IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. JAMES L. SHERLEY, et al., Plaintiffs,	)	
v.	)	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.	)	

MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS, AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Statutes

Other Authorities

TABLE OF AUTHORITIES

Rules

Regulations

TABLE OF AUTHORITIES

INTRODUCTION

The NIH Guidelines for funding human embryonic stem cell research are invalid both because they violate the Congressional prohibition on funding "research in which" embryos are destroyed or knowingly placed at risk, and because they were not promulgated in accordance with the procedures required by the Administrative Procedure Act ("APA"). The Court should deny Defendants' Motion to Dismiss and enjoin Defendants from taking any further action to implement or apply the Guidelines.

Defendants defend the Guidelines in three ways, but none justifies their clear violations of the Dickey-Wicker Amendment and the APA.

First, Defendants claim that none of the Plaintiffs has standing to challenge the Guidelines. But Defendants fundamentally misunderstand Plaintiffs' injuries, which are cognizable without respect to whether any individual embryonic stem cell grant is awarded or whether any one of Dr. Sherley's or Dr. Deisher's proposals is ultimately rejected. There is no denying that adult stem cell researchers will now face greater competition for federal grants. Under the law in this Circuit, that undeniable reality supplies the injury in fact required by Article III. Moreover, Defendants do not deny that the Guidelines will result in the destruction of embryos. Indeed, they could not, as the Guidelines regulate the very process by which embryos will be selected for destruction.

Second, Defendants argue that the Guidelines do not violate Dickey-Wicker because the word "research" can mean "piece of research," contending that this Court must defer to that interpretation—cribbed from dictionary.com—under *Chevron*. Plaintiffs are incorrect on both points. The plain language of the Dickey-Wicker Amendment clearly prohibits funding of embryonic stem cell research that incentivizes—or depends on—the destruction of embryos. But

even if this were not abundantly clear from the language of the statute, Defendants' interpretation would not be entitled to deference because Defendants have not—until this litigation—provided any interpretation of the term "research." And even now, Defendants do not interpret the statute based on any expertise, but rather based on their lawyers' selection of one dictionary's definition of the term. The law is clear that no deference is due under these circumstances.

Third, Defendants defend their failure to consider thousands of relevant comments explaining the scientific shortcomings and ethical concerns of embryonic stem cell research by arguing that the President required them to fund embryonic stem cell research as contemplated in the Guidelines. The President did no such thing. The Executive Order stated that NIH "*may*" fund "*responsible, scientifically worthy*" embryonic stem cell research "*to the extent permitted by law*," not that NIH "shall" fund embryonic stem cell research that is ethically irresponsible and scientifically unworthy. In any event, Defendants' legal argument—that an agency is immune from review under the APA simply because it followed a presidential directive—is wholly unsupported by the case law or established principles of administrative law. Indeed, Defendants' argument amounts to an unprecedented and shocking claim of unfettered Executive power to trump an Act of Congress at whim, and should be summarily rejected.

Defendants' arguments for dismissal of Plaintiffs' Complaint are unconvincing, and the Court should deny their motion. And because Plaintiffs have a high likelihood of success on the merits and will suffer irreparable injury absent an injunction, the Court should enjoin Defendants from funding embryonic stem cell research or further implementing the Guidelines.

ARGUMENT

I. The Standard Of Review

In reviewing a motion to dismiss, "the Court must accept the complaint's well-pled factual allegations as true and draw all reasonable inferences in the plaintiff's favor." *Allen v.*

Nicholson, 573 F. Supp. 2d 35, 38 (D.D.C. 2008) (internal quotation and alteration omitted); *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) ("[O]n a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim." (internal quotation and alteration omitted)). A plaintiff is "protected from an evidentiary attack on his asserted theory by the defendant" in a motion to dismiss. *Haase v. Sessions*, 835 F.2d 902, 904, 907 (D.C. Cir. 1987).

Throughout their brief, Defendants challenge Plaintiffs' factual allegations, but these arguments are inappropriate and should not be considered in ruling on their motion to dismiss. For example, Defendants set out to describe the purported "promise of human embryonic stem cell research," claiming that embryonic stem cell research could destroy cancer, cure Parkinson's disease and diabetes, and treat stroke victims, with the risk of only "benign" tumors. But the conclusions that Defendants draw (besides being factually erroneous and based on materials outside the administrative record, *see infra*, pp. 36-40), are squarely refuted by the allegations in Plaintiffs' Complaint. Plaintiffs alleged, for example, that "genetic instability is an inherent characteristic of hESCs, and one that inevitably causes hESCs injected into organisms to cause tumors," and that "hESCs have not shown promise of offering a safe or effective component of human therapy or medical treatments." Compl. ¶ 47. The Court "must accept the[se] well-pled factual allegations," *Allen*, 573 F. Supp. 2d at 38, and Defendants' simple disagreements with those allegations therefore cannot be considered in connection with their motion to dismiss. *Holy Land Found. for Relief & Dev. v. Ashcroft*, 333 F.3d 156, 165 (D.C. Cir. 2003).

Defendants' factual allegations are also inappropriate under the proper standard of review for Plaintiffs' motion for a preliminary injunction. The relevant facts in determining Plaintiffs' likelihood of success on the merits are those contained in the administrative record, not the facts

and justifications that Defendants now belatedly seek to advance through their counsel. *See, e.g.*, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988); *SEC v. Chenery Corp.*, 318 U.S. 80, 97 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."); *Fort Stewart Schs. v. Federal Labor Relations Auth.*, 495 U.S. 641, 651–652 (1990) ("[I]t is elementary that if an agency's decision is to be sustained in the courts on any rationale under which the agency's factual or legal determinations are entitled to deference, it must be upheld on the rationale set forth by the agency itself."). Defendants' *post-hoc* rationale for their decision and their attempt to justify the Guidelines based on the supposed extra-record "promise" of embryonic stem cell research are therefore irrelevant and insufficient.

II. Plaintiffs Have Standing To Challenge The Guidelines

Defendants challenge the standing of every Plaintiff in this action, effectively claiming that the Guidelines are insulated from review by any court. But the Guidelines cause cognizable and imminent injuries to Plaintiffs. For example, the Guidelines alter the competitive market for research grants by permitting enhanced competition from human embryonic stem cell researchers and thereby make it more difficult for non-embryonic stem cell researchers such as Dr. Sherley and Dr. Deisher to obtain funding; the Guidelines make it more difficult for both adoption agencies and adopting parents to secure embryos that can be implanted and born; and the Guidelines imminently increase the risk that embryos will be destroyed. It is well established that "the presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 53 n.2 (2006). *See also Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1266 (D.C. Cir. 2004). This case must therefore be allowed to proceed as long as *any* Plaintiff has standing.

A. Dr. Sherley And Dr. Deisher Face An Immediate Competitive Injury From Defendants' Funding Of Embryonic Stem Cell Research

In a well-established line of cases, the D.C. Circuit has consistently held that a party has standing if governmental action impairs the party's ability to compete, and that the party need not point to a specific loss it has suffered or will suffer due to the increased competition. Under that settled principle, plaintiffs "establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate potential to compete with the [litigants'] own sales." *Assoc. Gas Distrib. v. FERC*, 899 F.2d 1250, 1259 (D.C. Cir. 1990).

In case after case, the D.C. Circuit has held that a party "need not wait for specific, allegedly illegal transactions to hurt them competitively"; rather, "petitioners sufficiently establish their constitutional standing by showing that the challenged action authorizes allegedly illegal transactions that have the clear and immediate *potential to compete* with the petitioners' own sales." *Assoc. Gas*, 899 F.2d at 1259 (emphasis added); *see also, e.g.*, *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998) ("parties suffer constitutional injury in fact *when agencies lift regulatory restrictions on their competitors* or otherwise allow increased competition" (emphasis added)); *U.S. Telecom Ass'n v. FCC*, 295 F.3d 1326, 1331 (D.C. Cir. 2002) ("regulatory decisions that permit subsidization of some participants in a market can have the requisite injurious impact on those participants' competitors"); *Investment Co. Inst. v. F.D.I.C.*, 815 F.2d 1540, 1543 (D.C. Cir. 1987) ("The FDIC will deal petitioners competitive injury by *allowing insured nonmember banks to enter* the securities field indirectly through subsidiaries and affiliates." (emphasis added)); *New World Radio, Inc. v. FCC*, 294 F.3d 164, 172 (D.C. Cir. 2002) (explaining that D.C. Circuit applies "'competitor standing' doctrine to an

agency action that itself imposes a competitive injury, i.e., that provides benefits to an existing competitor or *expands the number of entrants* in the petitioner's market" (emphasis added)).[1]

There is little question that Plaintiffs in this case have sufficiently alleged that they will be injured by the increased competition for grants created by Defendants' new funding of embryonic stem cell research. Dr. Sherley and Dr. Deisher are both established scientists working in the field of adult stem cell research. Dr. Sherley and his research team are pursuing the study of normal molecular and biochemical processes in adult stem cells that are involved in cancer initiation and contribute to aging. Compl. ¶ 6. Dr. Sherley has applied for NIH funding approximately 41 times, twelve of which have led to funding. He alleges that he currently has a proposal pending, that he will continue to seek funding, and that "[w]ithout NIH funding, [he] would likely be unable to continue [his] research." Sherley Decl. ¶¶ 3, 4.[2] Similarly, Dr. Deisher specializes in adult stem cell therapies and regenerative medicine, and is in the process of applying for NIH grants for research on adult stem cells—indeed, she alleges that her current research "will *require* federal funding." Compl. ¶ 7 (emphasis added).[3] Both Dr. Sherley and Dr. Deisher allege that the Guidelines, which authorize federal funding for embryonic stem cell re-

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[1] *See also, e.g.*, *Adams v. Watson*, 10 F.3d 915, 921 (1st Cir. 1993) (noting that "many cases uphold 'competitor standing' based on 'unadorned allegations' of latent economic injury," and citing and discussing numerous cases).

