UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. JAMES L. SHERLEY, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civ. No. 1:09-cv-1575 (RCL)
KATHLEEN SEBELIUS, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

I. Introduction

Two scientists brought this lawsuit, asking this Court to find that the National Institutes of Health Guidelines for Human Stem Cell Research ("Guidelines") are invalid as a matter of law. The Court's initial dismissal of plaintiffs' case for lack of standing was reversed on appeal, and plaintiffs' Motion for Preliminary Injunction was reinstated. The Court promptly granted plaintiffs' Motion for Preliminary Injunction, but was again reversed on appeal, and the Court must now determine the merits of the case. Before the Court are plaintiffs' Motion for Summary Judgment, Pls.' Mot. Summ. J. [55], and defendants' Motion for Summary Judgment. Defs.' Mot. Summ. J. [58]. Having carefully considered the motions, oppositions, replies, supplemental briefing, the entire record in this case, and the applicable law, the Court will grant defendants' Motion for Summary Judgment and deny plaintiffs' Motion for Summary Judgment. A review of the background of the case, the governing law, the parties' arguments, and the Court's reasoning in resolving those arguments follows.

II. Background

The human body comprises over 200 different cell types—muscle cells, skin cells, nerve cells, and so on—that perform all of its particular functions. AR at 588. These specialized cells, however, are all the descendants of a pool of unspecialized cells in the early human embryo, which divide, grow, and transform into all of the body's cells in a manner whose orderliness and complexity boggles the mind. *Id.* This case involves those unspecialized cells, called "embryonic stem cells," which can be transformed into any one of the hundreds of cell types found in the human body.

Embryonic stem cells are one of three types of human stem cells, with the other two being adult and induced pluripotent[1] stem cells. Embryonic stem cells are found in human embryos, and are made available for scientific research by a process—called "derivation"—that destroys the embryo. Once embryonic stem cells are derived, they can be used to create "lines" of stem cells that replicate indefinitely and provide a constant source of cells for research purposes. AR at 704. A second type of stem cell—adult stem cells—are, unlike embryonic stem cells, "limited to producing only certain types of specialized cells," and "are found in certain tissues in fully developed humans, from babies to adults." AR at 589. The third type of stem cell—induced pluripotent stem cells—are mature cells that have been "reprogrammed" using viruses so that their development reverses course, returning them to a condition similar to that of embryonic stem cells. AR at 718. Like embryonic stem cells, induced pluripotent stem cells can transform into hundreds of specialized human cells, although just how similar induced pluripotent stem cells are to embryonic stem cells remains unknown. *Id.*

[1] "Pluripotent" means, in the context of stem cells, capable of transforming into all of the cell types of the human body. Embryonic stem cells are naturally pluripotent. Induced pluripotent stem cells are mature cells that become pluripotent through scientific manipulation. AR at 84.

Scientific interest in stem cells is driven by the recognition that, because they can be coaxed into forming particular body tissues, they hold the potential to advance medical science dramatically. AR at 587. Scientists hope to develop treatments for numerous diseases and conditions that continue to plague human beings—such as cancer, diabetes, and cardiovascular disease—by using stem cells to replace or rebuild damaged cells and tissues. *Id.* Since adult stem cells were first discovered in the 1950s, scientists have achieved success using such cells to develop treatments for human disease. AR at 593. But embryonic and induced pluripotent stem cells have only been available for scientific study since 1998, AR at 693, and so proven and safe therapeutic options involving these cell types are likely to require substantial additional research and time. AR at 600. Given the differences between the various stem cell types and their advantages and disadvantages as sources of potential therapies, the National Institutes of Health ("NIH") "believes that it is important to simultaneously pursue all lines of research." AR at 705.

Controversy has surrounded embryonic stem cell research since 1998, when scientists first succeeded in isolating and culturing stem cells from human embryos. In 1999, the NIH, finding that embryonic stem cells were "enormously important to science" and held "great promise for advances in health care," requested public comment on draft guidelines for funding embryonic stem cell research "in an ethical and legal manner." Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576, 67,576 (proposed Dec. 2, 1999). The NIH recognized that the establishment of stem cell lines from embryos had "generated much interest among scientists and the public, particularly among patients and their advocates, especially with regard to the ethical issues related to this research." *Id.*

Funding embryonic stem cell research with taxpayers' dollars raised legal issues as well. Federal funding potentially conflicted with a Congressional law, first enacted in 1996, known as the "Dickey-Wicker Amendment." That Amendment, reenacted every year since 1996 without alteration, prohibits the NIH from funding:

> (1) the creation of a human embryo or embryos for research purposes; or
> (2) 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)).

Consolidated Appropriations Act, 2010, Pub. L. 111-117, § 509(a), 123 Stat. 3034, 3280–81 (2009). The Dickey-Wicker Amendment defines "embryo" as "any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells." *Id.* at § 509(b).

Aware of possible conflict between the NIH's plan to fund embryonic stem cell research and the Dickey-Wicker Amendment, the Director of the NIH requested a legal opinion in 1998 from the Office of the General Counsel of the Department of Health and Human Services ("HHS") on "whether NIH funds may be used for research using human pluripotent stem cells."[2] 64 Fed. Reg. at 67,576. The NIH received that opinion in January 1999, in the form of a memorandum from former HHS General Counsel Harriet S. Rabb. AR at 311. Ms. Rabb concluded that the NIH could legally fund embryonic stem cell research. *Id.* She wrote that although the Dickey-Wicker Amendment prohibited funding for research involving embryos, embryonic stem cells "are not a human embryo" as defined by the Amendment. *Id.* Ms. Rabb noted that the Dickey-Wicker Amendment defined an "embryo" as an "organism," and that

[2] The NIH, in referring to "human pluripotent stem cells," is talking about embryonic stem cells (which are pluripotent).

scientific understanding recognized a distinction between the basic units of living creatures, such as stem cells, that cannot exist independently of the body for long, and organisms themselves, which perform on their own all of the life functions that allow them to grow and reproduce. AR at 312–13. She determined that stem cells "are not even precursors to human organisms," because stem cells can only develop into different cell types within the human body, while embryos can potentially develop into human organisms. *Id.* Based on Ms. Rabb's legal advice, the Director of the NIH convened a Working Group of the Advisory Committee to the Director to develop "appropriate guidelines governing . . . research involving the use of pluripotent stem cells derived from early human embryos in excess of clinical need." 64 Fed. Reg. at 67,577.

