. *Sec'y of Labor, Mine Safety and Health Admin. v. Nat'l Cement Co. of Cal., Inc*., 494 F.3d 1066, 1074–75 (D.C. Cir. 2007).

Finally, Defendants' counsel are simply wrong that NIH's unstated, unreasoned interpretation of "research" is longstanding. (Defs.' Mem. & Opp. at 32 [Dkt. #57-58].) That interpretation first appeared in legal briefs filed in this case, and it in fact contradicts positions Defendants have previously taken. In 1996, for example, NIH wrote a letter to Georgetown University researchers who were using federal dollars and equipment to conduct genetic tests on DNA derived from previously-destroyed embryos. (Sherley Decl., Ex. A.) The purpose of the letter, NIH wrote, was "to clarify . . . the NIH position on embryo research." *Id.* The agency explained that "analysis from DNA derived from a human embryo" violated the federal prohibition on research involving embryos, and that NIH equipment "may not be used for embryo work of any kind." *Id.* This conclusion—that research on materials *derived from* a human embryo violates Dickey-Wicker's prohibition against "research in which" embryos are destroyed or subjected to risk—cannot be squared with Defendants' litigation position that NIH has always interpreted Dickey-Wicker to permit funding of hESC research.[12]

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[12] This illegal research, led by Dr. Mark Hughes (then of Georgetown University), was the subject of a 1997 congressional subcommittee hearing. *See Continued Management Concerns At The NIH: Hearing Before the Subcomm. On Oversight & Investigations of the H. Comm. on Commerce*, 105th Cong. 26 (1997). The record of the hearing indicates that, according to NIH, Dr. Hughes' offense was use of NIH-funded single-cell genetic

[Footnote continued on next page]

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

Under the APA, Defendants were required to examine the relevant data, consider the important issues, respond to relevant comments, and articulate a sufficient explanation for their decision to fund human embryonic stem cell research. *See, e.g.*, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also* Defs.' Mem. & Opp. at 33 [Dkt. #57-58]. Yet, Defendants shirked these responsibilities and instead rammed their predetermined outcome through a Potemkin notice-and-comment process that flouted the most fundamental requirements of the APA. In an attempt to excuse their actions, Defendants retreat to the argument that the Executive Order commanded them to ignore important data and disregard significant comments. But that excuse is both factually and legally flawed, and it does not even begin to address the fact that Defendants failed to apply their own stated criteria of scientific worthiness and ethical responsibility. *See* 74 Fed. Reg. 18,578.

A. Defendants Entirely Failed to Consider and Respond to Important Issues and Comments That Addressed Fundamental Aspects of the Rulemaking

Defendants do not dispute that, in responding to the public comments and promulgating the Guidelines, NIH was required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43 (internal quotation omitted). Moreover, Defendants agree that "[a]n agency is obliged to respond to comments that are 'relevant to the agency's decision and which, if adopted, would require a change in the agency's proposed rule.'"

[Footnote continued from previous page]

analysis equipment to analyze DNA of cells that had been removed from an embryo. *Id.* at 13-15 (Statement of Dr. Harold E. Varmus, then-NIH Director). NIH did *not* allege that Hughes directly experimented with or destroyed embryos.

(Defs.' Mem. & Opp. at 33 (quoting *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977)).) Indeed, Defendants admit that this Court should "vacate an agency's decision [if it has] entirely failed to consider an important aspect of the problem." (*Id.* (quoting *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 658 (2007)).) That is precisely what occurred here.

Executive Order 13,505 provided that NIH "may" support "responsible, scientifically worthy" stem cell research. 74 Fed. Reg. 10,667. In addition, Defendants' notice of proposed rulemaking ("NOPR") stated that 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; Defs.' Resp. to Pls.' Stmt. of Material Facts ¶ 23 [Dkt. #59]. In other words, both the Executive Order and the NOPR belie Defendant's *ipse dixit* that "the scientific merit of hESC research was not an issue to be decided within the scope of the Guidelines." (Landis Decl. ¶ 16.)

