IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

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

TABLE OF CONTENTS

PAGE(S)

TABLE OF AUTHORITIES

CASES **PAGE(S)**

STATUTES AND REGULATIONS

MISCELLANEOUS

PRELIMINARY STATEMENT

The subject of human embryonic stem cell ("hESC") research is an emotionally charged one. On the one hand, many scientists believe that such research offers an unparalleled opportunity to develop treatment, and possibly cures, for a number of serious and life-threatening diseases. Many people accordingly hold strong beliefs that the federal government has a moral imperative to further that research. On the other hand, some people believe that a human embryo, from which hESCs are derived, holds the same moral status as a person. Many of these people believe strongly that the federal government should not fund hESC research.

This case is not, nor should it be, about that moral debate. Instead, despite the sensitivity of the subject matter, this is a case that can be easily resolved using familiar standards of justiciability and of review of agency action. The plaintiffs seek to enjoin Guidelines that the National Institutes of Health (NIH) recently issued to implement President Obama's Executive Order of March 9, 2009, regarding the availability of federal funding for hESC research. The plaintiffs, however, are unable to allege any concrete injury that any of them has suffered or would suffer from the issuance of the Guidelines, relying instead on speculative predictions of potential indirect effects of the Guidelines on the behavior of third parties. For this and other reasons, the plaintiffs lack standing to challenge the Guidelines.

The plaintiffs' substantive challenges also lack merit. The plaintiffs argue that the Guidelines are inconsistent with an appropriations rider, known as the Dickey-Wicker Amendment, which they contend prohibits the use of federal funds, *inter alia*, for *any* research involving hESCs, rather than, as the Amendment itself specifies, for "research in which a human embryo" is destroyed, discarded, or knowingly subjected to risk of injury or death. Given NIH's reasonable construction of that statute not to prohibit any and all uses of federal funds for hESC research, and the history of

Congressional awareness of and acquiescence in that construction, there should be no question that NIH's interpretation is rational. This Court should reject the plaintiffs' attempt to substitute their definition of scientific "research" for that of NIH. The plaintiffs also assert that NIH violated the Administrative Procedure Act (APA) in its promulgation of the Guidelines. NIH, however, rationally explained its choice of the standards that it developed in response to the President's direction in Executive Order No. 13,505, which is all that the Guidelines were intended to do and all that the APA requires. The fact that the agency did not oppose the President's policy on stem cell research or solicit comments on either the ethical or scientific basis for that policy does not demonstrate that it failed to rationally consider those relevant comments that it received in response to the draft guidelines.

The defendants accordingly respectfully request that the Court dismiss the Complaint for lack of jurisdiction or, in the alternative, for failure to state a claim. In light of the lack of standing for the plaintiffs or merit to their claims, as well as the lack of *any* irreparable harm to a party with a legally-cognizable interest, the defendants further respectfully request that the Court deny the plaintiffs' motion for a preliminary injunction.

BACKGROUND

I. The Promise of Human Embryonic Stem Cell Research

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

injuries, and many other disorders." *Id.* There are three primary kinds of stem cells available for research – hESCs, adult stem cells, and induced pluripotent stem cells. Each of these types of cells has its own capabilities and limitations. Accordingly, the consensus in the scientific community is that each of these types of cells is a worthy subject of research. National Institutes of Health ("NIH"), *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp.

Human embryonic stem cells have been available for research since 1998, when Dr. James Thomson of the University of Wisconsin developed a method to extract cells from a blastocyst.[1] NIH, *Regenerative Medicine 2006* at 3, http://stemcells.nih.gov/info/scireport/2006report.htm. This discovery holds the potential for great advances in medical research, due to the unique properties of these cells. Embryonic stem cells are pluripotent, meaning that they hold the capability to give rise to any of the approximately 200 types of cells in the human body. Richard Mollard, *Embryonic Stem Cells*, http://www.isscr.org/public/escells.htm. Embryonic stem cells can be maintained indefinitely, making them promising subjects for medical research. *Regenerative Medicine 2006* at 4.

Researchers do not aim to transplant undifferentiated human embryonic stem cells directly into the human body, as this practice would run the risk of forming a particular type of benign tumor known as a teratoma. *Understanding Stem Cells* at 5. Instead, one potential use for embryonic stem cells is to guide their differentiation into particular kinds of cells. The process of differentiation would be monitored and guided to ensure that only mature cells not capable of causing teratomas are created for use in human subjects. *Regenerative Medicine 2006*, Chapter 8 (updated June 2008), http://stemcells.nih.gov/info/scireport/2006Chapter8.htm. These differentiated cells, known as

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

derivatives, would then be used for treatment of certain disorders. *Id.* Embryonic stem cells also could be used to study disease mechanisms that cannot be studied in the human body, and to develop other, non-stem-cell-based therapies for these conditions. *Regenerative Medicine 2006* at 4.

Recent research suggests that these cell lines hold great promise for medical treatment:

- One recent study used hESC lines to generate "NK cells," a kind of white blood cell that destroys cancer, and found that the hESC-derived cells were better at destroying leukemia than cells derived from another type of stem cells. NIH, *Cancer-Destroying Cells Derived from Human Embryonic Stem Cells*, http://stemcells.nih.gov/research/scilit/highlights.

- Another recent study succeeded at differentiating hESC lines into the specific type of brain cell that is lost by patients who suffer from Parkinson's disease, suggesting the possibility that a treatment for that disease could be developed. *Understanding Stem Cells* at 16.

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

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

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

In addition to hESC lines, adult stem cell lines also provide a promising subject for research. *Understanding Stem Cells* at 8. Research on these cells began about 50 years ago with the discovery of hematopoietic stem cells, which are obtained from bone marrow or from umbilical cords. *Regenerative Medicine 2006* at 14-15. Unlike other adult stem cells, hematopoietic stem cells can be readily released into the blood for collection. Suzanne Kadereit, *Adult Stem Cells*,

http://www.isscr.org/public/adultstemcells.htm. Hematopoietic stem cells are the one type of adult stem cell that has been harvested in relatively large quantities for decades. As a result, this type of cell has been used for the vast majority of the diseases that have been treated with adult stem cells. NIH, *Hematopoietic Stem Cells*, http://stemcells.nih.gov/info/scireport/chapter5.asp. Although these types of cells have been available for research for decades, researchers have not yet been able to expand their capabilities beyond the hematopoietic system. *Id.*

Adult stem cells are multipotent, not pluripotent, meaning that they can differentiate only into a smaller set of specialized cells. *Hematopoietic Stem Cells*, *supra*. Researchers have not yet succeeded in using adult stem cells to produce some important classes of cells, such as neurons, the cells that are destroyed by neurodegenerative diseases like Alzheimer's disease or amyotrophic lateral sclerosis (ALS). *Id*. Recent research provides hope that adult stem cells might be able to be differentiated into a wider variety of cell types than scientists previously had believed, but it is too early to know whether that hope can be achieved. *Understanding Stem Cells* at 8. Some recent studies have concluded that adult stem cells will be able to develop only into a limited number of cell types. Suzanne Kadereit, *Adult Stem Cells*, *supra*.

A recent discovery provided a third type of stem cell that is available for research. In 2007, researchers identified conditions that would allow some specialized adult human cells to be reprogrammed genetically to assume a state that is similar to embryonic stem cells. *Regenerative Medicine 2006*, Chapter 8 (updated June 2008), *supra*. These reprogrammed cells are known as induced pluripotent stem cells (iPSCs). Research involving iPSCs is promising, but the research is at a very early stage, and it is too soon to know the full potential of iPSC research. *Understanding Stem Cells* at 12. In particular, it is not yet known whether iPSCs differ from hESCs in clinically

significant ways that would limit their usefulness. NIH, *Stem Cell Basics*, http://stemcells.nih.gov/info/basics/basics10.asp. The current procedure that is used to create iPSCs involves genetic manipulation of the cells through the use of viruses, which can cause cancer. Research is ongoing to develop a way to derive iPSCs without using viruses, but the subject requires further study. *Id.*

Because each of the three forms of stem cells - human embryonic stem cells, adult stem cells, and induced pluripotent stem cells – presents both advantages and disadvantages for researchers, a consensus has formed that there is scientific merit for further research involving each of these types of cell lines. In the words of Dr. Thomson, one of the pioneers of both hESC and iPSC research:

> Research on embryonic stem cells remains critically important. We have many unanswered questions, and the only way to realize the full potential of embryonic stem cells and other types of stem cells is a level playing field and unfettered inquiry. Human-induced pluripotent stem cells – the transformed adult cells that seem to mimic the qualities of embryonic stem cells – would not have been possible without research on human embryonic stem cells.

University of Wisconsin-Madison, *Professor Comments on Obama's Stem Cell Executive Action*, http://www.news.wisc.edu/16379.

II. Regulatory Background

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

contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." *Id.* The President directed that NIH "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." *Id.*, § 2. The President further directed NIH within 120 days to review existing guidelines on human stem cell research, and to "issue new NIH guidance on such research that is consistent with this order." *Id.*, § 3. President Obama's Order withdrew two directives that had been issued in the prior Administration: (1) a presidential statement of August 9, 2001, and (2) Executive Order No. 13,435 of June 20, 2007, 72 Fed. Reg. 34,591. *Id.*, § 5, 74 Fed. Reg. at 10,668.

The executive pronouncements by former President Bush that were withdrawn in Executive Order No. 13,505 permitted federal funding of some research using human embryonic stem cells, but limited the scope of the research for which federal funding could be made available. On August 9, 2001, President Bush announced that his Administration would permit federal funding to be used for research involving stem cell lines that were created by private or foreign researchers from "embryos that have already been destroyed," but would prohibit federal funding for research on stem cell lines created after the date of his announcement. *See* Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001). President Bush reiterated this policy decision when he issued Executive Order No. 13,435, 72 Fed. Reg. 34,591. That order formalized his previously stated position which prohibited federal funding for research on hESC lines created after August 9, 2001. *Id.* at 34,591-34,592. However, the order continued to permit federal funding to be used for research using approved hESC lines created prior to that date. *Id.* at 34,592.

