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.	)	

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

Plaintiffs can prevail in this action only if they can demonstrate that the language of the Dickey-Wicker Amendment in FY2010 appropriations unambiguously mandates their interpretation. The problem for plaintiffs is that neither Congress, which just recently enacted the provision, nor the Secretary who is charged with interpreting it subscribes to the view of the statute's "plain language" proffered by plaintiffs. In fact, plaintiffs' interpretation is inconsistent with the actions of presidential administrations and Congresses, both Democratic and Republican, for over a decade. Yet plaintiffs would have this Court ignore Congress's recent unambiguous expression of its intent in enacting Dickey-Wicker, as well as the history of prior enactments endorsing the same interpretation, through the expansive interpretation of a single word – "research" – divorced from its linguistic context in the statute, despite the fact that the term has a common meaning and usage that is contrary to the one suggested by plaintiffs. This Court should not accept plaintiffs' invitation to rewrite Dickey-Wicker to achieve a result contrary to Congress's stated intent.

Plaintiffs' expansive construction of the term "research" would also lead to absurd results. Science is a continuum, where advances in one area of discovery lead to the next search for a treatment or cure. Plaintiffs would collapse that continuum into an infinite whole in an attempt to prohibit any and all federal funding for hESC research. But such an expansive approach may have implications beyond the research that plaintiffs oppose, as advancements in science, including iPSC research, may continue to build upon discoveries made or techniques developed in past hESC research. This Court should not permit such a result, as it would overturn the legislative balance crafted by Congress in permitting NIH to fund research on

hESCs, but prohibiting funding for derivation – a balance that has existed for over a decade.

Plaintiffs fare no better in their claims under the APA. Executive Order No. 13,505 is clear. It revoked the prior limitations on federal funding for hESC research, and restored the evaluation of the worth of that research to the proper forum, NIH's peer review system. NIH was not free to disregard the Order and to reimpose the blanket prohibition that the President had withdrawn. Nor was NIH required to respond to comments that sought such a result.

ARGUMENT[1]

I. PLAINTIFFS' SPECULATIVE FEARS ABOUT COMPETITION FROM THE OPERATION OF THE FINAL GUIDELINES ARE NOT BORNE OUT BY THEIR PRACTICAL EXPERIENCE

After more than a year of litigation and the operation of the final Guidelines, neither plaintiff Sherley nor plaintiff Deisher can point to any actual financial harm they have suffered from the actions of defendants. Instead, plaintiffs fall back on the D.C. Circuit's conclusion *at the Motion to Dismiss stage* that plaintiffs had sufficiently alleged an imminent injury from competition due to (1) the purported need for plaintiffs to invest "more time and resources to craft a successful grant application"[2] and (2) the "additional injury" that would occur "whenever

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[1] Plaintiffs now admit – after numerous briefs and the filing of their Motion for Summary Judgment in advance of the submission of the administrative record – that their APA challenge "must be assessed on the basis of the administrative record alone." Pls.' Opp. at 3 n.1. Defendants accordingly believe it unnecessary to respond to plaintiffs' continued assertions about the state of stem cell science. There is no question that plaintiffs disagree with NIH and the mainstream scientific community about the possible worth of hESC research. *See, e.g.*, Landis Decl. ¶ 16. But this forum is undisputedly not the correct place for this debate.

[2] It is true, as plaintiffs note, that the D.C. Circuit believed that there would be "no doubt" that the number of grant applications involving hESCs would increase. *Sherley*, 610 F.3d at 74. However, the D.C. Circuit recognized that the injury that would result from this supposed competition was the investment of "more time and resources" by the plaintiffs in crafting their applications, not the mere existence of additional applications. *Id.* After all, if one were to

a project involving ESCs receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs." *Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010). However, the materials that plaintiffs now submit show that neither of these feared injuries has come to pass.

As an initial matter, plaintiff Deisher has not even attempted to submit an affidavit in support of plaintiffs' Opposition. Accordingly, the record establishes that Deisher has never applied for a research grant from NIH. Decl. of Deisher in Supp. of Pls.' Mot. for Summ. J. ¶ 3. Thus, regardless of the nature of the injury alleged to exist as a result of competition, Deisher has failed to demonstrate that she is an active competitor for funding from NIH.

While plaintiff Sherley has submitted an affidavit in support of plaintiffs' Opposition, the facts adduced from that document demonstrate that he has suffered no Article III injury from the operation of the Guidelines. The first "concrete harm" identified by Sherley is his allegation that he has "had four adult stem cell research grant applications go unscored since the Guidelines were implemented." Decl. of Sherley in Supp. of Pls.' Opp. ("Sherley Opp. Decl.") ¶ 3. However, the fact that Sherley's applications were unscored demonstrates that his applications did not even survive the first level of the peer review process, as Sherley's peers did not deem them scientifically worthy enough to be considered for funding by an institute or center within NIH. *See* Rockey Decl. ¶ 12. As these applications were not even eligible for consideration for funding, Sherley cannot demonstrate that they should be considered competitors with those

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assume that competition would result in no injury, then competition alone could not satisfy the requirements of Article III. Competition instead serves as a proxy for an injury such as a loss of profits or sales. *See DEK Energy Co. v. FERC*, 248 F.3d 1192, 1195 (D.C. Cir. 2001); *see also Sherley*, 610 F.3d at 74.

applications that were ultimately successful, let alone that they would have been funded "but for" the existence of hESC research applications.[3] *See Sherley*, 610 F.3d at 74.