Despite the criteria established by the Executive Order and the NOPR, Defendants *admit* that "[t]he Guidelines did not purport to decide the relative merits of different forms of stem cell research." (Landis Decl. ¶ 13.) Simply put, Defendants acknowledge they did not even attempt to decide one of the key issues relating to the Guidelines. Similarly, by their own admission, Defendants failed to consider approximately 30,000 public comments that opposed federal funding for human embryonic stem cell research on scientific and ethical grounds. (*See* Defs.' Resp. to Pls.' Stmt. of Material Facts ¶ 38 [Dkt. #59].) The Landis Declaration describes the way in which NIH dealt with comments regarding the ethical responsibility and scientific worth of human embryonic stem cell research. Dr. Landis candidly reveals that "[c]omments opposing

hESC research as a categorical matter . . . were deemed to fall outside the scope of the issues to be decided in promulgating the Guidelines." (Landis Decl. ¶ 11.)[13]

Dr. Landis attempts to salvage NIH's improper approach to the rulemaking by asserting that "NIH did not 'ignore' those comments but simply deemed them not relevant to the issues to be resolved and therefore not appropriate for discussion in the final Guidelines." (Landis Decl. ¶ 11.) But the purported distinction between ignoring comments and "simply deem[ing] them not relevant" is no distinction at all. Even Defendants appear to agree, candidly admitting in their brief that NIH "ignored . . . the relative merits" of hESC research. (Defs.' Mem. & Opp. at 37 [Dkt. #57-58].) In any event, just because many of the comments expressed a *categorical* opinion as to the ethical irresponsibility and scientific unworthiness of such research does not mean that the agency was free to disregard them. Dr. Landis repeatedly makes clear that comments opposing human embryonic stem cell research were "deemed not relevant to the promulgation of the final Guidelines." (Landis Decl. ¶ 12.) She adds that "NIH did not respond to comments that went beyond the scope of the rulemaking . . . including comments that categorically opposed hESC research on moral or ethical grounds." (*Id.*) Not only did NIH not "respond" to such comments, Defendants' admissions clarify that NIH *did not even consider* comments on the ethical irresponsibility and scientific unworthiness of human embryonic stem cell research. (*See id.* ¶ 13 ("[I]t was determined that [comments on the scientific merits of

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[13] Plaintiffs note that information recently came to their attention that the Comments of the U.S. Conference of Catholic Bishops—which were attached as Exhibit C to the August 19, 2009 Declaration of Bradley J. Lingo—were not timely filed in response to the Draft NIH Guidelines and are not part of the administrative record. It is undisputed that the Do No Harm comments cited in Plaintiffs' Statement of Undisputed Facts are part of the administrative record. (SOF ¶¶ 27–28; Defs.' Resp. to Pls.' Stmt. of Material Facts ¶ 27 ("Defendants do not dispute that they received the comments submitted by Do No Harm, *et al.*, and that they are part of the administrative record.") [Dkt. #59].)

human embryonic stem cell research] did not bear on the issues that were being decided in the rulemaking."); *id.* ("NIH did not address comments that, in contravention of the President's Executive Order, sought a blanket ban on federal funding for research involving hESCs."); *id.* ¶ 16 ("[T]he scientific merit of hESC research was not an issue to be decided within the scope of the Guidelines.").) In sum, Dr. Landis has made it abundantly clear that most, if not all, comments addressing the ethical and scientific merits of human embryonic stem cell research were simply disregarded during the rulemaking process.

Moreover, Defendants' assertion that *the majority* of comments received were not "relevant to the task at hand" (Defs.' Mem. & Opp. at 36 [Dkt. #57-58]), is shockingly cavalier. (*See generally* SOF ¶¶ 37–38; Defs.' Resp. to Pls.' Stmt. of Material Facts ¶¶ 37–38 (admitting that approximately 49,000 comments were received and failing to dispute that NIH disregarded as "unresponsive" approximately 30,000 of the comments) [Dkt. #59].) In direct contravention of the Executive Order and the NOPR, Defendants now attempt to justify their disregard of 30,000 comments by mischaracterizing the scope of the rulemaking. Specifically, Defendants describe "comments that were relevant to the formulation of the Guidelines" as "comments that addressed the substance of the informed consent procedures." (*See* Defs.' Mem. & Opp. at 36 [Dkt. #57-58].) If this Court were to sanction such *post hoc* re-writing of a rulemaking's scope, agencies would have sweeping power to deem irrelevant thousands of public comments that go to the heart of the rulemaking. Needless to say, such power would dilute the value of the notice-and-comment process. For this reason, it is unsurprising that the D.C. Circuit has previously expressed skepticism of agency attempts to exclude entire classes of comments, remarking in one case that it was "not at all persuaded by the [agency's] argument that [the] comments were