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

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

NIH stated, as it had in proposing draft guidelines, 74 Fed. Reg. 18,578 (Apr. 23, 2009), that the Guidelines were being issued to "implement Executive Order 13505" and establish policies and procedures "consistent with" the Executive Order. 74 Fed. Reg. at 32,170. The Guidelines established a two-part structure that would govern the types of human embryonic stem cell lines that could be used in research funded by NIH. If an applicant institution proposed research using cells derived from embryos donated on or after the effective date of the Guidelines, the researcher must either be limited to cell lines posted on a new NIH registry, or the researcher must submit an "assurance of compliance" with part A of the Guidelines. Part A requires that the research involves only hESCs that "have been derived from human embryos" that "were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by individuals . . . who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32,174. This part further requires documentation that the following requirements have been satisfied with respect to the embryos from which the stem cells to be used for research purposes were derived: (a) "[a]ll options" that were available at a particular facility pertaining to the embryos were explained to the patients who had sought reproductive treatment; (b) no payments were offered for the donated embryos; (c) the health care facility had policies and/or procedures to ensure that the quality of care available for potential donors would not be affected by their consent or refusal to donate embryos; (d) there was a "clear separation" –

demonstrated by a series of specific safeguards – between the patients' decision to create embryos for reproductive purposes and their decision to donate embryos for research purposes; and (e) the potential donors were provided with certain specified information as part of the consent process. 74 Fed. Reg. at 32,174-32,175.

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

The final Guidelines noted that funding "of the derivation of stem cells from human embryos is prohibited by" an annual budgetary provision, known as the Dickey-Wicker Amendment. *Id.* In responding to comments concerning this statement in the draft Guidelines, NIH indicated that it has "consistently interpreted [the Amendment] as not applicable to research using hESCs, because hESCs are not embryos as defined by" the Amendment. *Id.* at 32,173. In light of Congress's

knowledge that NIH has permitted funding of hESC research since 2001, and the annual reenactment of Dickey-Wicker by Congress without substantive change, NIH recognized Congress's acceptance of its position that the Amendment prohibits federal funding for "the derivation of stem cells from an embryo that results in the embryo's destruction" but not "research involving [hESCs] that does not involve an embryo nor result in an embryo's destruction." *Id.*

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

STANDARDS OF REVIEW

I. Preliminary Injunction

"A preliminary injunction is an extraordinary and drastic remedy; it is never awarded as of right." *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008) (citations and internal quotation marks omitted). For a plaintiff to obtain preliminary relief, he must clearly demonstrate: (1) that there is a substantial likelihood of success on the merits; (2) that he would suffer irreparable injury if the injunction is not granted; (3) that an injunction would not substantially injure other interested (nonmoving) parties; and (4) that the public interest would be furthered by the injunction. *E.g., CityFed Fin. Corp. v. OTS*, 58 F.3d 738, 746 (D.C. Cir. 1995). This Circuit in the past has applied a "sliding scale" analysis whereby a strong showing as to one factor could excuse a weak showing as to another. *See id.* at 747. That standard is no longer viable; instead, "under the Supreme Court's precedents, a movant cannot obtain a preliminary injunction without showing *both* a likelihood of success *and* a likelihood of irreparable harm, among other things." *Davis v. PBGC*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh & Henderson, JJ., concurring) (citing, *inter alia*, *Winter v.*

NRDC, 129 S. Ct. 365, 375-76 (2008)). Even under the "sliding scale" analysis, however, a plaintiff with little or no likelihood of succeeding on the merits could not obtain preliminary injunctive relief. *See, e.g., Apotex, Inc. v. FDA*, 449 F.3d 1249, 1253-54 (D.C. Cir. 2006).

II. Motion to Dismiss

A motion to dismiss should be granted when a court lacks subject-matter jurisdiction over an action, or the complaint fails to "state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(1), (6). A court may grant a Rule 12(b)(6) motion when a complaint does not contain allegations that support recovery under a viable legal theory. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). The standard of review is substantially the same for subject matter jurisdiction challenges pursuant to FED. R. CIV. P. 12(b)(1), but the Court may consider materials outside of the pleadings to determine whether jurisdiction exists. *Caesar v. United States*, 258 F. Supp. 2d 1, 2-3 (D.D.C. 2003).

ARGUMENT

I. The Plaintiffs Have Failed to Establish a Likelihood of Success on the Merits

A. This Court Lacks Jurisdiction over This Matter as the Plaintiffs' Speculative Allegations of Injury from NIH's Promulgation of the Guidelines Do Not Satisfy the Requirements of Article III

Before it may grant the plaintiffs' motion, this Court must establish that it has subject matter jurisdiction over the Complaint. *E.g. Dominguez v. District of Columbia*, 536 F. Supp. 2d 18, 23-24 (D.D.C. 2008). However, as the defendants demonstrate, such jurisdiction is lacking here. As an element of the fundamental "case or controversy" requirement of Article III, the plaintiffs "must establish that they have standing to sue." *McConnell v. FEC*, 540 U.S. 93, 225 (2003). There are three core requirements that must be demonstrated to establish standing: (1) "injury in fact, which

is concrete, distinct and palpable, and actual or imminent"; (2) "a causal connection between the injury and the conduct complained of—the injury has to be fairly trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] some third party not before the court"; and (3) "a substantial likelihood that the requested relief will remedy the alleged injury in fact." *Id.* at 225-26 (internal quotations and citations omitted). The burden is on the plaintiffs to establish their standing. *Warth v. Seldin*, 422 U.S. 490, 501 (1975). "When a plaintiff's asserted injury arises from the Government's regulation of a third party that is not before the court, it becomes 'substantially more difficult' to establish standing." *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 938 (D.C. Cir. 2004) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992)).

1. The Organizational Plaintiffs

a. Christian Medical Association ("CMA")

The plaintiffs allege that Christian Medical Association ("CMA"), a "non-profit association of doctors that is dedicated to improving the ethical standards of health care," will suffer injury to the organization itself from the operation of the Guidelines. According to CMA, "the Guidelines will frustrate CMA's purpose and require CMA to devote significant resources to address and counteract the grave ethical problems posed by illegal public funding of embryo research." Compl. ¶ 12.

These vague and conclusory allegations fall well short of what is required in this Circuit for organizational standing. As an initial matter, CMA's allegation that the Guidelines have "'frustrated' [its] objectives is the type of abstract concern that does not impart standing." *Nat'l Taxpayers Union v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995). As the D.C. Circuit has explained, an organization must show "'more than allegations of damage to an interest in 'seeing'

the law obeyed or a social goal furthered'"; indeed, the "'organization must allege that discrete programmatic concerns are being *directly and adversely* affected.'" *Id.* (emphasis added) (quoting *Am. Legal Found. v. FCC*, 808 F.2d 84, 92 (D.C. Cir. 1987)).

The Guidelines challenged here do not regulate CMA's activities, let alone prevent or make it more difficult for the organization to conduct any activities. CMA's assertion that it will devote more of its funding, in light of the Guidelines, to the issue of stem cell research is the type of self-imposed organizational decision that the D.C. Circuit has consistently rejected as a basis for Article III standing. *See Nat'l Taxpayers*, 68 F.3d at 1434 ("Unlike the injury alleged in *Havens Realty*, . . . Section 13208 has not forced NTU to expend resources in a manner that keeps NTU from pursuing its true purpose . . . . NTU cannot convert its ordinary program costs into an injury in fact from Section 13208."); *Ctr. for Law and Educ. v. Dep't of Educ.*, 315 F. Supp. 2d 15, 24 (D.D.C. 2004) (rejecting standing of organization to challenge regulations "that merely elect policies other than those advocated by" plaintiffs, even though "these policy choices [may] ultimately require [plaintiffs] to raise and spend more money in pursuit of their objectives"), *aff'd*, 396 F.3d 1152 (D.C. Cir. 2005); *Am. Farm Bureau v. EPA*, 121 F. Supp. 2d 84, 101 (D.D.C. 2000).

Even if an alleged organizational decision to spend more funds could establish Article III injury, the Complaint fails to identify how CMA intends to "counteract" the "grave ethical problems posed by illegal public funding of embryo research," or why CMA only now believes that such action is necessary. After all, "public funding of embryo research" was first authorized by President Bush in 2001, has been occurring now for almost a decade, and the Guidelines that form the basis of CMA's complaint have been effective for almost two months. Yet CMA cannot state that it is currently suffering any concrete injury, instead opining that some injury *will occur* at some

unspecified future point. That future-oriented allegation is purely speculative. It is just as easy to surmise that increased public attention to the ethical issues surrounding stem cell research would result in a corresponding increase in support for CMA's mission.

b. Nightlight Christian Adoptions ("Nightlight")

Plaintiff Nightlight Christian Adoptions ("Nightlight") alleges that it is a licensed "adoption" agency that "enables adoptive parents to adopt human embryos that are being stored in fertilization clinics." Compl. ¶ 8. According to Nightlight, it is injured by the Guidelines, as the Guidelines "decrease the number of embryos available for adoption," "impose a . . . burden on the resources that Nightlight devotes to facilitating embryo adoption," and "effectively discourage families with frozen embryos from considering embryo donation and adoption because they are led to believe that there is a high moral purpose in donating the embryos for research." *Id.*; *see also* Decl. of Ronald Stoddart ¶ 6. Nightlight seeks to proceed in this lawsuit on its own behalf, as well as on the behalf of "[p]laintiff [e]mbryos," who are alleged to be "persons" who may be represented by Nightlight as guardian *ad litem* pursuant to Federal Rule of Civil Procedure 17(c). *Id.*

i. Nightlight Alleges No Concrete Injury

Nightlight does not allege the type of concrete or imminent harm required to establish standing pursuant to Article III. It first alleges that the Guidelines "decrease the number of embryos available for adoption" and therefore "impose a consequent burden on the resources that Nightlight devotes to facilitating embryo adoption." Compl. ¶ 8. This allegation of a causal connection between the Guidelines and an economic impact on Nightlight is based on the allegation that "the Guidelines permit federal funding for research on stem cells that are derived from embryos that . . . could have been donated to an adoption agency such as Nightlight." *Id.*

The difficulty with this allegation is that it assumes an indirect connection between the Guidelines and adoption that relies entirely on the decisions of independent third parties not before the Court, i.e. 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. The declaration of the Executive Director of Nightlight, Ronald Stoddart, states that Nightlight matches "adopting families" with individuals who are willing to provide them with embryos. Stoddart Decl. ¶ 5. The Guidelines that the plaintiffs challenge do nothing to alter this business, as they are entirely unrelated to the regulation of embryonic "adoption" services. Instead, the Guidelines permit funding for research involving stem cells from only those embryos that were "donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32174. Despite that disconnect, the plaintiffs provide no factual allegation to demonstrate the purported causal link. *Cf. Renal Physicians Ass'n v. HHS*, 489 F.3d 1267, 1276 (D.C. Cir. 2007).

