IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JAMES L. SHERLEY, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 1:09-cv-01575-RCL
	)	
KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

MOTION FOR SUMMARY JUDGMENT

Defendants hereby move for summary judgment pursuant to Federal Rule of Civil Procedure 56 on the claims in the Complaint. In support of this Motion, defendants respectfully refer the Court to the accompanying Memorandum of Law and to the attached declaration of Story Landis. A proposed order is also attached.

Dated: September 27, 2010

Respectfully submitted,

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Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

Plaintiffs ask this Court to issue a permanent injunction against all NIH funding of human embryonic stem cell ("hESC") research based upon the supposedly "unambiguous" language of the Dickey-Wicker Amendment. Their interpretation of that Amendment, enacted 15 years ago and renewed in each successive appropriations bill without substantive change, is inconsistent with the approach of the last three Presidential administrations and five successive Congresses, since such research has been funded by NIH for almost a decade. In fact, in FY2010 appropriations to NIH, Congress removed any doubt about its position on the final guidelines challenged in this case. Explicitly recognizing the passage of the final guidelines, Congress stated that Dickey-Wicker's "language should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 111-220 at 223 (July 22, 2009); S. Rep. No. 111-66 at 121 (Aug. 4, 2009) ("The Committee is pleased that stem cell research was included as a special emphasis area in the NIH Challenge Grant program . . . . *The Committee also welcomes the recent release of guidelines for the use of human embryonic stem cells [hESC] with NIH funds . . .*") (emphasis added); *see also* H.R. Conf. Rep. No. 111-366 at 982 (Dec. 8, 2009) ("In implementing this conference agreement, the Departments and agencies should be guided by the language and instructions set forth in House Report 111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293."). In light of this unambiguous authority, plaintiffs' interpretation should be rejected.

Plaintiffs also assert that NIH violated the Administrative Procedure Act (APA) in its promulgation of the Guidelines. NIH, however, rationally explained its choice of the standards

that it developed in response to the President's direction in Executive Order No. 13,505, which is all that the APA requires. The fact that the agency did not oppose the President's policy on stem cell research or solicit comments on either the ethical or scientific basis for that policy does not demonstrate that it failed to rationally consider those relevant comments that it received in response to the draft guidelines.

Plaintiffs' claims do not have merit. However, even if this Court were to disagree, plaintiffs' claims under the Administrative Procedure Act do not provide this Court with the authority to permanently enjoin all future agency action with respect to hESC research, as this Court has "no jurisdiction to order specific relief" beyond invalidation of the agency action in question. *Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005).

Plaintiffs urge this Court to adopt an approach that fundamentally limits the future of scientific progress and disrupts research that offers hope to millions who suffer from currently incurable diseases. Defendants accordingly respectfully request that the Court deny plaintiffs' Motion for Summary Judgment and grant defendants' Motion for Summary Judgment.

STATEMENT OF FACTS

I. THE PROMISE OF HUMAN EMBRYONIC STEM CELL RESEARCH

Stem cell research holds great promise for the development of treatments for a wide range of serious and life-threatening diseases and conditions. *See* National Academies, *Understanding Stem Cells: An Overview of the Science and the Issues from the National Academies* at 2 (2009) (AR 587). Research into the unique properties of stem cells may lead to "major medical breakthroughs" that would "offer hope to people suffering from cancer, diabetes, cardiovascular disease, spinal-cord injuries, and many other disorders." *Id.* There are three

primary kinds of stem cells available for research – hESCs, adult stem cells, and induced pluripotent stem cells (iPSCs). Each of these types of cells has its own capabilities and limitations. Accordingly, the consensus in the scientific community is that each of these types of cells is a worthy subject of research. National Institutes of Health ("NIH"), *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp (AR 705); *see also* Declaration of Story Landis ¶ 16 ("Landis Decl."), attached hereto as Exhibit A.[1]

Human embryonic stem cells have been available for research only since 1998, when Dr. James Thomson of the University of Wisconsin developed a method to extract cells from a blastocyst.[2] NIH, *Regenerative Medicine 2006* at 3 (AR 617). The vast majority of such blastocysts used to derive stem cells come from in vitro fertilization (IVF) clinics, where it is standard practice for doctors to fertilize far more eggs than will ever be implanted, in an effort to maximize the chance of a successful pregnancy. *Understanding Stem Cells* at 5 (AR 590). This results in large stores of "excess" blastocysts, *id.*, which may be frozen indefinitely or discarded if they are not donated for research.

The discovery of human embryonic stem cells holds the potential for great advances in medical research due to the unique properties of these cells. Embryonic stem cells are

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[1]Defendants have attached the declaration of Dr. Landis to provide the court with background information about NIH's support of hESC research and its development of the Guidelines, as well as to address some of Plaintiffs' assertions regarding the scientific merits of hESC research that – while not material to the ultimate issues to be decided in this case – convey incorrect or misleading information. *See Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996) (recognizing the appropriateness of this type of declaration in record review cases); *Empresa Cubana Exportadora de Alimentos y Productos Varios v. U.S. Dep't of Treasury*, 606 F. Supp. 2d 59, 69 (D.D.C. 2009) (Lamberth, Chief Judge).

[2] The blastocyst is the sphere of cells that forms about five or six days after fertilization, with an inner cell mass that consists of 30 to 34 cells. *Understanding Stem Cells* at 4 (AR 589).

pluripotent, meaning that they hold the capability to give rise to any of the approximately 200 types of cells in the human body. *Regenerative Medicine 2006* at 1 (AR 615). Once a stem cell line is derived from a blastocyst, the cells are self-replicating and can be maintained indefinitely, making them promising subjects for medical research. *Regenerative Medicine 2006* at 4 (AR 618).

Researchers do not aim to transplant undifferentiated human embryonic stem cells directly into the human body, as this practice would run the risk of forming a particular type of benign tumor known as a teratoma. *Understanding Stem Cells* at 5 (AR 590). Instead, researchers coax human embryonic stem cells to differentiate into particular kinds of cells. Researchers aim to be able to use these differentiated cells, known as derivatives, to safely treat of a range of disorders for which there is no current cure. *Regenerative Medicine 2006* at 77-78 (AR 691-92). Very recently, the FDA approved the first clinical trial of an hESC-derived therapy to begin enrolling patients with spinal cord injuries. *See* Decl. of Dr. Francis Collins ¶ 6, Ex. A to Defs.' Mot. to Stay Prelim. Inj., Dkt. No. 48-2 ("Collins Decl."). Embryonic stem cells can also be used to study disease mechanisms that cannot be studied in the human body, and to develop other, non-stem-cell-based therapies for these conditions. *Regenerative Medicine 2006* at 4 (AR 618); *see also* Collins Decl. ¶ 7. Differentiated cells derived from hESC are already successfully being used to develop new therapeutic drugs for a number of diseases, including amyotrophic lateral sclerosis ("ALS" or "Lou Gehrig's disease") and spinal muscular atrophy. Collins Decl. ¶ 6.

Additional research suggests similar promise for medical treatment:

- One recent study used hESC lines to generate Natural Killer, or "NK" cells, a kind of white blood cell that destroys cancer, and found that the hESC-derived cells were better

at destroying leukemia than cells derived from another type of stem cells. NIH, *Cancer-Destroying Cells Derived from Human Embryonic Stem Cells*, http://stemcells.nih.gov/research/scilit/highlights (AR 723). hESC-derived NK cells not only destroyed human cancers in mice, but also protected mice from recurrence and metastasis. *See* Landis Decl. ¶ 21.

- Researchers have made significant progress in differentiating hESC lines into "beta cells," that is, the type of cell in the pancreas that produces insulin, suggesting promise for the treatment of Type 1 diabetes. *Understanding Stem Cells* at 17 (AR 602).

- Researchers have not only differentiated hESCs into dopamine neurons – the type of brain cell that is lost by patients who suffer from Parkinson's disease – but have succeeded in producing a large number of dopamine neurons and have transplanted them into an animal model of Parkinson's disease, eliciting clear behavioral recovery. *See* Landis Decl. ¶ 17; *see also Understanding Stem Cells* at 16 (AR 601).

- Researchers have also developed a method that uses hESC lines to develop neurons, while suppressing cells that might develop teratomas; this may lead to a safe and effective form of treatment for stroke victims. NIH, *Human Embryonic Stem Cell-Derived Neurons Treat Stroke in Rats*, available at http://stemcells.nih.gov/research/scilit/highlights/highlights2008.htm (AR 729).

These are only a few examples of recent peer-reviewed studies that indicate that hESC research will be extremely important for the development of medical knowledge. *See* NIH, *Stem Cell Information: Scientific Literature*, http://stemcells.nih.gov/research/scilit/highlights (AR 723-38) (collecting peer-reviewed studies involving hESC and other stem cells).