entirely beyond the scope of the rulemaking proceedings." *Petroleum Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1173 (D.C. Cir. 1994).

The comments the agency received here conclusively establish that hESC research is both scientifically unworthy and ethically irresponsible, given that adult stem cell research and induced pluripotent stem cell research together offer all of the purported benefits of hESC research and more, without any of the grave ethical problems associated with destroying human life or potential human life.[14] (*See* SOF ¶¶ 26–28, 30–32.) Defendants effectively concede as much, never disputing the scientific facts and ethical assertions in the record. *See* Defs.' Resp. to Pls.' Stmt. of Material Facts ¶¶ 26–28, 30–32 [Dkt. #59]; *Abate v. District of Columbia*, 659 F. Supp. 2d 156, 159–60 (D.D.C. 2009) ("Because [a party] did not controvert this fact, it is deemed admitted.")

Yet, having ignored the comments received during the notice-and-comment process, Defendants' counsel now attempt to offer a belated, *post hoc* smattering of allegedly possible scientific and ethical bases for Defendants' decision to fund human embryonic stem cell research. Defendants' counsel thus seek to accomplish in legal briefs what Defendants failed to

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[14] In fact, in addition to the Comments of Do No Harm, et al., the administrative record ("AR") contains voluminous comments documenting the scientific unworthiness and ethical irresponsibility of human embryonic stem cell research. (*See, e.g.*, AR 002643–44, 016673–77 (Comments of Presbyterians Pro-Life Research, Education, & Care, Inc.); AR 002965 (Comments of Christian Family & Children's Center); AR 009191 (Comments of The Hippocratic Resource); AR 013324–26 (Comments of Christian Medical Association); AR 015759 (Comments of Citizens for Science and Ethics); AR 015336–37 (Comments of New Jersey Catholic Conference); AR 016118–22 (Comments of Thomas More Society); AR 016200–02 (Comments of Members of Congress Opposed to Human Embryonic Stem Cell Research); AR 016425–27 (Comments of Catholic Medical Association); AR 016478–84 (Comments of Bioethics Defense Fund); AR 016925–26 (Comments of National Catholic Partnership on Disability); AR 015830–42 (Comments of Family Research Council) [Dkt. #66].)

do when the issue was before them. Their belated response is too little, too late. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based.").

Moreover, even if Defendants' allegations regarding the purported merits of hESC research were not entirely improper and legally irrelevant and inadmissible, they would still be factually incorrect. Indeed, the "promise" Defendants now claim for human embryonic stem cell research rests not on fact, but on Defendants' mischaracterizations and omissions. For example, Defendants' claim that a recent study that used stem cells to generate "Natural Killer," or "NK," cells "found that the hESC-derived cells were better at destroying leukemia than cells derived from another type of stem cells," ignores the serious limitations of that study and obscures its conclusions. (*See* Defs.' Mem. & Opp. at 4–5 [Dkt. #57-58]; Sherley Decl. ¶¶ 5–6.) Defendants likewise overstate the "significant progress" researchers have made "in differentiating hESC lines into" insulin-producing cells. (*See* Defs.' Mem. & Opp. at 5 [Dkt. #57-58]; Sherley Decl. ¶ 7.) And Defendants mischaracterize the status of stem cell research with regard to neurons, overestimating the potential of embryonic stem cell research while minimizing the considerable achievements of adult stem cell research in this area. (*See* Defs.' Mem. & Opp. at 5–6 [Dkt. #57-58]; Landis Decl. ¶ 18; Sherley Decl. ¶ 10–12.)