In an attempt to create a conflict where none exists, the plaintiffs allege that the defendants "discourage families . . . from considering embryo donation and adoption because they are led to believe that there is a high moral purpose in donating the embryos for research." Compl. ¶ 8. This is the definition of baseless speculation, as it requires the Court to assume that the mere existence of the Guidelines would cause individuals undergoing IVF treatment to change their minds about donating their excess embryos to entities such as Nightlight, and instead cajole them into donating the embryos for research purposes. These wholly discretionary decisions as to what to do with the embryos that families or individuals no longer need for reproductive purposes lie solely in the hands of third parties in IVF clinics, who have the ability to choose whether the embryos will be donated

for research, for "adoption" to Nightlight, or simply disposed of entirely. *See Allen v. Wright*, 468 U.S. 737, 759 (1984); *Community for Creative Non-Violence v. Pierce*, 814 F.2d 663, 669 (D.C. Cir. 1987); *Young America's Found. v. Gates*, 560 F. Supp. 2d 39, 50-52 (D.D.C. 2008).

The plaintiffs' allegations assume, with no basis, that the Guidelines would produce a sea change in potential donors' choices. However, the Guidelines simply set forth the type of hESC research proposals that would be considered by NIH for funding, and in so doing describe *limitations* on the types of stem cells that may be approved for use in federally-funded research. They do not create or initiate federal funding for stem cell research. The first guidelines governing federal funding for stem cell research were issued in August of 2000, federal funding began under President Bush as early as 2001, and President Obama's Executive Order in March of this year withdrew certain limitations placed on such research by former President Bush[2].

A look at the actual content of the Guidelines reveals the types of limitations that they impose on federally-funded research involving hESCs. The Guidelines mandate that the donation of embryos from which the stem cells are derived must be made "freely." Towards this end, the Guidelines require, *inter alia*, that a researcher proposing to use embryonic stem cells demonstrate that "[a]ll options available in the health care facility where treatment was sought pertaining to the embryos no longer needed for reproductive purposes were explained to the individual(s) who sought

[2] As with Nightlight, no named plaintiff can trace its alleged injuries to the actual effect of the Guidelines. NIH issued the guidelines challenged by the plaintiffs in this action in order to "implement Executive Order 13505." 74 Fed. Reg. at 32,170. While the Guidelines might have conditioned the availability of federal funding for research on certain hESC lines on specified documentation requirements, it did not, *ab initio*, make such expanded funding possible. That substantive action was taken instead by Executive Order 13,505, in which President Obama ended the effect of two actions by former President Bush that placed limitations on the availability of federal funding for research involving hESC lines. 74 Fed. Reg. at 10,668.

reproductive treatment," and that "[t]here was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes." 74 Fed. Reg. at 32,174. Thus, there is no reason to believe that the Guidelines themselves create any additional incentive for a donor to move away from the embryonic "adoption" services that Nightlight provides, particularly when the IVF health care facility is required to explain to the potential donor *all options*, including "adoption" if available, pertaining to embryos no longer needed for the donors' reproductive purposes.

Nevertheless, even if Nightlight's speculations as to causal connections were assumed to be true, Nightlight would still not have standing to sue. Even if the Guidelines themselves somehow reduced the pool of embryos available for "adoption," this would not show that Nightlight *itself* had been, or would be, injured. Nightlight's only allegation of such injury is its naked claim that a reduction in the pool of available embryos leads to a "consequent burden on the resources that Nightlight devotes to facilitating embryo adoption." Compl. ¶ 8. Yet that allegation is still speculative because it assumes that the pool of available embryos would be reduced by such a factor that Nightlight would have to turn away clients, or expend more resources, due to an insufficient number of available embryos per available client. After all, Nightlight states on its own website that "[a]s of Summer 2008, there are many embryos waiting for adoptive families." Nightlight Christian Adoptions, *Frequently Asked Questions by Adopting Families*, http://www.nightlight.org/downloads/FAQs%20from%20APs%2006%2030%2009.pdf. It is illogical, not merely speculative, to assume that these "many embryos waiting for adoptive families" would suddenly cease to exist as a result of the passage of the Guidelines.

ii. The First-to-File Rule Requires Dismissal of Nightlight and the Class of Embryos that It Purports to Represent

Nightlight's speculative allegations are certainly familiar to the federal defendants, as Nightlight has proffered substantially identical allegations in a lawsuit currently proceeding in the United States District Court for the District of Maryland. *Mary Scott Doe, et al. v. Barack Obama, et al.*, Civ. No. 09-0755. In that lawsuit, Nightlight and an "embryo," as two of the named plaintiffs, have sued HHS, NIH, their Directors, and President Obama, seeking injunctive relief against the implementation of Executive Order No. 13,505 and any guidelines issued by the federal agencies to implement that Order. *See, e.g.*, *Doe* Compl. ¶¶ 76, 77 (Dkt No. 1). The Complaint alleges, *inter alia*, that the federal funding of hESC research violates the Dickey-Wicker Amendment. *See id.* at 41-42. Nightlight seeks standing to sue to redress its own injuries from the alleged reduction of embryos available for "adoption" as well as third party standing to represent the alleged constitutional right to life of all embryos. *Id.* ¶ 81.

Nightlight, and the embryos that it seeks to represent in this lawsuit as guardian *ad litem*, should be dismissed on the basis of their pending lawsuit filed against the same federal defendants in the District of Maryland. "For more than three decades the rule in this circuit has been that '(w)here two cases between the same parties on the same cause of action are commenced in two different Federal courts, the one which is commenced first is to be allowed to proceed to its conclusion first . . . ." *Washington Metro. Area Transit Auth. v. Ragonese*, 617 F.2d 828, 830 (D.C. Cir. 1980); *see also Zerilli v. Evening News Ass'n*, 628 F.2d 217, 222 (D.C. Cir. 1980). "Considerations of comity and orderly administration of justice dictate that two courts of equal authority should not hear the same case simultaneously." *Washington Metro.*, 617 F.2d at 830.

Although the D.C. Circuit has cautioned that the first-to-file rule should not be applied mechanically in the case of concurrent lawsuits filed by both a plaintiff and a defendant, "there is no reason not to apply [the rule's] principles here," where the two lawsuits have both been filed by Nightlight. *Entines v. United States*, 495 F. Supp. 2d 84, 85 (D.D.C. 2007); *see also Semmes Motors, Inc. v. Ford Motor Co.*, 429 F.2d 1197, 1203 (2d Cir. 1970); *Kidd v. Andrews*, 340 F. Supp. 2d 333, 336 (W.D.N.Y. 2004). Accordingly, as Nightlight's challenge in the Maryland litigation, brought by an attorney on behalf of itself and the embryos it seeks to represent, "is closely related to the . . . . claim at issue here and could be raised in that litigation," "[c]onsiderations of comity preclude this court from resolving that claim." *Action for Children's Television v. FCC*, 827 F. Supp. 4, 15 (D.D.C. 1993).

iii. Plaintiff Embryos Lack Standing

Nightlight also seeks to proceed in the Complaint on behalf of embryos created for IVF purposes and no longer needed for such purposes. Compl. ¶ 8. According to the plaintiffs, the embryos "are persons that qualify for representation under Fed. R. Civ. P. 17(c)," with Nightlight representing their interests as guardian *ad litem*. *Id.* ¶¶ 8, 9. The defendants have addressed Nightlight's ability to serve as guardian *ad litem* for embryos, as well as any potential standing for such embryos to sue on their own, in their Opposition to the plaintiffs' Motion to Appoint Guardian *Ad Litem*. As the Opposition indicates, Nightlight is foreclosed by existing case law from raising the rights of the class of embryos that it seeks to represent, as "embryos" do not have enforceable rights as "persons" under the law. *See* Defs.' Opp. to Pls.' Mot. to App. Guardian *ad Litem*.

2. Plaintiffs Nelson and Flynn

Plaintiffs Shayne and Tina Nelson, and William and Patricia Flynn, are couples who have had a child through "adoption" of an embryo from Nightlight. Compl. ¶¶ 10, 11. Both couples allege that they "are seeking" or "seek" to "adopt" additional human embryos, and that the "promulgation of the Guidelines . . . jeopardizes the likelihood that embryos will become available in a timely manner for adoption and implantation." *Id.*

These allegations are the essence of speculation, rather than allegations of concrete and imminent harm from the passage of the Guidelines. As an initial matter, the declarations of each couple establish that they are, and have been, "seeking to adopt" an embryo, with the Flynns specifying that they have been seeking to do so since May 28, 2009. *See* Decl. of William T. Flynn ¶ 3; Decl. of Tina Nelson ¶ 3. Thus, each couple has purportedly been seeking an embryo with the assistance of Nightlight while the Guidelines, and Executive Order No. 13,505, have been in place, yet neither couple makes any allegation as to a current concrete burden or obstacle to "adoption" of one of the "many embryos waiting for adoptive families" that Nightlight describes. The plaintiffs' speculation as to future possibilities simply does not satisfy the concreteness and imminency requirements of Article III.[3] *See J. Roderick MacArthur Found. v. FBI*, 102 F.3d 600, 606 (D.C. Cir. 1996); *United Transp. Union v. ICC*, 891 F.2d 908, 913 (D.C. Cir. 1989).

The speculative nature of these allegations is magnified when one considers that the

[3] These deficiencies are not saved by allegations of past "adoptions," as they do not demonstrate that obstacles to current or future "adoptions" are either concrete or imminent, much less that they stem from the challenged Guidelines. If anything, the fact that the couples have "adopted" embryos in the past, even though federal funding for certain stem cell research had been permitted during the Bush administration, demonstrates that such funding poses no obstacles to "adoption."

Guidelines do not regulate embryonic "adoption" at all. As mentioned above, the Guidelines instead specify that, where this option is available, the possibility of embryonic "adoption" should be explained to potential donors. 74 Fed. Reg. at 32,174. The plaintiffs thus cannot argue that even their potential future interest in "adoption" is directly affected by the Guidelines; instead, their asserted injury could only stem from a very tenuous and indirect effect that the Guidelines might have on their likelihood of being able to "adopt." That likelihood, however, is far more directly affected by a long trail of potential intervening events that have nothing to do with the Guidelines, such as the decisions of third-party individuals as to whether they will donate their embryos to the plaintiffs through Nightlight in lieu of taking some other action with regard to their embryos, *see supra* at 14-17; the likelihood that the Guidelines would affect this independent, third-party decision, *see id.*; the likelihood that any such effect would reduce the pool of available "adoptees" to such a point that individuals would be inhibited in their ability to "adopt" an embryo; and the likelihood that the named plaintiffs, as opposed to some other potential "adoptive" couple, would be the ones who would lose out on the ability to "adopt." The existence of these unknown factors and potential intervening events alone defeats the named couples' standing. *Cf. Diamond v. Charles*, 476 U.S. 54, 66 (1986) ("The possibilities that such fetuses would survive and then find their way as patients to Diamond are speculative, and 'unadorned speculation will not suffice to invoke the federal judicial power.'") (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 44(1976)); *Roe v. Wade*, 410 U.S. 113, 128 (1973).