In addition to hESC lines, adult stem cell lines also provide a promising subject for research. *Understanding Stem Cells* at 8 (AR 593). Research on these cells began about 50 years ago with the discovery of hematopoietic stem cells, which are obtained from bone marrow or from umbilical cords. *Regenerative Medicine 2006* at 14-15 (AR 628-29). Unlike other adult stem cells, hematopoietic stem cells can be readily released into the blood for collection. *Regenerative Medicine 2006* at 22 (AR 636). Hematopoietic stem cells are the one type of adult stem cell that has been harvested in relatively large quantities for decades. As a result, this type

of cell has been used for the vast majority of the diseases that have been treated with adult stem cells. NIH, *Hematopoietic Stem Cells*, available at http://stemcells.nih.gov/info/scireport/chapter5.asp (AR 714). Despite their value in biomedical research, however, adult stem cells have serious limitations that fifty years of research have not been able to overcome. Collins Decl. ¶ 7. Adult stem cells are multipotent, not pluripotent, meaning that they can differentiate only into a smaller set of specialized cells. *Hematopoietic Stem Cells*, *supra*. Researchers have not yet succeeded in using adult stem cells to produce some important classes of cells, such as neurons, the cells that are destroyed by neurodegenerative diseases like Alzheimer's disease or amyotrophic lateral sclerosis (ALS). *See* Collins Decl. ¶ 7; Landis Decl. ¶ 18 n.3. Recent research provides hope that adult stem cells might be able to be differentiated into a wider variety of cell types than scientists previously had believed[3], but it is too early to know whether that hope can be achieved. *Understanding Stem Cells* at 8 (AR 593).

A recent discovery, made possible through the knowledge gained from studying hESC, provided a third type of stem cell that is available for research. Collins Decl. ¶ 7. In 2007, researchers identified conditions that would allow some specialized adult human cells to be reprogrammed genetically to assume a state that is similar to embryonic stem cells. *Regenerative Medicine 2006* at 85 (AR 699). These reprogrammed cells are known as induced pluripotent stem cells (iPSCs). Research involving iPSCs is promising, but the research is at a very early stage, and it is too soon to know the full potential of iPSC research. *Understanding Stem Cells* at 12 (AR 597). In particular, it is not yet known whether iPSCs differ from hESCs in

[3] Even after 50 years of adult stem cell research, scientists are concededly not even close to knowing its full potential. By contrast, hESC research was only begun 12 years ago and has been restricted since that time.

clinically significant ways that would limit their usefulness. NIH, *Stem Cell Basics*, http://stemcells.nih.gov/info/basics/basics10.asp (AR 718). The current procedure that is used to create iPSCs involves genetic manipulation of the cells through the use of viruses, which can cause cancer. Collins Decl. ¶ 7. In addition, some early evidence suggests that hESCs may be better at generating certain types of cells than iPSCs. Landis Decl. ¶ 20. Most scientists believe that it is essential to continue research on hESCs as we explore the potential of iPSCs. Collins Decl. ¶ 7.

Because each of the three forms of stem cells—human embryonic stem cells, adult stem cells, and induced pluripotent stem cells—presents both advantages and disadvantages for researchers, a consensus has formed that there is scientific merit for further research involving each of these types of cell lines. Landis Decl. ¶ 15.

II. REGULATORY BACKGROUND

On March 9, 2009, President Barack Obama issued Executive Order No. 13,505, 74 Fed. Reg. 10,667 (AR 10). The President noted the potential that research involving human embryonic stem cells holds for the understanding and treatment of a variety of diseases and conditions. *Id.*, § 1. He accordingly recited his policy determination that he would "remove . . . limitations on scientific inquiry" involving stem cells that had been imposed by prior Presidential actions, "expand NIH support for the exploration of human stem cell research," and "in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." *Id.* The President directed 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." *Id.*, § 2. The President

further directed NIH within 120 days to review existing guidelines on human stem cell research, and to "issue new NIH guidance on such research that is consistent with this order." *Id.*, § 3. President Obama's Order withdrew two directives that had been issued in the prior Administration: (1) a presidential statement of August 9, 2001, and (2) Executive Order No. 13,435 of June 20, 2007, 72 Fed. Reg. 34,591. *Id.*, § 5.

The executive pronouncements by former President Bush that were withdrawn in Executive Order No. 13,505 permitted federal funding of some research using human embryonic stem cells, but limited the number of stem cell lines for which federal funding could be made available. On August 9, 2001, President Bush announced that his Administration would permit federal funding to be used for research involving stem cell lines that were created by private or foreign researchers from "embryos that have already been destroyed," but would prohibit federal funding for research on stem cell lines created after the date of his announcement. *See Address to the Nation on Stem Cell Research From Crawford, Texas*, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001) (AR 19). President Bush reiterated this policy decision when he issued Executive Order No. 13,435, 72 Fed. Reg. 34,591 (AR 14). That order formalized his previously stated position which prohibited federal funding for research on hESC lines created after August 9, 2001. *Id.* at 34,591-34,592. However, the order continued to permit federal funding to be used for research using approved hESC lines created prior to that date. *Id.* at 34,592. In so doing, this policy reflected the necessary determination that such research was not research "in which" embryos are destroyed.

By withdrawing these directives, President Obama's Executive Order ended restrictions on federal funding that had limited the use of particular stem cell lines according to the date of

derivation, thereby "remov[ing]" what he deemed to be inappropriate political "limitations on scientific inquiry." In compliance with the President's directive to effectuate this policy through the promulgation of guidelines, NIH, after providing notice and considering responsive comments, issued final Guidelines on July 7, 2009. 74 Fed. Reg. 32,170 (AR 1).

NIH stated, as it had in proposing draft guidelines, 74 Fed. Reg. 18,578 (Apr. 23, 2009) (AR 7), that the Guidelines were being issued to "implement Executive Order 13505" and establish policies and procedures "consistent with" the Executive Order. 74 Fed. Reg. at 32,170. The Guidelines established a two-part structure that would govern the types of human embryonic stem cell lines that could be used in research funded by NIH. If an applicant institution proposed research using cells derived from embryos donated within the United States on or after the effective date of the Guidelines[4], the researcher must either be limited to cell lines posted on a new NIH registry, or the researcher must submit an "assurance of compliance" with part A of the Guidelines. Part A requires that the research involves only hESCs that "have been derived from human embryos" that "were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by individuals . . . who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32,174. This part further requires documentation that the following requirements have been satisfied with respect to the embryos from which the stem cells to be used for research

[4] For embryos donated outside of the United States on or after the effective date of the Guidelines, applicants must comply with Part A "or submit an assurance along with supporting information, that the alternative procedural standards of the foreign country where the embryo was donated provide protections at least equivalent to those provided by" Part A. 74 Fed. Reg. at 32,175. For embryos donated outside the United States before the effective date of these guidelines, applicants must comply with either Part A or Part B. *Id.*

purposes were derived: (a) "[a]ll options" that were available at a particular facility pertaining to the embryos were explained to the patients who had sought reproductive treatment; (b) no payments were offered for the donated embryos; (c) the health care facility had policies and/or procedures to ensure that the quality of care available for potential donors would not be affected by their consent or refusal to donate embryos; (d) there was a "clear separation" – demonstrated by a series of specific safeguards – between the patients' decision to create embryos for reproductive purposes and their decision to donate embryos for research purposes; and (e) the potential donors were provided with certain specified information as part of the consent process. 74 Fed. Reg. at 32,174-32,175.

For applicant institutions that propose research involving hESCs derived from embryos donated within the United States before the effective date of the Guidelines, and in which the hESCs to be used in the research are not listed on the new NIH registry, the applicant must demonstrate compliance with part A of the Guidelines, or submit materials to a Working Group of the Advisory Committee to the Director of NIH which will make recommendations regarding eligibility for NIH funding. *Id.* at 32,175. If the applicant chooses the last option, the material submitted must demonstrate that the cells were derived from embryos (1) "[t]hat were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose"; and (2) "were donated by donor(s) who gave voluntary written consent for the human embryos to be used for research purposes." *Id.* The Working Group will review the submitted materials, taking into account the same factors identified in part A of the Guidelines, including whether the donor was informed of other available options pertaining to the embryos, offered any inducements for donation, and informed about what would happen to the embryos following

donation for research. *Id.*

The final Guidelines noted that funding "of the derivation of stem cells from human embryos is prohibited by" an annual budgetary provision, known as the Dickey-Wicker Amendment. *Id.* In responding to comments concerning this statement in the draft Guidelines, NIH indicated that it has "consistently interpreted [the Amendment] as not applicable to research using hESCs, because hESCs are not embryos as defined by" the Amendment. *Id.* at 32,173. In light of Congress's knowledge that NIH has permitted funding of hESC research since 2001, and the annual reenactment of Dickey-Wicker by Congress without substantive change, NIH recognized Congress's acceptance of its position that the Amendment prohibits federal funding for "the derivation of stem cells from an embryo that results in the embryo's destruction" but not "research involving [hESCs] that does not involve an embryo nor result in an embryo's destruction." *Id.*

Nothing in the Guidelines purports to limit the availability of funding for research using adult stem cells or iPSCs. Instead, NIH recited in its draft Guidelines that "funding will continue to be allowed" for such research. 74 Fed. Reg. 18,578 (Apr. 23, 2009).

