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 TO DISMISS

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PRELIMINARY STATEMENT

In Executive Order No. 13,505, President Obama removed "limitations on scientific inquiry" imposed by President George W. Bush that had altered the ordinary operation of NIH's grant approval process by limiting the circumstances in which certain hESC research could be eligible for federal funding. The plaintiffs now ask this Court to reimpose these limitations, based on speculative allegations of injury that are wholly dependent on the future actions of a host of third parties, including IVF clinics, donors of embryos, hESC researchers, NIH grant reviewers, and the budgetary decisions of Congress. While the plaintiffs' opposition to hESC research is no doubt deeply felt, these abstract assumptions of injury do not establish a case or controversy that would provide this Court with jurisdiction to interfere with the policy decision of the President or NIH's established grant review process.

Even if this Court were to reach the merits of the plaintiffs' arguments, they fail to state a claim. The plaintiffs would have this Court declare unambiguous the application of the Dickey-Wicker Amendment to hESC research, based on their isolated reading of the single word "research." Although that word could be read in isolation either broadly or narrowly, its meaning is informed by its linguistic context in the statute. That context, combined with an understanding of Congress's express acquiescence to federal funding for hESC research for the past eight years, forecloses any conclusion that the statute unambiguously requires the plaintiffs' preferred result.

Finally, the defendants have failed to state a claim under the APA. Executive Order No. 13,505 is clear. It lifted the prior limitations on federal funding of hESC research, thereby returning 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 NIH was not free to disregard the Order and reimpose a blanket prohibition that President Obama had withdrawn. Nor was NIH required to respond to comments that sought such a result. As to

comments that addressed the substance of the proposed Guidelines themselves, however, NIH provided a reasoned explanation for its decision, which is all that the APA requires.

ARGUMENT

I. This Court Lacks Jurisdiction over This Matter[1]

A. Nightlight Christian Adoptions ("Nightlight")

1. Nightlight's Assumptions of Injury Are Speculative

The plaintiffs erroneously assert that "[d]efendants do not dispute that their decision to fund embryonic stem cell research will lead to fewer embryos being donated to Nightlight and therefore fewer embryos for adoptive parents . . . ." Pls.' Opp. at 11. To the contrary, the speculative nature of this claim lies at the heart of the defendants' objection to Nightlight's standing. Nightlight's allegations depend on the assumption that the Guidelines would cause third parties to donate their embryos for research purposes *rather than* provide those embryos to Nightlight, as though these were the only two options available to IVF patients. *See, e.g.*, Defs.' Mem. at 17.

Yet this either/or choice does not exist. Instead, the decision as to whether to (1) continue to store embryos, (2) discard them, (3) donate them for research purposes, or (4) give them to *any* agency involved in embryonic "adoption," let alone to Nightlight, depends solely upon the possible future action of third parties not before the Court. Accordingly, "it becomes substantially more difficult to establish standing." *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 938 (D.C. Cir. 2004) (internal quotation omitted). The plaintiffs attempt to minimize this burden by suggesting that they need only allege a "'causal relationship between the government policy and the

[1] The plaintiffs do not contend that the Christian Medical Association has standing, and so concede the point. *See* Defs.' Mem. at 12-14; *Sokos v. Hilton Hotels Corp.*, 283 F. Supp. 2d 42, 53 (D.D.C. 2003).

third-party conduct.'" Pls.' Opp. at 11 (quoting *Renal Physicians Ass'n v. HHS*, 489 F.3d 1267, 1275 (D.C. Cir. 2007)). However, as the full quotation reveals, that causal relationship must be supported, even at the pleading stage, by "*substantial evidence*" that "*leav[es] little doubt as to causation and the likelihood of redress*." *Id.* (emphasis added); *see also id.* at 1276 ("[I]t is not enough simply to plead this causative link.").

Ignoring the correct standard, the plaintiffs simply assert that the alleged causal connection "plainly" exists in the present case. Pls.' Opp. at 11. The plaintiffs' purported bases for this connection ring hollow. As an initial matter, the plaintiffs are simply incorrect in identifying the Guidelines as the government action that "lift[s] restrictions . . . on the Government's funding of embryonic stem cell research." Pls.' Opp. at 11. That substantive action was taken instead by the President in Executive Order No. 13,505. 74 Fed. Reg. at 10,668; *see also* Defs.' Mem. at 16 n.2.

In addition, the plaintiffs' conclusory allegation that "increased funding for" hESC research "will undeniably lead to an increase in the number of embryos required for research purposes, which will leave fewer embryos available for adoption," is simply speculation that is belied by the actual content of the Guidelines. Pls.' Opp. at 11-12. Even if one were to assume that current donations of embryos for research purposes are insufficient to meet the purported increase in demand (a speculative assumption itself), there is no reason to believe that this demand would trade off with embryos donated to Nightlight. The Guidelines expressly exclude embryos donated for "adoption" purposes from their reach, as a donor must give voluntary written consent to donate an embryo "for research purposes." 74 Fed. Reg. 32,170, 32,174 (July 7, 2009); *see also* Defs.' Mem. at 16-17.