3. Drs. Sherley and Deisher

The remaining plaintiffs named in the Complaint are two research scientists specializing in the use of adult stem cells, Dr. James Sherley and Dr. Theresa Deisher. Compl. ¶¶ 6, 7. According

to the Complaint, Drs. Sherley and Deisher are injured by the Guidelines because their implementation "will result in increased competition for limited federal funding and will thereby injure [the named scientists'] ability to compete *successfully* for . . . NIH stem cell research funds . . . ." *Id.* (emphasis added); *see also* Sherley and Deisher Decls. at ¶ 4.

Neither Dr. Sherley nor Dr. Deisher claims to have been denied research funding as a result of the Guidelines, or to be at imminent risk of a denial resulting from the Guidelines in the near future. Rather, their allegations of injury 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 them to lose or be denied research funding that either of them would otherwise have received in the absence of the Guidelines.[4] The difficulty with such an allegation is that it depends on several entirely speculative and largely erroneous assumptions about NIH's process for approving and funding grants.

As explained in the declaration of Sarah Rockey, NIH receives thousands of grant

[4] The actual loss of funding is pivotal for proof of injury in the present context, as the plaintiffs' allegations of "competitive" injury do not fit in the limited context in which the D.C. Circuit has permitted proof of increased competition alone to establish standing. *See, e.g., DEK Energy Co. v. FERC*, 248 F.3d 1192, 1195 (D.C. Cir. 2001); *see also Horizon Lines LLC v. United States*, 414 F. Supp. 2d 46, 53 (D.D.C. 2006). As opposed to these cases, in which the plaintiff is a market competitor *already* permitted by the government (or by the very nature of the free market) to compete, a research scientist has no current expectation or right to federal funding from NIH for future research projects. Thus, the Court cannot be "almost sure[]" that injury would occur in the present case, as there is no ability to predict that a researcher's proposal would be approved and then would actually compete for funds directly with another proposal, let alone that the rejection of any proposal would be a causal result of the government action challenged. *See DEK*, 248 F.3d at 1195. Nor is this a competitive bidding situation, where the defendants have purportedly deprived the plaintiffs of an opportunity to compete altogether, or on equal footing, with a competitor. *See, e.g., CC Distributors, Inc. v. United States*, 883 F.2d 146 (D.C. Cir. 1989). The plaintiffs do not, and could not, allege that the challenged Guidelines have inhibited them from competing for federal funding on equal footing with scientists who research involves hESCs.

applications each year from institutions seeking research funding. *See* Rockey Decl. ¶ 14. In order to even be considered for research funding, an application must be approved through a two-level peer review process. *Id.* ¶ 8. At the first level, a scientific review group comprised of non-federal scientists who have expertise in the subject area reviews each application for scientific merit. *Id.* ¶¶ 10, 11; *see also* 42 U.S.C. §§ 282(b)(9), 289a; 42 C.F.R. § 52h.2(k). If an application receives scores in the top half of the applications reviewed by the group, then it will be discussed orally at the group's meeting. *Id.* These applications are then given a final score that is used to determine the application's rank relative to other discussed applications. *Id.*

Scored applications are then submitted to the advisory council or board of the institute and center ("IC") of NIH that will consider whether to approve the application for funding. *Id.* ¶ 12; *see also* 42 U.S.C. §§ 284(b)(2)(B); 284a(a)(3). Each IC has an independent budget to fund research particular to its subject area (for example, cancer research at the National Cancer Institute), including, in most cases, a payline particular to extramural research funding. *Id.* ¶¶ 5, 15. This payline is not specific to individual research methodologies, such as cancer research *using stem cells*, but applies instead to all research proposals in the IC's subject area. *Id.* ¶¶ 15, 16. The scientists from the extramural community and the public representatives that make up the councils or boards review the applications and their respective scores and consider them based in part on the needs and research goals of the IC. *Id.* ¶ 12. The ultimate decision as to which grant applications to accept is based on the recommendations of this two-tiered peer review process. *Id.* ¶ 13; *see also* 42 U.S.C. §§ 284(b)(2)(B), 289a-1(a)(2).

Plaintiffs Sherley and Deisher allege injury from a potential loss of research funding, based on the assumption that their current or future applications for grant funding would be denied because

of a competing proposal for hESC research. This claim ignores the realities of the process by which grant applications are reviewed and funded. As the Rockey Declaration explains, for there even to be proposals "competing" for funding, each researcher's proposal must have survived each level of the peer review process. Accordingly, there first must be proposals involving both hESC and adult stem cell research that survive the first level of peer review, and the "competing" proposals must both then be submitted to the same potential funding component (IC) for the second level of peer review (for example, two proposals are submitted to NCI because they both involve cancer research). That is far from a likelihood, as half of the applications will not even survive the first round of peer review, there are 25 different funding components to evaluate applications, and ultimately only about 22% of applications will receive funding. *Id.* ¶¶ 4, 11, 14. Accordingly, any potential "competition" between proposals for hESC research and the plaintiffs' proposals remains speculative until each "competitor" has survived peer review and is being reviewed by the same funding component.[5] *See Donaldson v. United States*, 268 F. Supp. 2d 812, 820 (E.D. Mich. 2003), *aff'd*, 109 Fed.Appx. 37 (6th Cir. 2004)[6]; *see also TEVA Pharm. USA, Inc. v. Sebelius*, — F. Supp. 2d —, 2009 WL 2344910, at *14 (D.D.C. 2009) ("The interest that Apotex alleges in this suit . . . presumes final approval of

[5] Moreover, as explained previously, *supra* note 2, any such competition would not be a product of the Guidelines, which simply condition the availability of federal funding for research involving certain hESC lines. If anything, the plaintiffs' competition is *lessened* by the Guidelines, which restrict federal funding unless certain documentation requirements are met.

[6] As the Court stated in *Donaldson*, "any harm the plaintiff suffers emanates from the refusal of the USDA to approve his pre-applications for RBE grants, not from the decision of the USDA to confer RBE grants to cooperatives or other applicants whom the plaintiff contends are ineligible. Furthermore, the plaintiff has not shown that if the USDA ceased granting applications to cooperatives, his applications would win approval. . . . If the USDA determined that the plaintiff's RBE grant application had higher priority, then it would likely approve the application regardless of whether cooperatives had also submitted applications."

its [applications] and is speculative.").

However, even if these contingencies come to pass and an hESC research proposal is in competition for funding at the same IC with a proposal by one of the plaintiffs, there is still no non-speculative basis to conclude that such competition would threaten the plaintiffs' funding. In order for hESC research applications to threaten funding for the plaintiffs' research projects, the plaintiffs' applications would have to receive a score that is high enough to survive peer review but low enough that it borders on the limit of the IC's funding payline. There would then have to be a sufficient number of higher scoring hESC research proposals such that the IC chooses not to fund the plaintiffs' proposals within (or outside of) the payline, a factor that may vary each fiscal year depending on the budgetary decisions of Congress or the particular needs of an IC.

Given these uncertainties, the plaintiffs' fear that they would lose funding as a result of the Guidelines' allowance of hESC research proposals is pure conjecture. In fact, the only *concrete* evidence demonstrates that NIH remains committed to the funding of adult stem cell research at a very high level. NIH estimates that funding for non-embryonic human stem cell research will continue to increase through 2010 to approximately $311 million, over three times that of the projected total for hESC research funding. Rockey Decl. ¶ 18. And on July 20, 2009, 13 days after the effective date of the Guidelines, NIH awarded a supplemental grant to plaintiff Sherley's institute on top of the grant that the institute is already receiving this year pursuant to the Director's Pioneer Award Program.[7] *Id.* ¶ 22. Thus, there is no basis to assume that the plaintiffs are at any risk of an imminent loss of federal funding as a result of the Guidelines. *See Doe v. Shalala*, 862 F. Supp. 1421, 1428 (D. Md. 1994) ("Even if . . . NIH were to elect to fund fetal research projects . . ., there

[7] Plaintiff Deisher does not claim to have received any NIH research grants to this point.

is no basis for concluding that that decision would diminish funding for research projects involving Down's Syndrome or other genetic disorders."), *vacated as moot*, *Int'l Found. for Genetic Research v. Shalala*, 57 F.3d 1066 (4th Cir. 1995) (per curiam) (unreported); *see also Day v. Bond*, 500 F.3d 1127, 1134 (10th Cir. 2007) (refusing to speculate on budgetary mechanics of state university to determine whether plaintiffs might suffer injury from "competition for scarce tuition resources"); *Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002).

Ultimately, plaintiffs Sherley and Deisher ask this Court to grant them standing based on their desire for a partial economic monopoly over competition for federal funding of stem cell research. They do so even though their fears are no different from those of any other applicant for NIH federal research funding, as NIH funding components do not establish funding paylines by research methodology, such as the use of "stem cells" generally. Rockey Decl. ¶ 16. Thus, the plaintiffs seek permission to use the federal courts as an open forum for the forty-thousand-plus scientists who annually seek NIH funding to contest NIH's grant decisions, even though they have no right to or expectation of federal funding from NIH, which has the sole discretion to decide how to allocate its research dollars. *See, e.g., Marinoff v. HEW*, 456 F. Supp. 1120, 1122 (S.D.N.Y. 1978); *Grassetti v. Weinberger*, 408 F. Supp. 142, 150 (N.D. Cal. 1976). Such a result should not be permitted by this Court.

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

There is a second jurisdictional defect in the plaintiffs' claims. They seek to challenge the mere issuance of the Guidelines, despite the fact that they do not enjoy (or forfeit) any legal rights, or incur any legal oblations thereunder. The plaintiffs attempt to short-circuit the ordinary operation of NIH's peer review process, and to seek a judicial order barring NIH from even reviewing the

scientific merits of certain grant applications. But any challenge to the Guidelines is not ripe, and will not ripen until, at the very least, after NIH applies the Guidelines to evaluate proposals for funding for hESC research, and the effect of the Guidelines, if any, on stem cell (or other) research is known.

"The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (internal quotation omitted). The doctrine serves "'to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.'" *Id.* at 807-08 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967)). The determination of whether an administrative action is ripe for review requires an evaluation both of the fitness of the issues for judicial decision and of the hardship to the parties of withholding court consideration. *Nat'l Park Hospitality Ass'n*, 538 U.S. at 808. The plaintiffs' premature challenge to the Guidelines satisfies neither requirement.