[2] The fact that Dr. Sherley received funding pursuant to the Director's Pioneer Award Program (before NIH began awarding any grants for embryonic stem cell research), Mot. to Dismiss at 25, has nothing to do with Dr. Sherley's other currently pending and future grants, and the increased competition he faces and will face now that embryonic stem cell researchers are allowed unrestrained access to funding.

[3] Defendants are thus wrong that neither Dr. Sherley nor Dr. Deisher allege they are "at imminent risk of a denial [of funding] resulting from the Guidelines in the near future." Mot. to Dismiss at 22. *See* Compl. ¶¶ 6-7. And in any event, such allegations are not required under D.C. Circuit law. *See Assoc. Gas*, 899 F.2d at 1259.

search, "will result in increased competition for limited federal funding." Compl. ¶¶ 6, 7. The fact that embryonic stem cell researchers "have the clear and immediate *potential to compete* with" Plaintiffs' proposals is sufficient to confer standing on Plaintiffs. *Assoc. Gas*, 899 F.2d at 1259 (emphasis added). Dr. Sherley and Dr. Deisher "need not wait for specific, allegedly illegal transactions to hurt them competitively." *Id*.

Defendants claim that Plaintiffs' allegations of injury are insufficient to establish standing because they "depend on the assumption that an unspecified increase in the number of additional potential grant applicants might, at some unknown point in the future, cause [Plaintiffs] to lose or be denied research funding that either of them would otherwise have received in the absence of the Guidelines." Mot. to Dismiss at 22. But this, as shown above, is an inaccurate statement of the applicable law. The injury that Dr. Sherley and Dr. Deisher face is not the denial of a specific proposal, but increased competition that flows directly from the Guidelines' authorization of funding for embryonic stem cell research. Numerous courts have rejected Defendants' purported requirement that a plaintiff injured by competition point to a specific loss in the future resulting from increased competition. *See, e.g.*, *Assoc. Gas*, 899 F.2d at 1259 (plaintiffs "need not wait for specific, allegedly illegal transactions to hurt them competitively"); *La. Energy & Power*, 141 F.3d at 367 ("[Plaintiff] will be injured by increased price competition from [defendant] regardless whether that pricing turns out to be predatory, as [plaintiff] warns, or simply competitive, as [defendant] promises."); *see also UPS Worldwide Forwarding, Inc. v. U.S. Postal Service*, 66 F.3d 621, 626 (3d Cir. 1995); *Bullfrog Films, Inc. v. Wick*, 847 F.2d 502, 506 (9th Cir. 1988). Plaintiffs' *current* injury—being subjected to increased competition—is sufficient to give them standing.

The authority cited by Defendants is totally inapplicable to parties injured by increased competition. Unlike Dr. Sherley and Dr. Deisher, who both allege they have applied or are applying for NIH funding, Sherley Decl. ¶ 3 (stating that Dr. Sherley has an application pending); Deisher Decl. ¶ 3, the plaintiff in *Donaldson v. United States*, 268 F. Supp. 2d 812, 820 (E.D. Mich. 2003), had not suffered competitive injury because "he ha[d] not shown that he ha[d] submitted an application that [wa]s pending." And in *TEVA Pharm. USA, Inc. v. Sebelius*, 2009 WL 2344910, at *10 (D.D.C. July 31, 2009), this Court held that the plaintiff *had* standing. The statement from the court's opinion that Defendants quote in their brief was addressed to a party's motion to *intervene*, not any standing determination. *Id.* at *14.

Defendants attempt, in a footnote, to respond to the wealth of authority granting parties standing based on competitive injury, Mot. to Dismiss at 22 n.4, but their argument misstates both the applicable precedents and the facts in this case. Defendants claim that competitive standing can exist only if "a researcher's proposal would be approved and then would actually compete for funds directly with another proposal." Mot. to Dismiss at 22 n.4. But as set forth above, D.C. Circuit precedent does not support this assertion.

Defendants also mischaracterize the approval process—Dr. Sherley and Dr. Deisher *are* "already permitted by the government . . . to compete" for NIH funding, and as explained in the very declaration Defendants submitted, there is competition even at the *pre*-approval stage, when NIH narrows down the field of applicants based on the available funding. *See* Rockey Decl. ¶ 11. It is thus simply untrue that Dr. Sherley and Dr. Deisher are injured only after a proposal for embryonic stem cell research has been approved. Now that embryonic stem cell researchers are allowed to compete for funding, Plaintiffs risk being weeded out before Defendants even finalize their consideration of whether to fund Plaintiffs' research. *Id*.

Defendants further argue that Dr. Sherley's and Dr. Deisher's claim of injury is mere "conjecture" because NIH "estimates" that its funding for non-embryonic stem cell research will also increase. Mot. to Dismiss at 25. But Defendants' own characterization of NIH's funding demonstrates that adult stem cell researchers will now face more competition for NIH grants. According to Defendants, grant applications are submitted to an advisory counsel or board of the institute and center ("IC") of NIH, which then decides which applications to approve for funding. *See* Mot. to Dismiss at 23. Each IC has "an independent budget to fund research particular to its subject area" that includes "a payline particular to extramural research funding," *id.*, which is *not* "set according to the expected focus of the individual research projects." Rockey Decl. ¶¶ 15, 16. While there is not a preordained amount of money that is being spent on adult or embryonic stem cell research, competition for finite NIH funding is already extremely tight (only about 20 percent of applicants ever receive NIH funding), and funding of one proposal means that another proposal will necessarily be rejected. Rockey Decl. ¶¶ 8, 11 (indicating that the peer review process is inherently comparative, and that reviewers "generally discuss only the applications in the top half of the scores"); *id.* ¶ 13 ("Only applications that are favorably recommended by both levels of peer review are considered eligible for funding."); *id.* ¶ 14. Thus, adult and embryonic stem cell researchers must, by Defendants' own admission, compete for the same funds, within each IC, during the IC review. *Id.*

It is therefore a matter of "basic economic logic," "firmly rooted in the basic laws of economics," that these new entrants into the funding market will adversely affect Dr. Sherley's and Dr. Deisher's ability to obtain grants for their research. *United Transp. Union v. Interstate Commerce Comm'n*, 891 F.2d 908, 913 n.7 (D.C. Cir. 1989). *See also New World Radio*, 294 F.3d at 172 (agency action that "expands the number of entrants" imposes competitive injury);

La. Energy, 141 F.3d at 367; *Panhandle Producers & Royalty Owners Ass'n v. Economic Regulatory Admin.*, 822 F.2d 1105, 1108 (D.C. Cir. 1987) (holding plaintiff had competitive injury standing based on "undisputed economic principles"). Plaintiffs clearly have alleged a sufficient competitive injury to give them standing.

B. Nightlight And The Nelsons And Flynns Face Injury From An Increasing Scarcity Of Embryos

Both Nightlight Christian Adoptions ("Nightlight") and the adoptive parents (the Nelsons and the Flynns) will suffer direct injury as a result of a decrease in the availability of frozen embryos due to the Guidelines. As Plaintiffs alleged in their Complaint, *see* ¶ 8 ("Nightlight currently has a waiting list of families seeking to adopt embryos, and often these families must wait several months."), *id.* ("[T]he Guidelines, in unlawfully utilizing federal monies to fund human embryonic stem cell research, decrease the number of embryos available for adoption."), *id.* ¶ 10 ("Defendants' promulgation of the Guidelines in violation of federal law jeopardizes the likelihood that embryos will become available in a timely manner for adoption and implantation."), *id.* ¶ 11 ("Defendants' promulgation of the Guidelines jeopardizes the likelihood that human embryos will become available for Mr. and Mrs. Flynn to adopt in the future."), and as set forth in the Plaintiffs' declarations in support of their Motion for a Preliminary Injunction, *e.g.*, Stoddart PI Decl. ¶ 6; Nelson Decl. ¶ 4; Flynn Decl. ¶ 4, the Guidelines facilitate and promote the destruction of human embryos, which will necessarily make embryos more scarce, increase the cost of procuring embryos for adoption, and result in fewer adoptions. Accepting Plaintiffs' "factual allegations as true and draw[ing] all reasonable inferences in the plaintiff's favor," *Allen*, 573 F. Supp. 2d at 38—as this Court must in deciding a motion to dismiss—leads to the inescapable conclusion that Nightlight and the adoptive parents will face concrete injury from an increasing

scarcity of embryos. Likewise, Plaintiffs' evidentiary submissions in support of their motion for a preliminary injunction—which are uncontradicted in the record—establish the requisite injury.

Defendants 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 such as the Nelsons and Flynns to choose from. Instead, Defendants challenge Plaintiffs' factual allegations regarding imminent injury from the shrinking pool of embryos available for adoption, because, they claim, Plaintiffs "assume[] an indirect connection between the Guidelines and adoption that relies entirely on the decisions of . . . the individuals or families who initially decided to create the embryos for reproductive purposes and later agreed to the unused embryos' donation for research purposes." Mot. to Dismiss at 15.

The D.C. Circuit has held on numerous occasions that a plaintiff has standing when there is a "'causal relationship between the government policy and the third-party conduct.'" *Renal Physicians Ass'n v. U.S. Dept. of Health and Human Services*, 489 F.3d 1267, 1275 (D.C. Cir. 2007) (quoting *Nat'l Wrestling Coaches Ass'n v. Dep't of Education*, 366 F.3d 930, 941 (D.C. Cir. 2004)). *See also Tozzi v. United States Department of Health & Human Services*, 271 F.3d 301, 308 (D.C. Cir. 2001); *Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986). There is plainly such a connection here, because the Guidelines lift restrictions that have been in place for several years on the Government's funding of embryonic stem cell research that entails the destruction of human embryos,[4] and the increased funding for such embryonic stem cell research

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[4] Defendants' claim that the Guidelines simply "describe *limitations* on the types of stem cells that may be approved for use in federally-funded research" (Mot. to Dismiss at 16) is misleading. The Guidelines are far more permissive than the previous policy, in that they permit funding of research that uses stem cells derived from newly destroyed human embryos,

[Footnote continued on next page]

will undeniably lead to an increase in the number of embryos required for research purposes, which will leave fewer embryos available for adoption.