The plaintiffs note that "IVF facilities are *not* required by the Guidelines to mention adoption,

because most IVF facilities do not facilitate adoptions."[2] Pls.' Opp. at 12. This admission, rather than supporting Nightlight's standing, forecloses the assumption that it is the Guidelines, as opposed to IVF clinics or donors, that constrain "adoption." If "most IVF facilities do not facilitate adoptions," let alone deal directly with Nightlight, then that is the choice of those facilities. Having failed to offer an "adoption" option to this point, there is no reason to think they would do so now.

Perhaps in recognition of these deficiencies, the plaintiffs shift the focus from the overall supply of available embryos to the new assertion (not found in the Complaint) that "Nightlight . . . [has] an interest in obtaining the broadest and most diverse supply of embryos possible." Pls.' Opp. at 13. In other words, because "each embryo is a unique individual" with different characteristics, Nightlight alleges that it is injured if even one additional embryo is destroyed. *Id.* Putting aside the fact that this allegation still depends on the independent decisions of third-party donors and IVF clinics, Nightlight does not explain how it is itself injured as a result. Nightlight does not allege that clients are refusing its services because they cannot obtain "certain characteristics" that they apparently desire, or even that the pool of embryos will be reduced to such an extent that these unnamed "characteristics" will be unavailable to clients.[3] Stoddart MTD Decl. ¶ 2. Instead, its asserted interest in securing particular genetic characteristics in the embryos that parents might choose to "adopt" that would be indicative of preferred physical appearance or the like, *id.*, "is the

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[2] It is also true that the Guidelines do not require that IVF facilities offer donors the option to donate their embryos for research purposes.

[3] Nightlight now asserts that the existing pool of embryos "is constantly shrinking" and that "the present supply of embryos is insufficient to meet all of the demand." Pls.' Opp. at 13 n.5; Stoddart MTD Decl. ¶ 3. However, even assuming these new assertions to be correct (despite the fact that they expressly contradict Nightlight's own representations to clients on its Web site), they do not demonstrate that these obstacles are a product of the Guidelines.

type of abstract concern that does not impart standing." *Nat'l Taxpayers Union v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995).

2. Nightlight and the Embryos that It Purports to Represent Should Be Dismissed Pursuant to the First-to-File Rule

The plaintiffs suggest that concurrent cases must be identical in order for the first-to-file rule to apply. Pls.' Opp. at 17-18. However, as this Court has recognized, when a party is litigating a claim in another district that "is closely related to the . . . claim at issue here and could be raised in that litigation," "[c]onsiderations of comity preclude this court from resolving that claim." *Action for Childrens Television v. FCC*, 827 F. Supp. 4, 15 (D.D.C. 1993), *aff'd*, 59 F.3d 1249 (D.C. Cir. 1995); *see also Save Power Ltd. v. Syntek Fin. Corp.*, 121 F.3d 947, 950 (5th Cir. 1997). There is no question that the issues in the cases are closely related, or that Nightlight could have brought its claims in the Maryland suit. As if to emphasize that point, Nightlight and the embryos that it seeks to represent are plaintiffs in a second lawsuit filed in Maryland on August 21, 2009, that challenges the Guidelines directly by adding an APA claim to the original complaint. *See Doe, et al. v. Obama, et al.*, Civ. No. 8:09-02197-AW (Dkt. No. 1). This filing, although nominally a second lawsuit rather than an amendment to the first, eliminates the minor distinction upon which the plaintiffs rely.[4]

3. Existing Precedent Expressly Forecloses the Ability of an Embryo to Sue to Vindicate a Purported Right to Life

The plaintiffs invite this Court to do what no other federal court has done – accord frozen embryos "personhood" under federal law to vindicate a purported right to life. This position is untenable as a matter of first principles. "[T]the unborn have never been recognized in the law as

[4] Nightlight now alleges that it has asked to be dismissed from the first Maryland lawsuit, even though such dismissal has yet to occur. Stoddart MTD Decl. ¶ 10. Nightlight's allegation ignores its, and the embryos', continued participation in the second Maryland lawsuit.

persons in the whole sense," *Roe v. Wade*, 410 U.S. 114, 162 (1973), and the only courts to have addressed the right of embryos to sue under federal law have rejected such a right. *See Doe v. Shalala*, 862 F. Supp. 1421, 1426 (D. Md. 1994), *vacated as moot*, 57 F.3d 1066 (4th Cir. 1995) (unreported); *Roe v. Casey*, 464 F. Supp. 483, 486-87 (E.D. Pa. 1978); *see also, e.g.*, *Planned Parenthood v. Rounds*, — F. Supp. 2d —, 2009 WL 2600753, at *4 (D.S.D. 2009); *Doe v. Irvine Scientific Sales Co.*, 7 F. Supp. 2d 737, 742 (E.D. Va. 1998). Rather than addressing this authority, the plaintiffs simply ignore it, claiming wrongly that Defendants have "not cite[d] a single authority" holding that embryos are not "persons" under federal law.[5] Pls.' Opp. at 14.