First, the plaintiffs face no imminent hardship that could justify judicial intervention at this time.

> "Absent [a statutory provision providing for immediate judicial review], a regulation is not ordinarily considered the type of agency action 'ripe' for judicial review under the [. . . APA] until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him. (The major exception, of course, is a substantive rule which as a practical matter requires the plaintiff to adjust his conduct immediately . . . .)."

Nat'l Park Hospitality Ass'n, 538 U.S. at 808 (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871,

891 (1990)). By this standard, the plaintiffs' challenge to the Guidelines is not ripe, nor does this case fall within the exception noted in *National Park*. The Guidelines do not "have a direct and immediate impact" on the plaintiffs' "primary conduct." *Am. Fed'n of Gov't Employees v. Gates*, 486 F.3d 1316, 1331 (D.C. Cir. 2007). In other words, a challenge to a regulation is not ripe if the plaintiffs are "not required to engage in, or refrain from, any conduct." *Texas v. United States*, 523 U.S. 296, 301 (1998).

The NIH Guidelines that establish standards for grant applications by institutions or persons who seek funding for hESC research do not have any direct effect on the plaintiffs' primary conduct. Any legal rights or obligations that might be affected by the Guidelines "are not [the plaintiffs'] but those of [their] competitors, about which [they are] not in a position to complain." *Pfizer, Inc. v. Shalala*, 182 F.3d 975, 979 (D.C. Cir. 1999); *see also Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 58-59 (1993) (regulation that does not impose burdens, but instead sets criteria for benefits, not ripe in advance of an award or denial of benefits); *Ayuda, Inc. v. Reno*, 7 F.3d 246, 249 (D.C. Cir. 1993) (same).

Second, the issues are not fit for decision at this time. As discussed above, the Public Health Service Act requires a two-tier system of peer review whereby qualified experts review the merits of each grant proposal. 42 U.S.C. §§ 282(b)(9), 284a(a)(3), 289a. The Director of each Institute makes a funding decision only after receiving the recommendations required from both bodies. 42 U.S.C. §§ 284(b)(2)(B), 289a-1(a)(2). The plaintiffs seek to short-circuit this process, and to substitute the expert review that is required for each individual application with a categorical declaration from this Court. Because the plaintiffs seek to "inappropriately interfere with further administrative action," *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998), their claims

are not fit for decision now. Their claims accordingly are not ripe.

C. The Plaintiffs' Substantive Legal Challenges Lack Merit

1. The Defendants Have Rationally Interpreted the Dickey-Wicker Amendment to Permit the Federal Funding of Research on Embryonic Stem Cell Lines

The plaintiffs' first claim asserts that the defendants violated a congressional statute, known as the "Dickey" or "Dickey-Wicker" Amendment, which currently prohibits federal funding for "the creation of a human embryo or embryos for research purposes," or "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Pub. L. No. 111-8, Div. F, Title V, § 509(a), 123 Stat. 524, 803. In the Guidelines, NIH explained that, consistent with the definition of "embryo" in the Amendment, stem cells are not embryos. Accordingly, following the position first announced by NIH in formal guidelines issued in 2000, HHS has interpreted Dickey-Wicker as prohibiting federal funding for the "derivation of stem cells from an embryo that results in the embryo's destruction," but permitting federal funding for "research involving hESCs that does not involve an embryo nor result in an embryo's destruction." 74 Fed. Reg. at 32,173.

The plaintiffs' proffered interpretation of Dickey-Wicker would, if accepted, require a "much broader ban" on federal funding than that required by NIH. According to the plaintiffs, the "prohibition bans the funding of research, such as embryonic stem cell research, that is *dependent upon* and induces the destruction of human embryos." Pls.' Mem. at 8, 9 (emphasis added). The plaintiffs therefore believe that NIH's interpretation, as expressed in the Guidelines following notice and comment, is "untenable on its face." *Id.* at 9.

Of course, in deciding this issue, the standard of review that guides this Court is the familiar one established by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *see also Mount Royal Joint Venture v. Kempthorne*, 477 F.3d 745, 754 (D.C. Cir. 2007) ("If the agency enunciates its interpretation through notice-and-comment rule-making or formal adjudication, we give the agency's interpretation *Chevron* deference."). In *Chevron*, the Supreme Court held that courts reviewing an agency's interpretation of an applicable statute must "give effect to the unambiguously expressed intent of Congress," but that where the statute is ambiguous, the issue is whether the agency has adopted a "permissible construction of the statute." 467 U.S. at 843.

To find the agency's interpretation permissible, this Court need not conclude that it is "'the best interpretation of the statute,'" *United States v. Haggar Apparel Co.*, 526 U.S. 380, 394 (1999) (quoting *Atl. Mut. Ins. Co. v. Comm'r*, 523 U.S. 382, 389 (1998)), or that it is the "most natural one," *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). To the contrary, the plaintiffs bear the daunting burden of establishing that their reading of the statute is the "inevitable one," *Regions Hosp. v. Shalala*, 522 U.S. 448, 460 (1998), because Congress made a deliberate decision to "compel" the result they urge, *Auer v. Robbins*, 519 U.S. 452, 458 (1997), in terms so "unambiguously manifest," *Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687, 703 (1995), that the statutory language "cannot bear the interpretation adopted by the Secretary." *Sullivan v. Everhart*, 494 U.S. 83, 92 (1990). Thus, for the plaintiffs to prevail, theirs must be "the only possible interpretation" of the statute. *Regions Hosp.*, 522 U.S. at 460; *Sullivan*, 494 U.S. at 89. Plaintiffs' proposed interpretation falls far short of meeting this exacting standard.

a. The Plaintiffs' Broad Interpretation of Dickey-Wicker Is Not Commanded by the Language of the Amendment

The plaintiffs do not dispute that human embryonic stem cells are not embryos, as that term is used in the Dickey-Wicker Amendment. Instead, they suggest that Congress's use of the phrase "*research in which* . . . embryos are destroyed" commands such a broad reading of the term "research" that it would include all research that followed from, or preceded, the destruction of a human embryo. Because "research is a systematic process involving multiple steps and procedures with the overall purpose of advancing knowledge," the plaintiffs assert that the derivation of human embryonic stem cells resulting in an embryo's destruction should be considered "an integral part" of any stem cell "research." Pls.' Mem. at 9-10. However, this overly broad interpretation is not supported, let alone commanded, by the language of the Amendment.

As an initial matter, the common understanding of the term "research" is not as broad as the plaintiffs suggest. The term "research," standing alone, may be defined as a "piece of research," meaning that "research" can be segmented into discrete parts. RANDOM HOUSE DICT. (2009)[8] (defining "research" as "a particular instance or piece of research"). Thus, nothing in the common understanding of the term prohibits the conclusion that the initial scientific process of deriving stem cells from the embryo itself constitutes the "piece" or "instance" of research that the Amendment prohibits in this context.

The plaintiffs suggest that this interpretation is belied by HHS regulations concerning human subject research, which define "research" as a "systematic investigation including research development, testing and evaluation." 45 C.F.R. § 46.102(d). It is difficult, however, to understand

[8] The RANDOM HOUSE sources are available at http://dictionary.reference.com/.

how this definition, which is not expressly incorporated into the Dickey-Wicker Amendment, commands the plaintiffs' broad reading. The word "systematic" is not commensurate with the term "unending" or "undivided"; it refers instead to "having, showing, or involving a system, method, or plan." RANDOM HOUSE DICT. (2009). A particular research project involving stem cells can therefore be "systematic" or "methodical" without needing to include within its scope all steps that made the research possible. This conclusion is supported by NIH regulations governing the research grant process, which define the term "research" as "a systematic investigation, *study* or *experiment* designed to contribute to general knowledge relating broadly to public health[.]" 42 C.F.R. § 52.2 (emphases added).

Moreover, the plaintiffs' interpretation of the term "research" to encompass any scientific knowledge or process that precedes, or follows, an individual research project involving hESCs ignores the linguistic context of the term in the Amendment. The term "research" in Dickey-Wicker does not stand alone; it is followed and informed by the phrase "in which . . . embryos are destroyed." Thus, the research for which federal funding is prohibited is, as a threshold matter, only that "in which" embryos are used. The term "in which" typically has a limiting connotation when used as a prepositional phrase. *See* RANDOM HOUSE DICT. (2009) (defining "in," as a preposition, to be "used to indicate limitation or qualification, as of situation, condition, relation, manner, action, etc."). Thus, the particular "research" that is prohibited must be that "in which" an embryo is actually involved.

In addition, the plaintiffs' overly broad interpretation ignores the fact that the research targeted by the plain language of Dickey-Wicker is limited to those situations in which embryos "are" destroyed. The Amendment uses only the present tense; it does not extend to prohibiting

research involving embryos that "had been" or "were" destroyed in the past or to any potential incentive for destructions in the future. *See Sutton v. United Air Lines*, 527 U.S. 471, 482 (1999) ("Because the phrase 'substantially limits' appears in the Act in the present indicative verb form, we think the language is properly read as requiring that a person be presently-not potentially or hypothetically-substantially limited in order to demonstrate a disability."), superseded by Pub. L. No. 110-325 (2009); *Jason v. Summerfield*, 214 F.2d 273, 276 (D.C. Cir. 1954) ("The tense of the verbs used, 'exist' and 'is,' was the present tense. The 'reasonable grounds' had to be actually or really in being, presently, at the time of review."). Had Congress intended to prohibit all funding for research involving hESCs that had been derived through a non-federally-funded extraction process that resulted in the destruction of an embryo, or research that (however indirectly) might provide such an incentive in the future, it could have done so expressly by applying the prohibition to past, or future, derivations.[9]

---

[9] The plaintiffs cite three sources for the proposition that the term "research" has been defined broadly. None of these sources supports, let alone commands, the reading proposed by the plaintiffs. For example, in *Merck KgaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005), the statute in question did not even include the term "research." Instead, after an extensive discussion of the purposes of the specific provision in question, the Court interpreted the broadly-worded phrase "reasonably related to the development and submission of *any* information" to include preclinical research. *Id.* at 202. In fact, the Court's discussion of different phases of "research," including the use of the term "preclinical research," demonstrates that the word is often used to describe discrete aspects of a research project. *Id.* at 204. Similarly, in *Nat'l Ctr. for Mfg. Sciences, Inc. v. City of Ann Arbor*, 563 N.W.2d 65 (Mich. App. 1997), the state court of appeals held that, for purposes of a tax exemption, a company can be engaged in research even if no experiments are conducted in its actual headquarters. The question of whether the result would have been different if the term "research" had been limited to property "in which" experiments are conducted is, of course, not answered by the language or purposes of this isolated tax provision. These very different statutory contexts and congressional purposes demonstrate why the use of words in different statutes often provides little guide in statutory analysis. *See, e.g., United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200 (2001) (explaining danger in relying on definition of same word in different statutory contexts); *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341-42 (1997) ("Similarly, that other statutes have been