The guidelines were published in August 2000. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,976 (Aug. 25, 2000). The NIH had received about 50,000 public comments from "members of Congress, patient advocacy groups, scientific societies, religious organizations, and private citizens" in response to its guidelines. *Id.* Some commenters argued that the guidelines conflicted with the Dickey-Wicker Amendment; that they were too restrictive; that they were unnecessary; or that research on human embryonic stem cells was itself unnecessary because adult stem cells were satisfactory substitutes. *Id.* In response to commenters who questioned the NIH's decision to fund embryonic stem cell research in addition to adult stem cell research, the NIH concluded that "it is important to simultaneously pursue all lines of promising research," and presented a number of differences between adult and embryonic stem cells that warranted research on the latter. *Id.* The final guidelines required applicants for NIH grants to provide assurance that the stem cells used in the research were derived from only certain human embryos. *Id.* at 51,979. Embryos slated for derivation had to be "created for the purposes of fertility treatment" and "in excess of

the clinical need of the individuals seeking such treatment." *Id.* Various other conditions in the guidelines were designed to ensure that the embryo donor's consent was voluntary and informed. *Id.* at 51,979–80.

A change in Presidential administrations resulted in a significant change to federal stem cell policy. In August 2001, President George W. Bush stated in an evening address to the nation that "[e]mbryonic stem cell research offers both great promise and great peril." Address to the Nation on Stem Cell Research from Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 13, 2001), AR at 21. He recognized that this research "could help improve the lives of those who suffer from many terrible diseases." *Id.*, AR at 19. He noted that the United States has a long history of advancing science and medicine, as well as a "proud record of upholding the highest standards of ethics" while expanding science's limits. *Id.* Embryonic stem cell research, President Bush stated, "raises profound ethical questions" because the derivation process destroys the embryo from which stem cells are derived, therefore "destroy[ing] its potential for life." *Id.* "Like a snowflake, each of these embryos is unique, with the unique genetic potential of an individual human being." *Id.*

Torn between his confidence in the healing power of science and his belief that "human life is a sacred gift from our Creator," President Bush made what many have called a "Solomonic" decision: to permit federal funding for embryonic stem cell research, but only for such research as involved stem cells derived from embryos that had already been destroyed, where "the life and death decision has already been made." *Id.*, AR at 21. Like the previous administration, President Bush refused to impose a categorical ban on embryonic stem cell research, but he substituted a temporal limitation in the place of the embryo-source and informed consent limitations reflected in the NIH's then-current guidelines. Federal funding was available

only for embryonic stem cell research using stem cells derived from embryos that were destroyed before August 9, 2001—the date of President Bush's address to the nation. *Id.*

Since President Bush's policy continued to permit some federal funding for embryonic stem cell research, once again there were questions concerning whether even that, more restrictive, policy complied with the Dickey-Wicker Amendment. Dr. Ruth Kirchstein, then Acting Director of the NIH, received a legal opinion on the issue in January 2002 from HHS General Counsel Alex M. Azar II. AR at 303. Mr. Azar concluded that President Bush's policy was consistent with the plain language of the Dickey-Wicker Amendment. AR at 306. He looked to the ordinary and common meaning of the phrase "research in which" used in the text of the Amendment. *Id.* Mr. Azar cited to a dictionary that defined "in" as meaning "within the confines of; inside"; "within the area covered by"; "during the course of or before the expiration of"; "during or part of the act or process of"; "within the category or class of." AR at 307. He did not specifically define the term "research." Mr. Azar concluded that since President Bush's policy would provide federal funding only for stem cell lines created before his August 9, 2001 address and because it "provides no incentive for the destruction of additional embryos," the policy "does not provide federal funding for 'research in which [during the course of, during or part of the act or process of, or within the category or class of] embryos are destroyed, discarded, or knowingly subjected to risk of injury or death . . . .'" *Id.*

The winds of Federal stem cell policy shifted again in 2008, with the election of Barack Obama as President. In March 2009, President Obama issued an Executive Order nullifying former President Bush's stem cell policy. Exec. Order No. 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 11, 2009), AR at 12. The Order's purpose was to remove President Bush's limitations on the NIH's ability to fund and conduct human embryonic stem cell research, thereby "enhanc[ing]

the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." *Id.* President Obama authorized the NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." *Id.* He directed the NIH to publish new guidelines on human stem cell research consistent with his Order within 120 days. *Id.*

Several weeks later, the NIH requested public comment on draft guidelines. Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18,578, 18,578 (proposed Apr. 23, 2009). The NIH stated that the purpose of the draft guidelines was to implement President Obama's Executive Order, "to establish policy and procedures under which NIH will fund research in this area, and to help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law." *Id.* The proposed guidelines would permit funding for embryonic stem cell research using stem cells derived from embryos created for reproductive purposes and no longer needed for that purpose. *Id.* They also contained provisions ensuring that research funds would only go to research projects using stem cells that were derived from embryos that had been donated with the informed consent of the donor. *Id.* at 18,579. As such, these proposed guidelines represented a return to the policy and funding approach that existed before President Bush's administration.

The NIH, as it had back in 2000, received nearly 50,000 comments in response to its draft guidelines. National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,170 (July 7, 2009). In its final Guidelines, the NIH responded to certain categories of public comments that it had received, including comments indicating that the informed consent procedures set out in the draft guidelines were duplicative with existing procedures or too cumbersome, that the allowable sources of embryonic stem cells should be

expanded to embryos created solely for research purposes, and that the NIH's mechanisms for ensuring ongoing compliance with the guidelines were lacking. *Id.* at 32,171–74.

In the course of responding to comments seeking clarification of its statement in the draft guidelines that embryonic stem cells "are not themselves human embryos," 74 Fed. Reg. at 18,578, the NIH presented its longstanding interpretation of the Dickey-Wicker Amendment as not prohibiting federal funding for embryonic stem cell research because human embryonic stem cells "are not embryos" as defined by the Amendment. 74 Fed. Reg. at 32,173. The NIH stated further that the Guidelines "recognize the distinction, accepted by Congress, between the derivation of stem cells from an embryo that results in the embryo's destruction, for which Federal funding is prohibited, and research involving [human embryonic stem cells] that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted." *Id.*

The NIH also received numerous comments objecting to any federal funding whatsoever for embryonic stem cell research. *See e.g.*, AR at 2644. Commenters sought a categorical ban on embryonic stem cell research either for ethical or scientific reasons, or both. The NIH did not respond to such comments, believing them to be outside the scope of the rulemaking. Defs.' Mot. Summ. J. [58] 37. The NIH made minor revisions to the draft guidelines in response to certain comments, and then published the final Guidelines, with an effective date of July 7, 2009. *Id.* at 32,170.

A legal challenge to the Guidelines came swiftly. In August 2009, a group of plaintiffs, including Drs. James L. Sherley and Theresa Deisher—both of whom are scientists performing research involving adult stem cells—filed a lawsuit in this Court against various defendants, including the National Institutes of Health. Plaintiffs claimed that the Guidelines violated the

Dickey-Wicker Amendment and were promulgated in violation of the Administrative Procedure Act. Compl. [1] ¶1, 2. They sought declarations that the Guidelines are not in accordance with law, were promulgated without the observance of required procedures, are arbitrary and capricious, and that past acts by the NIH pursuant to the Guidelines, including previous decisions to fund embryonic stem cell research projects, are null and void. *Id.* at ¶79. They also sought to enjoin defendants from taking any future actions of any kind pursuant to the Guidelines or otherwise funding embryonic stem cell research. *Id.* That same day, they filed a Motion for Preliminary Injunction seeking an immediate cessation of actions taken pursuant to the Guidelines. Pls.' Mot. Prelim. Inj. [3] 1.