Defendants also claim that "IVF health care facilit[ies are] required to explain to the potential donor *all options*, including 'adoption,'" and therefore there is supposedly "no reason to believe that the Guidelines . . . create any additional incentive" for donating embryos for research purposes. Mot. to Dismiss at 17. But Defendants are wrong as a factual matter; IVF facilities are *not* required by the Guidelines to mention adoption, because most IVF facilities do not facilitate adoptions, Stoddart MTD Decl. ¶ 7, and therefore adoptions are not necessarily an "available option" within the meaning of the Guidelines. Mot. to Dismiss at 9. And even if Defendants were correct, the fact that donors are informed that they can give their embryos up for adoption does not amount to proof that the Guidelines will not cause a significant number of embryo donors to choose donation for research over adoption, given NIH's (erroneous) characterization of such research as ethically responsible and scientifically worthy. It strains credulity for Defendants to claim that the Guidelines will have no effect on any embryo donors.

Defendants also argue that because Nightlight's website states it has some embryos on hand, its allegation that it will be injured by the reduced supply of embryos available for adoption cannot support its standing to sue. Mot. to Dismiss at 17. But Defendants miss the point. It is not the case that some "pool of available embryos" can be divided equally among all "avail-

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[Footnote continued from previous page]

> which was strictly forbidden under the previous policy. Thus, the Guidelines (unlike the old policy) create an ongoing financial incentive for the destruction of additional human embryos. To be sure, the Guidelines do contain some limitations, but their clear effect is to open federal funding to new areas of destructive embryonic stem cell research that the Government has never before funded.

able client[s]," *id*.; rather, each embryo is a unique individual with varying characteristics and qualities. And just as with adoptions of already-born children, different families seek different characteristics when considering adoption. Stoddart MTD Decl. ¶ 2. For example, many families wish to adopt multiple embryos from the same donor parents; other families seek embryos from donors with certain physical characteristics. *Id*. Thus, it is not merely a "pool of available embryos" that is relevant. Instead, Nightlight and the adoptive parents have an interest in obtaining the broadest and most diverse supply of embryos possible. *Id.* ¶ 3. And each embryo destroyed in research is one less embryo that Nightlight could match with an adoptive family like the Nelsons or the Flynns. *Id.* ¶ 6.[5]

C. The Embryo Plaintiffs Plainly Face Imminent Risk Of Injury

The Embryo Plaintiffs have pleaded that they face (1) an "injury in fact" that is (2) "fairly . . . trace[able] to the challenged action of the defendant," and (3) "likely . . . redress[able] by a favorable decision." *Lujan*, 504 U.S. at 560–61. *See also Tozzi*, 271 F.3d at 307. Embryos plainly face imminent injury—namely, destruction—as a result of the Guidelines, which authorize and encourage embryo destruction by providing federal funding incentives for research involving such destruction. Indeed, NIH cannot deny this point, given that the Guidelines explicitly regulate the process by which embryos will be destroyed. A ruling prohibiting the unlawful use of federal funds to destroy embryos will redress this injury.

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[5] Defendants' "pool of available embryos" argument is illogical for the further reason that the existing pool is constantly shrinking. It is unclear how long an embryo may remain frozen before it is no longer viable for implantation, but on average, only 50 percent of embryos survive the thawing process. Stoddart MTD Decl. ¶ 8. Moreover, multiple rounds of IVF are often required before an implanted embryo results in a successful pregnancy. *Id.* ¶ 9.

Defendants claim that the Embryo Plaintiffs lack standing because no individual embryo can establish that he or she will be destroyed by federal funding and would otherwise have been preserved or adopted. But this is not required by Article III. Obviously not every embryo will be destroyed, but the law does not require that an embryo be destroyed to have standing to sue, if the challenged regulation raises the risk that he will be injured, which the Guidelines clearly do. *See, e.g.*, *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) ("When a litigant is vested with a procedural right, that litigant has standing if there is *some possibility* that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." (emphasis added)); *Natural Res. Def. Counsel v. EPA*, 464 F.3d 1, 4–5 (D.C. Cir. 2006) ("[W]e have recognized that increases in risk can at times be 'injuries in fact' sufficient to confer standing."); *La. Envtl. Action Network v. EPA*, 172 F.3d 65, 67–68 (D.C. Cir. 1999); *Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1234–35 (D.C. Cir. 1996). It is ridiculous to argue that an embryo does not have standing to challenge an action that threatens its life until that action has actually taken its life.

Defendants also claim that embryos are not "persons" under the law, and therefore cannot state a valid claim under the APA. Mot. to Dismiss at 19; GAL Opp. at 2-3. But they do not cite a single authority for this argument. The out-of-circuit authorities they cite relate instead to "personhood" under Fed. R. Civ. P. 17(c), and Defendants ignore the controlling D.C. Circuit precedent under Rule 17(c), *Hatch v. Riggs Nat'l Bank*, 361 F.2d 559, 566 (D.C. Cir. 1966), which squarely holds that embryos qualify as "persons" and deserve appointment of a guardian

when their interests are at issue.[6] *See also* GAL Reply Br. at 3. The D.C. Circuit in *Hatch* appointed a guardian "to protect the interests of unborn *persons*," *id.* (emphasis added), and repeatedly referred to the unborn as "persons." This is consistent with the laws of numerous States that include the unborn within the meaning of various statutes and legal protections. *See, e.g.*, Ark. Const. Amend. 68, § 2 ("The policy of Arkansas is to protect the life of every unborn child from conception until birth . . . ."); La. Rev. Stat. Ann. § 40:1299.35.0 ("The Legislature does solemnly declare and find in reaffirmation of the longstanding policy of this State, that the unborn child is a human being from the time of conception and is, therefore, a legal person for purposes of the unborn child's right to life . . . .").[7]

The language of the APA, 5 U.S.C. § 551(2), does not preclude embryos from suing under the statute, and "personhood" under the APA is construed broadly in order to effectuate Congress's intent to provide a judicial remedy to any person suffering a legal wrong as a result of agency action. *See City of Sausolito v. O'Neill*, 386 F.3d 1186, 1199–1200 (9th Cir. 2004); *see also FAIC Securities, Inc. v. United States*, 768 F.2d 352, 357 (D.C. Cir. 1985) (Scalia, J.) (review under the APA is "particularly broad in suits to compel federal agency compliance with

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[6] Defendants also cite *McGarvey v. Magee-Womens Hosp.*, 340 F. Supp. 751, 753 (W.D. Pa. 1972), where the court defined personhood under the Civil Rights Act as excluding the unborn, but this Court is required to follow *Hatch*, not a district court in Pennsylvania. *See, e.g.*, *Northwest Forest Resource Council v. Dombeck*, 107 F.3d 897, 900 (D.C. Cir. 1997) ("Simply stated, there was absolutely no basis for the trial court to conclude that it was bound by the decision of the Western District of Washington *on stare decisis* grounds.").

[7] *See also* La. Rev. Stat. Ann. § 9:123 ("An in vitro fertilized human ovum exists as a juridical person until such time as the in vitro fertilized ovum is implanted in the womb; or at any other time when rights attach to an unborn child in accordance with law."); Mo. Ann. Stat. § 1.205.1(1) ("The life of each human being begins at conception"); Utah Code Ann. § 76-7-301.1(1) ("[U]nborn children have inherent and inalienable rights that are entitled to protection by the state of Utah pursuant to the provisions of the Utah Constitution."); 720 Ill. Comp. Stat. Ann. § 510/1; Ky. Rev. Stat. Ann. § 311.710(5).

law, since Congress itself has pared back traditional prudential limitations by the Administrative Procedure Act, which affords review to any person 'adversely affected or aggrieved by [federal] agency action within the meaning of a relevant statute'" (citation omitted)). Embryos will plainly suffer legal wrongs from the Guidelines, and are entitled to sue under the APA.

The Court may also look to state law as an interpretive tool that is useful in determining whether the embryos are "persons" under the APA. *See, e.g.*, *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 728–29 (1979); Fallon, Richard H. et al., HART & WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 723 (5th ed. 2003) ("[I]n interpreting federal statutes or 'filling in' their gaps, [the question is whether] courts should fashion a distinctive federal rule of decision or should instead resort to state law."). *Kimbell Foods* held that in the absence of a "need for a nationally uniform body of law" and when state law would not "frustrate specific objectives of the federal programs" or "disrupt commercial relationships predicated on state law," federal courts should incorporate state law as the rule of decision to fill the gaps in federal statutes. 440 U.S. at 728–29. *See also F.D.I.C. v. McFarland*, 243 F.3d 876, 888 (5th Cir. 2001).

Reliance on the state law definitions of "personhood" is appropriate here. The mere fact that an embryo's ability to sue under the APA could vary from State to State does not amount to a "distinct need" for national standards, *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 98 (1991), especially because States have a legitimate interest in preserving life, *see Gonzales v. Carhart*, 550 U.S. 124, 156–57 (2007). And because the APA is construed very broadly, and is intended to provide broad standing to any person suffering a legal wrong, adopting the state law of "personhood" would not unduly frustrate the objectives of the APA. *City of Sausolito*, 386 F.3d at 1199. Finally, it is also appropriate to look to state law, because the law of domestic relations is a matter of state, not federal, concern. *De Sylva v. Ballentine*, 351 U.S. 570, 580 (1956)

(incorporating state law, because "there is no federal law of domestic relations, which is primarily a matter of state concern"). Numerous States recognize the "personhood" of embryos, *see supra* note 7; Lingo Decl., Exh. B, pp. C-1–C-18, and the Court should interpret the APA to allow the embryos residing in such States to challenge the Guidelines.

D. The Court Should Not Dismiss Nightlight Or The Embryos Under The First-To-File Rule

This Court need not, and should not, dismiss Nightlight and the Embryo Plaintiffs under the "first-to-file" rule. Defendants claim that another lawsuit, brought principally against the President for the issuance of Executive Order 13,505 requires dismissal of this lawsuit challenging Defendants' issuance of the Guidelines. This Court should reject that argument.