The plaintiffs ask the Court to ignore these limitations in Dickey-Wicker, arguing that the Amendment's use of the phrase "knowingly subjected to risk of injury or death" applies to hESC research because of the future incentive that funding for this research purportedly provides for "additional, newly derived stem cells." Pls.' Mem. at 15-16. This forward-looking interpretation, however, still depends on a view of the phrase in a vacuum, divorced from its context in the Amendment. The phrase "knowingly subjected to risk of injury or death" still only applies to that "research in which a human embryo" is involved. Accordingly, the possibility that stem cell research, or federal funding for the same, might affect the incentives of private third-parties who are undisputedly prohibited from receiving federal funding for the derivation of stem cells, does not mean that hESC research is prohibited by the plain language of Dickey-Wicker.[10]

---

more specific in their coverage of 'employees' and 'former employees,' . . . proves only that Congress *can* use the unqualified term 'employees' to refer only to current employees, not that it did so in this particular statute."). Finally, the plaintiffs point to NIH Web site guidance concerning human subject research where entities are considered engaged in such research when their project includes activities involving human subjects carried out by agents of another institution. Pls.' Mem. at 10. Of course, this section of the guidance applies to those projects who have received an award *expressly* for non-exempt human subjects research, and the specific statutory language from which the guidance flows applies to such research "conducted at or *supported by* such entity." 42 U.S.C. § 289 (emphasis added). Accordingly, plaintiffs' reference does little to support their broad definition of the term "research" as applying in a separate statutory context limited to those projects in which embryos are actually involved.

[10] Congress, in many contexts, expresses an intent that federal funding provided to an organization not be used for a particular purpose, even though the organization might still conduct prohibited activities with non-federal funds. *See, e.g., Velazquez v. LSC*, 164 F.3d 757, 763-64 (2d Cir. 1999) (rejecting plaintiffs' argument that government misinterpreted act's prohibition on use of federal funds for certain purposes when it permitted organizations to create affiliate to engage in prohibited activities). It does not defeat the purpose of the Amendment to conclude that Congress could have intended in Dickey-Wicker to prohibit funding of hESC derivation only, and not hESC research entirely. *See* Statement of Senator Frist, 147 Cong. Rec. S7846-0, *S7850 (July 18, 2001) ("While we find it important to scientific research and ethically acceptable that limited and strictly regulated [hESC] research proceed, this does not mean that federal funds should be used in the derivation of [hESC] cells.").

Moreover, the plaintiffs' argument assumes a causal connection that they only surmise to exist. The Guidelines require that hESC lines used in research supported by federal funding have been derived from human embryos "[t]hat were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose," and "[t]hat were donated by individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." 74 Fed. Reg. at 32,174. Thus, whether more embryos would be harmed in the future as a result of federal funding of hESC research is not something that is or could be known, as it would still depend on whether the embryo would otherwise have been discarded due to the discretionary decision of third-party donors of embryos that ultimately turn out to exceed the donors' reproductive needs.

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

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

The plaintiffs next attempt to justify their broad reading of the term "research" by comparing the prohibition in Dickey-Wicker on federal funding for the "creation" of an embryo "for research purposes" and the prohibition on funding for "research in which . . . embryos are destroyed." Pls.' Mem. at 7-8. According to the plaintiffs, the different wording of these provisions demonstrates that the first has a narrow purpose in targeting "creation" while the second involves a broader category of "research" than simply the "destruction" of embryos.

However, that, by itself, is an unexceptional proposition. A research project need not expressly seek to destroy an embryo as the focus of its research to fall within Dickey-Wicker's prohibition. Thus, research projects with a broader focus, such as the refinement of preimplantation genetic techniques or the improvement of IVF methodologies, would be ineligible for federal funding if, as part of that research project, embryos were threatened with destruction. The relevant question for purposes of this dispute is whether the project must *actually involve* embryos. With respect to that question, it is necessary to look at the language of the second clause, including the meaning of the phrase "in which . . . embryos are destroyed," in order to understand that the funding prohibition requires that embryos actually be used in the research at issue.

The plaintiffs suggest that Congress could have, if it wanted to do so, expressly worded the clause so as to prohibit funding for "specific acts" that destroy embryos. Pls.' Mem. at 8. However, the better question is why, in light of the extensive discussion and debate over embryonic stem cell research for the past fifteen years, Congress, if it wanted to do so, did not simply prohibit federal funding for all research involving hESCs outright. As Congress's behavior since the passage of

Dickey-Wicker indicates, it did not do so because that is not what the Amendment commands.

c. Congress Has Expressly Interpreted Dickey-Wicker to Permit Federal Funding for Stem Cell Research that Is "Dependent Upon" the Destruction of Human Embryos

Since 1995, the Dickey-Wicker Amendment has been included in NIH's annual appropriations without substantive change. While the Amendment has not changed, however, there has been a fundamental shift in federal funding for stem cell research. As the plaintiffs note, HHS first announced its interpretation of the Dickey-Wicker Amendment in 1999, in an opinion by General Counsel Harriet Rabb, that the Amendment does not prohibit federal funding for research on hESCs, as such cells are not embryos. *See* Rabb Memorandum, Ex. D to Lingo Decl. Following the opinion and an opportunity for notice and comment, NIH promulgated final Guidelines containing this interpretation that were made effective on August 25, 2000. *See* 65 Fed. Reg. 51,976. Although these Guidelines were later stayed and ultimately withdrawn at the direction of President George W. Bush, Congress had the opportunity in the meantime to correct any purported misinterpretation of Dickey-Wicker by NIH when it considered whether to renew the amendment in appropriations for fiscal year 2001. Congress did not do so. Instead, four months after the issuance of the August 2000 Guidelines in which NIH interpreted Dickey-Wicker, but before President Bush issued his proclamation on federal funding for hESC research, Congress passed an appropriations bill that included Dickey-Wicker without substantive change.[11] *See* Pub. L. No. 106-

[11] In announcing the budget for fiscal year 2000, Senator Arlen Specter explained that the budget for NIH maintained the Dickey-Wicker Amendment, which permitted hESC research to "go forward now with private funding extracting the stem cells from embryos, and then the Federal funding coming in on the stem cells which have been extracted." 145 Cong. Rec. S11585-07, *S11586 (Sept. 29, 1999). Senator Specter explained that Dickey-Wicker would be retained due to the withdrawal of an initiative to "allow Federal funding to NIH on extracting stem cells from the embryos." *Id.* at *S11587; *see also* 146 Cong. Rec. S9447-01 (Sept. 28,

554, 114 Stat. 2763 (Dec. 21, 2000); *cf. Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 845-46 (1986) ("Congress has twice amended the [Act] since the [agency] declared by regulation [its position] but has not overruled the [agency's] assertion of jurisdiction.").

Lest its silence be deemed inconclusive, Congress would repeatedly make it clear during the Bush Administration that, in Congress's view, Dickey-Wicker does not prohibit federal funding for hESC research. Following President Bush's August 9, 2001, address, Congress reenacted Dickey-Wicker in substantially the same form in the 2002 budget for NIH, explaining that the Amendment was fully consistent with the President's policy of permitting research using certain hESCs that had been derived from embryos. *See* H.R. Rep. No. 107-229 at 180 (Oct. 9, 2001) ("The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells and carried out in accordance with policy outlined by the President."); *see also* S. Rep. No. 107-84 at 18 (Oct. 11, 2001) ("The Committee urges the NIH to move quickly to support all types of stem cell research, including embryonic, adult, and cord blood . . . .").

Since 2001, Congress has repeatedly expressed its view that President Bush's policy permitting research on stem cell lines in existence prior to August 9, 2001, did not violate Dickey-Wicker, despite the fact that such research necessarily "depended upon" the prior destruction of human embryos. *See* H.R. Rep. No. 110-231 (July 13, 2007); H.R. Rep. No. 108-636 (Sept. 7, 2004); H.R. Rep. No. 108-188 (July 8, 2003). And that intent has continued despite the change in administrations, as Congress repeated this language in the House Committee's statement regarding

---

2000).

the current year's NIH appropriation bill, despite the inauguration of President Obama one month earlier. 155 Cong. Rec. H2089-01, H2278 (Feb. 23, 2009). In fact, following the issuance of the final Guidelines at issue in this action, the House has passed a 2010 appropriations bill for NIH, currently under consideration by the Senate, that retains Dickey-Wicker. The Committee Report accompanying the bill explains that the bill's "language should not be construed to limit Federal support for research involving human embryonic stem cells carried out in accordance with policy outlined by the President." H.R. Rep. No. 111-220 (July 22, 2009).

Thus, since 2001, Congress has known that HHS and NIH would be providing federal funding for hESC research, and Congress has agreed that this funding is permitted by the language and purpose of Dickey-Wicker. In light of Congress's knowledge of and express acquiescence in the provision of federal funding for research on stem cells from derived human embryos, the plaintiffs' assertion that Congress unambiguously intends in its annual reenactment of Dickey-Wicker to prohibit federal funding for hESC research is simply not plausible. *See, e.g., FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000) ("[I]t is hardly conceivable that Congress—and in this setting, any Member of Congress—was not abundantly aware of what was going on."); *FDIC v. Philadelphia Gear Corp.*, 476 U.S. 426, 437 (1986) ("At no point did Congress criticize the FDIC's longstanding interpretation . . . .").

There is no dispute that the current Guidelines, in implementing President Obama's policy as expressed in Executive Order No. 13,505, expands on the research allowed by President Bush, as stem cell lines may now include those derived after August 9, 2001. However, the plaintiffs' broad interpretation of "research" conflicts with the policies of both administrations, as these policies similarly rely on the distinction between federal funding for the derivation of stem cells from

embryos, a process in which the embryo is destroyed, and research involving stem cell lines created after the stem cells themselves have been derived. When President Bush made his speech on August 9, 2001, he announced his support for federal funding for research involving hESC lines that had been derived following the passage of Dickey-Wicker, including lines derived from embryos during the late 1990's when it appeared that federal funding would first be available pursuant to federal guidelines. Thus, the plaintiffs' contention that, under President Bush, federal funding of hESC research was permitted because the "life and death" decision had already been made for the embryos from which the stem cells were derived is simply a fiction; the hESC research for which federal funding was permitted still depended upon the prior destruction of an embryo. Accordingly, the plaintiffs' distinction finds no support in the language of Dickey-Wicker.