Defendants filed a Motion to Dismiss, arguing that plaintiffs lacked standing under Article III of the Constitution and that they had failed to state a claim for which relief could be granted. Defs.' Mot. Dismiss [22] 2. This Court granted defendants' motion, concluding that no plaintiff met all of the requirements of standing and that therefore the Court lacked subject matter jurisdiction over the lawsuit. *Sherley v. Sebelius*, 686 F. Supp. 2d 1, 3 (D.D.C. 2009). With respect to Drs. Sherley and Deisher, the Court noted that they had alleged in their Complaint that the Guidelines had increased competition for limited NIH funds and would therefore make it more difficult for them to compete successfully for those funds. *Id.* at 6. The Court found, however, that mere "increased competition for funding is an insufficient injury to impart standing." *Id.*

Plaintiffs appealed, challenging only this Court's determination that Drs. Sherley and Deisher lacked standing. The Court of Appeals for the District of Columbia reversed, finding that both Dr. Sherley and Dr. Deisher had standing. *Sherley v. Sebelius*, 610 F.3d 69, 70 (D.C. Cir. 2010). It held that Drs. Sherley and Deisher suffered an "actual, here-and-now injury"

because "the Guidelines have intensified the competition for a share in a fixed amount of money," with the result that "plaintiffs will have to invest more time and resources to craft a successful grant application." *Id.* at 74. The Court reversed this Court's Order dismissing plaintiffs' claims while also reinstating plaintiffs' Motion for Preliminary Injunction. *Id.* at 75.

With plaintiffs' Motion for Preliminary Injunction ripe for decision, this Court promptly ruled and found that "the likelihood of success on the merits, irreparable harm to plaintiffs, the balance of the hardships, and public interest considerations each weigh in favor of a preliminary injunction." *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 70 (D.D.C. 2010). In particular, this Court concluded that the Guidelines violated the Dickey-Wicker Amendment's prohibition on federal funding for "research in which a human embryo or embryos are destroyed." *Id.* at 70 (quoting Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009)). This Court determined that the term "research" had "only one meaning, *i.e.*, 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.'" *Id.* (quoting 45 C.F.R. § 46.102(d)). Rejecting defendants' argument that "research" meant "a piece of research," this Court found that the Dickey-Wicker Amendment's prohibition "encompasses *all* 'research in which' an embryo is destroyed, not just the 'piece of research' in which the embryo is destroyed." *Id.* at 71. After concluding that embryonic stem cell research is research in which an embryo is destroyed according to the Dickey-Wicker Amendment, this Court held that the Guidelines violated that Amendment and that plaintiffs had shown a strong likelihood of success on the merits. *Id.* at 71–72. This Court applied the other preliminary injunction factors, found them to be satisfied, and granted plaintiffs' motion. *Id.* at 73.

Defendants sought and received a stay of this Court's injunction from the D.C. Circuit, which later vacated the injunction on appeal. *Sherley v. Sebelius*, No. 10-5287, 2011 WL 1599685, at *1 (D.C. Cir. Apr. 29, 2011). Contrary to this Court's conclusion, the Court of Appeals held that "plaintiffs are unlikely to prevail [on the merits] because Dickey-Wicker is ambiguous and the NIH seems reasonably to have concluded that, although Dickey-Wicker bars funding for the destructive act of deriving an [embryonic stem cell] from an embryo, it does not prohibit funding a research project in which an [embryonic stem cell] will be used." *Id.* The Court determined that the meaning of the word "research" is "flexible enough to describe either a discrete project or an extended process." *Id.* at *6.

Having determined the statute to be ambiguous, the Court of Appeals proceeded to step two of the framework set out in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), which requires judicial deference to an agency interpretation of an ambiguous statute so long as it reflects a "permissible construction of the statute." 467 U.S. at 842–43. While noting that defendants had not defined "research" in so many words, the Court rejected plaintiffs' contention that defendants had not offered an interpretation warranting judicial deference by concluding that NIH's use of the term "research" implicitly gave it a narrow scope. *Sherley*, 2011 WL 1599685, at *6. After concluding that the NIH's implicit interpretation was reasonable, *id.* at *7–8, the Court held that plaintiffs had failed to show that they were likely to succeed on the merits and that the other preliminary injunction factors weighed against the award of a preliminary injunction. *Id.* at *10.

With the preliminary injunction order vacated by the Court of Appeals, the lawsuit returned to this Court for review of the parties' competing motions for summary judgment.

III. Standard of Review

Summary judgment is the appropriate mechanism for deciding whether agency action is supported by the administrative record and is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C.A. § 706(2)(A) (2011). The district court judge "sits as an appellate tribunal" in such cases. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "The 'entire case' on review is a question of law." *Id.* Therefore, the usual summary judgment standard doesn't apply. Instead, it is the agency's role to resolve factual issues and reach a decision that is supported by the administrative record, and it is the judge's role to determine whether the evidence in the administrative record "permitted the agency to make the decision it did." *Stuttering Found. of Am. v. Springer*, 498 F. Supp. 2d 203, 207 (D.D.C. 2007) (quoting *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 769 (9th Cir. 1985)).

IV. Analysis

Before the Court are plaintiffs' Motion for Summary Judgment and defendants' Motion for Summary Judgment. Plaintiffs argue that the Guidelines should be set aside because they violate the Dickey-Wicker Amendment and were promulgated in violation of the APA; plaintiffs contend that nothing in the D.C. Circuit's opinion vacating the preliminary injunction compels this Court to reach a different conclusion. Pls.' Supplemental Br. [82] 1. Defendants seek an award of summary judgment in their favor, countering that the D.C. Circuit's opinion dealt a mortal wound to plaintiffs' Dickey-Wicker Amendment claims and that plaintiffs' APA claims likewise fail because they are premised upon a basic misunderstanding of what was at issue in the NIH's promulgation of the Guidelines. Defs.' Supplemental Mem. [81] 1, 10 n.4. The Court will discuss these and other arguments in the analysis that follows.

A. Standing

Defendants continue to press their claim that the Court lacks subject matter jurisdiction over this lawsuit because plaintiffs lack standing under Article III of the Constitution. Defs.' Mot. Summ. J. [58] 14–15. To establish standing, a plaintiff must identify an injury in fact that is actual or imminent and traceable to the challenged action of the defendant, and show as well that it is likely, and not merely speculative, that a favorable decision would redress the plaintiff's injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Sherley*, 610 F.3d at 72. A plaintiff claiming standing under the APA must also show that the requirements of prudential standing are satisfied by demonstrating that his or her claims fall "arguably within the zone of interests to be protected or regulated by the statute in question." *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 488 (1998); *Sherley*, 610 F.3d at 74.