The two lawsuits are quite different. The Maryland lawsuit to which Defendants refer (*Doe, et al. v. Obama, et al.*, No. AW-09-cv-0755 (D. Md.)) was a challenge to the President's *Executive Order*, which did not institute funding for embryonic stem cell research, but instead authorized Defendants to consider funding such research. The *Doe* complaint does not challenge the Guidelines—indeed, it was filed before their promulgation—and does not allege violations of the APA. The *Doe* complaint does reference the Dickey-Wicker Amendment, but it alleges that the *Executive Order*, not the Guidelines, violates Dickey-Wicker. Defendants are therefore wrong in asserting that the present case is based "on the same cause of action" or is "the same case." Mot. to Dismiss at 18.

Defendants rely principally on *Wash. Metro. Area Transit Auth. v. Ragonese*, 617 F.2d 828, 830 (D.C. Cir. 1980), but that case is inapposite. The D.C. Circuit dismissed a subsequently filed lawsuit, without prejudice, because resolution of the second lawsuit *depended* on resolution of issues in the first lawsuit. The court explained:

> We agree with Judge Smith that WMATA could not obtain enforcement of its contract until it had been determined when WMATA's contractual rights, if any, would accrue,

> and that proceedings capable of making this determination were already pending before the United States District Court for the Eastern District of Virginia.

Id. at 829. *See also id.* at 830 (prior case "prerequisite" to second case). This is clearly not the situation here. Resolution of the *Doe* lawsuit is in no way a prerequisite to a decision here; the two lawsuits challenge two different government actions and therefore the first-to-file rule has no bearing on the present Plaintiffs' challenge to the Guidelines.

Moreover, Nightlight is in the process of being dismissed as a plaintiff in the lawsuit in Maryland, which therefore will no longer be a "pending lawsuit" for purposes of the first-to-file doctrine. Prior to the filing of Defendants' motion to dismiss, Nightlight had already directed its counsel to dismiss Nightlight from the case, which counsel in the Maryland case has stated he will accomplish. Stoddart MTD Decl. ¶ 10.

E. Plaintiffs' Claims Are Ripe For Review

Defendants' ripeness arguments wholly misunderstand the injury Plaintiffs allege, because none of the Plaintiffs' injuries requires any determination by Defendants regarding *which* embryonic stem cell research to fund. Defendants claim that Plaintiffs seek to "short-circuit" Defendants' system for reviewing proposals and making funding decisions, Mot. to Dismiss at 28, but Defendants are mistaken because Plaintiffs' injury occurs before any individual project is funded. The fact that Defendants have announced they are going to fund embryonic stem cell research and acknowledge they will do so makes the issues in this case ripe for adjudication.

Dr. Sherley's and Dr. Deisher's claims are ripe because their alleged injuries do not arise from denial of a specific research proposal, but from the increased competition created by the Guidelines. *See supra*, pp. 5-10. The cases discussed above hold that a "competitive injury" sufficient to confer standing arises when the Government changes the rules and by doing so harms a plaintiff competitively, not when the specific effect of that increased competition is suffered.

Assoc. Gas, 899 F.2d at 1258 (plaintiffs "need not wait for specific, allegedly illegal transactions to hurt them competitively"). These cases have similarly rejected any argument that issues are not ripe until a specific loss from increased competition occurs. *See, e.g.*, *La. Energy*, 141 F.3d at 368; *Regular Common Carrier Conference v. United States*, 793 F.2d 376, 378–79 (D.C. Cir. 1986).

In *Chamber of Commerce v. Reich*, 57 F.3d 1099 (1995), the D.C. Circuit reversed a district court's decision dismissing a challenge to an Executive Order as unripe. In doing so, the D.C. Circuit rejected the same argument the Government makes here—that adjudication of guidelines for awarding contracts should await the award of an actual contract. *Id.* at 1100–01. The Court held that the plaintiffs' challenge was ripe even though they had not actually been denied a contract, because "the injury alleged . . . is not the sanction that the Secretary might ultimately impose"; rather, "the mere existence of the Order alters the balance of bargaining power between employers and employees." *Id.* at 1100. Dr. Sherley and Dr. Deisher have similarly already suffered the requisite injury by being forced to compete with embryonic stem cell researchers for NIH funding; they need not wait to be injured *further* for their claims to be ripe.

The same holds true for Nightlight and the Nelsons and Flynns. Defendants do not dispute that the Guidelines will lead to almost immediate destruction of embryos, and as Plaintiffs have alleged, this will inevitably shrink the supply of embryos available for adoption. Compl. ¶ 8; Stoddart MTD Decl. ¶ 6. The embryos will be destroyed regardless of *which* research proposal Defendants fund. Indeed, the Guidelines create an immediate incentive to destroy embryos for new cell lines, because the Guidelines do not grandfather in all pre-existing cell lines. This means that many pre-existing cell lines for which embryos have already been destroyed may not receive federal funding and there will be a need to create additional eligible lines. *See* 74 Fed.

Reg. 32,172. In addition, scientists have explained that due to the genetic and epigenetic instability of existing cell lines, new cell lines are necessary to develop embryonic stem cell research. Lingo Decl., Exh. B, p. I-1.

Defendants acknowledge that there will be substantial funding of embryonic stem cell research and that this funding will lead to the destruction of embryos; their only claim is that they have not yet decided *which* proposals to fund. But the resolution of which embryonic stem cell projects Defendants will fund is irrelevant to the injury Plaintiffs allege, and Plaintiffs' injuries are therefore ripe for review.

III. The Guidelines Are Precluded By The Dickey-Wicker Amendment

A. The Dickey-Wicker Amendment Plainly Bars Research That Requires The Destruction Of Embryos

Federal funding may not be used for research that leads to, and indeed depends upon, the destruction of embryos. Pub. L. No. 111-8, § 509(a)(2). By authorizing the funding of "research in which" embryos are destroyed, the Guidelines clearly violate this prohibition. *See* Pub. L. No. 111-8, § 509(a)(2). Defendants do not deny that the stem cell derivation process (a necessary step in stem cell research) destroys the human embryo. They claim, however—relying on an online dictionary—that "research" can mean a "piece of research," Mot. to Dismiss at 31, and thus argue that because they propose to fund only a "piece" of an overall research effort that does not involve the destruction of embryos, they do not violate Dickey-Wicker. As an initial matter, Defendants have never properly expressed or adopted this newly proffered definition of "research." Defendants' counsel's attempt to use their chosen definition of "research" to provide a *post hoc* justification for the Guidelines is unavailing, both because agency counsel cannot validly offer an interpretation not expressed in a properly promulgated agency rule and because their reading of Dickey-Wicker contradicts the natural meaning of the provision. The statutory

phrase "research in which" necessarily encompasses *all* of the research project at issue, not merely a selected "phase" or "piece" of research. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

Defendants' own Human Subject Protection Regulations—which are referenced in the Dickey-Wicker Amendment—define "research" not as a particular task, but as a "systematic investigation" that includes multiple steps. 45 C.F.R. § 46.102(d). Defendants' counsel acknowledge that the word "systematic" refers to "having, showing, or involving a system, method, or plan," Mot. to Dismiss at 32, but ignore the clear import of that definition for this case, contending that a research project does not need to "include within its scope all steps that made the research possible." *Id.* The question is not whether all "steps that made the research possible" are included in the scope of research, but whether the derivation process is part of the researcher's "plan" or "method." By Defendants' own understanding of "systematic," there is no justifiable reason for excluding the derivation process from the overall research program.[8]

Defendants cite no authority that supports their claim. And their attempt to distinguish the authorities that have reached opposite conclusions is unconvincing. Defendants argue that the court decisions and HHS guidance cited in Plaintiffs' opening brief "do not command" Plaintiffs' reading of the statute because the interpretations occurred in "different statutory contexts."

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[8] Defendants' narrow reading of the term "research" to mean "piece of research" also ignores the fact that Dickey-Wicker also prohibits research in which embryos are "discarded." It is not tenable to assert that this prohibition bans funding for only that "piece of research" in which an embryo would be discarded. Yet under Defendants' interpretation of "research," the discarding of an embryo is its own research project. The Amendment's prohibition of federal funding for "research in which an embryo is . . . discarded" plainly prohibits the use of federal funds in a research project in which an embryo would be discarded during or at the conclusion of that project. Defendants' extraordinarily narrow conception of "research" would foreclose that necessary reading of the statute.

Mot. to Dismiss at 33–34 n.9.[9] But Defendants fail to cite *any* "context" in which "research" has been interpreted to exclude integral parts of the research process.

Moreover, Defendants ignore the "context" of the Dickey-Wicker Amendment, which prohibits funding for (1) the *specific act* of creating a human embryo for research purposes, and also (2) any "*research in which*" a human embryo is destroyed or knowingly threatened. Defendants' cramped interpretation of "research" collapses these two distinct prohibitions, by claiming that the only procedure that cannot be funded under Dickey-Wicker is the actual creation or destruction of the embryos. If Congress intended such a result, the Amendment would reflect as much. *See Ali v. Fed. Bureau of Prisons*, 128 S. Ct. 831, 840 (2008) (rejecting petitioner's interpretation of a statute, in part because "[h]ad Congress intended to limit [the statute's] reach as petitioner contends, it easily could have written [it that way]").[10]

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[9] *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) ("There is simply no room in the statute for excluding certain information from the exemption on the basis of *the phase of research* in which it is developed or the particular submission in which it could be included." (emphasis added)); Department of Health and Human Services, *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html (concluding that an institution that receives federal funding is generally engaged in human subject "research" "*even where all activities involving human subjects are carried out by employees or agents of another institution*." (emphasis added)); *Nat'l Ctr. for Mfg. Sciences, Inc. v. City of Ann Arbor*, 563 N.W.2d 65, 68 (Mich. Ct. App. 1997) (agreeing that "research is not limited to a specific experiment" but includes "other critical steps in the research process [such as] the definition of the research agenda, raising the money to perform the necessary experiments, and the monitoring and evaluation of the results").