In sum, for the reasons set forth above and in Plaintiffs' motion for summary judgment, this case involves a quintessential APA violation. *See, e.g.*, *Am. Mining Congress v. EPA*, 907 F.2d 1179, 1190 (D.C. Cir. 1990) ("[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.'"). And, as discussed below, Defendants' excuse for their actions is woefully inadequate.

B. NIH Did Not Even Attempt to Satisfy Its Own Stated Criteria for the Rulemaking

According to Defendants' 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. Defendants nonetheless completely ignored *their own* stated criteria in issuing the Guidelines.

An agency "must defend its analysis before the court upon the basis it employed in adopting that analysis"—even if "the [agency] was not required" by statute to base its decision on those grounds. *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 177 (D.C. Cir. 2010) (citing *Chenery Corp.*, 318 U.S. at 87); *see Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 814–15 (D.C. Cir. 1983). After establishing criteria for the comment process, an agency cannot "arbitrarily and narrowly circumscrib[e] the scope of relevant factors" by deeming comments "irrelevant." *Ad Hoc Telecommc'ns Users Comm. v. FCC*, 680 F.2d 790, 798 (D.C. Cir. 1982) (MacKinnon, J., concurring).

As Defendants admit in their Response to Plaintiffs' Statement of Material Facts, it is "undisputed" that helping to ensure "NIH-funded research [involving human embryonic stem cells] is ethically responsible, scientifically worthy, and conducted in accordance with applicable law" was "one of the stated purposes of the Draft Guidelines." (Defs.' Resp. to Pls.' Stmt. of Material Facts ¶ 23 [Dkt. #59].)[15] After establishing these criteria for the notice and comment process, Defendants were not free to ignore them. Moreover, Defendants were not free to ignore entire swaths of comments because they took a certain viewpoint or expressed the opinion in a

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15 NIH reiterated those criteria in promulgating the final Guidelines. 74 Fed. Reg. at 32,170.

"categorical" manner. Defendants have offered no justification for ignoring comments that go directly to the very criteria that they themselves set forth. Instead, Defendants assert that "it is immaterial whether Defendants addressed comments that raised categorical ethical objections to the funding of hESC research . . . ." (Defs.' Resp. to Pls.' Stmt. of Material Facts ¶ 33 [Dkt. #59].)

Defendants freely admit that they received comments addressing the ethical responsibility and scientific worth of human embryonic stem cell research (*id.* ¶¶ 26, 27, 30, 31, 33), and they disregarded such comments simply by labeling them not relevant. (*Id.*) "Defendants do not dispute that they deemed comments advocating a blanket ban on all funding for hESC research . . . not relevant to the promulgation of the Guidelines." (*Id.* ¶ 38.) Further, in issuing the Guidelines, Defendants ignored the vast evidence regarding the superiority of adult stem cell and induced pluripotent stem cell research, and the fact that those forms of research are available without any of the serious ethical concerns raised by human embryonic stem cell research. (*See id.* ¶¶ 26–28, 30–32.) This evidence went directly to the stated purposes of the Draft Guidelines, and Defendants offer no reasonable justification as to why it was ignored. In sum, Defendants acted inconsistently with the APA and settled administrative law by completely ignoring their own rulemaking criteria in issuing the Guidelines.

C. The President Did Not Direct NIH to Fund Embryonic Stem Cell Research—and, Even if He Had Done So, NIH Was Still Required to Comply with the APA

Defendants attempt to justify their disregard of the administrative process by claiming that "NIH obviously would have acted inconsistently with the [Executive] Order if it had refused to issue the Guidelines on the ground . . . that all hESC research, categorically, lacked merit." (Defs.' Mem. & Opp. at 35 [Dkt. #57-58].) But Defendants misconstrue the President's Order.

And, in any event, the President lacks the power to exempt the Guidelines from review under the APA.

1. The Executive Order Did Not Compel NIH to Fund Embryonic Stem Cell Research

Although the President may have removed the restrictions on federal funding that had been imposed by prior presidential action, he did *not* direct NIH to fund embryonic stem cell research or to ignore all public comments describing the scientific and ethical concerns of such research. In fact, the Order required careful consideration of just such comments. What is more, NIH's approach of branding tens of thousands of comments as irrelevant conflicted directly with the President's stated purpose of removing this issue from the "political" process, thereby allowing NIH to solicit comments and 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).