III. PROCEDURAL BACKGROUND

Plaintiffs filed the present lawsuit and moved for a preliminary injunction on August 19, 2009. Dkt. No. 3. On September 14, 2009, defendants opposed the motion and moved to dismiss plaintiffs' Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Dkt. Nos. 22, 23. On October 27, 2009, this Court granted defendants' Motion to Dismiss on standing grounds, holding that no plaintiff had alleged injury sufficient to satisfy the requirements of Article III. Dkt. No. 36. Plaintiffs appealed, and the D.C. Circuit reversed this

Court's decision and remanded the case for consideration of plaintiffs' Motion for Preliminary Injunction. 610 F.3d 69, 74 (D.C. Cir. 2010).

On the same day that the mandate was entered on the district court docket, this Court granted plaintiffs' Motion for Preliminary Injunction.[5] Dkt. Nos. 44, 45. According to the Court's Memorandum Opinion, plaintiffs had established a likelihood of success on the merits of their Dickey-Wicker claim as well as irreparable harm. *Id.* The order that the Court entered enjoined "defendants and their officers, employees, and agents . . . 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." Dkt. No. 45. Defendants appealed the Order and moved to stay its effect pending appeal of the preliminary injunction. Dkt. No. 48. Following denial of the motion, defendants moved for a stay in the Court of Appeals. The Court granted an administrative stay pending briefing on the Motion, which has since been fully briefed and argued in the Court of Appeals.

On September 9, 2010, plaintiffs filed the instant motion for summary judgment. Dkt. No. 55.

STANDARD OF REVIEW

In the typical case, summary judgment should be granted when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). However, the Rule 56(c) standard is inapplicable to APA cases due to the

[5] This Court has not yet ruled on defendants' pending Motion to Dismiss for failure to state a claim.

court's limited role in reviewing the agency's decision based upon the administrative record. *Cape Cod Hosp. v. Sebelius*, 677 F. Supp. 2d 18, 29 (D.D.C. 2009); *Hosp. of Univ. of Penn. v. Sebelius*, 634 F. Supp. 2d 9, 12 (D.D.C. 2009). Rather, "summary judgment serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Cape Cod Hosp.*, 677 F. Supp. 2d at 29 (internal quotation omitted). "In other words, the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Id.* (internal quotation omitted).

ARGUMENT

I. PLAINTIFFS' SUBMISSIONS ON SUMMARY JUDGMENT CONTINUE TO RELY ON SPECULATION ABOUT FUTURE INJURY DESPITE THE EXISTENCE OF SUPPOSED COMPETITION FOR THE PAST YEAR

Defendants recognize that the D.C. Circuit, in reversing this Court's decision dismissing the case for lack of standing, held that plaintiffs "will have to invest more time and resources to craft a successful grant application," which is a "here-and-now injury," and that "[t]he Doctors 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." 610 F.3d 69, 74 (D.C. Cir. 2010). However, plaintiffs have done little to satisfy their burden on summary judgment to support these predictions by the court of appeals.

Plaintiffs' declarations, submitted on summary judgment in support of their claim of standing, continue to show that they have suffered no injury as a result of the Guidelines. Neither of the injuries suggested by the D.C. Circuit—which reviewed plaintiffs' allegations at the pleadings stage—have proven to be true in the declarations submitted by plaintiffs. As an

initial matter, Dr. Deisher has still not even submitted a grant application to NIH. Deisher Decl. ¶ 3. She has apparently been "currently in the process of applying" for NIH funding for an entire year, without any indication as to when she might actually submit an application, much less that the research she proposes would actually be accepted or deemed scientifically worthy. Thus, her assertion that she must receive NIH funding "[i]n order to continue [her] research" rings hollow, as it begs the question of how she has been able to fund her "research" up to this point. *Id.*

Plaintiff Sherley has at least alleged that he has submitted two applications to NIH for grants. Sherley Decl. ¶ 4. However, despite this allegation, as well the vague assertion in his counsel's letter to the D.C. Circuit that his "chief competitor" on a pending application is a company using hESCs[6], 610 F.3d at 74, Sherley does not allege that he has lost any funding as a direct result of this supposed "competitor." In fact, Sherley attaches to his declaration an exhibit of his grant applications that demonstrates that he has continued to receive NIH funding *even after* the issuance of the final guidelines. Sherley Decl., Ex. A. Nor does Sherley allege that he took any concrete steps in response to this supposed competition. Instead, all that Sherley alleges is that the guidelines "will result in increased competition." *Id.* ¶ 5. Thus, after the passage of a year where funding was provided for hESC applications under the new guidelines, and months after Sherley informed the D.C. Circuit about his "competitor," Sherley still does not allege that he has expended any extra effort or lost any funding as a result of this supposed competition. This absence of proof suggests that plaintiffs' supposed competitive injury remains entirely speculative—a creature of their own making. Such speculation does not fulfill

[6] Even though we are now at the summary judgment stage, Sherley does not provide the basis for his counsel's assertion to the Court of Appeals, much less identify who that competitor is.

plaintiffs' burden to demonstrate their standing at the summary judgment stage.

II. CONSISTENT WITH THE LONG-STANDING INTERPRETATION OF NIH, THE DICKEY-WICKER AMENDMENT PERMITS THE FEDERAL FUNDING OF RESEARCH ON HUMAN EMBRYONIC STEM CELL LINES

Plaintiffs' first claim asserts that defendants violated a congressional statute, known as the "Dickey" or "Dickey-Wicker" Amendment, which currently prohibits federal funding for "the creation of a human embryo or embryos for research purposes," or "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))." *See* Pub. L. No. 111-117, Title V, § 509 (2010). In the Guidelines, NIH explained that, consistent with the definition of "embryo" in the Amendment, stem cells are not embryos. Accordingly, following the position first announced by NIH in formal guidelines issued in 2000, HHS has consistently interpreted Dickey-Wicker as prohibiting federal funding for the "derivation of stem cells from an embryo that results in the embryo's destruction," but permitting federal funding for "research involving hESCs that does not involve an embryo nor result in an embryo's destruction." 74 Fed. Reg. at 32,173 (AR 4); 65 Fed. Reg. 51,976 (Aug. 25, 2000) (AR 24); *see also* Prelim. Inj. Mem. Op., Dkt. No. 44, at 5 ("Defendants have maintained this interpretation of the Dickey-Wicker Amendment since 1999. Congress, however, has not altered the Dickey-Wicker Amendment in response.") (internal citation omitted).

Plaintiffs take issue with this long-standing, consistent interpretation, asserting that "Dickey-Wicker unambiguously prohibits the federal funding of research—such as embryonic stem cell research—that requires and induces the destruction of human embryos." Pls.' Mem. at

14. And this Court held in granting plaintiffs' Motion for Preliminary Injunction that, "as demonstrated by the plain language of the statute, the unambiguous intent of Congress is to prohibit the expenditure of federal funds on 'research in which a human embryo or embryos are destroyed,'" and "ESC research is clearly research in which an embryo is destroyed." PI Mem. Op. at 10. Defendants respectfully assert that this conclusion is supported by neither the plain language of Dickey-Wicker nor the congressional intent to the contrary, expressly reiterated for the last decade.

A. NIH's Interpretation of Dickey-Wicker Is Justified by the Traditional Tools of Statutory Interpretation at Step One of *Chevron*

In deciding the statutory interpretation issue raised by plaintiffs, this Court has already correctly recognized that the standard of review that guides the Court is the familiar one established by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See* PI Mem. Op. at 9-10 (evaluating plaintiffs' Dickey-Wicker challenge under *Chevron*); *see also Mount Royal Joint Venture v. Kempthorne*, 477 F.3d 745, 754 (D.C. Cir. 2007) ("If the agency enunciates its interpretation through notice-and-comment rule-making or formal adjudication, we give the agency's interpretation *Chevron* deference.").