Even if this Court were to be the first to assume that embryos are entitled to sue as "persons" under the APA, embryos would still not have standing to vindicate their purported injury in this case. Standing requires more than just any injury; it must be an injury to a "legally protected interest," *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992), and implicate a "legally cognizable right." *McConnell v. FEC*, 540 U.S. 93, 227 (2003). That interest here is a purported right to life that is currently unrecognized by the Supreme Court. *Roe*, 410 U.S. at 158, 162; *see also* Defs.' Opp. to Pls.' Mot. for Appt. of Guardian *ad Litem*.

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[5] With relevant authority uniformly unfavorable to their position, the plaintiffs are forced to rely on *Hatch v. Riggs Nat'l Bank*, 361 F.2d 559 (D.C. Cir. 1966), a pre-*Roe* case dealing with unborn heirs' interest in an irrevocable trust. Pls.' Opp at 14. But *Hatch* neither mentions embryos nor addresses the right of the unborn to assert an "unqualified interest" in life. *See* Defs.' Opp. to Pls.' Mot. for Appt. of Guardian *ad Litem* at 5. The plaintiffs also argue that federal law should not govern the APA's definition of "person," invoking *United States v. Kimbell Foods, Inc.*, 440 U.S. 715 (1979). But this is a matter of statutory interpretation, not federal common law. *See Northwest Airlines, Inc. v. Transport Workers Union*, 451 U.S. 77, 97 (1981). There is no reason to believe that Congress intended any one state's law to govern the meaning of "person." *See Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43-44 (1989).

B. The Nelsons and Flynns

The plaintiffs group the Nelsons and Flynns with Nightlight in their standing analysis. This approach reveals an inherent problem, as the Nelsons and Flynns provide no indication of any concrete and imminent injury that they would suffer *individually* from the Guidelines. The plaintiffs seem to assume that the Nelsons and Flynns may establish standing by alleging future injury to some potential adoptive parent who stands in a position similar to their own. Pls.' Opp. at 11. Such an allegation is not permitted to establish standing, as the Nelsons and Flynns must allege a concrete and imminent harm to themselves as individuals. *See, e.g., Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 39 (1972); *Sierra Club v. Morton*, 405 U.S. 727, 740 (1972).

When the allegations of the Nelsons and Flynns are viewed in individual terms, they are clearly inadequate. The Nelsons and Flynns simply allege that they are currently seeking to adopt another embryo. *See* Decl. of William T. Flynn ¶ 3; Decl. of Tina Nelson ¶ 3. Yet despite these current intentions, occurring while Executive Order No. 13,505 and the Guidelines have been in place, neither couple alleges any specific obstacle to their current efforts to adopt an embryo, or the unavailability of any particular genetic "characteristic" they desire. Defs.' Mem. at 20.

C. Drs. Sherley and Deisher

Plaintiffs Sherley and Deisher do not contend that they have alleged a concrete and imminent likelihood of losing research funding as a result of the Guidelines. *See, e.g.*, Pls.' Opp. at 7. Rather, they believe such allegations unnecessary, as they purportedly suffer injury solely from the purported "increased competition that flows directly from the Guidelines' authorization of funding" for hESC research. *Id.* However, the plaintiffs' claim of injury from increased competition for research grants is drastically different than that of an existing participant in a free market for customers and sales.

See New World Radio, Inc. v. FCC, 294 F.3d 164, 170 (D.C. Cir. 2002) (noting that competitive standing cases "are premised on the petitioner's status as a *direct* and *current* competitor whose bottom line may be adversely affected by the challenged government action"). Plaintiffs Sherley and Deisher are not current market participants in this sense; they have no preexisting entitlement or right to funding provided by NIH. Regardless of Dr. Sherley's success in obtaining funding for some of his prior applications, each of his or Dr. Deisher's future applications must be submitted anew and found to have scientific merit before it can even be eligible for funding. Rockey Decl. ¶ 13. Thus all scientists, including the plaintiffs, are new participants each time that they apply for funding. Whether they are more or less likely to receive funding during each new application process depends on numerous independent factors, including the subject matter of the research, the needs of an IC, the merit to the research, and Congress's budgetary decisions. *Cf. New World Radio*, 294 F.3d at 172 (". . . New World's 'chain of events' argument depends on the independent actions of third parties, distinguishing its case from the 'garden variety competitor standing cases' . . . .").