The second "concrete harm" identified by Sherley is that he has "had to alter [his] practices regarding applications for NIH funding," presumably by submitting "more grant applications than ever before in [his] career." Sherley Opp. Decl. ¶ 4. However, the mere submission of more applications, regardless of their merit, was not the injury predicted by the D.C. Circuit, which thought instead that a scientist would have to expend "more time and resources to craft a *successful* grant application." *Sherley*, 610 F.3d at 74 (emphasis added). With regard to that type of injury, Sherley alleges only that, following the Guidelines, he "must make a concerted effort to minimize the harmful impact of NIH's misperception that embryonic stem cell research is preferable to adult stem cell research." Sherley Opp. Decl. ¶ 4. Whatever the source of this misguided fear and resultant efforts, it cannot be traced to the passage and implementation of the final Guidelines by NIH, as NIH has consistently stated that it continues to support and encourage all stem cell research, including adult stem cell research—the scientific worth of which is decided during the peer review process on a case-by-case basis. *See, e.g.*, Rockey Decl. ¶¶ 18, 19 (". . . NIH remains committed to the funding of eligible research applications involving nonembryonic stem cells.")

Plaintiff Sherley continues to receive NIH grant funding despite the existence of the Guidelines. While he may fear that his work with adult stem cells will be categorically

[3] Moreover, one of the four unscored applications submitted by Sherley was rejected in peer review before the final Guidelines were even effective. Sherley Opp. Decl. ¶ 3. Thus, his three unscored applications do not appear uncommon in light of his past record, as he had three applications go unscored in the first six months of 2000 alone. *See* Ex. A to Sherley Decl. in Supp. of Pls.' Mot. for Summ. J.

disregarded despite the millions in funding that continue to flow in support of such research, that baseless speculation does not demonstrate the harms that the D.C. Circuit predicted would flow from the existence of the Guidelines.

II. THE DICKEY-WICKER AMENDMENT PERMITS RESEARCH USING HUMAN EMBRYONIC STEM CELLS

A. The Traditional Tools of Statutory Interpretation Do Not Compel Plaintiffs' Interpretation of Dickey-Wicker

Defendants respectfully assert that their interpretation of Dickey-Wicker is the only one consistent with the language of the Amendment and the expressed intent of Congress in the legislative history. 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. 32,170, 32,173 (July 7, 2009) (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). That longstanding interpretation has been repeatedly endorsed by legislative history accompanying the statute's reenactment for the past decade.

Plaintiffs proffer a contrary, and supposedly unambiguous, understanding of this provision based on a reading of one word – "research" – in isolation from its linguistic context in the statute. According to plaintiffs, the term "research" must be read so broadly that all activities that preceded or followed an individual research project are encompassed as part of that project

for the purposes of the Amendment. But when this language is read in the context of the words surrounding it and in light of the Amendment's legislative history, it is apparent that plaintiffs cannot "demonstrate that the statute clearly forbids the agency's interpretation or that the interpretation is unreasonable." *Consarc Corp. v. OFAC*, 71 F.3d 909, 914 (D.C. Cir. 1995).

Plaintiffs suggest that NIH's long-standing interpretation of the Dickey-Wicker Amendment, applied to permit federal funding of hESC research over the past decade, is simply "contrived" by "counsel" in a manner contrary to the "plain text of the Dickey-Wicker Amendment" and the prior ruling of this Court. Pls.' Opp. at 6. Plaintiffs ignore the order of the D.C. Circuit in this case, which has issued a stay pending defendants' ongoing appeal of this Court's grant of plaintiffs' motion for preliminary injunction. *See* Sept. 28, 2010, Order Granting Motion for Stay Pending Appeal, Case No. 10-5287. That order held that defendants had met the demanding standards for a stay pending appeal. *See Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc*., 559 F.2d 841, 843 (D.C. Cir. 1977).

Plaintiffs continue to assert their expansive interpretation of the term "research" based on an HHS human subject protection regulation that defines research as "a systematic investigation." Pls.' Opp. at 8. But "systematic" does not mean "limitless" or "unending," as plaintiffs would have it. *See* Defs.' Mem. in Supp. at 17-18 (quoting Random House Dictionary's definition of systematic as "having, showing, or involving a system, method, or plan"). Plaintiffs ignore this pivotal fact because it demonstrates that a "discrete act or experiment" constitutes "research" as long as the act or experiment shows or involves a system, method, or plan. In fact, in common usage the terms "research" and "experiment" act as synonyms. *See, e.g.*, ROGET'S 21ST CENTURY THESAURUS (3d Ed. 2010); WEBSTER'S NEW

WORLD DICT. AND THESAURUS (2d Ed. 2002). And, despite plaintiffs' attempt to ignore it altogether, NIH regulations that govern the extramural grant process expressly define the term "research" to include a single, discrete "study" or "experiment." 42 C.F.R. § 52.2.