[10] Defendants also fixate on the word "are" and claim that because the Amendment uses only the present tense, it does not extend to the past destruction of embryos. Mot. to Dismiss at 32–33. But Defendants miss the point: The statute bans the destruction of embryos as part of the research project, which is a continuing process. The destruction of embryos is part of the embryonic stem cell research process, and so it is only logical to speak of the destruction as an event that is concurrent with the "research." Moreover, not even Defendants can really believe their argument, because its implications are absurd. If the Dickey-Wicker Amend-

[Footnote continued on next page]

Defendants also argue that the Supreme Court's use of "preclinical research" in *Merck KGaA* "demonstrates that the word is often used to describe discrete aspects of a research project." Mot. to Dismiss at 33 n.9. Of course, it is possible to isolate one "phase" of a research project by adding a qualifier that refers only to that phase, just as it is possible in any circumstance to isolate and discuss one aspect of a larger whole (for example to talk about "the *first leg* of a cross-country trip," or the "*first-quarter* of a football game"). But Congress did not limit the reach of Dickey-Wicker to only one "phase" or "piece" of a research project; it banned funding for *all* "research in which" embryos are destroyed. Thus, even under their newly proffered definition, Defendants cannot prevail merely by establishing that some "pieces" of the research at issue do not destroy human embryos. Instead, Defendants must establish that *no* "piece" of the research project at issue involves the destruction of human embryos. This they cannot do.

Even assuming that the word "research" could be limited to a specific "piece" of that research, moreover, the Guidelines would still violate Dickey-Wicker. Congress not only prohibited funding for research in which embryos are "destroyed," but also research in which embryos are "knowingly subjected to risk of injury or death." Pub. L. No. 111-8, § 509(a)(2). Thus, while NIH is forbidden to fund the derivation of stem cells from human embryos, it is also for-

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ment prohibited only the funding of present or future destruction of human embryos, as Defendants now argue, then NIH could fund even the *already-completed* act of destroying human embryos that was necessary to produce the human embryonic stem cell lines for which researchers are now seeking NIH approval. Not even Defendants take that position, instead conceding that they cannot fund such destruction (even though it has by definition already occurred with respect to any NIH-approved stem cell lines). 74 Fed. Reg. 32,175 ("NIH funding of derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research."). Thus, Defendants' argument based on verb tense must be rejected as inconsistent with NIH's own interpretation of the statute.

bidden to fund research that it knows will entail or risk the destruction of human embryos by anyone. Defendants do not deny that the federally funded research will create the need for additional, newly derived cells, and thus concede that by funding embryonic stem cell research, they (and the researchers they fund) are knowingly subjecting additional embryos to risk of death.

In order to give any meaning to the phrase "knowingly subjected to risk of injury or death," Defendants must be prohibited from funding research that they know will place additional human embryos at substantial risk of destruction. Any other construction of the statute ignores the obvious: The derivation process necessarily destroys an embryo. The language of Dickey-Wicker bans federal funding from being used for that purpose, but it also does something more: It bans funds from being used for "research in which an embryo is . . . knowingly subjected to risk of injury or death." It is incontrovertible that Defendants are knowingly placing human embryos at substantial risk of destruction by funding embryonic stem cell research.[11]

B. Defendants' Reliance On Legislative History Is Misplaced

Faced with the reality that the Guidelines violate the plain terms of Dickey-Wicker, Defendants cite bits of legislative history in an attempt to support their untenable position. But their failure to cite the competing statements only highlights how little help such legislative history statements are to the interpretation of the statute. For example, the Amendment's author, Congressman Jay Dickey, has explained that federal funding of embryonic stem cell experiments that incentivizes the destruction of human embryos "undermines the spirit and letter of the law."

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[11] A contrary interpretation would be "at odds with one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 129 S. Ct. 1558, 1567 (2009) (internal quotation and alteration omitted).

Special Hearing on Stem Cell Research: Hearing Before the Subcommittee on Labor, Health, and Education of the S. Comm. on Appropriations, 106 Cong. 9-10 (Nov. 4, 1999). Numerous other legislators have similarly expressed their view that the Dickey-Wicker Amendment precludes Defendants' funding for embryonic stem cell research.[12]

Defendants cite competing authorities, and there are obviously legislators in Congress who have different views. But there is only one Congress, and Congress speaks through the words of the statute—not floor statements or committee reports. As the Supreme Court and D.C. Circuit have repeatedly held, "legislative history is irrelevant to the interpretation of an unambiguous statute." *United States ex rel. Totten v. Bombardier Corp*. 380 F.3d 488, 494 (D.C. Cir. 2004) (Roberts, J.) (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 808-09 n.3 (1989)). *See also Dep't of Housing and Urban Dev. v. Rucker*, 535 U.S. 125, 132 (2002) ("[R]eference to legislative history is inappropriate when the text of the statute is unambiguous.").

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[12] *See, e.g.*, Statement of Representative Schaffer, 145 Cong. Rec. E1696-02, 1696-97 (July 30, 1999) ("The Dickey/Wicker amendment prohibits the use of federal funds for the creation of a human embryo for research purposes or for research in which an embryo is 'destroyed, discarded or knowingly subjected to risk of injury or death.' While HHS has tried to rewrite the current law on embryo research, it is clear that Congress has prohibited all funding of 'research in which' embryos are destroyed or discarded. Simply stated, the taxpayer funding of research which relies on the intentional killing of human beings would violate the law."); Statement of Senator Brownback, 147 Cong. Rec. S6393-01, 6394 (July 19, 2004) ("As my colleagues are well aware, Congress outlawed federal funding for harmful embryo research in 1996 and has maintained that prohibition ever since. The ban is broad-based and specific; funds cannot be used for 'research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death.' The intent of Congress is clear—if a research project requires the destruction of human embryos no federal funds should be used for that project."); *id.* (placing in the record a letter from twenty Senators to NIH urging it to withdraw the "Clinton-era guidelines which call for the destruction of human embryos for the purpose of subsequent Federal funding for the cells that have been derived from the process of embryo destruction" because they were "contrary to the law and Congressional intent," and stating that "[c]learly, the destruction of human embryos is an integral part of the contemplated research, in violation of the law.").

Dickey-Wicker's terms are clear: NIH cannot fund research that results in the destruction of human embryos. The Guidelines plainly violate that prohibition by authorizing the funding of embryonic stem cell research that incentivizes, and causes, the destruction of human embryos. Defendants' attempt to avoid the clear import of the statute based on the statements of a few individual legislators and reports is unconvincing. "If Congress wished to achieve that result, it needed to enact different statutory language. It c[an]not achieve that result, in the face of the statutory language it enacted, simply by inserting a passage in a committee report." *Penn. Protection & Advocacy, Inc. v. Houston*, 228 F.3d 423, 427-28 (3d Cir. 2000) (Alito, J.).

Even if this Court were to consider committee reports as probative evidence of *Congress's* intent, Defendants' reliance on the House committee reports is misplaced. The committee reports cited by Defendants state only that the Dickey-Wicker Amendment should "not be construed to limit federal support for research involving human embryonic stem cells and carried out in accordance with policy outlined by the President." *See, e.g.*, H.R. Rep. No. 107-229 at 180 (Oct. 9, 2001). This statement has been included in several reports since 2001, but until now, the President's policy has been to *prohibit* stem cell research that incentivizes the destruction of embryos. Thus, this legislative history provides *no* support for the validity of the Guidelines. Defendants also point to a committee report relating to the *unenacted* 2010 appropriation bill (H.R. Rep. No. 111-220 (July 22, 2009)), but obviously that report (which repeats the same language from past reports to endorse the previous policy) is entitled to no weight.

Moreover, far more probative than the snippets of legislative history cited by Defendants is the factual setting that led to the enactment of the Dickey-Wicker Amendment in the first place. As explained in Plaintiffs' Motion for Preliminary Injunction (at 9), by refusing to fund

research that destroys embryos, Congress was not trying to save taxpayer money. Rather, Congress was concerned about the moral implications of such research.

In 1994, the Human Embryo Research Panel convened by then-NIH-Director Harold Varmus recommended that NIH fund research using "surplus" human embryos, and that recommendation was adopted by Director Varmus. *See* Christine L. Feiler, *Note: Human Embryo Experimentation: Regulation and Relative Rights*, 66 Fordham L. Rev. 2435, 2459–61 (1998) (discussing circumstances under which Congress passed Dickey-Wicker). Before any grants were made under NIH's new standards, however, Congress enacted the Dickey-Wicker Amendment to override Director Varmus's decision and prevent federal funding of research that entails the destruction of or injury to human embryos. *See* Balanced Budget Downpayment Act, Pub. L. No. 104-99, 110 Stat. 26, 34, Title I, § 128 (Jan. 26, 1996).

Defendants' reading of Dickey-Wicker ignores the reality that the amendment was enacted to prevent the same type of research at issue here, namely, research that entails (or threatens) the destruction of human embryos. Defendants' interpretation would make Congress's act a nullity.

C. Defendants Are Not Entitled To *Chevron* Deference

Defendants argue that this Court must defer to the agencies' interpretation of "research" contained in the Dickey-Wicker Amendment. Mot. to Dismiss at 30–31. But to receive deference, there must first be a reasoned interpretation by the agency, and neither NIH nor HHS has ever proffered an interpretation of "research" that this Court could analyze for reasonableness under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Chevron deference is not implicated unless (1) the agency has in fact interpreted the statutory term or provision in question, *Pub. Citizen, Inc. v. United States Dep't of Health and Human Services*, 332 F.3d 654, 661 (D.C. Cir. 2003), and (2) the "the agency interpretation

claiming deference was promulgated" in a rule "carrying the force of law," *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Here, Defendants have offered no agency interpretation of the statutory term "research," the critical term at issue in this litigation. Their counsel's appeal to *Chevron* is therefore inapplicable, even aside from the fact that the plain statutory text precludes Defendants' position.