The Executive Order directed NIH to review all "existing NIH guidance and other widely recognized guidelines on human stem cell research" and "issue new guidance on" "human stem cell research." There was no specific requirement to fund human *embryonic* stem cell research. Exec. Order No. 13,505, 74 Fed. Reg. 10,667. Indeed, the Order provides only that NIH "may" support "responsible, scientifically worthy" stem cell research. The Order did not purport to remove NIH's discretion to consider *whether* human embryonic stem cell research qualifies as ethically responsible or scientifically worthy—precisely the issues that the comments addressed and that NIH ignored.

Moreover, the President stated that NIH could fund embryonic stem cell research "*to the extent permitted by law*." *Id.* (emphasis added). Thus, not only is the Order permissive as to whether NIH must fund embryonic stem cell research at all, it also requires that NIH follow all

applicable law—which includes the APA—when issuing its guidance. *See Natural Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 765 (3rd 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, E.O. 12291 specifically states that any action taken pursuant to it must be in compliance with applicable law.").

NIH claims that because it must consider funding applications on an "application-by-application basis," it therefore could not consider categorical comments regarding ethical responsibility, as required in its own NOPR and Guidelines. (Defs.' Mem. & Opp. at 35–36 (claiming that "making categorical announcements as to the merits of hESC research" would "displace the statutory peer-review procedures") [Dkt. #57-58].) This is wrong on several levels. *First*, a categorical approach to ethical issues is sensible and common. As recognized even by the National Bioethics Advisory Commission—created by President Clinton and whose members the President appointed (*see* Exec. Order 12,975, 60 Fed. Reg. 52,063 (1995)—"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) (emphasis added) (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.).)

Second, the Guidelines do, in fact, make numerous categorical determinations as to ethical responsibility. For example, the Guidelines closely regulate the manner in which human embryos must (on a going-forward basis) be selected for destruction in order to qualify for federal funding, and they categorically prohibit federal funding of research involving ESC lines

derived after July 7, 2009, in a non-compliant manner. 74 Fed. Reg. at 32,174, § II.A.. The Guidelines also 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, seemingly also for ethical reasons.

Indeed, far from rejecting all categorical ethical determinations in favor of a case-by-case consideration at the grant application process, NIH in fact expressly *rejected* that approach *in favor of* a categorical resolution of ethical concerns. In promulgating the Guidelines, NIH noted that some commenters "suggested that the current regulatory structure of [Institutional Review Board] review under the Common Rule [*i.e.*, the Human Subject regulations] addresses the core ethical principles need for appropriate oversight of hESC derivation." 74 Fed. Reg. at 32,171. NIH expressly *declined* to follow that suggested case-by-case approach. Noting that the existing plethora of guidelines on hESC research had "result[ed] in a patchwork of standards," NIH "concluded that employing the IRB review system . . . would not ameliorate stated concerns about variations in standards for hESC research and would preclude the establishment of an NIH registry of hESCs eligible for NIH funding, because there would be no NIH approval of particular hESCs." *Id*. Accordingly, NIH instead chose to "articulate policies and procedures that will allow the NIH to create a Registry" of approved hESCs and that will "provide . . . a specific set of standards reflecting currently recognized ethical principles and practices specific to embryo donation . . . ." *Id*. NIH thus made the categorical determination that any hESC line meeting the standards set forth in the Guidelines and listed on the Registry would be automatically eligible for use in federally funded research; no further ethical consideration is

required or contemplated under the Guidelines. *Id*. at 32,175 (§ II.D) (Registry "list[s] hESCS *eligible for use in NIH funded research*") (emphasis added).[16]

Thus, NIH has engaged in precisely the sort of "categorical" ethical determinations that it claims it cannot undertake. *Id.* And it made the categorical ethical determination that it would fund human embryonic stem cell research using any hESCs listed on its Registry without considering any of the comments that directly addressed the issue, on the purported ground that those comments raised "categorical" objections. Such reasoning defies belief as well as logic, and plainly violates the APA.