In their Opposition, plaintiffs argue that derivation must be considered part of the "systematic" process for hESC research, based on the assertion that "hESCS are derived solely and specifically for use in the experimentation phase of hESC research." Pls.' Opp. at 9. However, even assuming this assertion to be true, the fact that a scientist may engage in research with the intent that the product of that research be used as the subject of subsequent research does not demonstrate that both projects must be considered as an indivisible whole.[4] For example, the development of the culturing process for biological tissues in 1907 was a necessary precursor to the use of human tissues in research today. But the fact that a researcher in 2010 uses a 1907 discovery as an element of his or her research does not mean that the researcher is necessarily engaged in the *same* research as that conducted by his or her predecessor.

Moreover, plaintiffs are incorrect that "[d]erivation of hESCs" is "an unavoidable step" in *each* research project carried out by an hESC researcher. Pls.' Opp. at 9. Stem cell lines provide a long-term supply of multiplying cells that can be shared among scientists for different research, including research towards the development of therapies to treat human disease. Stem cells that

[4] Derivation research is not limited solely to the creation of hESCs for subsequent research, as research is often conducted on the method of derivation itself. Such research may include "experiments designed to test how best to culture the embryonic cells and experiments relating to the timing of derivation." Landis Decl. ¶ 15. A timing experiment may not produce a usable hESC line, but it still constitutes research into derivation. *See, e.g.*, Stephenson and Braud, Derivation of the King's College London Human Embryonic Stem Cell Lines, *at* http://www.springerlink.com/content/w401g674327n2l57/fulltext.html; O'Leary et al., Stem Cells and Development: The Influence Of Early Embryo Traits On Human Embryonic Stem Cell Derivation Efficiency, *at* http://www.liebertonline.com/doi/abs/10.1089/scd.2010.0338.

were derived from a single embryo to create a stem cell line may multiply for a period of years to provide stem cells for countless scientific research projects. For example, one stem cell line, known as "H9," that was created by a researcher at the University of Wisconsin in 1998, has been used in more than 360 published research studies and remains one of the most highly requested stem cell lines. Lines H1 and H7, also developed at the University of Wisconsin, have been used in approximately 300 and 100 research studies, respectively. *See* Loser et al., *Human Embryonic Stem Cell Lines and Their Use in International Research*, STEM CELLS 244 (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1002/stem.286/full. In fact, of the 75 stem cell lines approved for use under the new Guidelines at the time defendants' Motion for Summary Judgment was filed, only two were derived from embryos donated after July 7, 2009. Landis Decl. ¶ 14. Thus, an individual researcher, when selecting an hESC line from the NIH stem cell registry to use in research, does not require the new derivation of hESCs, and does not conduct research in which an embryo is destroyed or discarded. *See* Stem Cell Registry, http://grants.nih.gov/stem_cells/registry/current.htm.

Of course, the derivation of cells from an embryo was at one time needed for the development of an hESC line. Similarly, hESC research would not exist without the isolation of a single type of cell from a teratocarcinoma in 1964 or the first discovery of the cell in 1665.[5] Plaintiffs would have this court adopt such an expansive understanding of the term "research"

[5] In fact, even research that plaintiffs support would be encompassed by their broad understanding of the term "research." Induced pluripotent stem cells, for example, depended upon advancements in hESC research, since hESC research created the culture conditions for iPSCs. *See, e.g.*, Monya Baker & James Thomson, *Shifts from Embryonic Stem Cells to Induced Pluripotency*, NATURE, Aug. 14, 2008 ("One of the legacies is if those culture conditions hadn't been worked out for human embryonic stem cells, iPS cells wouldn't have worked."), *available at* http://www.nature.com/stemcells/2008/0808/080814/full/stemcells.2008.118.html.

that these advancements would be included as part and parcel of hESC research occurring in 2010, because, in plaintiffs' view, they are all elements of the "systematic" process that gave rise to such research. Such a result demonstrates the limitless reach of plaintiffs' interpretation, as it is difficult to imagine what prior research would not be included in this "systematic" process.

Ultimately, however, it is unnecessary, and unhelpful, to debate the meaning of the term "research" in the abstract, rather than its use in the Dickey-Wicker Amendment itself. As defendants have explained throughout this litigation, it is not simply "research" that is prohibited, it is "research *in which* a human embryo or embryos *are*" destroyed or otherwise subjected to a risk of injury. Plaintiffs do not provide an explanation for this modifying language, preferring instead to define the term "research" so broadly that it renders construction of all context superfluous. But that approach provides this Court with little basis for understanding why Congress crafted Dickey-Wicker in the manner that it did.