Moreover, it is no coincidence that the competitive standing cases cited by the plaintiffs involve participants in private economic markets. These businesses compete for sales with one another on a zero-sum basis, and each presumably would prefer to be the recipient of every purchase made in that market. When a new entrant is permitted into the market, the laws of economics permit the assumption that increased competition will lead to a drop in prices or sales for each existing competitor. *See, e.g., Idaho Power Co. v. FERC*, 312 F.3d 454, 461 (D.C. Cir. 2002). These market forces are inapposite to research grants. The plaintiffs' applications can be approved alongside hESC applications; such funding is not mutually exclusive. *See* Rockey Decl. ¶ 19. The supposed competitive "injury" is simply not proportionally shared by all research scientists as it would be by

market participants, so as to justify an assumption of economic harm.

Rather than trying to fit a square peg into a round hole, the proper approach is to apply the traditional analysis that governs standing. This analysis, rather than competitive standing, has been applied in analogous contexts involving the denials of grant applications. *See Donaldson v. United States*, 268 F. Supp. 2d 812, 820 (E.D. Mich. 2003).[6] As with the unsuccessful applicant in *Donaldson*, the plaintiffs' allegations of injury are entirely speculative, premised on assumptions of future actions by multiple parties, including Congress's annual budgetary decisions. These allegations contradict the only available concrete evidence, which indicates that the focus of their research – adult stem cells – will continue to receive funding and support from NIH, as demonstrated by a predicted outflow three times that for hESC research. *See* Rockey Decl. ¶ 18.

Even assuming that the competitive standing cases could apply here, the plaintiffs' allegations would still be insufficient to establish standing. "The nub of the 'competitive standing' doctrine is that when a challenged agency action authorizes allegedly illegal transactions that will *almost surely cause* petitioner to lose business, there is no need to wait for injury from specific transactions to claim standing." *El Paso Natural Gas Co. v. FERC*, 50 F.3d 23, 27 (D.C. Cir. 1995) (emphasis added); *see also DEK Energy Co. v. FERC*, 248 F.3d 1192, 1195 (D.C. Cir. 2001). That standard excludes allegations of competition that demonstrate only that an agency action permits "the first step in the direction of future competition," rather than "itself impos[ing] a competitive injury." *New World Radio*, 294 F.3d at 172.

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[6] The plaintiffs are incorrect that the Court's decision in *Donaldson* is limited to situations in which a plaintiff has not submitted an application for a grant (as may be the case for plaintiff Deisher, *see* Deisher Decl. ¶ 3), as that fact was only one of several speculative contingencies cited by the Court as the basis for its conclusion. *See* 268 F. Supp. 2d at 820.

The "competition" that the plaintiffs face from hESC researchers is, at most, a preliminary step in the direction of future competition. For there even to be hESC proposals competing for funding with the plaintiffs' proposals, both sets of proposals must be judged to have scientific merit and both must pertain to the subject area (*e.g.*, cancer research) covered by the same IC such that they are competing for the same federal dollars (as each IC maintains an independent budget). *See* Defs.' Mem. at 24. The mere fact that hESC researchers are able to submit proposals does not show that they are in direct competition with the plaintiffs for funding by the same IC at the same time, let alone that these proposals would have such a competitive effect that the plaintiffs' funding would be at stake. *Cf. DEK Energy*, 248 F.3d at 1196 ("Some of this gas may well wend its way into DEK's markets. But without more information from which to infer quantities capable of having a market effect, that is an inadequate basis for [standing].") (internal citation omitted).

Moreover, there is a more fundamental issue with the plaintiffs' allegations of competitive injury here. Contrary to the plaintiffs' repeated assumptions, it is Executive Order No. 13,505 – not the Guidelines – that withdrew the blanket hESC funding restrictions ordered by President Bush and thereby enabled hESC researchers to submit proposals for funding. Defs.' Mem. at 24 n.5; *see also* 74 Fed. Reg. at 10,668. If there is any effect from the Guidelines separate from the Order, it is actually one that reduces competition, as the substantive effect of the Guidelines is to restrict the hESC lines that may be used in research based on certain specified requirements.

II. The Plaintiffs' Challenge to the Guidelines Is Not Ripe for Review

The defendants have shown that the plaintiffs' claims are not ripe, for two reasons. Defs.' Mem. at 26-29. First, the plaintiffs suffer no hardship requiring review, because the Guidelines do not have any direct effect on their primary conduct. *See Nat'l Park Hospitality Ass'n v. Dep't of*

Interior, 538 U.S. 803, 808 (2003). Second, the plaintiffs' claims are not fit for decision, because the evaluation of the merits of particular areas of scientific research is required by law to be conducted by experts in NIH's peer review process, rather than by counsel or by this Court in judicial review of the Guidelines. 42 U.S.C. §§ 282(b)(9), 284a(a)(3), 289a.