Defendants do not argue that plaintiffs' alleged injuries are not traceable to the Guidelines or redressable by this Court, or that plaintiffs cannot meet the requirements of prudential standing. Instead, defendants argue that plaintiffs' declarations "continue to show that they have suffered no injury as a result of the Guidelines." Defs.' Mot. Summ. J. [58] 13. With respect to Dr. Deisher, defendants say that she "has still not even submitted a grant application to NIH," indicated "when she might actually submit an application," or shown "that the research she proposes would actually be accepted or deemed scientifically worthy." *Id.* at 13–14. Defendants argue that Dr. Deisher therefore has failed to show that she is an "active competitor for funding from NIH." Defs.' Reply Mem. [73] 3.

With respect to Dr. Sherley, defendants note that he has "at least alleged that he has submitted two applications to NIH . . . [and that] the guidelines 'will result in increased competition'," but "[he] still does not allege that he has expended any extra effort or lost any

funding as a result of this supposed competition." Defs.' Mot. Summ. J. [58] 14. Responding to plaintiffs' claim that Dr. Sherley has in fact expended extra effort by submitting "more applications for funding than ever before in his career," Pls.' Combined Reply [72] 6, defendants say that the "mere submission of more applications, regardless of their merit, was not the injury predicted by the D.C. Circuit, which thought instead that a scientist would have to expend 'more time and resources to craft a *successful* grant application.'" Defs.' Reply Mem. [73] 4 (quoting *Sherley*, 610 F.3d at 74).

Plaintiffs generally respond by arguing that "the question of Plaintiffs' standing has been resolved by the D.C. Circuit's opinion." Pls.' Mot. Summ. J. [55] 12. They argue that the D.C. Circuit held that "the undisputed increased competition that Plaintiffs face as a result of the Guidelines—and not any loss of funding or injury *resulting* from the increased competition—is sufficient in and of itself to confer Article III standing." Pls.' Combined Reply [72] 4.

In its opinion reversing this Court's determination that plaintiffs' lacked standing, the D.C. Circuit explained that the doctrine of competitor standing "addresses the [injury-in-fact requirement of Article III standing] by recognizing that economic actors 'suffer [an] injury in fact when agencies lift regulatory restrictions on their competitors or otherwise allow increased competition' against them." *Sherley*, 610 F.3d at 72 (quoting *La. Energy & Power Auth. v. FERC*, 141 F.3d 364, 367 (D.C. Cir. 1998)). The Court of Appeals recognized the various ways in which increased competition could injure a plaintiff, including losing sales, being forced to lower prices, and "expend[ing] more resources to achieve the same sales." *Id.* Furthermore, "[b]ecause increased competition almost surely injures a seller in one form or another, he need not wait until 'allegedly illegal transactions . . . hurt [him] competitively' before challenging the . . . governmental decision that increases competition." *Id.* (quoting *La. Energy*, 141 F.3d at

367). A plaintiff must show "an actual or imminent increase in competition, which increase we recognize will almost certainly cause an injury in fact." *Id.* at 73.

Turning to Drs. Sherley and Deisher, the Court of Appeals found that the "Doctors have met the basic requirement for competitor standing." *Id.* at 74. Because there is a fixed amount of money available for research grants, and because the Guidelines will increase the number of grant applications involving embryonic stem cells, the "Guidelines have intensified the competition" for those limited funds. *Id.* Because of that competition, "plaintiffs will have to invest more time and resources to craft a successful grant application. That is an actual, here-and-now injury." *Id.*

This Court concludes that plaintiffs' reading of the D.C. Circuit's opinion is the correct one, and that plaintiffs have Article III standing. Defendants' arguments are based upon a basic misreading of the D.C. Circuit's opinion—namely, defendants contend that the Court concluded that plaintiffs must show not only an increase in competition but also specific injuries caused by that increased competition in order to satisfy the injury in fact requirement. But the Court of Appeals made clear that increased competition alone is "an actual, here-and-now injury" because "plaintiffs will have to invest more time and resources to craft a successful grant application." *Id.* The Court of Appeals was not, as defendants suggest, "predicting" that plaintiffs might, at some point in the future, have standing if they could show that the increased competition caused them to suffer specific injuries. It concluded that they had standing "here and now" because the Guidelines had changed the playing field, requiring plaintiffs to expend more resources than they would otherwise have had to expend in order to win a grant from the NIH. This "here and now" injury is as present today as it was when the D.C. Circuit held that plaintiffs had Article III

standing. Defendants have not offered any evidence suggesting that the Guidelines' effect on the competition for NIH grants has changed or been negated by other factors.

Therefore the Court finds that plaintiffs have standing under the ruling of the District of Columbia Circuit Court of Appeals.

B. Whether the Guidelines Violate the Dickey-Wicker Amendment

The APA states that a reviewing court "shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." § 706(2)(A). Plaintiffs argue that the Guidelines violate the Dickey-Wicker Amendment in two different ways. First, they argue that the Dickey-Wicker Amendment unambiguously prohibits federal funding for embryonic stem cell research because such research is "research in which a human embryo or embryos are destroyed . . . ." Pls.' Mot. Summ. J. [55] 13 (quoting Pub. L. No. 111-117, § 509(a)(2), 123 Stat. 3034, 3280–81 (2009)). Second, plaintiffs argue that federal funding for embryonic stem cell research is barred because it is "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . . ." Pls.' Supplemental Br. [82] 3 (quoting § 509(a)(2), 123 Stat. at 3280–81).

Defendants respond that the Guidelines do not violate the Dickey-Wicker Amendment because funding for embryonic stem cell research is not prohibited by the law. They claim that HHS has "consistently interpreted Dickey-Wicker as prohibiting federal funding for the 'derivation of stem cells from an embryo that results in the embryo's destruction,' but permitting federal funding for 'research involving [human embryonic stem cells] that does not involve an embryo nor result in an embryo's destruction.'" Defs.' Mot. Summ. J. [58] 15 (quoting 74 Fed. Reg. at 31,173, AR at 4). Defendants seek judicial deference to their interpretation of the

Dickey-Wicker Amendment under the standard articulated in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). The D.C. Circuit has summarized the *Chevron* standard as follows:

> Under the *Chevron* analysis, judicial review of an agency's interpretation of a statute under its administration is limited to a two-step inquiry. At the first step, we inquire into whether Congress has directly spoken to the precise question at issue. If we can come to the unmistakable conclusion that Congress had an intention on the precise question at issue, our inquiry ends there; this Court naturally must give effect to the unambiguously expressed intent of Congress.
>
> However, if the statute before us is silent or ambiguous with respect to the specific issue before us, we proceed to the second step. At this stage, we defer to the agency's interpretation of the statute if it is reasonable and consistent with the statute's purpose; we are not free to impose our own construction on the statute, as would be necessary in the absence of an administrative interpretation.