Plaintiffs concede that the prepositional phrase "in which" modifies and "necessarily limit[s]" the term "research." Pls.' Op. at 10-11 n.6. However, they argue that it exists only to demonstrate that "*all* NIH funding" is not prohibited. *Id.* Plaintiffs do not argue that this is the *only* possible limitation of the phrase, as such a result would draw into Dickey-Wicker's prohibition all research that relates, even tangentially, to embryo research. In fact, as Judge Kavanaugh noted at the recent oral argument on defendants' Motion to Stay, Congress crafted Dickey-Wicker to apply to "research *in which* an embryo is destroyed, not research," as plaintiffs would have it, "*for which* an embryo is destroyed." Transcript of Sept. 27, 2010 Oral Argument, at 43 (emphasis added). Congress could have made it clear that it intended to foreclose funding for all research that followed, however remotely, from the prior destruction of an embryo.

Instead, Congress prohibited only that research "in which" an embryo was actually involved.[6]

This reading is supported by Congress's use of the present tense – "are destroyed" – as opposed to extending the statute's reach to embryos that "had been" or "were" destroyed to make present research possible. Plaintiffs discount this language because their broad reading of "research" would include all past actions that made such research possible. *See* Pls.' Opp. at 12. That tautological reasoning ignores the fact that the term "research" may, in a vacuum, have several rational meanings. The question is whether to read the term, in the context of Dickey-Wicker, as broadly as plaintiffs suggest or whether it may be read in the fashion asserted by defendants. With respect to that question, the Supreme Court has held that Congress's choice of verb tense is a telling guide.[7] *See, e.g.*, *United States v. Wilson*, 503 U.S. 329, 333 (1992).

As support for their expansive reading, plaintiffs press the argument that Dickey-Wicker's prohibition on funding for research in which embryos are "knowingly subjected to risk

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[6] This distinction explains why plaintiffs are incorrect to suggest that NIH would permit the funding of 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." Pls.' Opp. at 11. There is a clear distinction between such research and hESC research, as preimplantation genetic diagnosis ("PGD") research *actually involves* an embryo as part of the research itself. Moreover, PGD research may pose a risk of harm to the embryo and its potential implantation and development as part of the actual research project, as PGD requires a biopsy of a human embryo and the extraction of a cell. *See, e.g.*, American Society of Reproductive Medicine, Preimplantation Genetic Testing: A Practice Committee Opinion, at S138-S139 (Nov. 2008) (describing how the PGD procedure may result in the "decreased viability" of an embryo), *at* http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Preimplantation_genetic_testing(1).pdf.

[7] Plaintiffs assert that the use of the present tense canon in this case would permit NIH to fund even the already-completed act of destroying human embryos. Pls.' Opp. at 12. Of course this misguided hypothetical ignores the fact that there "are" still embryos involved in the research in question, regardless of the timing of the funding decision.

of injury or death" applies to hESC research because the Guidelines "*necessitate* the destruction of human embryos by using and creating demand for hESCs," which presumably creates demand for additional embryonic destruction. Pls.' Opp. at 13. According to plaintiffs, "[m]isled 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." Pls.' Opp. at 14-15.

Even if this Court were to speculate about the future risk to embryos that are not even part of the research in question (ignoring the limitations of the plain language of Dickey-Wicker[8]), the Court has already rejected the extensive chain of events proffered by plaintiffs:

> The choice, however, is not simply whether to donate embryos for research or for adoption. The donors must choose between continuing to store the embryos, discarding them, donating them for research, or giving them to an adoption agency involved in embryonic adoption. This choice is *solely within the discretion of individuals in possession of embryos that are no longer needed for reproductive purposes*. By allowing funding for hESC research, the guidelines do not interfere with the discretion of potential donors.

Oct. 27, 2009, Mem. Op. at 5-6, Dkt. No. 36 (emphasis added). Thus, as this Court has determined, 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

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[8] Plaintiffs' assertion that Dickey-Wicker's language of risk to embryos demonstrates that "[o]nly a *risk* is required, not the actual realization of that risk." Pls.' Opp. at 14. However, that "risk" must still be connected to "research in which a human embryo or embryos" are involved. Thus, if research *actually involving* an embryo poses risk to that embryo, such as preimplantation genetic diagnosis, then NIH does not fund the activity. Nothing in the language of the statute demands the illogical expansiveness inherent in plaintiffs' interpretation. *Cf. Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 343 (1928) ("Life will have to be made over, and human nature transformed, before prevision so extravagant can be accepted as the norm of conduct, the customary standard to which behavior must conform.").

donors of embryos that ultimately turn out to be unnecessary for the donors' reproductive needs.[9]

Plaintiffs base their speculation on the prediction of scientists about the approval of new hESC lines for research under the Guidelines. Pls.' Opp. at 16-17 (citing comments by Dr. Jeffrey R. Botkin). But the fact that new stem cell lines are available due to the lifting of the August 2001 date restriction does not show that these lines were created from embryos destroyed due to the availability of federal funding for hESC researchers. In fact, the evidence establishes precisely the opposite, as 73 of the 75 stem cell lines on the NIH registry at the time defendants' Motion was filed were developed from embryos donated before the issuance of the final Guidelines (*i.e.*, at a time when federal funding for research on such lines was unavailable), *see* Landis Decl. ¶ 14, and plaintiffs certainly cannot show that the remaining lines were created from embryos destroyed because the Guidelines were in existence. The fact remains that hESCs have been, and will continue to be, derived from human embryos in the absence of federal funding. Thus, plaintiffs' assertion that the final Guidelines somehow create a "known risk" to embryos is meritless when the Guidelines do nothing to change the private sources of funding for the process of derivation itself.[10]