In *Chevron*, the Supreme Court held that courts reviewing an agency's interpretation of an applicable statute must "give effect to the unambiguously expressed intent of Congress," but that where the statute is ambiguous, the issue is whether the agency has adopted a "permissible construction of the statute." 467 U.S. at 843. As this Court has recognized, the search for unambiguous intent under the first step of *Chevron* requires the Court to "employ the traditional tools of statutory interpretation, including the text of the statute, legislative history, the structure of the statute and its purpose." *Cape Cod Hosp. v. Sebelius*, 677 F. Supp. 2d at 30. The use of

such tools in the present case compels the interpretation of Dickey-Wicker asserted by defendants.

1. The Language of Dickey-Wicker Supports Defendants' Long-Standing Interpretation

Plaintiffs do not dispute that human embryonic stem cells are not embryos, as that term is used in the Dickey-Wicker Amendment. Instead, they suggest that Congress's use of the phrase "research in which . . . embryos are destroyed, discarded, or knowingly subjected to risk of injury or death" commands such a broad reading of the term "research" that it would include all research that followed from, or preceded, the destruction of a human embryo. *See* Pls.' Mem. at 15 (arguing that Dickey-Wicker applies to all research that "necessarily requires" the destruction of an embryo). In support of their interpretation of this single term in the statute, plaintiffs do not point to any common understanding of the term, as revealed by a dictionary definition. *Cf. Wis. Dep't of Revenue v. William Wrigley, Jr., Co.*, 505 U.S. 214, 223 (1992) (Scalia, J.) (resorting to dictionaries to determine how words in statute are "commonly understood"). Rather, plaintiffs point to NIH's definition of the term "research" in regulations, unrelated to those challenged here, which define the term as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." Pls.' Mem. at 16.

Of course this definition, which is not in any way incorporated into the Dickey-Wicker Amendment, does not command plaintiffs' broad reading of the statute. The word "systematic" is not commensurate with the term "unending" or "undivided"; it refers instead to "having,

showing, or involving a system, method, or plan." RANDOM HOUSE DICT. (2010)[7]. A particular research project involving stem cells can therefore be "systematic" or "methodical" without needing to include within its scope all steps that made the research possible. After all, the most relevant definition of the term "research" in NIH regulations is the one that actually pertains to the extramural grant process. That regulation defines the term "research" as "a systematic investigation, *study* or *experiment* designed to contribute to general knowledge relating broadly to public health[.]" 42 C.F.R. § 52.2 (emphases added). Thus, even a "study" or "experiment" can be "systematic" in nature. There is no possible understanding of the term, taking into account its ordinary definition, that mandates the unlimited construction proffered by plaintiffs.

The common understanding of "systematic" is entirely consistent with the common understanding of the term "research," as well as NIH's construction of that term. The term "research," standing alone, may be defined as a "diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications," or a "particular instance or piece of research." RANDOM HOUSE DICT. (2010). Under either definition, research may be understood to include separate research projects, such as a cell biology experiment or an embryonic stem cell cancer study. Thus, nothing in the common understanding of the term compels the conclusion that the term "research" must be read so broadly that any antecedent or subsequent advancements in scientific knowledge, or the development or production of every tool used in scientific research, must be grouped together as a unitary whole for purposes of

[7] The Random House sources are available at http://dictionary.reference.com/.

Dickey-Wicker.[8]

However, while plaintiffs ask this Court to focus on the solitary term "research" to the exclusion of the terms that surround it, that is of course something that this Court cannot do. *See, e.g., Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 596 (2004) (recognizing the "cardinal rule that [s]tatutory language must be read in context [since] a phrase gathers meaning from the words around it.") (internal quotation omitted). Contrary to plaintiffs' narrow focus,

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[8] The plaintiffs cite three sources for the proposition that the term "research" has been defined broadly. None of these sources supports, let alone commands, the reading proposed by the plaintiffs. For example, in *Merck KgaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005), the statute in question did not even include the term "research." Instead, after an extensive discussion of the purposes of the specific provision in question, the Court interpreted the broadly-worded phrase "reasonably related to the development and submission of any information" to include preclinical research. *Id.* at 202. In fact, the Court's discussion of different phases of "research," including the use of the term "preclinical research," demonstrates that the word is often used to describe discrete aspects of a research project. *Id.* at 204. Similarly, in *Nat'l Ctr. for Mfg. Sci., Inc. v. City of Ann Arbor*, 563 N.W.2d 65 (Mich. App. 1997), the state court of appeals held that, for purposes of a tax exemption, a company can be engaged in research even if no experiments are conducted in its actual headquarters. The question of whether the result would have been different if the term "research" had been limited to property "in which" experiments are conducted is, of course, not answered by the language or purposes of this isolated tax provision. These very different statutory contexts and congressional purposes demonstrate why the use of words in different statutes often provides little guide in statutory analysis. *See, e.g., United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200 (2001) (explaining danger in relying on definition of same word in different statutory contexts); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341-42 (1997) ("Similarly, that other statutes have been more specific in their coverage of 'employees' and 'former employees,' . . . proves only that Congress can use the unqualified term 'employees' to refer only to current employees, not that it did so in this particular statute."). Finally, the plaintiffs point to NIH Web site guidance concerning human subject research where entities are considered engaged in such research when their project includes activities involving human subjects carried out by agents of another institution. Pls.' Mem. at 16. Of course, this section of the guidance applies to those projects who have received an award expressly for non-exempt human subjects research, and the specific statutory language from which the guidance flows applies to such research "conducted at or supported by such entity." 42 U.S.C. § 289 (emphasis added). Accordingly, plaintiffs' reference does little to support their broad definition of the term "research" as applying in a separate statutory context limited to those projects in which embryos are actually involved.

the term "research" in Dickey-Wicker does not stand alone; it is followed and informed by the phrase "in which . . . embryos are destroyed . . . ." Thus, the research for which federal funding is prohibited is, as a threshold matter, only that "in which" embryos are used. The term "in which" typically has a limiting connotation when used as a prepositional phrase. *See* RANDOM HOUSE DICT. (2010) (defining "in," as a preposition, to be "used to indicate limitation or qualification, as of situation, condition, relation, manner, action, etc."). Thus, the particular "research" that is prohibited must be that "in which" an embryo is actually involved in the particular research project.

In addition, plaintiffs' overly broad interpretation ignores the fact that the research targeted by the plain language of Dickey-Wicker is limited to those situations in which embryos "are" destroyed, discarded, or knowingly subjected to risk of injury or death. The Amendment uses only the present tense; it does not extend to prohibiting research involving embryos that "had been" or "were" destroyed in the past or to any potential incentive for destructions in the future. *See Carr v. United States*, 130 S. Ct. 2229, 2236 (June 1, 2010) (holding that the use of present tense, rather than past or present perfect, "reinforces the conclusion" that the plain language of an act does not include past actions); *Sutton v. United Air Lines*, 527 U.S. 471, 482 (1999) ("Because the phrase 'substantially limits' appears in the Act in the present indicative verb form, we think the language is properly read as requiring that a person be presently - not potentially or hypothetically - substantially limited in order to demonstrate a disability."), *superseded by* Pub. L. No. 110-325 (2009); *Jason v. Summerfield*, 214 F.2d 273, 276 (D.C. Cir. 1954) ("The tense of the verbs used, 'exist' and 'is,' was the present tense. The 'reasonable grounds' had to be actually or really in being, presently, at the time of review."). Had Congress

intended to prohibit all funding for research involving hESCs that had been derived through a non-federally-funded extraction process that resulted in the destruction of an embryo, or research that (however indirectly) might provide such an incentive in the future, it could have done so expressly by applying the prohibition to past, or future, derivations.

To counter this assertion, plaintiffs seek refuge in the fact that Dickey-Wicker also prohibited "research in which embryos are 'discarded.'" Pls.' Mem. at 17. It is unclear what purpose such a recognition serves, as defendants do not dispute that the discarding of an embryo *in the course of a particular research project* is prohibited. Thus, the many research projects that would actually involve the destruction or discarding of an embryo, such as the refinement of preimplantation genetic techniques or the improvement of IVF methodologies (to name only a few), are ineligible for federal funding.[9] The fact remains that such research projects remain entirely separate and distinct from proposed research projects on hESC lines.[10]

Plaintiffs' reading of the language of Dickey-Wicker to include any and all research on

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[9] These types of research projects actually involving embryos are, after all, the very types of research that concerned NIH and Congress prior to the passage of Dickey-Wicker. *See, e.g.*, NIH, Report of the Human Embryo Research Panel, at v (Sept. 1994) (noting that the Panel had been created to examine issues concerning "preimplantation human embryo research").