Instead of setting forth the agencies' interpretation of "research," Defendants contend in the Guidelines that their funding of embryonic stem cell research does not violate Dickey-Wicker because "hESCs are not embryos as defined by Section 509."[13] 74 Fed. Reg. 32,173. But the relevant question is not whether embryonic stem cells are embryos, but rather whether the derivation of those cells occurs within the scope of "research" that receives funding. Because the agencies have never answered that question in a rule carrying the force of law,[14] this Court has no basis on which to apply *Chevron* deference to Defendants' *ipse dixit* conclusion that the Guidelines are consistent with Dickey-Wicker. *See, e.g.*, *Pub. Citizen*, 332 F.3d at 661 (holding

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[13] This interpretation is based on the memorandum of former HHS General Counsel Harriet Rabb. *See* Mot. for PI at 12; Lingo Decl., Exh. D. Like the Guidelines, the Rabb Memorandum does not examine whether this theory is consistent with Dickey-Wicker's prohibition on "research in which embryos are destroyed" but instead focuses only on whether an embryonic stem cell is an embryo. *Id.*

[14] As explained in Plaintiffs' opening brief, Mot. for PI at 13, a 2002 HHS internal memorandum analyzed the meaning of "research in which" when evaluating the legality of President Bush's policy to fund embryonic stem cell research on existing lines in which the life and death decision had already been made. *See* Lingo Decl., Exh. B, pp. F-1–F-8. The memorandum concluded that President Bush's policy did not violate Dickey-Wicker based on its conclusion that the policy "provide[d] no incentives for the destruction of additional embryos." *Id.* p. F-5. NIH seems to contend that this memorandum is consistent with its current position. But that is clearly not the case. The current Guidelines are not limited to existing lines, and therefore *do* authorize funding that will incentivize the further destruction of embryos. Under the view now being advocated by the government, it is totally *irrelevant* whether federal funding provides "incentives for the destruction of additional embryos," yet that was a key element of the 2002 memorandum's reasoning.

that *Chevron* was "inapplicable"—even though the agency's guidance "does contain a reference" to the statute at issue—because "there is no place in the manual where the agency explains *why* it believes that [its conclusion] satisfies the statut[e]" (emphasis in original)).

Only now, in this litigation, do Defendants (or rather, their counsel) attempt to articulate why they believe that embryonic stem cell research that depends on the *further* destruction of human embryos is consistent with Dickey-Wicker's prohibition on the funding of "research in which" human embryos are destroyed. But this belated attempt to interpret "research" in a legal brief is entitled to no deference under *Chevron* because that interpretation was not promulgated in a rule "carrying the force of law." *Mead*, 533 U.S. at 226-27; *see also Bowen*, 488 U.S. at 212 ("[W]e have declined to give deference to an agency counsel's interpretation of a statute where the agency itself has articulated no position on the question, on the ground that Congress has delegated to the administrative official and not to appellate counsel the responsibility for elaborating and enforcing statutory commands." (internal quotation omitted)); *City of Kansas City v. Dept. of HUD*, 923 F.2d 188, 192 (D.C. Cir. 1991) (refusing to award *Chevron* deference to a "*post hoc* rationale developed as part of a litigation strategy"). If Defendants seek *Chevron* deference, they must go through the proper procedures.

Even if the *post hoc* explanations proffered by Defendants in this litigation were entitled to *Chevron* deference, moreover, no such deference would be due to the interpretation here, which involved no exercise of Defendants' expertise. As "*Mead* and *Chevron* explain . . . a key rationale behind affording deference to agencies is that their interpretations are properly informed by their experience and their expertise." *Crowley v. Fed. Bureau of Prisons*, 312 F. Supp. 2d 453, 459 (S.D.N.Y. 2004). An agency cannot "rest simply on its parsing of the statutory language—it must bring its experience and expertise to bear in light of competing interests

at stake." *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (internal quotation and alteration omitted).

Even now, in their briefing to this Court, Defendants' counsel do not attempt to explain their position by drawing on Defendants' expertise. Rather, they simply parse the words of the statute and rely on a definition selected from dictionary.com to support counsel's view that "research" can mean "a piece of research." Putting aside the tautological nature of that definition—under which "research" means "research"—an agency does not gain the benefit of *Chevron* simply by scouring the pages of a dictionary (or, in this case, the Internet) and finding the layman's definition that it believes best expresses its "view" of a statutory term. *Alarm Indus. Commc'n Comm. v. F.C.C.*, 131 F.3d 1066, 1069 (D.C. Cir. 1997) (holding that an agency is afforded no deference when it attempts to give "its meaning to the provision on the basis of a dictionary"). Anyone can consult a dictionary; an agency, if it wants *Chevron* deference for its interpretation, must draw on its developed expertise. Because Defendants have not done so here, the Guidelines "reflect[] no consideration of other possible interpretations, no assessment of statutory objectives, no weighing of congressional policy, [and] no application of expertise." Defendants are therefore not entitled to deference (*Chevron*, *Skidmore*, or otherwise).[15] *Id.*

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[15] In *Mead*, the Court noted that even where an agency's interpretation is not entitled to *Chevron* deference, that interpretation may still be entitled to some "respect proportional to its 'power to persuade'" where the agency "bring[s] the benefit of specialized experience to bear on the subtle questions in th[e] case." 533 U.S. at 235 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). However, because NIH has not brought its "specialized experience to bear," its interpretation is not entitled to any more respect than the interpretation of any other litigant that comes before this Court.

IV. Defendants Violated The Administrative Procedure Act

Defendants do not dispute that, in responding to the public comments and promulgating the Guidelines, NIH was required to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation omitted). Neither do Defendants dispute that, in reviewing their decision, the Court must determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* at 43. Their primary response, however, is a remarkably broad and sweeping assertion of the Executive's purported power to nullify an act of Congress. According to Defendants, they were not required to comply with the APA's requirement that they offer a reasoned basis for their decision to fund embryonic stem cell research because, they claim, the President instructed them to do so.

This is wrong for two independently sufficient reasons. *First*, Defendants mischaracterize the President's Executive Order, which stated that the agency "*may*" fund embryonic stem cell research that is "responsible" and "scientifically worthy." *Second*, Defendants' argument is baseless in any event, because the President cannot insulate agency action from the requirements of the APA.

Defendants' weak response to Plaintiffs' APA challenge serves only to underscore the woefully inadequate job they did in responding to the comments they received, which, as set forth in Plaintiffs' Preliminary Injunction Motion, demonstrated that embryonic stem cell research is medically and scientifically unworthy and ethically irresponsible in light of developments and prospects for further advances in adult and induced pluripotent stem cell research. Defendants do not even attempt to show that they properly responded to the numerous public

comments questioning the scientific and ethical basis for Defendants' decision. Moreover, Defendants still do not adequately justify their rejection of various proposals that would have strengthened the efficacy of the Guidelines.

Thus, Defendants have failed to "articulate a satisfactory explanation" for funding embryonic stem cell research or for the way in which they chose to regulate such funding. Accordingly, Defendants' actions were arbitrary and capricious and not in accordance with the procedures mandated by law, and the Court should set aside the Guidelines.

A. The President Did Not Direct NIH To Fund Embryonic Stem Cell Research

The thousands of comments submitted to NIH urging it not to fund scientifically unworthy and ethically irresponsible embryonic stem cell research were clearly relevant to Defendants' decision to publish guidelines for federal funding of such research. Yet, Defendants concede that they refused to consider (much less explain away) the scientific and ethical concerns raised in the notice and comment procedure, allegedly because the President "directed" them to proceed in this manner and they "would have acted inconsistently with the Order if [they] had refused to issue the Guidelines" to fund embryonic stem cell research. Mot. to Dismiss at 43–44.

Defendants misconstrue the President's Order, because it contained *no* such directive. Although the President may have "removed the restrictions on federal funding that had been imposed by prior presidential action," Mot. to Dismiss at 43, he did *not* direct NIH to fund embryonic stem cell research or to ignore all public comments describing the scientific and ethical concerns of such research. Indeed, such actions would have conflicted directly with the President's stated purpose of removing this issue from the "political" process, thereby allowing NIH to so-

licit comments and bring "its experience and expertise to bear in light of competing interests at stake." *Peter Pan Bus Lines*, 471 F.3d at 1354.[16]

For that reason, the Order directed NIH to review all "existing NIH guidance and other widely recognized guidelines on human stem cell research" and "issue new guidance on" "human stem cell research." There was no specific requirement to fund human *embryonic* stem cell research. Exec. Order No. 13,505, 74 Fed. Reg. 10,667. Indeed, the Executive Order provides only that NIH "may" support "responsible, scientifically worthy" stem cell research. Not surprisingly, the Executive Order did not purport to remove NIH's discretion to consider *whether* human embryonic stem cell research qualifies as ethically responsible or scientifically worthy—precisely the issues that the comments addressed and that NIH ignored. Moreover, the President stated that NIH could fund embryonic stem cell research "*to the extent permitted by law*." *Id.* (emphasis added). Thus, not only is the Order permissive as to whether NIH must fund embryonic stem cell research at all, it also requires that NIH follow all applicable law—which includes the APA—when issuing its guidance. *See Nat. Res. Def. Council, Inc. v. E.P.A.*, 683 F.2d 752 (3rd Cir. 1982) ("[Executive Order] 12291 says nothing about the notice and comment requirements of the APA, and does not attempt to authorize an agency to act without complying with

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[16] Indeed, Dr. Francis Collins, the current director of NIH and a defendant in this case, does not appear to share his attorneys' view that the President's Order contained such a directive. *See* Press Release, National Institutes of Health, *NIH Opens Website for Human Embryonic Stem Cell Lines for Approval and Announces Members of Working Group* (Sept. 21, 2009), *available at* http://www.nih.gov/news/health/sep2009/od-21.htm ("I appreciate the willingness of [the members of the stem cell working group] to assist NIH in supporting responsible, scientifically worthy human stem cell research, as *encouraged* by the President's Executive Order." (emphasis added)).

those requirements. Rather, E.O. 12291 specifically states that any action taken pursuant to it must be in compliance with applicable law.").