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[9] Plaintiffs' suggestion that "[e]mbryos can be and are stored for years, even decades, before being implanted and carried to term" is irrelevant. Pls.' Opp. at 14. If an individual chooses to implant and carry a frozen embryo to term, rather than donate that embryo, then of course that embryo would be unaffected by the Guidelines, which indisputably apply only to hESCs "derived from human embryos: . . . [t]hat were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose." 74 Fed. Reg. at 32,174.

[10] As a final attempt to draw a causal connection where none exists, plaintiffs point to the citation in Dickey-Wicker to 45 C.F.R. § 46.204(b) and 42 U.S.C. § 289g(b) concerning research on fetuses in utero. Pls.' Opp. at 15. According to plaintiffs, these laws prohibit "greater than minimal" harm to a living fetus even assuming that the fetus is intended to be aborted. *Id.* However, the fact remains that these regulations still apply to those living fetuses actually "involved in research," 45 C.F.R. § 46.204, and not to all potential future incentives that such

B. The Legislative History Demonstrates Congress's Unquestioned Awareness of the Passage of the Final Guidelines And Approval of NIH's Interpretation of Dickey-Wicker

Plaintiffs continue to press the assertion that "[t]he legislative history Defendants rely on is . . . indeterminate." Pls.' Opp. at 18. However, this is plainly not a matter of dueling "statements supporting both parties' positions." *Id.* It is instead a case where defendants have proffered the Conference Report adopting the House and Senate reports for 2010 appropriations to NIH, in which Congress stated in no uncertain terms 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 273 (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

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research might provide. That conclusion is demonstrated by the fact that Congress in fact permits federal funding to be used in research involving fetal tissue even when that tissue was obtained from an aborted fetus. *Compare* Pub. L. No. 111-117, Title V, § 507 (2010) *with* 42 U.S.C. § 289g-1. Using plaintiffs' reasoning, such federal funding would be prohibited because it provides an "incentive" to conduct abortions. Plaintiffs attempt to distinguish these contexts by pointing to the "firewall" created between researchers and decisions by individuals related to the "timing, method or procedures used to terminate a pregnancy." Pls.' Opp. at 16 n.8. That is of course, the same objective of the Guidelines challenged here, as "[d]ecisions related to the creation of human embryos for reproductive purposes should have been made free from the influence of researchers proposing to derive or utilize hESCs in research." 74 Fed. Reg. at 32,174. And, even in the discouraged situation where a physician and researcher would be the same individual, the Guidelines impose a number of substantive restrictions to ensure that the decision to donate an embryo is purely voluntary. *See id.* at 32,174-32,175.

111-220 and Senate Report 111-66 accompanying the bill, H.R. 3293.").

Of course, interpretation must begin with the language of the statute itself. But that does not mean that the clear legislative history here is irrelevant to the debate. In fact, as plaintiffs do not dispute, the Supreme Court has "repeatedly stated" that committee reports serve as the "authoritative source for finding the Legislature's intent." *Garcia v. United States*, 469 U.S. 70, 76 (1984). Accordingly, this Court and the D.C. Circuit have continued to rely on such reports as "unambiguous clue[s]" of congressional intent. *See* Defs.' Mem. in Supp. at 24 (quoting, *inter alia*, *Miller v. Holzmann*, 575 F. Supp. 2d 2, 7 (D.D.C. 2008) (Lamberth, Chief Judge)).

Plaintiffs attempt to minimize this clear evidence of congressional intent by arguing that congressional ratification does not exist in the present case, as it can occur only where Congress has enacted "positive legislation" and the agency's interpretation is "longstanding . . . without pertinent change." Pls.' Opp. at 19-20. As an initial matter, the legislative history here is not relevant *only* in determining whether Congress has ratified an interpretation of an existing statute. The Dickey-Wicker Amendment is unique in that its statutory prohibition does not exist absent its inclusion in annual appropriations by Congress. Thus, what is relevant is first and foremost the intent of Congress in the *current* manifestation of Dickey-Wicker. With respect to that question, the Committee Reports cited by defendants demonstrate unambiguously that Congress did not intend for Dickey-Wicker to prohibit all federal funding for hESC research.