[10] Plaintiffs criticize NIH's decision to permit a researcher who has derived stem cell lines from later submitting a research proposal involving only stem cells and not derivation. Pls.' Mem. at 18. However, Congress, in many contexts, expresses an intent that federal funding provided to an organization not be used for a particular purpose, even though the organization might still conduct prohibited activities with non-federal funds. *See, e.g.*, *Velazquez v. LSC*, 164 F.3d 757, 763-64 (2d Cir. 1999). It does not defeat the purpose of the Amendment to conclude that Congress could have intended in Dickey-Wicker to prohibit funding of hESC derivation only, and not hESC research entirely. *See* Statement of Senator Frist, 147 Cong. Rec. S7846-0, *S7850 (July 18, 2001) ("While we find it important to scientific research and ethically acceptable that limited and strictly regulated [hESC] research proceed, this does not mean that federal funds should be used in the derivation of [hESC] cells.").

hESCs would render the phrase "in which a human embryo or embryos are destroyed" entirely superfluous, while at the same time putting at risk federal funding for an untold number of potential scientific endeavors. If the term "research" must be read to include all acts that necessarily preceded the hESC research project for which federal funding is sought, or research that might ultimately flow from the project, then it is hard to see where the dividing line might be. Science is a continuum, where past advances in cell biology made development of stem cell lines possible, and where new advances might alter those techniques. Plaintiffs' broad reading of the term "research" in the Dickey-Wicker Amendment suggests that all such research should therefore also be prohibited, an absurd result that should not be entertained by this Court. *See, e.g.*, *Pub. Citizen v. DOJ*, 491 U.S. 440, 454 (1989).

2. Congress Has Expressly Ratified NIH's Interpretation of Dickey-Wicker

Even if this Court were to find that ambiguity exists in the plain language, no doubt is present in the legislative history, as Congress has expressly ratified NIH's interpretation of Dickey-Wicker. Dickey-Wicker is a rider to an annual appropriations bill and, as such, it must be renewed with each appropriations bill passed by Congress. The most recent bill that currently governs congressional appropriations to NIH (passed while this case was on appeal) includes the same Dickey-Wicker language that has been included in NIH appropriations since 1995. *See* Pub. L. No. 111-117, Title V, § 509 (2010). In both Committee Reports accompanying the bill, Congress could not have been more clear as to the precise issue before this Court. There, Congress noted that the Dickey-Wicker Amendment's "language should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President" and expressly "welcome[d]" the release of

final guidelines permitting such research. H.R. Rep. No. 111-220 at 223 (July 22, 2009); S. Rep. No. 111-66 at 121 (Aug. 4, 2009) ("The Committee is pleased that stem cell research was included as a special emphasis area in the NIH Challenge Grant program . . . . The Committee also welcomes the recent release of guidelines for the use of human embryonic stem cells [hESC] with NIH funds . . . ."); *see also* H.R. Conf. Rep. No. 111-366 at 982 (Dec. 8, 2009) ("In implementing this conference agreement, the Departments and agencies should be guided by the language and instructions set forth in House Report 111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293.").

As defendants have noted in prior briefs, this express ratification followed a decade of congressional ratification under President Bush while federal funding was, with Congress's full knowledge, being actively provided to hESC researchers. Congress repeatedly and expressly acquiesced to the use of federal funds for such research—research that also undisputedly depended upon the prior destruction of an embryo.[11] *See, e.g.*, H.R. Rep. No. 107-229 at 180 (Oct. 9, 2001) ("The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells . . . and carried out in accordance with policy outlined by the President."); S. Rep. No. 107-84 at 18 (Oct. 11, 2001) ("The Committee urges the NIH to move quickly to support all types of stem cell research, including embryonic, adult, and cord blood . . . ."); *see also, e.g.*, H.R. Rep. No. 110-231 (July 13, 2007); H.R. Rep. No. 108-636 (Sept. 7, 2004); H.R. Rep. No. 108-188 (July 8, 2003).

[11] In their Motion for Summary Judgment, plaintiffs no longer suggest, since they cannot, that their linguistic argument applies only to the final guidelines and not hESC research performed under President Bush.

Plaintiffs try to suggest to this Court, despite the extensive briefing on this issue, that the legislative history is close since both defendants rely on conflicting "statements in the legislative history." Pls.' Mem. at 20 (citing Statement of Sen. Specter from footnote of defendants' Motion to Dismiss). However, this is not a case of dueling floor statements; indeed, it is a case of definitive, express, and repeated congressional ratification of defendants' interpretation in Committee reports. The Supreme Court has consistently relied on such reports—which are an "authoritative source for finding the Legislature's intent" that trump individual "comments from the floor," *Garcia v. United States*, 469 U.S. 70, 76 (1984)—as evidence of express congressional approval of an interpretation. *See Melkonyan v. Sullivan*, 501 U.S. 89, 96 (1991) (citing Senate and House Reports as proof that "Congress responded to this split in the federal courts by explicitly adopting and ratifying the *McDonald* approach"); *CFTC v. Schor*, 478 U.S. 833, 847 (1986) (citing House Report as proof of "explicit[] affirm[ance]" of CFTC's authority); *FDIC v. Philadelphia Gear Co.*, 476 U.S. 426, 437-38 (1986) (citing reports of both Houses as evidence that Congress "has expressly incorporated [agency regulations] into the statutory scheme"); *CIR v. Bilder*, 369 U.S. 499, 502 (1962) ("We consider the Commissioner's position unassailable in light of the congressional purpose explicitly revealed in the House and Senate Committee Reports on the bill."); *see also, e.g.*, *Miller v. Holzmann*, 575 F. Supp. 2d 2, 7 (D.D.C. 2008) (Lamberth, Chief Judge) (referring to Senate Report in stating that "[h]appily, here, Congress left an additional, unambiguous clue to its intent in drafting . . . ."); *id.* at 8 n.11 ("And where statutory language is unclear, resort to the legislative tea leaves is a well-accepted interpretive step.").

This authoritative and "unambiguous clue" in the Committee Reports is far different than

those circumstances in which legislative history might be clouded or conflicting. After all, while plaintiffs try to convince this Court to ignore the clear legislative history, Pls.' Mem. at 21, it is the majority view of this Court, the D.C. Circuit, and the Supreme Court that legislative history is one of the traditional tools of statutory interpretation to be used at Step One of the *Chevron* analysis. *See, e.g., Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ.*, 550 U.S. 81 (2007); *Maine Pub. Utils. Comm'n v. FERC*, 454 F.3d 278, 282 (D.C. Cir. 2006); *Cal. Metro Mobile Commc'ns, Inc. v. FCC*, 365 F.3d 38, 44-45 (D.C. Cir. 2004); *Tax Analysts v. IRS*, 350 F.3d 100, 103 (D.C. Cir. 2003); *Cape Cod Hosp.*, 677 F. Supp. 2d at 30; *see also, e.g., Samantar v. Yousuf*, 130 S. Ct. 2278, 2287 n.9 (June 1, 2010) ("'Our precedents demonstrate that the Court's practice of utilizing legislative history reaches well into its past. . . . We suspect that the practice will likewise reach well into the future.'") (quoting *Wisonsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 611-12, n.4 (1991) (internal citation omitted)).

Plaintiffs ignore this authoritative evidence because it demonstrates conclusively that Congress has for years expressly rejected their supposedly "unambiguous" interpretation of Dickey-Wicker. This is not simply Congress permitting agency action through silence. Though there is ample precedent holding that where Congress repeatedly reenacts legislative language against a backdrop of a specific agency interpretation, that re-enactment alone may ratify the interpretation, *see, e.g.*, *Schor*, 478 U.S. at 845-46 ("Congress has twice amended the [Act] since the [agency] declared by regulation [its position] but has not overruled the [agency's] assertion of jurisdiction."), the record here provides far stronger, unambiguous evidence that Congress intended to *ratify* NIH's interpretation, in the form of express statements about the scope of Dickey-Wicker. This Court should not accept plaintiffs' invitation to ignore what it has

previously recognized as unambiguous evidence of congressional intent.

3. Plaintiffs' Resort to the Alleged Causal Relationship Between the Guidelines And the Destruction of an Embryo Is Not Supported by the Plain Language of Dickey-Wicker Or the Practical Effect of the Guidelines

Plaintiffs ask the Court to ignore the clear meaning of Dickey-Wicker, arguing that the Amendment's use of the phrase "knowingly subjected to risk of injury or death" applies to hESC research because of the "incontrovertible" future incentive that funding for this research purportedly provides for "more embryonic stem cells." Pls.' Mem. at 19. Hyperbole and rhetoric aside, plaintiffs' proposed interpretation of this phrase still occurs in a vacuum, divorced from its context in the Amendment. The phrase "knowingly subjected to risk of injury or death" still only applies to that "research in which a human embryo" is involved. Accordingly, the possibility that stem cell research, or federal funding for the same, might affect the incentives of private third-parties who are undisputedly prohibited from receiving federal funding for the derivation of stem cells, does not mean that hESC research is prohibited by the plain language of Dickey-Wicker (which, of course, says nothing about "incentives" for destruction in its plain language).