The plaintiffs do not attempt to dispute either of these two points. Instead, they argue that, because they allege a "competitive injury," they are excused from their ordinary burden to show that their claims are ripe. Pls.' Opp. at 18-20. No such categorical rule exists, of course; a litigant who alleges a competitive injury must show fitness and hardship in the same manner as any other litigant. *See, e.g., Worth v. Jackson*, 451 F.3d 854, 861-62 (D.C. Cir. 2006); *Pfizer Inc. v. Shalala*, 182 F.3d 975, 979 (D.C. Cir. 1999); *Sociedad Anonima Vina Santa Rita v. Dep't of Treas.*, 193 F. Supp. 2d 6, 25 (D.D.C. 2001).

Unlike the claimants in the cases cited in the opposition brief, the plaintiffs here cannot allege any direct effect on their primary conduct. There is no sense, for example, in which Dr. Sherley or Dr. Deisher would change the manner in which they apply for NIH grants because NIH now will also accept applications for grants for hESC research. Because no such allegation is possible, their claims are not ripe at this time.

III. The Plaintiffs' Substantive Legal Challenges Lack Merit

A. The Defendants' Interpretation of Dickey-Wicker Is Rational

1. The Defendants' Interpretation Is Entitled to *Chevron* Deference

The plaintiffs' argument that the defendants' interpretation of the Dickey-Wicker Amendment is not entitled to *Chevron* deference both ignores the content of the Guidelines and misunderstands the *Chevron* inquiry. They assert that *Chevron* applies when "(1) the agency has in

fact interpreted the statutory term or provision in question, and (2) the agency interpretation claiming deference was promulgated in a rule carrying the force of law." Pls.' Opp. at 27-28 (internal citations and quotations omitted). 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 Joint Venture v. Kempthorne*, 477 F.3d 745, 754 (D.C. Cir. 2007). 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.

Instead, the plaintiffs argue that this extensive interpretation is not entitled to *Chevron* deference because the Guidelines do not define the "statutory term 'research.'" Pls.' Opp. at 28. They apparently reason that, unless an agency defines every relevant word of a statute in its rulemaking, the agency may not later defend itself using the traditional tools of statutory interpretation. *See id.* at 28-29. This argument finds no support in the case law, which has rejected the notion that deference is owed only to express definitions of language – much less every word of that language – in a rulemaking.[7] *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 . . . .").

The plaintiffs' next argument, that the defendants did not use their "experience" or

[7] The 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, the 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 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.

"expertise" in interpreting Dickey-Wicker, is simply wrong. Pls.' Opp. at 29-30. 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 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).

2. The Plaintiffs Have Failed to Demonstrate that the Language of Dickey-Wicker Unambiguously Commands Their Overly Broad Interpretation

As relevant here, the Dickey-Wicker Amendment prohibits federal funding for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Pub. L. No. 111-8, Div. F, § 509(a)(2), 123 Stat. 524, 803 (2009).[8] The plaintiffs proffer a 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 the plaintiffs, the term "research" must be read so broadly that all activities that preceded or followed the subject matter of an individual research project are encompassed as part of that project for the purposes of the Amendment. *See, e.g.*, Pls.' Opp. at 20-21. However, when this language is read in the context of the words surrounding it and

[8] That statute has expired, but its conditions have been adopted in a continuing resolution that appropriates funds for NIH through October 31, 2009. Pub. L. No. 111-68, Div. B, § 101, 123 Stat. 2023, 2044 (Oct. 1, 2009).

in light of the Amendment's legislative history, it is apparent that the 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).

The plaintiffs claim their interpretation of the word "research" is compelled by separate HHS regulations that define "research" as a "systematic investigation." Pls.' Opp. at 21 (citing 45 C.F.R. § 46.102(d)). Here again, however, the plaintiffs gloss over the ordinary meaning of "systematic" as involving a "system, method or plan," Defs.' Mem. at 32, by assuming that the "plan" of an hESC researcher unambiguously requires the destruction of an embryo, even if the researcher does not propose to use an embryo in a research project. Pls.' Opp. at 21. This assumption finds no support in the regulations that govern the NIH grant process, which define the term "research" only as "a systematic investigation, *study* or *experiment* designed to contribute to general knowledge relating broadly to public health[.]"[9] 42 C.F.R. § 52.2 (emphasis added); *see also, e.g.*, 42 C.F.R. § 2a.2; 48 C.F.R. § 2009.570-2.