2. An Executive Order Cannot Circumvent a Statute

Even if the President *had* directed NIH to fund embryonic stem cell research without responding to comments from the public, NIH would not be insulated from review under the APA. Any authority the Executive Branch has to fund embryonic stem cell research originated in Congress, which limited the authority it delegated by enacting the APA. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) ("The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes."). Moreover, 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 simply because the policy was

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16 *See also* 74 Fed. Reg. at 32,172 (stating that the final Guidelines provide "clear guidance" that "ensur[e] adherence to strict ethical standards" by "establishing a set of conditions that will maximize ethical oversight, while ensuring that the greatest number of ethically derived hESCs are eligible for Federal funding."); *id.* (discussing "the only way to establish eligibility" for federal funding "for embryos donated in the U.S. on or after the effective date of the Guidelines").

dictated by the President. Indeed, if the President could simply dictate the details of any agency rule that is subject to notice and comment procedures, "the opportunity to comment [would be] meaningless." *Home Box Office*, 567 F.2d at 35.

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

Defendants have not disputed the facts establishing that they entered the rulemaking period with an unalterably closed mind. Comments from NIH's leadership make clear that Defendants were unequivocally committed to expanding human embryonic stem cell research, irrespective of what comments were submitted during the rulemaking period. Once the NOPR had been issued and comments had been submitted on the ethical responsibility and scientific merit of human stem cell research, Defendants were required to show a "flexible and open-minded attitude" toward the rulemaking. *Fed. Express Corp. v. Mineta*, 373 F.3d 112, 120 (D.C. Cir. 2004) (quoting *Nat'l Tour Brokers Ass'n v. United States*, 591 F.2d 896, 902 (D.C. Cir. 1978)). In their Response to Plaintiffs' Statement of Material Facts, Defendants do not dispute that NIH's Acting Director made the statements cited by Plaintiffs that establish his closed mind on the topic of the rulemaking. (Defs.' Resp. to Pls.' Stmt. of Material Facts ¶¶ 25, 38 [Dkt. #59].) As they did during the rulemaking period, Defendants instead claim that these undisputed facts are "not relevant to NIH's promulgation of the guidelines and not material to the issues before this Court." *Id.* Statements of fact that are not controverted are deemed to be admitted as true. *See Abate*, 659 F. Supp. 2d at 159–60 ("Because [a party] did not controvert this fact, it is deemed admitted.").

These uncontroverted statements by Acting Director Kington establish that Defendants entered the rulemaking period with 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). Before the comment period even began, Director Kington stated that "[w]e

will expand greatly the number of cell lines eligible for funding," establishing that the agency officials had already made up their minds to expand human embryonic stem cell research. (SOF ¶ 25; Aden Decl., Ex. I (also declaring that "[w]e know of several hundred cell lines that will meet the guideline standards")).) While a mere policy discussion prior to the comment period would not constitute an "unalterably closed mind," *see C & W Fish Co., Inc. v. Fox*, 931 F.2d 1556, 1564–65 (D.C. Cir. 1991), a pre-declaration of the result of the rulemaking constitutes precisely the sort of prejudgment that cannot stand. In fact, the concern "that NIH acting Director Raynard Kington had entered the rulemaking proceeding 'with an unalterably closed mind'" was expressed in the comments (SOF ¶¶ 34–36), although Defendants dismiss this concern as "immaterial." (Defs.' Resp. to Pls.' Stmt. of Material Facts ¶¶ 34–36 [Dkt. #59].)

Instead of addressing this prejudgment, Defendants sound a familiar refrain, claiming that the Executive Order mandated their action and that they were essentially required to disregard comments that categorically opposed human embryonic stem cell research. (Defs.' Mem. & Opp. at 38–39.) The question of whether agency officials entered the process with an "unalterably closed mind," however, "should focus on the agency member's prejudgment," rather than on a "failure to weigh the issues fairly." *C & W Fish Co.*, 931 F.2d at 1564; *see Nehemiah Corp.*, 546 F. Supp. 2d at 847. Such prejudgment is evident here.