Moreover, plaintiffs' speculation about the "virtual certainty" that "more human embryos will be destroyed" as a result of the issuance of the final guidelines is supported by no citation to materials in the record; rather, it is a product of plaintiffs' speculation that is belied by history and the language of the final guidelines. After a year of federal funding for hESC research under the guidelines challenged in this case, plaintiffs do not identify any "surge" in embryo donation or embryo destruction by scientists. In fact, of the 75 stem cell lines approved for use under the new guidelines, only two were derived from embryos donated after July 7, 2009. Landis Decl.

¶ 14. In other words, they were developed from embryos donated when no federal funding was available. Accordingly, whatever "knowledge" plaintiffs impute to hESC researchers about the supposed increased incentive for destruction is misguided.[12]

In light of the plain language of the guidelines, it is unsurprising that plaintiffs' purported causal connection remains pure speculation. The Guidelines require that hESC lines used in research supported by federal funding have been derived from human embryos "[t]hat were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose," and "[t]hat were donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32,174. Thus, 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 rather than donate them for science. Plaintiffs certainly do not, and cannot, suggest that, in the absence of the guidelines, there would be some wholesale shift away from discarding embryos or donating them for private research, as such an allegation is pure speculation. Accordingly, whether more embryos would be harmed in the future as a result of federal funding of hESC research is not something that is or could be known, as it would still depend on whether the embryo would otherwise have been discarded due to the discretionary decision of third-party donors of embryos that ultimately turn out to exceed

[12] Plaintiffs' suggestion that "a privately funded researcher destroys an embryo in order to satisfy a request for embryonic stem cells from a federally funded scientist," Pls.' Mem. at 19, misunderstands the scientific process. Rather than prepared as they are ordered, the typical researcher chooses a stem cell line that has already been developed and is therefore already on an NIH-approved registry. *See, e.g.*, Deposited Cell Lines (listing available stem cell lines for research), at http://www.wicell.org/index.php?option=com_oscommerce&Itemid=192.

the donors' reproductive needs.[13]

4. The Structure of Dickey-Wicker Does Not Mandate Plaintiffs' Interpretation

Plaintiffs next attempt to justify their broad reading of the term "research" by comparing the prohibition in Dickey-Wicker on federal funding for the "creation" of an embryo "for research purposes" and the prohibition on funding for "research in which . . . embryos are destroyed." Pls.' Mem. at 14-15. According to plaintiffs, the different wording of these provisions demonstrates that the first has a narrow purpose in targeting "creation" while the second involves a broader category of "research" than simply the "destruction" of embryos.

However, that, by itself, is an unexceptional proposition. A research project need not overtly seek to destroy an embryo as the focus of its research to fall within Dickey-Wicker's prohibition. Thus, as discussed previously, numerous research projects with a broader focus, such as the refinement of preimplantation genetic techniques or the improvement of IVF methodologies, would be ineligible for federal funding if, as part of that research project, embryos were threatened with destruction. The relevant question for purposes of Dickey-Wicker is whether the project must actually involve embryos. With respect to that question, it is

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[13] Plaintiffs also attempt to cloud the issue by suggesting that 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." Pls.' Mem. at 17-18. However, the fact that NIH takes into account the manner in which stem cells had previously been derived, in determining whether a research project that later seeks to use that line is eligible for federal funding, says nothing at all as to whether the person who seeks to perform research using that line was also involved in the derivation. Moreover, plaintiffs' straw man assertion that the guidelines regulate "the process by which embryos are destroyed" is of course false. *See* Pls.' Mem. at 18. As plaintiffs know (or should know), the NIH guidelines instead allow the use of stem cell lines created only through voluntary donation of spare embryos; they do not set the method by which stem cell lines are themselves derived (let alone fund such derivation).

necessary to look at the language of the second clause, including the meaning of the phrase "in which . . . embryos are destroyed," in order to understand that the funding prohibition requires that embryos actually be used in the research at issue.

Plaintiffs suggest that Congress could have, if it wanted to do so, expressly worded Dickey-Wicker so as to prohibit their interpretation, suggesting that otherwise Dickey-Wicker is a "Rube Goldberg-style" statute. Pls.' Mem. at 15. However, if there is anything in this case that depends on twisted logic, it is plaintiffs' suggestion that, despite NIH's consistent interpretation of Dickey-Wicker for the past 11 years and the adoption of NIH's interpretation by three separate Presidential administrations and five consecutive Congresses, it is now "unambiguously" clear that Congress intends to prohibit all hESC research through the annual passage of Dickey-Wicker. The better question is why, in light of the extensive discussion and debate over embryonic stem cell research for the past fifteen years, Congress, if it wanted to do so, did not simply prohibit federal funding for all research involving hESCs outright. As Congress's behavior since the passage of Dickey-Wicker indicates, it did not do so because that is not what the Amendment commands.

B. Even if this Court Deems the Language of the Guidelines Ambiguous, then It Should Defer to NIH's Interpretation Under *Chevron* Step Two

Where statutory language is ambiguous, the issue under step two of *Chevron* is only whether the agency has adopted a "permissible construction of the statute," at which point deference is due to the agency interpretation. *Chevron*, 467 U.S. at 843. To find the agency's interpretation permissible, this Court need not conclude that it is "'the best interpretation of the statute,'" *United States v. Haggar Apparel Co.*, 526 U.S. 380, 394 (1999) (quoting *Atl. Mut. Ins. Co. v. Comm'r*, 523 U.S. 382, 389 (1998)), or that it is the "most natural one," *Pauley v.*

BethEnergy Mines, Inc., 501 U.S. 680, 702 (1991). To the contrary, plaintiffs bear the daunting burden of establishing that their reading of the statute is the "inevitable one," *Regions Hosp. v. Shalala*, 522 U.S. 448, 460 (1998), because Congress made a deliberate decision to "compel" the result they urge, *Auer v. Robbins*, 519 U.S. 452, 458 (1997), in terms so "unambiguously manifest," *Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687, 703 (1995), that the statutory language "cannot bear the interpretation adopted by the Secretary." *Sullivan v. Everhart*, 494 U.S. 83, 92 (1990). Thus, for the plaintiffs to prevail, theirs must be "the only possible interpretation" of the statute. *Regions Hosp.*, 522 U.S. at 460; *Sullivan*, 494 U.S. at 89.

Under this deferential standard, plaintiffs do not, and cannot, contend that defendants' interpretation is impermissible or irrational at step two of *Chevron*. Instead, plaintiffs argue that the interpretation is not entitled to *Chevron* deference *even if* the language of the statute is ambiguous. This argument is not well founded, as it ignores both the content of the Guidelines and misunderstands the *Chevron* inquiry. Plaintiffs assert that, for *Chevron* to apply, an agency must "interpret the statutory provision in question" and "do so in a rule 'carrying the force of law.'" Pls.' Mem. at 22-23. However, there is no dispute that the Guidelines constitute a substantive rule, issued through notice and comment, that carries the force of law. *See Mount Royal*, 477 F.3d at 754. And there is no dispute that the Guidelines explicitly interpret Dickey-Wicker and its application to hESC research in response to comments on the precise issue in question in this litigation. *See* 74 Fed. Reg. at 32,173 (AR 4).

Thus, plaintiffs are not actually contending that NIH failed to comply with the two requirements that they cite. Rather, plaintiffs rest on the further, unsupported assertion that NIH,

in promulgating the final rule, was required to define every term of Dickey-Wicker, including the term "research." Pls.' Mem. at 23. Of course the Supreme Court has expressly rejected this notion, as agencies need not define every term of a statute in order to receive *Chevron* deference.[14] *See Nat'l R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407, 420 (1992) ("But the fact that the ICC did not in so many words articulate its interpretation of the word 'required' does not mean that we may not defer to that interpretation . . . .").