In any event, focusing specifically on the issue of ratification, plaintiffs' argument errs in conflating the various methods used to determine congressional ratification and mischaracterizing the nature of the congressional action in the present case. It is difficult to understand plaintiffs' assertion that "positive legislation" is required for ratification but lacking

here. To the extent that plaintiffs are suggesting that Congress cannot ratify an agency interpretation unless it affirmatively amends a statute, they are incorrect, as reenactment of a statute without change may alone establish a presumption that Congress intends to adopt an agency interpretation. *See, e.g.*, *Pub. Citizen v. HHS*, 332 F.3d 654, 668 (D.C. Cir. 2003). Moreover, this is not simply a case about the "routine reenactment of Dickey-Wicker without alteration." Pls.' Opp. at 19. It is instead a situation where Congress has, in fact, recently enacted "positive legislation" for FY2010 and, in the course of the legislative process, affirmatively adopted the agency's interpretation. Such evidence unquestionably demonstrates congressional awareness and endorsement of the agency's position. *See Pub. Citizen*, 332 F.3d at 669; *Ass'n of Am. Railroads v. ICC*, 564 F.2d 486, 493 (D.C. Cir. 1977).

Plaintiffs are also misguided in suggesting that Congress may approve only an agency interpretation that is consistent and longstanding. Certainly, in cases (unlike the present one) where express congressional recognition and adoption of the agency position is lacking, evidence that the administrative interpretation is both consistent and longstanding serves as a proxy for the missing affirmative evidence of congressional knowledge and approval of the agency's position. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000); *Isaacs v. Bowen*, 865 F.2d 468, 475 (2d Cir. 1989). However, when Congress expressly states that it is aware and approves of an agency's interpretation, as it did here, that alone is clear evidence of congressional intent. *See, e.g.*, *Melkonyan v. Sullivan*, 501 U.S. 89, 96 (1991).

In any event, as this Court has recognized, defendants' interpretation of Dickey-Wicker to permit the funding of hESC research is both longstanding and consistent. *See* Prelim. Inj. Mem. Op. at 5. HHS first announced its interpretation of the Dickey-Wicker Amendment in 1999, in

an opinion by General Counsel Harriet Rabb, which held that the Amendment does not prohibit federal funding for research on hESCs, as such cells are not embryos. *See* Rabb Memorandum (AR 311). Following that opinion and an opportunity for notice and comment, NIH promulgated final Guidelines in 2000 that adopted this interpretation. 65 Fed. Reg. 51,976. There is no dispute that President Bush's policy on stem cell research provided a narrower set of hESC lines for research. However, the policy under President Bush continued to rely upon the interpretation previously promulgated by the agency, as NIH under President Bush provided funding for hESC research, which required the same distinction between federal funding for the derivation of stem cells from embryos – a process in which the embryo is destroyed – and research involving stem cell lines that have already been created – after the derivation process has ended but before the federally-funded research takes place. Thus, while the presidential *policy* might have changed the manner in which the agency *interpretation* is applied to permit (or prohibit) funding, HHS did not reverse its underlying conclusion that federal funding is permitted for hESC research. *See* Azar Mem. at 4-5 (AR 306-07) (defining "in which" to narrow the understanding of the term "research" and explaining that "these derivation processes were not funded with federal dollars").

Indeed, plaintiffs' counsel asserted to the D.C. Circuit that he personally believed that President Bush's policy would also be prohibited by Dickey-Wicker. *See* Transcript of Sept. 27, 2010 Oral Argument, at 59 ("JUDGE KAVANAUGH: Then the short answer is, the prior policy violates the statute. MR. HUNGAR: In my opinion, yes."). Both policies relied on the distinction proffered by defendants now and for the past decade, and Congress was well aware

that federal funding continued to flow to hESC research.[11]

C. The Agency's Interpretation of Dickey-Wicker, Expressed Through Notice And Comment Rulemaking, Is Deserving of *Chevron* Deference in the Event This Court Determines the Language to Be Ambiguous

Finally, if this Court were to hold the statutory language of Dickey-Wicker ambiguous after the use of the traditional tools of statutory construction, including legislative history, the Court should defer to NIH's rational interpretation as expressed in the final Guidelines. To counter this deference, plaintiffs continue to press their novel argument that an agency interpretation is undeserving of deference under step two of *Chevron* if an agency does not define every term of the statute that, in plaintiffs' view, would be "relevant" to a court's interpretation of the statutory language. *See* Pls.' Opp. at 22.

Plaintiffs' argument has been directly rejected by the Supreme Court. *See Nat'l R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407, 420 (1992). Instead, as the cases cited by plaintiffs recognize, an agency must provide an interpretation of the statute that contains "reasoning that we can evaluate for its reasonableness." *Pub. Citizen*, 332 F.3d at 661. That standard is easily met here, where the agency provided an extensive interpretation of the application of Dickey-Wicker to hESC research. *See* 74 Fed. Reg. at 32,173. In that interpretation, NIH made clear its understanding of the term research to permit a distinction between the stem cell extraction process and research using the stem cells that had already been

[11] Plaintiffs point to a 1996 letter from NIH to "Georgetown University researchers" to claim that NIH has applied its interpretation inconsistently. However, as defendants have explained on appeal, that letter demonstrates precisely how consistent NIH's interpretation has been. The research at issue in the letter involved pre-implantation genetic diagnosis, which is research using human embryos to detect genetic abnormalities in the embryos. *See* Ex. A to Sherley Opp. Decl. In 1996, as today, federal funding for such research was unavailable.

derived. *See id.* ("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.").