Defendants suggest that it is "entirely unsurprising" that NIH did not "make categorical announcements as to the merits of hESC research," because these decisions supposedly take place during the "ordinary operation of NIH's peer review system." Mot. to Dismiss at 44. But this argument is belied by the Guidelines, which do not postpone until the peer-review process the decision of whether to fund embryonic stem cell research as a category, but rather expressly authorize funding for such research. 74 Fed. Reg. 32,170 (Guidelines "establish policy and procedures under which the NIH *will* fund such research" (emphasis added)); *id.* at 32,171 ("The Guidelines allow for funding of research using hESCs derived from embryos . . . ."); *id.* at 32,172 (Guidelines "establish[] a set of conditions that will maximize ethical oversight, while *ensuring that the greatest number of ethically derived hESCs are eligible for Federal funding*." (emphasis added)). Defendants also contend in their Motion to Dismiss that the decision to fund embryonic stem cell research had already been made. Mot. to Dismiss at 43-44. In addition, many of the comments NIH received during the public process asserted that embryonic stem cell research is *never* scientifically worthy or ethically responsible. By determining, in the Guidelines, that such research is at least *sometimes* scientifically worthy and ethically responsible, Defendants rejected these comments. Failing to articulate a reasoned basis for rejecting the comments was arbitrary and capricious.

Because Defendants have not proffered any valid reason for failing to "respond[] to significant points raised by the public," *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir. 1977), they have violated the procedural requirements of the APA, *see* 5 U.S.C. § 553, and the Guidelines must be set aside. *See Am. Mining Congress v. EPA*, 907 F.2d 1179, 1190–91 (D.C.

Cir. 1990) ("[T]he agency's failure to respond to . . . specific challenges in the record is fatal here, since 'the points raised in the comments were sufficiently central that agency silence . . . demonstrate[s] the rulemaking to be arbitrary and capricious.'").

B. Even If Defendants Had Been Ordered By The President To Fund Embryonic Stem Cell Research, That Would Not Exempt The Guidelines From Review Under The APA

Even if the President *had* directed NIH to fund embryonic stem cell research without responding to comments from the public, NIH would not be insulated from review under the APA. Any authority the Executive Branch (including the President) has to fund embryonic stem cell research originated in Congress, which limited the authority it delegated by enacting the APA. *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) ("The legislative power of the United States is vested in the Congress, and the exercise of quasi-legislative authority by governmental departments and agencies must be rooted in a grant of such power by the Congress and subject to limitations which that body imposes.").[17] And nothing in the APA authorizes the President to direct an agency to violate the APA by ignoring relevant public comments during the rulemaking process, or in any way exempts an agency's actions from APA review simply because the policy was dictated by the President. Indeed, if the President could simply dictate the details of every agency rule that is subject to notice and comment procedures, "the opportunity to comment [would be] meaningless." *Home Box Office*, 567 F.2d at 35.

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[17] Although the APA exempts some agency action from the notice and comment procedures, *see* 5 U.S.C. § 553(a), NIH does not claim protection under any of the enumerated exemptions. In any event, NIH submitted its proposed guidelines to notice and comment, and, in arguing that it should receive *Chevron* deference in interpreting Dickey-Wicker, is claiming the protections of the APA's rulemaking procedures. *See* Mot. to Dismiss at 30.

The cases cited by Defendants do not support the startling contention that the President by issuing an Executive Order can exempt a federal agency from the notice-and-comment procedures Congress mandated in the APA. Mot. to Dismiss at 44. Indeed, those cases support the opposite proposition. For example, in *Building & Construction Trades Department, AFL-CIO v. Albaugh*, 295 F.3d 28, 33 (D.C. Cir. 2002), the court held that "if an executive agency . . . *may lawfully implement* the Executive Order, then it must do so." (emphasis added). If notice-and-comment rulemaking is required, then an agency cannot "lawfully implement" a President's order without *fully* engaging in the process. In other words, the agency cannot ignore evidence in the administrative record because it would be inconsistent with the purported directive. Although Congress has delegated some of its lawmaking power to the Executive Branch, *see Sierra Club v. Costle*, 657 F.2d 298, 406 n.524 (D.C. Cir. 1981), Congress limits that authority through the APA. The President cannot override this process, and the agency cannot "lawfully implement" an executive order without considering all relevant information that is submitted in the notice-and-comment process.

Thus, even if the President had ordered the agency to fund embryonic stem cell research (which he did not), Defendants failed to lawfully implement this directive by violating the requirements of notice-and-comment rulemaking under the APA.

C. Defendants Violated the APA By Failing To Articulate Any Reason Why Embryonic Stem Cell Research Is "Scientifically Worthy" And "Ethically Responsible"

Defendants do not even claim that they offered a reasoned decision for funding embryonic stem cell research. (Their only argument in this regard is that they were not required to explain this decision, but as set forth above, that is demonstrably incorrect.) The Guidelines purport to fund only research that is "ethically responsible, scientifically worthy, and conducted in accordance with applicable law," 74 Fed. Reg. at 32,170, but as Plaintiffs demonstrated in their

Motion for a Preliminary Injunction, Defendants failed to meet their own stated criteria. Although adult stem cell research delivers far greater scientific and medical benefits with fewer disadvantages, is ethically responsible, and comports with the law (Lingo Decl., Exh. B, pp. 1–19, B-1–B-5, C-1–C-18, E-1–E-9, G-1–G-8, H-1–H-7, I-1–I-11, J-1–J-8), Defendants have failed even to consider these points, let alone offer a reasonable explanation why embryonic stem cell research is worthy of funding under their stated criteria. *See, e.g.*, *United States Telecomm. Ass'n v. FCC*, 227 F.3d 450, 461 (D.C. Cir. 2000) ("Fundamental principles of administrative law require that . . . the agency must examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." (internal quotation marks omitted)); *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 817 (D.C. Cir. 1983) (stating that the APA "demands an adequate explanation when [such an alternative is] rejected").

Embryonic stem cell research is fraught with problems, and has shown no sign of leading to any concrete scientific advances. (Lingo Decl., Exh. B pp. I-1–I-3.) But Defendants did not acknowledge any of these problems or explain why the problems did not concern them. This omission invalidates the Guidelines. *See Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992) (citing *State Farm*, 463 U.S. at 43).

Defendants now, through their counsel in this Court, attempt to explain the "promise of human embryonic stem cell research," but this *post-hoc* rationale for their action does not fulfill the Agency's obligations under the APA. *City of Kansas City*, 923 F.2d at 192 ("'Arbitrary and capricious' review . . . demands evidence of reasoned decisionmaking *at the agency level*; agency rationales developed for the first time during litigation do not serve as adequate substitutes." (emphasis in original)); *see also Citizens to Preserve Overton Park v. Volpe*, 401

U.S. 402, 419 (1971) ("'*post hoc*' rationalizations . . . have traditionally been found to be an inadequate basis for review").

And, in any event, Defendants grossly exaggerate the supposed "promise" of embryonic stem cell research. For instance, Defendants dismiss the risks of embryonic stem cell research by claiming that such risks include only *benign* tumors, Mot. to Dismiss at 3, but this is untrue and ignores the fact that these teratomas are fatal in vital organs. *See, e.g.*, Lingo Decl., Exh B, p. I-2; *Cysts At Spinal Cord Treatment Sites Led To FDA Hold On Geron's Stem Cell Trial Thursday*, August 27, 2009, *available at* http://www.stemcellresearchnews.com/absolutenm/anmviewer.asp?a=1781&z=9 (stating embryonic stem cell teratomas are not always benign); Lars M. Bjorklund, et al., *Embryonic stem cells develop into functional dopaminergic neurons after transplantation in a Parkinson rat model*, 99 PNAS 4 at 2344–49 (Jan. 8, 2002), *available at* http://www.pnas.org/cgi/content/abstract/99/4/2344 (study stating that 20% of the mice involved in the study died from teratoma formation). As another example, Defendants claim that adult stem cells have been "available for research for decades," but have not yet been expanded "beyond the hematopoeietic system." Mot. to Dismiss at 5. This is another falsity—adult stem cells beyond the hematopoeietic system became the subject of research in the late 1990s and have been demonstrated to give rise to multiple cell types beyond the hematopoeietic system. *See* Nilanjana Sengupta, et al., *Regulation of Adult Hematopoietic Stem Cells Fate for Enhanced Tissue-specific Repair*, 17(9) Molecular Therapy at 1594–1604 (July 7, 2009); *see also* Lingo Decl., Exh. B, p. G-3 n.20.

Defendants continue to perpetuate the myth that embryonic stem cells can be used to treat certain diseases, but such assertions are misleading. Each of the therapies Defendants describe, Mot. to Dismiss at 4, can be accomplished utilizing either adult stem cells or induced pluripotent

cells. Defendants' attempt to laud human embryonic stem cell research for Parkinson's disease disregards the administrative record, which establishes that Parkinson's is unlikely to benefit from stem cell therapy until the underlying pathology is more clearly understood and controlled. Lingo Decl., Exh. B, p. 12. And Defendants' reliance on research involving theoretical treatment for stroke victims, Mot. to Dismiss at 4, is unhelpful; the FDA has put a hold on the trial that Defendants cite, because the rats involved in the study developed what are likely teratomas. *Cysts At Spinal Cord Treatment Sites Led To FDA Hold On Geron's Stem Cell Trial Thursday*, August 27, 2009, *available at* http://www.stemcellresearchnews.com/absolutenm/anmviewer.asp?a=1781&z=9. It is therefore simply untrue that embryonic stem cell research promises safe and effective human therapies, and Defendants' implications to the contrary are misleading and baseless.