It is entirely possible that the term "research" could, in a vacuum, be given a broad reading. But that does not resolve the question of what Congress intended through its inclusion of the term in the Amendment. The plaintiffs do not contest that the statute's prepositional phrase, "in which," has a limiting connotation that provides context to the preceding term, "research." *See* Defs.' Mem. at 32. Nor do the plaintiffs dispute that the use of the present tense in the statute evokes Congress's intent to limit the application of the phrase to the present usage. *See id.* at 32-33. Rather, the plaintiffs simply refer back to their broad reading of the term "research," and assert that the present

[9] It is unclear how the plaintiffs can state that "[d]efendants fail to cite *any* 'context' in which 'research' has been interpreted to exclude integral parts of the research process," when the defendants previously cited this regulation. *See* Defs.' Mem. at 32.

tense canon would have an "absurd" application here because it would permit NIH to fund a completed project that involved the destruction of embryos. Pls.' Opp. at 22-23 n.10. This misguided hypothetical ignores the fact that there "are" still embryos involved in that project, regardless of the timing of the funding decision, and it obscures the implications for the plaintiffs' argument that Dickey-Wicker should apply to any potential future incentive for the destruction of embryos, as such a focus is belied by the statutory language.[10] *See Sutton v. United Air Lines*, 527 U.S. 471, 482 (1999), *superseded by* Pub. L. No. 110-325 (2009).

The only risk of an absurd result in this case would be the widespread implications for research funding produced by the plaintiffs' overly broad interpretation. *See, e.g., Pub. Citizen v. DOJ*, 491 U.S. 440, 454 (1989); *see also* Defs.' Mem. at 35. The plaintiffs' reading of the statute suggests that Congress intended that all research that necessarily precedes, or follows from, the destruction of an embryo would be ineligible for funding. Thus, funding for important advances in cell biology, for example, should have been prohibited along with all hESC research. That is certainly not the result intended by Congress, let alone one that should be adopted by this Court.

3. The Legislative History Surrounding Dickey-Wicker's Passage and Annual Reenactment Forecloses the Plaintiffs' Broad Interpretation

The plaintiffs refer to the defendants' discussion of the legislative history of the Dickey-Wicker Amendment as "bits of legislative history" cited "in an attempt to support their untenable

[10] Plaintiffs entirely ignore defendants' previous brief when they assert that "[d]efendants . . . concede that by funding [hESC] research, they . . . are knowingly subjecting additional embryos to risk of death." Pls.' Opp. at 24; *see* Defs.' Mem. at 34-35; *see also* Defs.' Mem. at 36-37 (countering the plaintiffs' argument regarding the context of the Amendment).

position."[11] Pls.' Opp. at 24. That aggressive characterization gives inadequate credence to the express acquiescence by Congress to the funding of hESC research over the past eight years.

As an initial matter, the plaintiffs continue to ignore the fact that NIH has previously expressed its position on the effect of Dickey-Wicker. *See* Defs.' Mem. at 37-38. In August 2000, NIH issued final Guidelines containing the interpretation, yet Congress, in enacting Dickey-Wicker without substantive change some four months later, took no action with regard to the interpretation. *See* 65 Fed. Reg. 51,976; Pub. L. No. 106-554, App. A, § 510, 114 Stat. 2763, 2763A-71 (Dec. 21, 2000). Given the plaintiffs' concession that Congress was fully aware of NIH's interpretation, *see, e.g.*, Pls.' Opp. at 25 n.12, Congress's inaction is persuasive evidence that the full body did not intend to overrule the agency's interpretation. *See CFTC v. Schor*, 478 U.S. 833, 845-46 (1986).

Moreover, following former President Bush's address in August 2001, Congress has repeatedly stated that Dickey-Wicker did not prohibit funding that was being provided, under President Bush, for hESC research. Congress's repeated approval of such funding was expressed, not in "snippets" of legislative history, but in Committee Reports accompanying appropriations bills for NIH in 2001, 2003, 2004, 2007, 2009, and in the draft bill for 2010. *See* Defs.' Mem. at 38-39. The plaintiffs characterize this overwhelming history as "competing" with their citations to the statements of individual legislators. *See* Pls.' Opp. at 24-25, 25 n.12. However, "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill, which

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[11] The plaintiffs ask this Court to ignore legislative history altogether, as the statutory language is "unambiguous." *See* Pls.' Opp. at 25. That circular argument, however, ignores the Supreme Court's and D.C. Circuit's repeated usage of legislative history under step one of *Chevron* as one of the traditional tools of statutory interpretation. *See, e.g., Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ.*, 550 U.S. 81, 89 (2007); *Pharm. Res. & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001).

represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation." *Garcia v. United States*, 469 U.S. 70, 76 (1984) (internal quotation omitted); *see also id.* ("We have eschewed reliance on the passing comments of one Member . . . ."); *Miller v. Holzmann*, 575 F. Supp. 2d 2, 7 (D.D.C. 2008).[12]

The plaintiffs conclude by referring to the "context" of the initial enactment of the Dickey-Wicker Amendment in response to a 1994 report by a bioethics commission that recommended that "NIH fund research using 'surplus' human embryos." Pls.' Opp. at 27. That report, however, proposed funding for research *actually involving* embryos, including "[r]esearch involving preimplantation genetic diagnosis" and "[r]esearch involving the *development* of embryonic stem cells." NIH, Report of the Human Embryo Research Panel (Sept. 1994), at xvii (emphasis added), available at http://www.bioethics.gov/reports/past_commissions/. Congress's statutory focus, in response to this report, on research directly involving embryos provides further proof that NIH rationally interpreted Dickey-Wicker to prohibit funding only for that type of research.