Plaintiffs next assert that this comprehensive interpretation is undeserving of deference because defendants cite a dictionary definition in this litigation that was not included in the final Guidelines. *See* Pls.' Opp. at 22-23. Here plaintiffs confuse the tools of statutory interpretation that are used under step one of *Chevron* with the deference that is owed to the agency interpretation under step two. 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). Defendants' use of these tools in this litigation are not forbidden "post hoc" justifications; rather, they are expressly permitted under step one to assist the Court in understanding whether the relevant statutory language compels plaintiffs' interpretation. *See, e.g.*, *Bank of Am. N.A. v. FDIC*, 244 F.3d 1309, 1319 (11th Cir. 2001).

If, under *Chevron* step one, the court decides that the statute is ambiguous, then the Court must proceed to *Chevron* step two. Under *Chevron* step two, the inquiry shifts to the deference due the interpretation provided by the agency. In the present case, that interpretation contains NIH's explanation of the specific scientific terminology contained in an appropriations rider that has controlled NIH's budgetary decisions for fifteen years, based on NIH's understanding of those scientific terms as well as its years of experience with Congress on this issue. *See* 74 Fed. Reg. at 32,173; *see also* 65 Fed. Reg. 51,976. 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 the Guidelines would be undeserving of deference under step two of *Chevron*. *See Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000) (internal quotation omitted).

III. NIH COMPLIED WITH THE ADMINISTRATIVE PROCEDURE ACT

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

Plaintiffs, once again, attempt to convert the agency's notice-and-comment process into a forum for matters that were outside the scope of the Guidelines. They again claim that NIH should have found, as a categorical matter, that hESC research lacks scientific merit and that such research therefore is unethical. They accordingly reason that NIH should have used the Guidelines as a vehicle to declare that it would reject all applications for federal funding for hESC research, in advance of a review of the actual content of any such application. As defendants have shown, plaintiffs fundamentally misunderstand the matters that were at issue in the rulemaking. NIH was directed to issue the Guidelines under Executive Order No. 13,505, which removed the limits that had been placed on funding for hESC research imposed in the prior Administration, and thereby returned the evaluation of the scientific merits of hESC research grant proposals to their proper place – NIH's statutorily-mandated two-tier system of expert peer review. *See* 42 U.S.C. §§ 282(b)(9), 284a(a)(3), 289a.

Plaintiffs have never addressed this effect of the Executive Order, despite now having had several opportunities to do so in briefing before this Court and the court of appeals. They instead continue to attack a straw-man argument that the defendants have *not* made – *i.e.*, that the Executive Order directly mandated that funds be awarded for hESC research. Pls.' Opp. at 31-

36. There is no dispute that the Executive Order did not mandate that NIH fund any particular hESC research proposal. Nor was it lacking in content, however. The Order revoked the directives of the prior Administration that had limited the number of cell lines available for use in federally-funded research – limitations imposed by no existing statute or regulation. Exec. Order No. 13,505, § 5, 74 Fed. Reg. at 10,668. In place of the prior directives, 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).

NIH thus was required under the Order to prepare guidance on ethical standards for hESC research, and to do so in a manner consistent with the Presidentially-declared policy in favor of expanding NIH support for stem cell research. NIH would have squarely violated the Order if it had declined to issue guidelines for the ethical conduct of hESC research, or if it had used the rulemaking to declare as a categorical matter that its support for stem cell research would be contracted, not expanded. As plaintiffs must concede, NIH was duty-bound to follow the Executive Order unless it was statutorily prohibited from doing so. *See Bldg. & Constr. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 33 (D.C. Cir. 2002).

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, the Executive Order 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 have *never* disputed – nor could they do so – that the statutory scheme reserves this scientific evaluation for the peer review process.

The Executive Order expressly declares that it must be "implemented consistent with applicable law," and that it may not be construed "to impair or otherwise affect" NIH's statutory scheme. Exec. Order No. 13,505, § 4(a), (b). Commenters who sought to displace the statutorily-prescribed system of case-by-case peer review, and to substitute in its place a categorical declaration that hESC research lacks any scientific merit (a view that is certainly not prevalent within the scientific community, Defs.' Mem. in Supp. at 2-7), simply did not speak to any matter that was actually at issue in formulating the Guidelines. Accordingly, NIH properly reserved to expert peer review the task of evaluating the scientific merits of particular research proposals. *See Mobil Oil Exploration & Producing Se. Inc. v. United Distrib. Co.*, 498 U.S. 211, 230 (1991).

Plaintiffs further argue that the Executive Order did not override the requirements of the APA, a proposition that defendants have never disputed. Pls.' Opp. 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. As

defendants have shown, NIH considered all of the comments that were submitted to it, and responded to those 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 consider. Landis Decl. ¶¶ 11-13.[12] Indeed, NIH made a number of substantive changes to the final Guidelines in response to relevant public comments. *See, e.g.*, 74 Fed. Reg. at 32,171 (revising definition of human embryonic stem cell); *id.* at 32,173 (requiring donor to be informed that consent may be withdrawn).