In an attempt to show that Congress has not acquiesced in federal funding of hESC research, as demonstrated by its express permission for such funding under President Bush, the plaintiffs argue that NIH has inconsistently interpreted the Amendment. Pls.' Mem. at 12-13. As support for this argument, they point to an internal agency memorandum issued in 2002, as well as language in a 2001 Senate bill proposing to end existing limitations on stem cell research. *Id.* Neither action demonstrates that NIH has acted inconsistently with respect to its position that hESC research does not involve, and therefore does not pose harm to, embryos.

As an initial matter, the 2002 internal memorandum did not purport to evaluate whether HHS's position, as expressed in the 1999 Rabb memorandum or in the 2000 guidelines, was correct. Instead, the memorandum sought to evaluate whether President Bush's policy was legally defensible. In any event, the memorandum's findings on that score are consistent with the defendants' position that Dickey-Wicker permits federal funding for hESC research. In construing the language of the

Amendment, the 2002 memorandum expressly rejects the plaintiffs' broad interpretation of Dickey-Wicker, noting that the common usage and definitions of the words "in" and "which" imply a narrow connotation to the term "research." *See* Ex. B to Lingo Decl. at F-5.

Nor does the plaintiffs' citation to language from a Senate bill in 2001 demonstrate that Congress intended to reject NIH's interpretation. The plaintiffs argue that the bill contained language that would have amended Dickey-Wicker to expressly permit federal funding for all hESC research, yet this language was ultimately dropped when President Bush expressed his disapproval. However, the plaintiffs do not point to any indication by Congress as to why this language was dropped—a major omission because Congress may have rejected the language for numerous reasons, including deeming it unnecessary in light of the Amendment's application solely to research involving human embryos and their destruction. *See PBGC v. LTV Corp.*, 496 U.S. 633, 650 (1990) ("Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change.") (internal quotations omitted).

As the language of the Dickey-Wicker Amendment is ambiguous and does not on its face prohibit the NIH interpretation, repeated in the Guidelines, of the scope of the Dickey-Wicker prohibition, this Court should defer to the agency's interpretation. *Chevron*, 467 U.S. at 843.

2. NIH Complied with the Administrative Procedure Act in Issuing Its Guidelines

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

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

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

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

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

The bulk of the plaintiffs' arguments concern their views regarding the relevant merits, scientifically and ethically, of hESC research, adult stem cell research, and iPSC research. They assert that hESC research has been proven, as a categorical matter, to be inferior to the other two

forms of research, that it would be unethical for NIH to fund inferior hESC research in light of these alternatives, and that NIH therefore should have used the Guidelines as an opportunity to announce that it would reject all applications from researchers who proposed to pursue hESC research. The plaintiffs argue that NIH failed to respond adequately to commenters who sought such a categorical ban, Pls.' Mem. at 30-32, or that NIH otherwise failed to adequately explain its decision not to impose this ban, Pls.' Mem. at 16-25.

These arguments fundamentally misunderstand what was at issue in the rulemaking. By issuing Executive Order No. 13,505, President Obama removed the restrictions on federal funding that had been imposed by prior presidential action, thereby restoring the *status quo ante* in which research using hESC lines is eligible for federal funds. The Order declares the President's policy in favor of removing political "limitations on scientific inquiry," expanding "NIH support for the exploration of human stem cell research," and enhancing "the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." Exec. Order No. 13,505, § 1, 74 Fed. Reg. 10,667. In keeping with these policies, the Order informs NIH that it may "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law," *id.*, § 2, and directs NIH to review existing guidance documents on stem cell research, including provisions establishing appropriate safeguards, and to "issue new NIH guidance on such research that is consistent with this order," *id.*, § 3.

The President thus directed NIH to prepare guidance that would describe standards for the responsible conduct of federally-funded hESC research. NIH, of course, was not free to ignore the President's instructions. "[Executive Branch] officers are duty-bound to give effect to the policies

embodied in the President's direction, to the extent allowed by the law." *Bldg. & Constr. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 32 (D.C. Cir. 2002); *see also Sierra Club v. Costle*, 657 F.2d 298, 406 n.524 (D.C. Cir. 1981). NIH obviously would have acted inconsistently with the Order if it had refused to issue the Guidelines on the ground (as the plaintiffs would have it, contrary to the scientific consensus) that all hESC research, categorically, lacked merit, or if it had disagreed with the President's policy determination that the moral balance weighed in favor of potentially life-saving research and, thus, against a blanket ban on any one type of stem cell research.

Moreover, nothing in the Executive Order purported to override the ordinary operation of NIH's peer review system. As described above, NIH's statutorily-established procedures require that the merits of individual research proposals be decided on an application-by-application basis by expert reviewers. Those procedures do not contemplate that NIH will decide the merits of particular research proposals through rulemaking. It is therefore entirely unsurprising that NIH performed its duty under the Executive Order, which was to establish standards for hESC research, not to make categorical announcements as to the merits of hESC research or any other kind of research.

NIH thus properly addressed the matters that were at issue in the formulation of the Guidelines – namely, its decision as to the procedures required for the responsible pursuit of hESC research – and properly ignored matters that were not – namely, the relative merits of yet-to-be submitted applications for funds for hESC research or for any other kind of research. Those merits obviously are best addressed in the peer review process, not in a rulemaking conducted in advance of the review of individual applications. NIH was under no obligation to overturn the statutory peer review process and instead address the scientific merits of hESC research in this rulemaking. *See Mobil Oil Exploration & Producing Se. Inc. v. United Distrib. Co.*, 498 U.S. 211, 230 (1991)

(agency acted rationally by declining to address issue in rulemaking where "the agency could compile relevant data more effectively in a separate proceeding").

The plaintiffs next argue that NIH was required to address state laws that purportedly conflict with the Guidelines. Pls.' Mem. at 25. This argument is misplaced. First, the plaintiffs are simply wrong in their claim that Congress directed NIH to defer to state law on the subject of hESC research. Neither of the statutes misleadingly quoted by the plaintiffs requires anything of the sort. *See* 42 U.S.C. § 243(a) (authorizing HHS to "cooperate with . . . State[s] . . . in the enforcement of their quarantine and other health regulations"); 42 U.S.C. § 284(c)(1) (NIH directors shall coordinate institutes' research activities "with similar programs of other public and private entities"). In the absence of any Congressional direction to the contrary, the APA did not require NIH to discuss the general policy goals of any one state's law[12], or of any federal regulatory regime other than its own, before it issued the Guidelines. *See PBGC v. LTV Corp.*, 496 U.S. at 645-46. Moreover, the Guidelines do not in any way purport to pre-empt state law that regulates the disposition of embryos; they instead recite that NIH-funded research will be conducted "in accordance with applicable law." 74 Fed. Reg. at 32,170. It is up to each researcher to determine whether the research he proposes to

[12] Contrary to the plaintiffs' assertion, the overwhelming trend in state law is to recognize, either by statute or judicial decision, that the decision of how to dispose of embryos created during IVF treatment is a personal one that is best reserved to the person or persons who sought IVF treatment. *See, e.g.,* Cal. Health & Safety Code § 125315(b); Conn. Gen. Stat. § 19a-32d(c); Fla. Stat. Ann. § 742.17; 410 Ill. Comp. Stat. 110/5; Kan. Stat. Ann. § 65-6702; Md. Code Ann., Econ. Dev. § 10-438(c); Mass. Gen. Laws Ann. ch. 111L, § 4 (West Supp. 2008); Mich. Const. art. 1, § 27(2)(b); Mo. Const. art. 3, § 38(d); N.J. Stat. Ann. § 26:2Z-2; *see also, e.g., Cahill v. Cahill,* 757 So.2d 465, 468 (Ala. Civ. App. 2000); *In re Marriage of Witten*, 672 N.W.2d 768, 783 (Iowa 2003); *Kass v. Kass*, 696 N.E.2d 174, 180 (N.Y. 1998); *In re Marriage of Dahl*, 194 P.3d 834, 839 (Or. Ct. App. 2008), *review denied*, 204 P.3d 95 (Or. 2009); *Davis v. Davis*, 842 S.W.2d 588, 602-03 (Tenn. 1992); *Roman v. Roman*, 193 S.W.3d 40, 50 (Tex. App. 2006), *cert. denied*, 128 S. Ct. 1662 (2008); *Litowitz v. Litowitz*, 48 P.3d 261, 271 (Wash. 2002).

do or is doing (with or without federal funds) is consistent with state law. Consequently, there was no need for NIH to address a non-existent effect of the Guidelines. *Compare Wyeth v. Levine*, 129 S. Ct. 1187, 1201-02 (2009) (requiring reasoned explanation for agency's claim that regulation has preemptive effect).

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

The plaintiffs fare no better when they address the matters that were actually relevant in the process of formulating the final Guidelines. They claim that NIH failed to explain its reasoning adequately. The APA, however, requires only that "the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(c). NIH easily met this minimal standard.

The plaintiffs first contend that NIH should have prohibited researchers from having any contractual or other relationship with IVF clinics, and that NIH failed to explain its decision not to impose such a prohibition. Pls.' Mem. at 28. However, the Guidelines expressly require documentation of a "clear separation" between the decision to create embryos for reproductive purposes and the decision to donate embryos for research purposes, 74 Fed. Reg. at 32,174, specifically requiring further that the decision to create embryos for reproductive purposes should be free from the influence of any hESC researchers, *id.* As an additional safeguard, the Guidelines recommend that the physician attending to reproductive clinical care and the hESC researcher be different persons, unless separation is not practicable. *Id.*

With respect to the last requirement, NIH explained that it did not categorically prohibit attending physicians involved in reproductive care or treatment from also performing hESC research,

as such a categorical rule would not be required for "ethical donation" so long as the other mandatory requirements of the Guidelines are fulfilled. 74 Fed. Reg. at 32,173. The Guidelines themselves explain what NIH considered to be "ethical donation"—the donation of embryos that "were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose." *Id.* at 32,174. The Guidelines assure that this standard is met by requiring documentation of a clear separation between the decision to create embryos for reproductive purposes and the decision to donate embryos, and documentation that the donors' decision is free from influence from any researchers. Given these multiple safeguards, it is apparent that NIH considered, and rejected, the notion that an additional prophylactic rule was required to ensure that embryos were created for reproductive purposes only.