B. NIH Complied with the Administrative Procedure Act

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

The plaintiffs have devoted a large portion of their briefing to their self-professed view that hESC research lacks scientific merit, that it accordingly would be unethical to fund such research, and that therefore NIH should have used the Guidelines as a vehicle to declare that it would reject

[12] The plaintiffs suggest that former President Bush's policy "has been to *prohibit* stem cell research that incentivizes the destruction of embryos" and that the legislative history therefore does not support NIH's interpretation. Pls.' Opp. at 26. The plaintiffs' argument cannot be squared with hESC research funded under President Bush, as that research still relied on hESC lines developed from destroyed embryos. Defs.' Mem. at 39-40.

all applications for federal funding for hESC research, in advance of a review of the actual content of any such application. As the defendants have previously explained, the plaintiffs' arguments on this score fundamentally misunderstand the matters that were at issue in the Guidelines. NIH was directed to issue the Guidelines by 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. Defs.' Mem. at 42-46.

The plaintiffs do not address the defendants' explanation of the effect of the Executive Order. Instead, they posit 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 – and devote a significant portion of their brief to a rebuttal of this straw argument. Pls.' Opp. at 31-36. The defendants fully agree 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 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).

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 even the plaintiffs concede, NIH was required to follow the Executive Order unless it was statutorily prohibited from doing so. Pls.' Opp. at 36 (citing *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 plaintiffs' preferred wholesale ban on funding for hESC research nor instructed NIH that it must award funds for such research. 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. The plaintiffs do not offer *any* argument to dispute that the statutory scheme reserves this evaluation in the first instance for the peer review process. They instead question, without basis, whether peer review groups will undertake that review fairly. Pls.' Opp. at 34. The plaintiffs rely on their inferences from the final Guidelines to support their doubts, but those inferences present no reason to believe that the members of NIH's peer review groups will not take seriously their obligation to review grant applications on their scientific merits. *Cf. Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415 (1971) (administrative action is entitled to a

"presumption of regularity").

The Executive 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). Commenters who sought to displace the statutorily-prescribed system of case-by-case peer review, and to substitute in place of that system a categorical declaration that hESC research lacks any scientific merit (a view that is not prevalent within the scientific community, Defs.' Mem. at 2-6), 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.[13]

The plaintiffs further argue that the Executive Order did not override the requirements of the APA, a proposition that the defendants do not dispute. 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. 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. NIH was under no obligation to expand the scope of the Guidelines to cover a separate topic – the scientific merits of hESC research generally. *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

[13] The defendants fully agree with the plaintiffs' assertion that the motions presently before the Court are not the appropriate venue to decide the scientific value of hESC research. *See* Pls.' Opp. at 38-39. It is the plaintiffs' one-sided presentation of those views that necessitated the defendants' brief discussion, taken largely from NIH's Web site, of the numerous contrary views. The defendants pause only to note that, under the plaintiffs' standard, hESC research must already have been proven to cure serious diseases such as Parkinson's before such research could lawfully be funded. This obviously puts the cart before the horse.

(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").

2. NIH Rationally Explained Its Decision with Respect to the Matters that Actually Were at Issue

The plaintiffs reiterate three of their comments regarding the informed-consent standards that NIH established in the Guidelines, and they again assert that NIH failed to respond to these comments. Pls.' Opp. at 40-41. The defendants have already explained that NIH did, in fact, respond to each of these comments. Defs.' Mem. at 46-48. In each instance, NIH provided a response that enables the Court "to see what major issues of policy were ventilated and why the agency reacted to them as it did." *City of Portland v. EPA*, 507 F.3d 706, 714 (D.C. Cir. 2007) (internal quotation and ellipses omitted). The APA requires nothing more. *Id.* The plaintiffs seek now to litigate the substantive merits of their comments, rather than the adequacy of NIH's response. This attempt should be rejected.