Finally, Defendants argue that the newspaper article quoting Acting Director Kington is irrelevant because it is "not part of the administrative record." (Defs.' Mem. & Opp. at 38 n.16 [Dkt. #57-58].) When making the determination of an agency official's closed mind, however, the D.C. Circuit and other courts do not limit their inquiry to the administrative record. *See Consumers Union of the U.S., Inc. v. FTC*, 801 F.2d 417, 426–27 (D.C. Cir. 1986) (considering a statement made at a press conference and one printed in a newspaper article); *Nehemiah Corp.*,

546 F. Supp. 2d at 848 (holding that a newspaper article could be considered because it met the "agency bad faith" exception to consideration of extra-record materials, "at least in the context of a prejudgment claim"). The undisputed evidence of Director Kington's predetermined decision, and Defendants' admissions before this Court showing that they refused even to consider suggestions that they follow a different course, conclusively establish that Defendants prejudged the issue and entered the rulemaking with an unalterably closed mind.

V. Permanent Injunctive Relief, and a Declaration That the Guidelines Are Invalid and Vacated, Are Necessary and Appropriate to Remedy Defendants' Ongoing Violation of Federal Law.

Aside from their arguments on the merits (which are unpersuasive for the reasons set forth above), Defendants' only response to Plaintiffs' request for injunctive relief is to claim that the requested relief is overly broad and not an appropriate remedy under "settled principles of administrative law." (Defs.' Mem. & Opp. at 40–41 (quoting *Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005)) [Dkt. #57-58].) In light of the invalidity of the Guidelines, however, and considering that this Court has previously found that the equitable considerations favor injunctive relief, *Sherley*, 704 F. Supp. 2d at 72-73, Defendants' claims regarding the scope and propriety of injunctive relief are simply inapposite.

First, Plaintiffs have requested injunctive relief only as is necessary to remedy the ongoing violation of federal law. Such relief is consistent with equitable doctrines and established law in this jurisdiction. The D.C. Circuit has adopted the view that a finding of illegal agency action, even with regard to a single individual, can result in "'programmatic' relief." *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998). "[I]f the plaintiff prevails, the result is that the *rule is invalidated*, not simply that the court forbids its application to a particular individual." *Id.* (emphasis added).

That the resulting "programmatic relief" may "affect[] the rights of parties not before the court" does not present any bar to an injunction. *Id.* This Court has held that when an agency policy is facially invalid, "[i]ssuing a nationwide injunction is . . . called for because the declaratory judgment alone is inadequate . . . ." *Am. Lands Alliance v. Norton*, No. Civ. A. 00-2239 (RBW), 2004 WL 3246687, at *3–4 (D.D.C. June 2, 2004). In *American Lands Alliance*, an injunction was necessary, the court reasoned, because "refusal to sustain a broad injunction is likely merely to generate a flood of duplicative litigation." *Id.* ("[A]n injunction issued here only as to the plaintiff organizations and their members would cause all others affected by the [invalid rule] to file separate actions for declaratory relief in this circuit."). Defendants claim that "requiring parties not before this Court to return funds distributed to them would do nothing to remedy plaintiffs' alleged injuries" (Defs.' Mem. & Opp. at 41–42 [Dkt. #57-58]), but that is simply inaccurate. The returned funds would be available for use funding subsequent research grants, and thus Dr. Sherley and Dr. Deisher would have the opportunity to compete for additional funding. *See, e.g.*, *Population Inst. v. McPherson*, 797 F.2d 1062, 1081 (D.C. Cir. 1986) (recognizing irreparable harm from the illegal distribution of funds because "no funds will remain available for distribution" to plaintiffs); *Ambach v. Bell*, 686 F.2d 974, 986 (D.C. Cir. 1982). An injunction is necessary to end the ongoing violation of federal law and to eliminate the recognized injury that Drs. Deisher, Sherley, and others are suffering as a result of the illegal Guidelines.