Nuclear Info. Resource Serv. v. Nuclear Regulatory Comm'n, 969 F.2d 1169, 1173 (D.C. Cir. 1992) (en banc) (citations, internal quotation marks, and brackets omitted).

The Court will proceed to examine each of plaintiffs' Dickey-Wicker Amendment claims in the light of the *Chevron* standard and the D.C. Circuit's conclusions in *Sherley v. Sebelius*, No. 10-5287, 2011 WL 1599685, at *1 (D.C. Cir. Apr. 29, 2011).

1. "Research in which a human embryo or embryos are destroyed . . ."

a. *Chevron* step one

Chevron requires the Court to consider whether Congress, in the Dickey-Wicker Amendment, has provided an answer to the following question: whether embryonic stem cell research is "research in which a human embryo or embryos are destroyed . . . ." § 509(a)(2), 123 Stat. at 3280–81. Plaintiffs argue that by funding embryonic stem cell research, the Guidelines violate this provision of the Dickey-Wicker Amendment. Pls.' Mot. Summ. J. [55] 13 (quoting § 509(a)(2), 123 Stat. at 3280–81). They contend that the statute's prohibition against "funding

any 'research in which' embryos are destroyed necessarily encompasses *all* of the research project at issue, not merely a selected 'phase' or 'piece' of research." *Id.* at 16.

At the outset, the Court notes that the D.C. Circuit's opinion, vacating the award to plaintiffs of a preliminary injunction, constrains this Court on remand. As stated above, this Court initially agreed with plaintiffs' understanding of the Dickey-Wicker Amendment, finding that the term "research" in the statute bore only the broader meaning of a "systematic investigation, including research and development, testing and evaluation, designed to develop or contribute to generalizable knowledge." *Sherley*, 704 F. Supp. 2d at 70 (quoting 45 C.F.R. § 46.102(d)). On appeal, however, the D.C. Circuit rejected this Court's view, concluding that the text of the Dickey-Wicker Amendment is ambiguous. *Sherley*, 2011 WL 1599685, at *6. The D.C. Circuit stated clearly that the term "research" is "flexible enough to describe either a discrete project or an extended process," a fact that reinforces that Court's "conclusion that the text is ambiguous." *Id.* Therefore, absent a compelling reason to depart from that holding, the Court is constrained to adopt it at this stage of the proceedings.

Plaintiffs suggest that the Court may disregard the D.C. Circuit's opinion. They state that "although the D.C. Circuit majority did not find a likelihood of success on the argument that the Guidelines fund research in which embryos are destroyed, this Court is not precluded from granting Plaintiffs summary judgment based on that claim . . . ." Pls.' Supplemental Br. [82] 2. Plaintiffs cite *University of Texas v. Camenisch*, 451 U.S. 390 (1981), which held that "the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits." *Camenisch*, 451 U.S. at 395. This is because a "decision denying a preliminary injunction 'rests on nothing more than a tentative appraisal of the probable result

on the merits,' and thus it generally 'do[es] not constitute law of the case.'" Pls.' Supplemental Br. [82] 9 (quoting *Wilcox v. United States*, 888 F.2d 1111, 1114 (6th Cir. 1989)).

Plaintiffs err in urging this Court, via an exception to the law-of-the-case doctrine, to disregard the D.C. Circuit's opinion. That doctrine doesn't apply here. The doctrine known as "law of the case" states that when a court decides upon a rule of law, that decision should continue to apply to the same issues in later stages of the same case. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 815–16 (1988). The doctrine "promotes the finality and efficiency of the judicial process by 'protecting against the agitation of settled issues.'" *Id.* at 816 (quoting *Moore's Federal Practice* ¶ 0.404[1] (1984) 118). Since the law-of-the-case doctrine "merely expresses the practice of courts generally to refuse to reopen what has been decided, not a limit to their power," it is discretionary. *Id.* at 817 (quoting *Messinger v. Anderson*, 225 U.S. 436, 444 (1912)). However, courts should follow the rule "in the absence of extraordinary circumstances . . . ." *Id.*

However, this isn't a situation where a court is asked to exercise its discretion by reconsidering a rule of law that it decided in a prior stage of the case. Nor are the facts of this case similar to *Camenisch*, where the district court's award of a preliminary injunction and finding that the plaintiff was likely to succeed on the merits were upheld on appeal. *Camenisch*, 451 U.S. at 392–93. Here, the Court of Appeals, vacating this Court's decision to award plaintiffs a preliminary injunction, ruled as a matter of law that the term "research" in the Dickey-Wicker Amendment is ambiguous. *Sherley*, 2011 WL 1599685, at *6. This situation is properly governed—not by the law-of-the-case doctrine and its exceptions—but by the "mandate rule," which posits that "[w]hen matters are decided by an appellate court, its rulings, unless reversed by it or by a superior court, bind the lower court." *Ins. Group Comm. v. Denver &*

R.G.W.R. Co., 329 U.S. 607, 612 (1947). Whereas the law-of-the case doctrine promotes finality and efficiency, the mandate rule promotes the additional interest of hierarchy. *See Doe v. Chao*, 511 F.3d 461, 465 (4th Cir. 2007); *see also* 18B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 4478 (2d ed. 1987) (stating that "[t]he very structure of a hierarchical court system demands" that a lower court on remand be bound by the law of the case established on appeal). "This is not to say that appellate courts are somehow superior or always correct, but only that our system has been served well by the availability of review and the need for appropriate review to be final." *Doe*, 511 F.3d at 465.

The Court's determination that it is bound by the D.C. Circuit's conclusion that "research" in the Dickey-Wicker Amendment is ambiguous as a matter of law is buttressed by the fact that plaintiffs haven't offered any new information or reasoning that was unavailable to the D.C. Circuit and that would cause this Court to consider departing from that Court's holding as to the meaning of "research." This issue was carefully briefed and argued before both this Court and the Court of Appeals, and the only thing that has changed since this Court first considered the question of whether "research" in the statute is ambiguous is that the D.C. Circuit has made it abundantly clear that the term is ambiguous as a matter of law. While it may be true that by following the Court of Appeals' conclusion as to the ambiguity of "research," this Court has become a grudging partner in a bout of "linguistic jujitsu," *Sherley*, 2011 WL 1599685, at *10 (Henderson, J., dissenting), such is life for an antepenultimate court.

Therefore the D.C. Circuit's conclusion that the term "research" in the Dickey-Wicker Amendment is ambiguous binds this Court.

b. *Chevron* step two

Since the Dickey-Wicker Amendment doesn't answer the precise question at issue because "research" has been determined to be ambiguous in the statute, the Court must proceed to step two of *Chevron*, which requires deference to the NIH's interpretation of the Dickey-Wicker Amendment if it is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843.