Second, the plaintiffs argue, cryptically, that NIH did not adequately explain why the Guidelines did not require that donors in all instances be informed of the alternative of "embryo adoption." Pls.' Mem. at 30. The Guidelines require that donors be informed of "[a]ll options available in the health care facility where treatment was sought pertaining to the embryos," 74 Fed. Reg. at 32,174, thereby expressly requiring information on "embryo adoption" if that alternative is available. NIH explained that it could only reasonably require IVF clinics to explain the alternatives that actually are available at that particular facility. *Id.* at 32,173. NIH cannot be faulted for not requiring information on an alternative unavailable at the donors' chosen IVF facility.

The plaintiffs further argue that NIH failed to explain adequately its choice of wording in its description of the Guidelines' informed consent procedures. Pls.' Mem. at 32. As noted above, the Guidelines require documentation showing that a donor was informed of a series of matters, including in particular that the donor be informed "[w]hat would happen to the embryos in the

derivation of hESCs for research." 74 Fed. Reg. at 32,174. The plaintiffs argue that NIH should have required specific language to the effect that the donated embryo would be destroyed. The plaintiffs fail to explain how such language would add any substance to what the Guidelines already require. In any event, NIH fully explained its reasoning in declining the plaintiffs' suggestion:

> Given the wide variety and diversity of forms, as well as the various policy, statutory and regulatory obligations individual institutions face, the NIH declines to provide exact wording for consent forms, and instead endorses a robust informed consent process where all necessary details are explained in an ongoing, trusting relationship between the clinic and the donor(s).

74 Fed. Reg. at 32,173. NIH acted reasonably by requiring that donors be informed in substance of the effect that donation would have on an embryo, while recognizing that people of good will with differing beliefs would choose different terminology to describe that effect.

In each instance, NIH's response to the plaintiffs' suggestions "demonstrates that [it] considered and rejected [their] arguments . . . . This is all that the APA requires." *City of Waukesha v. EPA*, 320 F.3d 228, 258 (D.C. Cir. 2003); *see also Pub. Citizen*, 988 F.2d at 197.

c. NIH Allowed Sufficient Time to Comment

The plaintiffs next argue that NIH allowed insufficient time to comment on the draft Guidelines. Pls.' Mem. at 34. This claim borders on the frivolous. The draft Guidelines established a 33-day period in which the public could submit comments. 74 Fed. Reg. at 18,578. This more than satisfied the minimal requirements of the APA. "Notice is adequate if it provides 'interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.'" *Omnipoint Corp. v. FCC*, 78 F.3d 620, 629 (D.C. Cir. 1996) (quoting 5 U.S.C. § 553(c)). The APA does not require that the comment period be any particular length, so long as notice is adequate. *See id.* (upholding 7-day comment period); *see also Florida Power & Light Co.*

v. United States, 846 F.2d 765, 772 (D.C. Cir. 1988) (upholding 15-day comment period).

There can be no serious dispute that NIH provided the public with a sufficient opportunity to comment on the draft Guidelines. NIH received approximately 49,000 comments on the Guidelines. 74 Fed. Reg. at 32,170.[13] Among the comments that NIH received was the plaintiffs' 113-page submission. (Lingo Decl., Ex. B.) The opportunity for comment was obviously no empty formality; NIH made a number of substantive changes to the final Guidelines in response to the public comments. *See, e.g.,* 74 Fed. Reg. at 32,171 (revising definition of human embryonic stem cell); *id.* at 32,173 (requiring donor to be informed they may withdraw consent until embryos are used, or information linking embryos to donors is no longer retained). The plaintiffs and others had, and exercised, a meaningful opportunity to comment on the draft Guidelines. The APA requires nothing further. *See Omnipoint Corp.*, 78 F.3d at 629-30; *Florida Power & Light Co.*, 846 F.2d at 772; *Conf. of State Bank Supervisors v OTS*, 792 F. Supp. 837, 844 (D.D.C. 1992).

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

The plaintiffs lastly argue that the Guidelines should be invalidated because Acting NIH Director Kington purportedly held a predisposition in favor of federal funding for human embryonic stem sell research. Pls.' Mem. at 35. There is a strong presumption that agency decision-makers act in good faith. For that reason, agency action is judged on the basis of the reasons that the agency has

[13] Notwithstanding the plaintiffs' contrary claim, NIH accepted and reviewed all of these comments, with the exception of a small number of inappropriate submissions, such as spam emails or submissions that used offensive language. Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm. That NIH did not respond to every comment it received, whether because the comment dealt with matters outside the scope of the Guidelines, was duplicative, or for any other reason does not mean the comment was not reviewed.

stated therefor, and an inquiry into the decision-maker's supposed bad faith is only permitted in exceedingly narrow circumstances. *See United States v. Morgan*, 313 U.S. 409, 421-22 (1941). This presumption applies with particular force to rulemakings. A decision-maker "may be disqualified [from an informal rulemaking] only where there has been a clear and convincing showing that [he] has an unalterably closed mind on matters critical to the disposition of the proceeding." *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979)).

The plaintiffs do not come close to making such a showing. They rely on a comment attributed to Acting Director Kington in a newspaper article published after the final Guidelines were issued, to the effect that NIH had received a large number of comments debating whether hESC research should be funded at all, and that those comments did not speak to the issue under consideration in the draft Guidelines. But, as noted above, the Executive Order required NIH to draft guidelines that would implement the President's policy decision to "expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." Exec. Order No. 13,505, § 1, 74 Fed. Reg. 10,667. Commenters who asked the NIH to refuse to follow the Executive Order simply did not speak to any matter that was actually at issue in the rulemaking, and the Acting Director did not display any disqualifying bias by so stating. "An agency should not apologize for being predisposed to implementing the goals that Congress [or, here, the President] has set for it. To call such an attitude 'bias' . . . misses this central point." *Ass'n of Nat'l Advertisers*, 627 F.2d at 1168 (internal quotation omitted; ellipses in original); *see also C&W Fish Co. v. Fox*, 931 F.2d 1556, 1565 (D.C. Cir. 1991) (agency official may express policy views without being

disqualified from rulemaking).[14]

The plaintiffs also refer to, but grossly mischaracterize, an April 2009 NIH notice that they allege shows that the agency pre-determined the content of the Guidelines. That notice governed the status of funds for stem cell research pending the issuance of the final Guidelines. It recited that previously-approved stem cell research could continue, but that "no new uses of human embryonic stem cells may be initiated" before the final Guidelines were issued. It further recited that NIH would hold applications for new funding for hESC research until after the Guidelines became final, after which time applications could be modified if necessary. NOT-OD-09-85 (Apr. 17, 2009), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html. The Notice does not contain the slightest hint – let alone "a clear and convincing showing" – that Acting Director Kington, or any other person, prejudged any aspect of the Guidelines.

Finally, the plaintiffs rely on comments attributed to the Acting Director in a newspaper article to the effect that the number of cell lines eligible for funding would increase. This is a simple truism. As a result of the proclamation of President Bush on August 9, 2001, and his subsequent Executive Order, only 21 embryonic stem cell lines were eligible for use in federally-funded research before Executive Order No. 13,505 lifted the restrictions imposed in the prior Administration. NIH, *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp. As the newspaper article cited by the plaintiffs recites, there are significantly more than 21 hESC lines already in existence that were ineligible for use in federally-funded research until President Obama's

---

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

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

II. The Plaintiffs Cannot Satisfy the Remaining Requirements for the Issuance of a Preliminary Injunction

A. The Plaintiffs Have Not Shown Irreparable Harm that Would Justify the Extraordinary Remedy of a Preliminary Injunction

This Circuit "has set a high standard for irreparable injury. First, the injury must be both certain and great; it must be actual and not theoretical. The moving party must show the injury complained of is of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm. Second, the injury must be beyond remediation. . . . The key word in this consideration is irreparable." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297-98 (D.C. Cir. 2006) (internal quotations omitted). The plaintiffs, in their motion filed approximately six weeks after the effective date of the Guidelines, do not remotely make any showing that they face any injury at all, let alone one that is immediate and irreparable.

The plaintiffs first assert that the "plaintiff embryos" face irreparable injury. This Court should not indulge the fiction that embryos are proper plaintiffs in this proceeding, or that embryos have any judicially-cognizable rights that could override the informed decisions of persons who sought IVF treatment, but who no longer needed the embryos for reproductive purposes. *See* Defs.' Opp. to Pls.' Mot. for Appt. of Guardian *ad Litem*. The plaintiffs next argue that Nightlight or the potential embryo adopters would be harmed if federal funds were available for hESC research. But, as has been explained above, the Guidelines only apply where human embryonic stem cell lines have

been created from embryos that have been freely donated by persons who have been informed of all of the available alternatives. These plaintiffs' fear of injury is thus entirely theoretical; they do not show any link, let alone an imminent one, between the eligibility of hESC research for federal funds and the availability of embryos for adoption. Lastly, the researcher plaintiffs argue that they face injury in that they later might not be awarded funds from NIH. This, too, is an entirely theoretical concern. The researchers' fear that they face increased competition in later funding decisions does not in any sense show a "clear and present" need for preliminary relief.

B. The Issuance of a Preliminary Injunction Would Harm Other Parties, and Is Contrary to the Public Interest

There are a multitude of parties who would be substantially injured if the Guidelines were to be enjoined. Millions of people suffer from serious ailments, such as Alzheimer's disease, Parkinson's disease, and type 1 diabetes, for whom hESC research holds out the promise of treatment. These people have waited for years for federal restrictions to be lifted for research into potentially life-sustaining treatment. Of less significance – but still outweighing the concerns of the plaintiffs – are the interests of hESC researchers, who have waited for a fair opportunity to pursue their scientific research on a level playing field. These researchers' interest in obtaining federal funds obviously is no less than that of the plaintiff researchers here.

The public interest weighs strongly against the issuance of a preliminary injunction. Numerous recent studies continue to demonstrate that hESC research is likely to lead to major advances in medicine. *See supra* at 4. There is a strong public interest that artificial "limitations on scientific inquiry" be removed, in order "to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." Exec. Order No.

13,505, § 1, 74 Fed. Reg. 10,667.

CONCLUSION

For the foregoing reasons, the defendants respectfully request that the Court deny the plaintiffs' motion for a preliminary injunction. The defendants further respectfully request that the Court dismiss the complaint for lack of jurisdiction or, in the alternative, for failure to state a claim based on the arguments contained herein.

Dated: September 14, 2009

Respectfully submitted,

TONY WEST
Assistant Attorney General

CHANNING D. PHILLIPS
Acting United States Attorney

/s/ Eric Womack
SHEILA M. LIEBER, IL Bar No. 1567038
Deputy Director
ERIC R. WOMACK, IL Bar No. 6279517
JOEL McELVAIN, DC Bar No. 448431
Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave., NW
Washington, DC 20001
Tel: (202) 514-4020
Fax: (202) 616-8470

Attorneys for Defendants