Plaintiffs' next argument, that NIH did not use its "experience" or "expertise" in interpreting Dickey-Wicker, is baseless. Pls.' Mem. at 24. The argument ignores the actual interpretation in the Guidelines, which explains NIH's understanding of the scientific terminology in an appropriations rider that has controlled NIH's budgetary decisions for fifteen years. *See* 74 Fed. Reg. at 32,173; *see also* 65 Fed. Reg. 51,976 (Aug. 25, 2000). In light of the fact that "[a]s long as the agency stays within [Congress'] delegation, it is free to make policy choices in interpreting the statute," it is hard to see how the agency's reasoned interpretation in

[14] The record does not support plaintiffs' assertion that NIH did not explain "whether the derivation of [hESC's] occurs as part of 'research' that receives funding." Pls.' Mem. at 23; *see* 74 Fed. Reg. at 32,173 (AR 4) ("Since 1999, the Department of Health and Human Services (HHS) has consistently interpreted this provision as not applicable to research using hESCs, because hESCs are not embryos as defined by Section 509. . . . These guidelines therefore recognize the distinction, accepted by Congress, between the derivation of stem cells from an embryo that results in the embryo's destruction, for which Federal funding is prohibited, and research involving hESCs that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted."). The present case stands in stark contrast to the one cited by plaintiffs in *Public Citizen v. HHS*, 332 F.3d 654, 661 (D.C. Cir. 2003), where the agency, in a manual rather than a formal regulation, simply cited to statutory language rather than providing an explanation, as NIH did in the present case, of why the language is inapplicable. *See* Pls.' Mem. at 23 n.7.

the Guidelines would be undeserving of deference under step two of *Chevron*.[15] *See Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000) (internal quotation omitted).

Moreover, the present case is not one where the agency first announced its interpretation of Dickey-Wicker in the challenged rule. As this Court has expressly held, "Defendants have maintained this interpretation of the Dickey-Wicker Amendment since 1999" yet "Congress . . . has not altered the Dickey-Wicker Amendment in response." Prelim. Inj. Mem. Op., Dkt. No. 44, at 5. This conclusion has great import, as such interpretations are due particular deference from this Court. *See, e.g.*, *Barnhart v. Walton*, 535 U.S. 212, 220 (2002) ("[T]his Court will normally accord particular deference to an agency interpretation of 'longstanding' duration."); *id.* ("Congress has frequently amended or reenacted the relevant provisions without change. . . . These circumstances provide further evidence - if more is needed - that Congress intended the Agency's interpretation, or at least understood the interpretation as statutorily permissible."). Accordingly, NIH's interpretation of Dickey-Wicker—one ratified by Congress for the past decade—is deserving of great deference.

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[15] Plaintiffs' novel argument to the contrary misunderstands the two-part *Chevron* inquiry. Under step one, a court determines whether a statute unambiguously forecloses an agency interpretation. This step is a legal one that is decided using the traditional tools of statutory interpretation. *See, e.g.*, *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 n.9 (1984). Accordingly, counsels' use of these tools in this litigation does not constitute a forbidden "post hoc" justification; rather, they are expressly permitted under step one to assist the Court in understanding whether the relevant statutory language compels the result that the plaintiffs claim. *See, e.g.*, *Bank of Am. N.A. v. FDIC*, 244 F.3d 1309, 1319 (11th Cir. 2001). If that particular result is not compelled, then the Court must proceed to *Chevron* step two, at which point substantial deference is due to the agency's conclusion.

III. NIH COMPLIED WITH THE ADMINISTRATIVE PROCEDURE ACT IN ISSUING FINAL GUIDELINES

Plaintiffs argue that NIH acted unlawfully in issuing the Guidelines because it purportedly failed to explain its reasoning adequately. The scope of this Court's review of the adequacy of an agency's reasoning under the APA is narrow:

> [W]e will not vacate an agency's decision unless it has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007) (internal quotation omitted). Under this narrow standard of review, "a court is not to substitute its judgment for that of the agency, and should uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1810 (2009) (internal quotations omitted).

This Court's review of the sufficiency of an agency's responses to comments in a rulemaking is similarly limited. An agency is obliged to respond to comments that are "relevant to the agency's decision and which, if adopted, would require a change in an agency's proposed rule." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977). This requirement is not "particularly demanding." *Pub. Citizen Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993). The agency need not respond to comments that raise issues that are not material to the rulemaking; instead, "[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors." *Covad Comm'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006) (internal quotation omitted).

A. NIH Was Not Required to Address Matters that Were Irrelevant to the Rulemaking

The bulk of plaintiffs' arguments concern their views regarding the relevant merits, scientifically and ethically, of hESC research, adult stem cell research, and iPSC research. They assert that hESC research has been proven, as a categorical matter, to be inferior to the other two forms of research, that it would be unethical for NIH to fund purportedly inferior hESC research in light of these alternatives, and that NIH therefore should have used the Guidelines as an opportunity to announce that it would reject all applications from researchers who proposed to pursue hESC research. Plaintiffs argue that NIH failed to respond adequately to commenters who sought such a categorical ban, Pls.' Mem. at 26-29, or that NIH otherwise failed to adequately explain its decision not to impose this ban, Pls.' Mem. at 30-31.

These arguments fundamentally misunderstand what was at issue in the Guidelines. By issuing Executive Order No. 13,505, President Obama removed the directives of the prior Administration that had limited the number of cell lines available for us in federally-funded research – limitations imposed by no existing statute or regulation. Exec. Order No. 13,1505, § 5, 74 Fed. Reg. at 10,668. In their place, the Order declared that its purpose was "to *remove* [political] limitations on scientific inquiry, to *expand* NIH support for the exploration of human stem cell research, and in so doing to *enhance* the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." *Id.*, § 1, 74 Fed. Reg. at 10,667 (emphasis added). The Order accordingly informed NIH that it may "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law," *id.*, § 2, and directed NIH to review the safeguards provided in existing widely recognized guidelines for stem cell research, and to

"issue new NIH guidance on such research that is *consistent* with this order," *id.*, § 3 (emphasis added).

The President thus directed NIH to prepare guidance that would describe standards for the responsible conduct of federally-funded hESC research. NIH, of course, was not free to ignore the President's instructions. "[Executive Branch] officers are duty-bound to give effect to the policies embodied in the President's direction, to the extent allowed by the law." *Bldg. & Constr. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 32 (D.C. Cir. 2002); *see also Sierra Club v. Costle*, 657 F.2d 298, 406 n.524 (D.C. Cir. 1981). NIH obviously would have acted inconsistently with the Order if it had refused to issue the Guidelines on the ground (as plaintiffs would have it, contrary to the scientific consensus) that all hESC research, categorically, lacked merit, or if it had disagreed with the President's policy determination that, with appropriate ethical safeguards, the moral balance weighed in favor of potentially life-saving research and, thus, against a blanket ban on any one type of stem cell research.

Moreover, nothing in the Executive Order purported to override the ordinary operation of NIH's peer review system. To the contrary, the Order expressly declares that it may not be construed "to impair or otherwise affect" NIH's statutory scheme. Exec. Order No. 13,505, § 4(b). NIH's statutory scheme requires that the merits of individual research proposals be decided on an application-by-application basis by expert reviewers. 42 U.S.C. §§ 282(b)(9), 284a(a)(3), 289a. Those procedures are established for the express purpose of ensuring that scientifically unworthy or poorly designed research proposals will not receive federal funding; they do not contemplate that NIH will decide the merits of particular research proposals through rulemaking. It is therefore entirely unsurprising that NIH performed its duty under the Executive

Order, which was to establish standards for hESC research, and not to displace the statutory peer-review procedures by making categorical announcements as to the merits of hESC research or any other kind of research.

Plaintiffs do not dispute the foregoing description of the effect of the Executive Order, or of the operation of NIH's peer-review system. Instead, they imagine an argument that defendants have *not* made – *i.e.*, that the Executive Order directly mandated that funds be awarded for hESC research – and devote a significant effort to a rebuttal of this straw argument. (Pls.' Mem. at 33-34.) The defendants fully agree that the Executive Order did not mandate that NIH fund any particular hESC research proposal. The Executive Order neither invited NIH to impose a categorical ban on funding for hESC research (as plaintiffs would have it) nor instructed NIH that it must award funds for such research (as plaintiffs imagine, incorrectly, that defendants argue). Instead, as noted, the Executive Order simply restored the ordinary operation of NIH's statutorily-mandated two-level system of peer review, in which qualified experts review the scientific merits of particular research proposals, including proposals for the funding of hESC research. *See* 42 U.S.C. §§ 282(b)(9), 284a(a)(3), 289a.