Plaintiffs, however, argue that even if the Court concludes that the statute is ambiguous, defendants would not deserve judicial deference because they have never "proffered an authoritative interpretation of 'research' that this Court could analyze for reasonableness under *Chevron*." Pls.' Mot. Summ. J. [55] 22. Plaintiffs argue that the only interpretation provided by defendants is their statement in the Guidelines that the Dickey-Wicker Amendment is not violated because embryonic stem cells "are not embryos" as defined by the Dickey-Wicker Amendment. *Id.* at 23 (quoting 74 Fed. Reg. at 32,173). Plaintiffs claim that it is irrelevant whether embryonic stem cells are or are not embryos, and that to receive deference defendants should have answered the question of whether the derivation of stem cells from embryos "occurs as part of [the] 'research' that receives funding." *Id.* Because, according to plaintiffs, defendants did not answer that question "in a rule carrying the force of law [], there is no interpretation to which this Court can defer." *Id.* Plaintiffs further argue that defendants' "*post hoc* litigation position" on the definition of "research" should receive no deference because it's not the product of the agency's expertise, Pls.' Combined Reply [72] 22–23, but merely a "definition cribbed from a dictionary." Pls.' Mot. Summ. J. [55] 24.

Defendants concede that the Guidelines do not themselves explicitly set out the definition of "research" relied upon for their interpretation of the Dickey-Wicker Amendment. Defs.'

Opp'n [57] 30–31. However, they argue that they are not required to define every term of a statute to receive deference for their interpretation, *id.*, and that the guidelines do in fact contain "an extensive interpretation of the application of Dickey-Wicker to [human embryonic stem cell] research." Defs.' Reply [73] 17. Defendants claim that their interpretation in the guidelines makes clear "[the NIH's] understanding of the term research to permit a distinction between the stem cell extraction process and research using the stem cells that had already been derived." *Id.* 17–18. Defendants also defend their use of a dictionary to define "research" as "expressly permitted under step one [of *Chevron*] to assist the Court in understanding whether the relevant statutory language compels plaintiffs' interpretation." Defs.' Reply [73] 18.

The D.C. Circuit's opinion, unfortunately for plaintiffs, has taken the question of deference to the NIH's interpretation off the table. The Court of Appeals considered the question of deference to the NIH's interpretation of the Dickey-Wicker Amendment, and found that deference was due. *Sherley*, 2011 WL 1599685, at *8. The Court determined that the NIH's use of the term "research" in the Guidelines "implicitly but unequivocally gave [it] a narrow scope, thus ensuring no federal funding will go to a research project in which an embryo is destroyed." *Id.* at *6. On the question of whether NIH's implicit, narrower definition of "research" was reasonable, the Court of Appeals looked to the surrounding terms—such as Congress's use of "in which" and "are" instead of "for which" and "were"—as well as Congress's reenactment of the Dickey-Wicker Amendment year after year despite its knowledge that the NIH had been funding embryonic stem cell research since 2001, to conclude that the NIH's interpretation was "entirely reasonable." *Id.* at *8.

Once again, plaintiffs haven't offered any new information or reasoning that was unavailable to the D.C. Circuit and that would cause this Court to consider departing from that

Court's decision to afford deference to defendants' interpretation. Plaintiffs' arguments reprise those made to, and ultimately rejected by, the Court of Appeals as it reviewed this Court's decision to grant a preliminary injunction. *See* Brief of Appellees at 35–37, *Sherley v. Sebelius*, No. 10-5287 (D.C. Cir. Oct. 28, 2010).

Therefore this Court, following the D.C. Circuit's reasoning and conclusions, must find that defendants reasonably interpreted the Dickey-Wicker Amendment to permit funding for human embryonic stem cell research because such research is not "research in which a human embryo or embryos are destroyed . . . ."

2. "Research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . ."

Plaintiffs also argue that embryonic stem cell research violates the Dickey-Wicker Amendment's prohibition on funding "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . . ." Pls.' Combined Reply [72] 13 (citing § 509(a)(2), 123 Stat. at 3280–81). They assert that "the Guidelines . . . have created a need for additional, newly derived human embryonic stem cells, and thus for the destruction of additional human embryos. As a consequence, it is incontrovertible that by funding embryonic stem cell research, Defendants . . . are knowingly subjecting additional embryos to risk of death." Pls.' Mot. Summ. J. [55] 19.

Defendants acknowledge that the "court of appeals did not directly dispose of this argument," Defs.' Supplemental Mem. [81] 5, but suggest that the Court had its doubts about whether it is "distinct from the plaintiffs' principal argument that all [embryonic stem cell] research is research in which an embryo is destroyed . . . ." *Sherley*, 2011 WL 1599685, at *9. Defendants argue that "the language on which plaintiffs rely—referring to embryos that are 'knowingly subjected to risk of injury or death'—applies only to 'research in which' that harm

will occur." Defs.' Supplemental Mem. [81] 5. Defendants understand the Dickey-Wicker Amendment only to bar funding for research projects "in which an embryo is knowingly subjected to a risk of harm in the context of the embryo's use in that particular project." *Id.* According to this interpretation, the Dickey-Wicker Amendment only bars funding for research projects "*actually involving* an embryo" and that pose "risk to that embryo, such as preimplantation genetic diagnosis[3] . . . ." Defs.' Reply [73] 11 n.8.

Plaintiffs respond that defendants' argument "requires a blatant rewriting of the statutory text" because it "depends upon adding the term 'involved' as a condition for the ban in the statute." Pls.' Supplemental Br. [82] 5. They believe that the Dickey-Wicker Amendment bans funding for research that knowingly subjects *any* embryos—involved in the research or not—to risk of injury or death. *Id.*

a. *Chevron* step one

Again following the *Chevron* two-step analysis, the Court must first determine whether the Dickey-Wicker Amendment provides a clear answer to the following question: whether embryonic stem cell research is "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . . ." To answer this question, "the court must exhaust the traditional tools of statutory construction." *S. Cal. Edison Co. v. F.E.R.C.*, 195 F.3d 17, 22 (D.C. Cir. 1999). The starting point is the text itself, and the Court must consider the statutory language at issue as well as the language and design of the statute as a whole. *Id.* at 23.