First, the plaintiffs again claim that NIH should have prohibited researchers from having any relationship with IVF clinics to ensure the ethical donation of embryos. The Guidelines, however, require that hESC lines be derived from 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. Grant applicants must document compliance with a number of safeguards before NIH will determine that this standard has been met. In particular, the Guidelines require proof of a "clear separation" between the decision to create embryos for reproductive purposes and the decision to donate embryos, and proof that the decision to create embryos was free from the influence of any hESC

researchers. *Id.* The Guidelines further recommend, but do not require, that the attending physician and the hESC researcher be different persons, unless separation is not practicable. *Id.* NIH explained that, given the other safeguards in the Guidelines, an absolute bar was unnecessary to ensure ethical donation. 74 Fed. Reg. at 32,173. The multiple levels of documentation in the Guidelines show that NIH gave careful consideration to this issue, which is all that the APA requires. *See City of Waukesha v. EPA*, 320 F.3d 228, 258 (D.C. Cir. 2003).

Second, the plaintiffs repeat their argument that NIH should have required every IVF clinic to inform donors of the alternative of "embryo adoption." The Guidelines do require that donors be informed of "[a]ll options available in the health care facility where treatment was sought pertaining to the embryos." 74 Fed. Reg. at 32,174. Thus, if a clinic offers "embryo adoption" as an option, it must explain that alternative to a potential donor. NIH, of course, does not have direct authority to dictate the options that clinics provide. It accordingly explained that, because different clinics offer different services, it would not impose a blanket rule, but instead would only require clinics to explain the alternatives that actually are available at a particular facility. 74 Fed. Reg. at 32,173. Again, NIH's response shows that it considered, and rejected, the plaintiffs' proposed alternative.

Third, the plaintiffs again assert (briefly) that NIH should have required that consent forms contain specific language, for example, language that an embryo is a "living, human being." As the defendants have already shown, NIH explained in the Guidelines that research institutions and IVF clinics face a "wide variety" of regulatory regimes, and that these institutions already use a wide variety of consent forms. Accordingly, NIH reasoned, it would not provide exact wording for consent forms, but instead would encourage that the substance of the informed consent process be fulfilled in the manner appropriate for the individual clinic and donor. 74 Fed. Reg. at 32,173. Once

again, NIH showed that it considered and rejected the plaintiffs' alternative formulation. The mere fact that NIH did not adopt the plaintiffs' suggestions does not give rise to a claim under the APA.

3. NIH Allowed Sufficient Time to Comment

The plaintiffs continue to assert their meritless claim regarding the length of the comment period. NIH's draft Guidelines established a 33-day period for public comment. 74 Fed. Reg. 18,578 (Apr. 23, 2009). NIH received thousands of comments in response during that period, including the plaintiffs' lengthy submission. NIH made a number of changes to the final rule in response to the comments that it received. *See* 74 Fed. Reg. at 32,171, 32,173. There is no question that NIH provided an adequate comment period. In any event, the plaintiffs have had the benefit of four months' worth of hindsight since they made their submission. During that time, they have not identified any further (or relevant) comment that they would have wished to add if the comment period had been longer. The APA requires such a showing of prejudice for a party to challenge whether the agency provided it with an adequate opportunity for comment. *See, e.g., Omnipoint Corp. v. FCC*, 78 F.3d 620, 630 (D.C. Cir. 1996). NIH obviously provided adequate time to comment, and the plaintiff's frivolous claim to the contrary should be rejected.

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

As the defendants have explained, 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. Defs.' Mem. at 50 (quoting *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979)). The plaintiffs do not provide any showing, let alone a "clear

and convincing" one, of agency bias in the promulgation of the Guidelines.

The 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 categorical ban on funding for hESC research.[14] Pls.' Opp. at 42-43. The 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.

The plaintiffs also reiterate the same mischaracterizations that they relied upon in their preliminary injunction motion. They again assert that NIH "telegraphed" the outcome of the Guidelines by announcing that it would accept grant applications for hESC research in the interim. Once again, however, they fail to inform the Court that, in the same notice, NIH also stated that it would not evaluate those applications until after the Guidelines were issued, and that it barred any new uses of hESCs until that time. NOT-OD-09-85 (Apr. 17, 2009), http:/grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html. The plaintiffs also, again, rely on a newspaper article that attributed to Mr. Kington a comment that the number of hESC lines

[14] The plaintiffs also repeat their misleading characterization of the article on which they base this argument. Their brief is written to suggest that Acting Director Kington was quoted as saying that NIH "disregarded" comments that proposed a ban on hESC research funding. That quotation is not his, but is instead the reporter's characterization. In fact, as the defendants have previously explained, NIH accepted and reviewed all such comments, responding to those that fell within the scope of the Guidelines. Defs.' Mem. at 49 n.13.

eligible for use in NIH-funded research would increase. As the 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. 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).

CONCLUSION

For the foregoing reasons, the defendants respectfully request that the Court dismiss the complaint for lack of jurisdiction or, in the alternative, for failure to state a claim.

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CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2009, 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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