Plaintiffs further argue that the Executive Order did not override the requirements of the APA, a proposition that defendants do not dispute. (Pls.' Mem. at 35-36.) But the question *whether* NIH was required to follow rulemaking procedures is logically separate from the question of *which* comments submitted in the rulemaking were relevant to the task at hand. 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. *See, e.g.*, 74 Fed. Reg. at 32,171 (addressing defintion of human

embryonic stem cell in response to comments); *id.* at 32,173 (addressing informed consent requirements in response to comments). But NIH was under no obligation to convert the subject matter of the Guidelines into a completely separate topic – the scientific merits of hESC research generally – simply because plaintiffs ignored the intended purpose of the Guidelines. *See, e.g., Nat'l Mining Ass'n v. MSHA*, 116 F.3d 520, 549 (D.C. Cir. 1997) (upholding agency's reasonable rejection of comments that were outside the scope of the rulemaking); *see also Am. Iron & Steel Inst. v. EPA*, 886 F.2d 390, 398 (D.C. Cir. 1989) (a rulemaking "is not a license for bootstrap procedures by which petitioners can comment on matters other than those actually at issue, goad an agency into a reply and then sue on the grounds that the agency had re-opened the issue").

NIH thus properly addressed the matters that were at issue in the formulation of the Guidelines – namely, its decision as to the procedures required for the responsible pursuit of hESC research – and properly ignored matters that were not – namely, the relative merits of yet-to-be submitted applications for funds for hESC research or for any other kind of research. Those merits obviously are best addressed in the peer review process, not in a rulemaking conducted in advance of the review of individual applications. NIH was under no obligation to preempt the statutory peer review process and instead address the scientific merits of hESC research in this rulemaking. *See Mobil Oil Exploration & Producing Se. Inc. v. United Distrib. Co.*, 498 U.S. 211, 230 (1991) (agency acted rationally by declining to address issue in rulemaking where "the agency could compile relevant data more effectively in a separate proceeding"); *see generally NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 295 (1974) (agency has discretion to decide that relevant information is best developed through adjudicatory procedures,

not rulemaking).

B. Plaintiffs Have Not Met Their Heavy Burden to Show that Bias Infected the Rulemaking

Plaintiffs lastly argue that the Guidelines should be invalidated because Acting NIH Director Kington purportedly held a predisposition in favor of federal funding for human embryonic stem cell research. Pls.' Mem. at 31-33. There is a strong presumption that agency decision-makers act in good faith. For that reason, agency action is judged on the basis of the agency's stated rationale, and an inquiry into the decision-maker's supposed bad faith is only permitted in exceedingly narrow circumstances. *See United States v. Morgan*, 313 U.S. 409, 421-22 (1941). This presumption applies with particular force to rulemakings. A decision-maker "should be disqualified [from an informal rulemaking] only where there has been a clear and convincing showing that [he] has an unalterably closed mind on matters critical to the disposition of the proceeding." *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979)).

Plaintiffs do not come close to making such a showing. They rely on a comment attributed to Acting Director Kington in a newspaper article published after the final Guidelines were issued, to the effect that NIH had received a large number of comments debating whether hESC research should be funded at all, and that those comments did not speak to the issue under consideration in the draft Guidelines.[16] But, as noted above, the Executive Order required NIH to draft guidelines that would implement the President's policy decision to "expand NIH support

[16] The plaintiffs's cited materials are not part of the administrative record, and they do not even attempt to make the extraordinary showing that would justify their reference to these extra-record materials. *See Commercial Drapery Contractors, Inc. v. United States*, 133 F.3d 1, 7 (D.C. Cir. 1998); *see also Florida Light & Power v. Lorion*, 470 U.S. 729, 743-44 (1985).

for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." Exec. Order No. 13,505, § 1, 74 Fed. Reg. 10,667. Commenters who asked NIH to refuse to follow the Executive Order simply did not speak to any matter that was actually at issue in the rulemaking, and the Acting Director did not display any disqualifying bias by so stating. "An agency should not apologize for being predisposed to implementing the goals that Congress [or, here, the President] has set for it. To call such an attitude 'bias' . . . misses this central point." *Ass'n of Nat'l Advertisers*, 627 F.2d at 1168 (internal quotation omitted; ellipses in original); *see also C&W Fish Co. v. Fox*, 931 F.2d 1556, 1565 (D.C. Cir. 1991) (agency official may express policy views without being disqualified from rulemaking).[17]

Plaintiffs also rely on comments attributed to the Acting Director in a newspaper article to the effect that the number of cell lines eligible for funding would increase. This is a simple truism. As a result of the proclamation of President Bush on August 9, 2001, and his subsequent Executive Order, only 21 embryonic stem cell lines were available for use in federally-funded research before Executive Order No. 13,505 lifted the restrictions imposed in the prior Administration. NIH, *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp) (AR 705). As is well-known, many additional hESC lines were created after President Bush's proclamation. *See, e.g.*, Landis Decl. ¶ 14. Those existing lines were ineligible for use in federally-funded research until President Obama's Executive

[17] NIH has made no secret that, as policy matter, it recognizes the importance of pursuing hESC research along with other forms of stem cell research. *See* 65 Fed. Reg. 51,976 (Aug. 25, 2000) ("Given the enormous potential of stem cells to the development of new therapies for the most devastating diseases, it is important to simultaneously pursue all lines of promising research.").

Order lifted the restrictions imposed by his predecessor. Nothing in the APA required the Acting Director to pretend to be blind to the existence, or the effect, of the Executive Order. *See PLMRS Narrowband Corp. v. FCC*, 182 F.3d 995, 1002 (D.C. Cir. 1999) ("[W]e presume that policymakers approach their quasi-legislative task of rulemaking with an open mind – but not an empty one.")

IV. PLAINTIFFS ARE NOT ENTITLED TO PERMANENT INJUNCTIVE RELIEF

Plaintiffs seek wide-sweeping injunctive relief from this Court. They ask the Court not only to vacate the Guidelines that are the subject of this action, but also to permanently enjoin defendants "from implementing, applying, or taking any action whatsoever pursuant to the NIH Guidelines, or otherwise funding research involving human embryonic stem cells as contemplated in the NIH Guidelines." (Dkt. No. 55-21.) Further, they ask this Court to adjudicate the rights of parties not before it, by directing defendants "to immediately inform any NIH grant recipients in possession or control of federal funds granted under the Guidelines for human embryonic stem cell research that any remaining and unspent NIH-granted funds may not be spent on human embryonic stem cell research but must be returned to NIH to fund lawful research." (*Id.*) Plaintiffs are not entitled to such wide-sweeping relief.

Plaintiffs' request for an injunction "is based on a flawed premise." *Palisades*, 426 F.3d at 403. Under the APA, this Court reviews discrete agency actions – such as the promulgation of the Guidelines at issue here – and it lacks the authority to expand its review beyond the specific agency action before it. *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 66 (2004). Accordingly, "under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case

must be remanded to the agency for further action consistent with the correct legal standards." *Palisades Gen. Hosp.*, 426 F.3d at 403 (internal quotation omitted). The Court may not take the further step, beyond vacating the Guidelines, to devise a specific remedy for the agency to follow. *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999).[18]

Even if an injunction were a form of relief available here, plaintiffs could not show their entitlement to it. "'An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course.'" *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761 (2010) (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-12 (1982)). A plaintiff must demonstrate his standing to seek, and his entitlement to, each form of equitable relief that he requests. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). As a result, "[i]f a less drastic remedy (such as partial or complete vacatur of [the agency's] decision) [is] sufficient to address [the plaintiffs'] injury, no recourse to the additional and extraordinary relief of an injunction [is] warranted." *Monsanto*, 130 S. Ct. at 2761.

Despite the clear instructions from the Court in *Monsanto* (which goes uncited in their summary judgment motion), plaintiffs make no effort at all to explain why, if they were to prevail in this case, they would need the extraordinary remedy of a structural injunction in addition to the setting aside of the Guidelines. Similarly, an injunction requiring parties not

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[18] If this Court were to award judgment to plaintiffs on their notice-and-comment claims, the proper remedy would be a remand without vacatur. There is far more than "a serious possbility" that the Secretary could remedy any supposed APA violation on remand. *See Allied Signal Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). And vacatur would cause numerous "disruptive consequences," *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 756 (D.C. Cir. 2002), given the numerous research projects that are currently pending that depend on NIH funds, and given the scientific and economic losses that would result from the cancellation of such funds. Collins Decl., ¶¶ 7-14.

before this Court to return funds distributed to them would do nothing to remedy plaintiffs' alleged injuries, even if the Court had the power to award such relief against non-parties, which it clearly does not.

In sum, plaintiffs could be entitled at the most to an order remanding this matter to the agency. And they may not obtain even that relief, as the Guidelines are entirely lawful.

CONCLUSION

For the foregoing reasons, defendants respectfully request that this Court deny plaintiffs' Motion for Summary Judgment and grant Defendants' Motion for Summary Judgment.

Dated: September 27, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2010, I caused a true and correct copy of the foregoing to be served on Plaintiffs' counsel electronically by means of the Court's ECF system.

/s/ Eric Womack
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