The Court has already concluded that the term "research" in the Amendment is ambiguous, having either the narrow meaning of a discrete research project or the broader

[3] Preimplantation genetic diagnosis ("PGD") is a procedure used with embryos fertilized in vitro to determine if they carry mutations predisposing them to hereditary diseases. AR at 84. PGD requires the removal of one cell from the embryo. AR at 696. PGD is ineligible for federal funding because it poses a risk of harm to embryos involved in the procedure. Defs.' Reply Mem. [73] 10 n.6.

meaning of an extended process of research. Because that word is ambiguous, the Court already determined that the Dickey-Wicker Amendment's plain text did not answer the question of whether embryonic stem cell research is "research in which a human embryo or embryos are destroyed . . . ." The same is true here, in the case of the "subjected to risk" prong. If "research" is defined broadly as an extended process of research that includes the derivation step, then clearly embryonic stem cell research would be "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . ." because derivation not only subjects embryos to risk, but results in their destruction. In fact, under the broad definition of "research," the most germane language in the Dickey-Wicker Amendment would be its prohibition on funding "research in which a human embryo or embryos are destroyed . . . ," not its prohibition on funding research in which embryos are knowingly subjected to risk.

However, if "research" is defined narrowly as a research project or "piece" of research, federal funding of embryonic stem cell research would not violate the Dickey-Wicker Amendment. The text contains limiting language that, in combination with a narrow definition of "research," compels this conclusion.

The key limiting words are the words that directly follow "research" in the statute: "in which." "In" means "contained or enclosed by; inside; within . . . ." *Webster's New World Dict. of the Am. Language, College Ed.* 1664 (1968); *see also Am. Heritage Dict., Second College Ed.* 3141 (1985) (defining "in" as "within the limits, bounds, or area of . . . ."). "Which," on the other hand, is a word that is "used as a relative pronoun preceded by *that* or a preposition in a clause that defines or restricts the antecedent . . . ." *Am. Heritage Dict.* at 1376. Taken together, the words "in which" restrict the types of research for which funding is prohibited to research that knowingly subjects a human embryo or embryos to risk of injury or death *within* the

research. An example of such a prohibited piece of research would be, as defendants note, preimplantation genetic diagnosis. That research (unlike derivation) doesn't necessarily destroy human embryos, but it subjects them to some risk of injury or death *inside* that research. Therefore, the NIH cannot fund preimplantation genetic diagnosis. However, if human embryos are knowingly subjected to risk not *in* the research itself but *from* or *as a result of* it, federal funding would not be prohibited by the Dickey-Wicker Amendment because such research isn't "research *in which* a human embryo or embryos are . . . knowingly subjected to risk or injury or death . . . ." *See* Defs.' Supplemental Mem. [81] 5 ("[Congress] could have chosen the phrase '*from which*' had it meant the prohibition to extend beyond the discrete research project in question to reach any possible future incentive for destruction.").

If the ambiguous word "research" is interpreted to mean a "piece of research," it follows that embryonic stem cell research would not be "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death" because embryonic stem cell research doesn't knowingly subject embryos to risk of injury or death *in* that research. It doesn't include or involve embryos such that they could be knowingly subjected to risk *in* the research. This is not, as plaintiffs contend, adding the word "involve" to the statute. Pls.' Supplemental Br. [82] 5. This reading emerges entirely from Congress's choice of the words "in" and "which." If Congress had intended to expand the types of prohibited research to include research "from which" or "as a result of which" embryos are subjected to risk, it had available to it prepositions other than "in" that would have made that intention effective. Congress could even have chosen a much more straightforward grammatical construction by prohibiting "research *that knowingly subjects* embryos to risk of injury or death."[4] Research can subject something to risk without

[4] In fact, plaintiffs nearly concede that this alternative language would have achieved the result they seek when they say that "[b]y the statute's plain terms, any federally funded research *that subjects embryos to more than minimal*

involving it. But the awkward passive construction Congress chose appears tailor-made to accommodate the preposition "in" and the restrictions that it brings, as it was certainly not chosen for its literary merit.

Therefore the Court concludes that it must proceed to step two of *Chevron* because the plain text of the Dickey-Wicker Amendment doesn't answer the question of whether embryonic stem cell research is "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . . ."

b. *Chevron* step two

Since the Dickey-Wicker Amendment doesn't answer the question of whether embryonic stem cell research is "research in which a human embryo or embryos are . . . knowingly subjected to risk," the Court must defer to the NIH's interpretation of the Amendment if it is based upon a permissible construction of the statute. *Chevron*, 467 U.S. at 843.

The Court has already concluded that deference is due to defendants' interpretation of the term "research" in the context of plaintiffs' first Dickey-Wicker Amendment claim. As noted by the Court of Appeals and discussed above, that narrow definition of "research" favored by the NIH is not explicitly set out in the Guidelines but follows implicitly from the NIH's determination that the Guidelines do not violate the Dickey-Wicker Amendment because embryonic stem cell research, unlike derivation, "does not involve an embryo [or] result in an embryo's destruction . . . ." 74 Fed. Reg. at 32,173. This statement by the NIH in the Guidelines would make no sense if the broader definition of research as an extended process of research were employed, since it would clearly make embryonic stem cell research merely a later step in a process of research that included the derivation step. Also, as the quotation from the NIH's

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risk violates the funding ban . . . ." Pls.' Combined Reply [72] 13 (emphasis added). That, however, is not the statute's "plain terms": it prohibits federal funding for "research *in which* a human embryo or embryos are subjected to risk," § 509(a)(2), 123 Stat. at 3280–81 (emphasis added), not "research that subjects embryos to risk."

Guidelines makes clear, the NIH presented its view in the Guidelines that the Dickey-Wicker Amendment did not bar funding of embryonic stem cell research because that research "does not *involve* an embryo . . . ." 74 Fed. Reg. at 32,173 (emphasis added).

The conclusion that the NIH reasonably interpreted the Dickey-Wicker Amendment's "knowingly subjected to risk" language to permit federal funding for embryonic stem cell research follows naturally once "research" is narrowly defined. The NIH reasonably concluded that the Dickey-Wicker Amendment prohibited federal funding for research projects "in which" human embryos are knowingly subjected to risk, such as preimplantation genetic diagnosis, but did not prohibit research projects, such as embryonic stem cell research, that do not involve embryos and so cannot knowingly subject them to risk "in" the research. As stated in the Court's consideration of *Chevron* step one, Congress had available to it alternative formulations—such as "from which" or "as a result of which"—that would have indicated an intent to prohibit research projects that, while not involving embryos, nevertheless knowingly subjected them to risk. Congress, however, did not choose those words, preferring "in which" and leading the NIH to the reasonable conclusion that the Dickey-Wicker Amendment is only concerned with research involving embryos.

The Court also notes that plaintiffs' interpretation of the Dickey-Wicker Amendment's "knowingly subjected to risk" prong would require the Court to read the various prongs of the Amendment in inconsistent ways, despite the fact that each one shares the same key words: "research in which a human embryo or embryos are . . . ." § 509(a)(2), 123 Stat. at 2380–81. Taking, for example, the "destroys" prong, the obvious reason why derivation cannot be funded and embryonic stem cell research can be is that derivation involves and destroys embryos while embryonic stem cell research does not. The whole definitional battle over the breadth of the

term "research" was intended to determine where the embryo was involved. While it might be true that embryonic stem cell research, without involving embryos, could nevertheless cause their destruction, that involvement in the research is required to make out a violation of the Dickey-Wicker Amendment's "destroys" prong. Likewise, only research "in which" embryos are involved and discarded violates the "discarded" prong of the Amendment, not research that leads or contributes to that result without involving embryos. Plaintiffs' would have the final prong of the Amendment ("subjected to risk") constitute the only prong of the Amendment where embryos need not be involved, clashing with the requirements of the Amendment's previous prohibitions and the clear impact of the words "in which" on the meaning of the Amendment.