Similarly meritless is Defendants' argument that this Court lacks authority to permanently enjoin Defendants from funding research that violates federal law. (Defs.' Mem. & Opp. at 40 [Dkt. #57-58].) While the Supreme Court has cautioned against "pervasive oversight by federal courts over the manner and pace of agency compliance," *Norton v. S. Utah Wilderness*

Alliance, 542 U.S. 55, 66 (2004), an order directing Defendants to cease violating federal law is a far cry from the "pervasive oversight" contemplated by the Court. Defendants rely heavily on the recent decision in *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010), in which the Court rejected the district court's injunction against prospective agency action. But that holding turned on the fact that the agency "had not yet exercised its authority" and therefore "any judicial review of such a decision is premature." *Id.* at 2758. Here, NIH has exercised its authority by issuing the Guidelines in violation of federal law and by distributing hundreds of millions of taxpayer dollars for illegal purposes—injunctive relief is timely and necessary. In light of the illegal NIH Guidelines that constitute an ongoing violation of federal law, the proper remedy is for those Guidelines to be vacated and any further implementation or execution of those Guidelines to be permanently enjoined.

Defendants also claim that "[i]f this Court were to award judgment to plaintiffs on their notice-and-comment claims, the proper remedy would be a remand without vacatur." (Defs.' Mem. & Opp. at 41 n.18 [Dkt. #57-58].) However, the D.C. Circuit has "made clear that '[w]hen a reviewing court determines agency regulations are unlawful, the *ordinary result is that the rules are vacated*—not that their application to the individual petitioners is proscribed.'" *Nat'l Mining Ass'n*, 145 F.3d at 1409 (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)). In the cases Defendants cite, the D.C. Circuit did remand without vacatur, but in each case the reason was that the *factual* adjudication necessary was more properly left to the agency, rather than the district court on remand. *See Palisades Gen. Hosp.*, 426 F.3d at 403–04; *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1011–12 (D.C. Cir. 1999). These cases are inapplicable, because the question whether the Guidelines violate the Dickey-Wicker Amendment and the APA is a *legal* determination, and the district court undoubtedly has

equitable power to remedy this ongoing legal violation. Defendants claim that "the Secretary could remedy any supposed APA violation on remand" (Defs.' Mem. & Opp. at 41 n.18), but they have repeatedly made clear that they will consider comments on the ethical responsibility and scientific worth of embryonic stem cell research to be "not relevant to the promulgation of the final Guidelines." (Landis Decl. ¶ 12.) The ethical irresponsibility and scientific unworthiness of human embryonic stem cell research would not magically disappear if the Guidelines were reconsidered on remand, and Defendants do not identify a single area of factual development to be followed on remand that could justify reissuance of the Guidelines in anything like their present form.

Finally, Defendants erroneously claim that vacatur is improper because "it would cause numerous 'disruptive consequences'" (Defs.' Mem. & Opp. at 41 n.18 [Dkt. #57-58]), citing the "numerous research projects that are currently pending" that would be disturbed by an interruption of the illegal funding. *Id.* Defendants and amici again seek to conjure their speculative "'parade of horribles'" that this Court has already rejected. (Order of Sept. 7, 2010, at *1 [Dkt. #53]; *see* CAMR Brief, at 25–27 [Dkt. #62].) "[T]he threat of disruptive consequences cannot save a rule when its fundamental flaws 'foreclose [the agency] from promulgating the same standards on remand.'" *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008) (quoting *Natural Res. Def. Council v. EPA*, 489 F.3d 1250, 1261–62 (D.C. Cir. 2007)). Here, because the ethical irresponsibility and scientific unworthiness of human embryonic stem cell research would foreclose a reissuance of the same Guidelines, the claimed "disruptive consequences" cannot save the Guidelines.

Because Plaintiffs have made a proper showing under the established factors for injunctive relief, this Court should vacate the Guidelines and enjoin Defendants from further implementing, executing, or funding research pursuant to those illegal Guidelines.

CONCLUSION

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. In addition, Defendants' motion for summary judgment should be denied.

Dated: October 14, 2010

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of October, 2010, I electronically filed the foregoing Combined Reply in Support of Summary Judgment, Opposition to Defendants' Motion for Summary Judgment, and Response to Amici Curiae with the Clerk of the United States District Court for the District of Columbia by using the CM/ECF system, which will serve a copy of the foregoing on the following parties and potential amici:

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