More fundamentally, however, Defendants' erroneous assertions miss the point, because their belated attempt to articulate a reasoned basis for the decision to fund embryonic stem cell research comes too late and in the wrong forum. In promulgating the Guidelines, Defendants were required to provide a reasoned response in the administrative record to the numerous comments they received from the public. *City of Kansas City*, 923 F.2d at 192; *Volpe*, 401 U.S. at 419. By Defendants' own admission, Mot. to Dismiss at 42-44, they failed to do so, and Defendants nowhere articulated any rational justification for their decision to fund embryonic stem cell research despite the overwhelming evidence that such research is scientifically dubious and morally problematic. And Defendants' attempt to supply now a justification for their decision is inappropriate, both because their bare disagreement with Plaintiffs' factual allegations is inappropriate in a motion to dismiss and because Defendants were required to articulate their reasoning in response to the comments, not in legal briefs.

D. Defendants' Responses To The Obvious Loopholes In The Guidelines Are Unpersuasive

In addition to comments raising concerns about *whether* to fund embryonic stem cell research, Defendants received numerous public comments on the draft guidelines regarding *how* Defendants could fund the research in a way that was less ethically irresponsible. Here again, Defendants failed to articulate a reasoned basis for rejecting the criticisms they received, and in doing so violated the APA.

The Guidelines' conflict-of-interest provisions leave loopholes that eviscerate their effectiveness in effectuating a "clear separation" between creating embryos for reproductive purposes, and utilizing them for research. Mot. for PI at 28-29. Defendants have yet to explain why it is ethically responsible to allow IVF physicians both to guide the decision of how many embryos to create and then also to utilize and destroy those same embryos to derive embryonic stem cells for research that the same physicians may conduct with federal funds. *Id*. That the donors' decision was "free from influence from any researchers" is no response to Plaintiffs' argument that the conflict lies in the fact that the person who encourages the creation of the embryos can also benefit from any "extra" embryos by also being the person who derives the stem cells and conducts the federally funded research. Defendants have failed to articulate a reason for their rejection of these important public comments, and in doing so violated the APA. *Am. Mining Congress*, 907 F.2d at 1190; *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006).

Defendants also ignored comments stressing that consent cannot be informed unless donors are notified that their embryo is a living, human being, and that many States have laws prohibiting the destruction of these human beings. Lingo Decl., Exh. B, pp. C-1–C-18. Defendants' response to this argument is that the Guidelines require IVF clinics to inform donors of the availability of embryo adoption, because each clinic must explain the alternatives available at that

particular facility. Mot. to Dismiss at 47. But this ignores the fact that most IVF facilities do not facilitate or handle adoptions. Instead, a third party (like Nightlight) often makes the adoptions possible. Stoddart MTD Decl. ¶ 7. Defendants' argument is therefore misleading—IVF clinics are seldom obligated to mention adoption because the clinic itself will in most cases not provide adoption services. In order to have donors' truly informed consent, Defendants should require IVF facilities to inform donors that research destroys a living, human life, and that adoption is an alternative to having the embryo destroyed for research purposes.

E. The Public Comment Period Was Too Short

The issues facing Defendants in promulgating the Guidelines were undeniably complex, as evidenced by the 49,000 comments NIH received in response to its draft guidelines. Yet, Defendants allowed a mere 34 days for comment, and issued the final Guidelines 41 days thereafter. The truncated period was insufficient either to give the public sufficient time to comment fully on the draft guidelines, or to allow NIH to analyze and incorporate changes based on the comments it received. *See Fla. Power & Light Co. v. United States*, 846 F.2d 765, 771 (D.C. Cir. 1988) (noting that agency notice must give "adequate time for comments," and that interested parties should be able "to comment meaningfully"); *In re Estate of Smith v. Bowen*, 656 F. Supp. 1093, 1097–99 (D. Colo. 1987) (holding that a 60-day period was inadequate).

Defendants respond to this argument by citing a few cases that have upheld shorter comment periods, but in almost every case, the short deadline was required by either the urgency of the situation or the timeline set by Congress. *See Omnipoint Corp. v. FCC*, 78 F.3d 620, 629 (D.C. Cir. 1996) (seven-day comment period justified due to "the 'urgent necessity for rapid administrative action under the circumstances'" (quoting *Northwest Airlines v. Goldschmidt*, 645 F.2d 1309, 1321 (D.C. Cir. 1981))); *Florida Power & Light Co.*, 846 F.2d at 772 (15-day period sufficient because "Congress gave [the agency] only ninety days to report and forty-five more

days to enact a final rule. Given Congress' deadline, the Commission maintains that the fifteen days for comment were reasonable."). Defendants have not sought to justify the short comment period in this case based on any similar necessity, and there was none.

Determining whether embryonic stem cell research is "ethically responsible" and scientifically worthy," and if so how, was a difficult task (or would have been if Defendants attempted to perform it). Rather than taking sufficient time to analyze the issues and come to a reasoned judgment, Defendants rushed through the process, and in doing so violated the APA.

F. Defendants Had An Unalterably Closed Mind

By arguing at length that they were directed by the President to fund embryonic stem cell research, Defendants foreclose the argument that Acting Director Kington entered the notice-and-comment period with anything other than "an unalterably closed mind on matters critical to the disposition of the proceeding." *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979). Mot. to Dismiss at 50.

Defendants argue that an "agency official may express policy views without being disqualified from rulemaking," Mot. to Dismiss at 51, but that is not the issue in this case. Director Kington did much more than simply express a view with respect to embryonic stem cell research; he expressly prejudged the outcome of *these specific Guidelines*. He reported to the press that in the Guidelines, NIH "*will* expand greatly the number of cell lines eligible for funding." Guatam Naik, *NIH Offers Rules for Embryonic Stem Cell Research*, Wall St. J., Apr. 17, 2009, *available at* http://online.wsj.com/article/SB123999343505429693.html (emphasis added). And he telegraphed the predetermined outcome by encouraging the submission of applications for embryonic stem cell research even before the issuance of the draft guidelines. *See* Implementation of Executive Order on Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, NOT-OD-09-085 (Apr. 17, 2009), *available at*

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html. ("NIH will accept applications for research proposing to use human embryonic stem cells during the period of Guidelines development . . . .").

For this reason, Defendants' reliance on *C&W Fish Co., Inc. v. Fox*, 931 F.2d 1556 (D.C. Cir. 1991), does not support their argument, because there the court focused only on the agency official's alleged prejudgment of the *issue*, not prejudgment with respect to an actual proposed rule. *Id.* at 1565. Indeed, the D.C. Circuit explained that although "a failure to weigh the issues fairly" does not establish an "unalterably closed mind," the "focus" should be "on the agency member's prejudgment." *Id. C&W Fish Co.* did not hold that an agency official may prejudge the substance of an actual regulation on which his agency is allowing public notice and comment.

After the Guidelines were issued, moreover, Kington admitted that he and the agency had *totally ignored* all the public comments that raised questions about whether to fund embryonic stem cell research. Jeffrey Young, *Administration Unveils Stem Cell Rules*, The Hill, July 6, 2009, *available at* http://thehill.com/homenews/administration/49462-administration-unveils-stem-cell-rules (admitting that of the "[a]bout 30,000" comments "debat[ing] whether the NIH should be funding embryonic stem cell research," NIH "disregarded all such comments," and it instead branded such comments with the (ironic) label "unresponsive," because "[NIH] actually did not ask the public *whether* we should fund research on human embryonic stem cells. [NIH] asked the public *how* we should fund human embryonic stem cell research." (emphasis added)). Indeed, Defendants do not dispute that Kington made these comments. This very sort of "unalterably closed mind" caused the court to strike down a regulation in *Nehemiah Corp. of America v. Jackson*, 546 F. Supp. 2d 830, 848 (E.D. Cal. 2008), and the Court should do so here as well.

V. Plaintiffs Face Irreparable Injury If The Court Does Not Issue A Preliminary Injunction, And This Injury Outweighs Any Perceived Harm To Third Parties

Plaintiffs will be irreparably injured if Defendants are allowed to issue funding under the Guidelines. Defendants do not deny that additional embryos will be destroyed as a result of such funding; nor do they deny that once an embryo is destroyed, it is gone forever. Defendants simply contend that the embryos should not be part of this litigation. But as explained above, *supra* at pp. 13-16, the Embryo Plaintiffs have valid interests that can and should be protected in this Court. In addition, the destruction of these embryos results in irreparable injury to those wishing to adopt them or place them for adoption. Stoddart PI Decl. ¶ 6; Stoddart MTD Decl. ¶ 3; Nelson Decl. ¶ 4; Flynn Decl. ¶ 4.

NIH's resources are limited, and Drs. Sherley and Deisher face imminent increased competition from embryonic stem cell researchers for those limited resources. In addition, both Dr. Sherley and Dr. Deisher have alleged that obtaining NIH funding is *necessary* for their continued research. Sherley Decl. ¶¶ 3, 4; Deisher Decl. ¶ 3. As explained above, "basic economic logic" dictates that Dr. Sherley's and Dr. Deisher's opportunity to receive funds will be diminished if their grant applications are forced to compete with those of embryonic stem cell researchers, *United Transp.*, 891 F.2d at 913, and because there is no adequate remedy for this lost opportunity, they will be irreparably injured. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) (finding irreparable harm where there is "no adequate compensatory or other corrective relief" even though harm is economic in nature).

Defendants make a half-hearted attempt to argue that the irreparable injury caused to Plaintiffs—which, in the case of the embryos, is death—is outweighed by interests of third parties who have "waited for years" for the government to fund embryonic stem cell research. But Defendants fail to explain how that supposed harm outweighs the harm to Plaintiffs, whose lives

and livelihoods are threatened by further implementation of the Guidelines. Thus, the equities strongly favor an injunction.

CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss should be denied, and Plaintiffs' motion for a preliminary injunction should be granted. Plaintiffs respectfully request a hearing on their motion for a preliminary injunction.

Dated: September 28, 2009

Respectfully Submitted,

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Certificate of Service

I hereby certify that on September 28, 2009, I caused a true and correct copy of the foregoing Memorandum In Opposition to Defendants' Motion To Dismiss, and Reply In Support of Plaintiffs' Motion For A Preliminary Injunction to be served on Defendants' counsel electronically by means of the Court's ECF system.

/s/ Bradley J. Lingo
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