In contrast, NIH properly declined plaintiffs' invitation to convert the subject matter of the Guidelines into a completely separate topic – the scientific merits of hESC research – that was reserved instead for the statutory peer-review process. Plaintiffs contend that "the purported distinction between ignoring comments and 'simply deem[ing] them not relevant' is no distinction at all," Pls.' Opp. at 26, apparently contending that an agency must respond to any comment that is submitted to it in a rulemaking, no matter how far afield the commenter has roamed from the rulemaking's purpose. The APA, obviously, holds to the contrary. *See 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"); *see also Nat'l Mining Ass'n v. MSHA*, 116 F.3d 520, 549 (D.C. Cir. 1997).

[12] Plaintiffs apparently dispute this point, but they base their argument on elided quotations from Dr. Landis's declaration that obviously distort the declaration's meaning. *Compare* Pls.' Opp. 25-27 *with* Landis Decl. ¶¶ 11-13.

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

As defendants have shown, a party must make a "clear and convincing showing" that the decision-maker in an informal rulemaking "has an unalterably closed mind on matters critical to the disposition of the proceeding" in order to succeed on a claim that the decision-maker should be disqualified from the rulemaking. *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979). Plaintiffs do not provide any showing, let alone a "clear and convincing" one, of agency bias in the promulgation of the Guidelines.

Plaintiffs repeat their claim that Acting NIH Director Kington prejudged the outcome of the matters that *were* at issue in the rulemaking when he explained publicly what *was not* at issue, namely, whether or not NIH should impose a new categorical ban on the use of its funds in hESC research. Pls.' Opp. at 36-37. Plaintiffs' argument suffers from the same logical flaw as their claim that NIH somehow acted irrationally by not imposing such a ban. NIH was not at liberty to use the Guidelines as a vehicle to declare that hESC research is meritless (even if such a declaration could be squared with the overwhelming contrary scientific consensus). Instead, the evaluation of the merits of grant proposals for scientific research is reserved for the judgment of experts in the statutorily-mandated peer review procedure. *See* 42 U.S.C. §§ 282(b)(9), 284a(a)(3), 289a. Plaintiffs also, again, rely on a newspaper article that attributed to Dr. Kington a comment that the number of hESC lines eligible for use in NIH-funded research would increase. As defendants have already explained, this comment does nothing more than acknowledge the obvious. Only 21 hESC lines were eligible under the previous Administration's policy; there are now more lines already in existence that have been derived by private parties

since August 2001, and that have become eligible for funding since Executive Order No. 13,505 removed the limitations that were imposed by the prior Administration. *See, e.g.,* Landis Decl. ¶ 14. NIH was not required to pretend to be ignorant of this obvious fact. *See PLMRS Narrowband Corp. v. FCC*, 182 F.3d 995, 1002 (D.C. Cir. 1999).

IV. PLAINTIFFS ARE NOT ENTITLED TO INJUNCTIVE RELIEF

As defendants have shown, under the APA, this Court has "no jurisdiction to order specific relief." *Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). Instead, "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." *Id.* at 403 (internal quotation omitted). Further, even if an injunction were an available form of relief here, plaintiffs would bear the burden to show why "recourse to [that] additional and extraordinary relief" would be warranted, in addition to the ordinary remedy of vacatur of the rulemaking. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2761 (2010).

Plaintiffs misconstrue the clear instructions from the court of appeals in *Palisades* and the Supreme Court in *Monsanto*. They make no effort whatsoever to explain why the vacatur of the Guidelines would not remedy their alleged injuries. Instead, they attempt to distinguish *Monsanto* on the ground that the agency there "had not yet exercised its authority." Pls.' Opp. at 40. Plaintiffs baldly mischaracterize that decision. In *Monsanto*, the agency *had* issued a rule, which the district court vacated; the Supreme Court held that the additional relief of an injunction was unwarranted, in part because the agency had not yet responded to the district court's vacation of the prior rule. 130 S. Ct. at 2758. So too here.

Defendants have also shown that, if plaintiffs were to prevail on their notice-and-comment claims, the proper remedy would be a remand without vacatur. Plaintiffs dispute this point, claiming that there is not "a single area of factual development to be followed on remand." Pls.' Opp. at 41. They directly contradict their own theory under their APA claims. Plaintiffs have claimed that NIH should have, but failed to, use the rulemaking to circumvent its peer review process and to make categorical pronouncements as to the relative value of different forms of research. The Guidelines were not intended for that purpose, as defendants have explained. But even if plaintiffs were correct, the remedy that would be available to them would be a remand for the agency to address that issue – not for the Court to accept plaintiffs' invitation to act as a substitute peer review committee. And that remand should be without vacatur, given the disruptive consequences that would occur from the cancellation of funding for projects already in progress. *See Allied Signal Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993); *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 756 (D.C. Cir. 2003).

CONCLUSION

Defendants' motion for summary judgment should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 28, 2010, I caused a true and correct copy of the foregoing Reply to be served on Plaintiffs' counsel electronically by means of the Court's ECF system.

/s/ Eric Womack
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