Furthermore, plaintiffs' view would lead to such a far-reaching construction of the Dickey-Wicker Amendment that it would prohibit federal funding for research entirely unrelated to embryos or embryonic stem cells if the research nevertheless posed some risk to embryos—for example, a research project involving dangerous chemicals or explosive gasses that was in the vicinity of an embryo storage facility—even if the risk of harm to the embryos was merely minimal. *See* Pls.' Combined Reply [72] 15–16. A tank of propane in an adjacent laboratory would be enough, no matter what sort of research the scientists in that laboratory were engaged in. But the language of the statute doesn't bear this strange result. The availability to Congress of alternative formulations for the statute's prohibitions—such as using "from which" or "as a result of which" instead of "in which"—compels the conclusion that by choosing "in which," Congress intended to restrict in a reasonable way the types of research that run afoul of the

Dickey-Wicker Amendment's prohibition on federal funding for "research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death . . . ."[5]

Therefore the Court finds that the NIH's conclusion that embryonic stem cell research is not "research in which a human embryo or embryos are . . . subjected to risk of injury or death . . ." is based upon a permissible construction of the statute and entitled to deference.

C. Whether the Guidelines Were Promulgated in Violation of the APA

Plaintiffs argue that even if the Guidelines do not violate the Dickey-Wicker Amendment, they must nevertheless be vacated because they were promulgated in violation of the Administrative Procedure Act. Pls.' Supplemental Br. [82] 6. Plaintiffs argue that defendants violated the APA's notice-and-comment requirements by (1) failing to respond to relevant and significant public comments, Pls.' Mot. Summ. J. [55] 26; and (2) entering the rulemaking period with an "unalterably closed mind." *Id.* at 31. Plaintiffs want the Guidelines set aside because, they argue, by failing to examine relevant data and articulate a satisfactory explanation for the decision to fund embryonic stem cell research, defendants acted arbitrarily and capriciously within the meaning of 5 U.S.C. § 706(2)(A).

Agency rulemaking must comply with section 553(b)-(c) of the APA, which requires notice of the proposed rulemaking, an opportunity for interested persons to comment on the proposed rule, and a "concise general statement" of the rule's basis and purpose. 5 U.S.C.A. §

[5] Many of the words in the Dickey-Wicker Amendment—"destroy," "discard," "create"—do not strictly require the direct application of force. *See Babbitt v. Sweet Home Chapter of Cmtys. for a Greater Oregon*, 515 U.S. 687, 701 (1995). Therefore if Congress had decided to prohibit federal funding for "research *that* destroys, discards, or knowingly subjects embryos to risk of injury or death," this Court would be inclined to favor a broader construction of the Amendment. Research could destroy, discard, or subject to risk embryos without directly involving them. But Congress specifically chose the narrower meaning by prohibiting funding of "research *in which* an embryo or embryos *are . . . knowingly subjected* to risk of injury or death . . . ." The text clearly indicates that it is "in" the research that embryos are destroyed, discarded, or subjected to risk of harm.

553(b)-(c) (2011); *see also Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 (D.C. Cir. 1977). These requirements assist judicial review and also "provide fair treatment for persons affected by a rule." *Home Box Office*, 567 F.2d at 35. The agency must respond to "significant points raised by the public," *id.* at 35–36, but only if such comments, "if true, raise points relevant to the agency's decision and . . . , if adopted, would require a change in the agency's proposed rule . . . ." *Id.* at 35 n.58. The APA's procedural requirements would likewise be rendered meaningless if an agency member had "an unalterably closed mind on matters critical to the disposition of the proceeding." *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979).

Plaintiffs argue that defendants violated the APA when they "completely ignored every public comment categorically objecting to funding of embryonic stem cell research, despite the fact that those comments plainly were relevant to the proposed rulemaking and raised significant questions about the ethical and scientific problems with such research." Pls.' Mot. Summ. J. [55] 26. Defendants agree that the APA requires that the NIH "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.'" Defs.' Mot. Summ. J. [58] 33 (quoting *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977)). However, defendants argue that plaintiffs "fundamentally misunderstand what was at issue in the Guidelines." *Id.* at 34. Defendants, interpreting Executive Order 13,505, say that President Obama "directed NIH to prepare guidance that would describe standards for the responsible conduct of federally-funded [human embryonic stem cell] research," *id.* at 35, not to determine through rulemaking whether embryonic stem cell research should be federally funded at all. Defendants contend that the NIH was "duty-bound to follow the Executive Order unless it was statutorily prohibited from doing so." Defs.' Reply Mem. [73]

20 (citing *Bldg. & Constr. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 33 (D.C. Cir. 2002)).

Plaintiff's argument for notice-and-comment violations fails for two reasons: (1) because the NIH's notice of proposed rulemaking did not invite (and therefore the NIH wasn't obligated to respond to) comments on the topic of *whether* to fund human embryonic stem cell research; and (2) because the President's Executive Order 13,505 required the promulgation of Guidelines for funding embryonic stem cell research, and the NIH wasn't obligated to consider comments that, if adopted, would cause it to disobey the President and create an unlawful rule.

As the D.C. Circuit has held, "[t]he whole rationale of notice and comment rests on the expectation that the final rules will be somewhat different and improved from the rules originally proposed by the agency." *Trans-Pacific Freight Conference v. FMC*, 650 F.2d 1235, 1249 (D.C. Cir. 1980). To that end, the NIH called for comment on draft guidelines that would "implement Executive Order 13505," "establish policy and procedures under which NIH will fund research in this area, and [] help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law." 74 Fed. Reg. at 18,578. In its notice of proposed rulemaking, the NIH did not invite comments on the topic of whether embryonic stem cell research should be funded at all, nor was it obligated to do so simply because plaintiffs believe such comments are relevant. *See Cable & Wireless P.L.C. v. F.C.C.*, 166 F.3d 1224, 1235 (D.C. Cir. 1999) (rejecting a claim that the FCC ignored relevant comments because the comments at issue were not solicited in the notice of proposed rulemaking). Plaintiffs' comments would not, if adopted, lead to improvements in the Guidelines' scheme for funding ethically responsible and scientifically worthy embryonic stem cell research—they would lead instead to a wholesale ban on such funding. The NIH rightly disregarded comments

that provided no assistance regarding the task at hand: to create guidelines for funding embryonic stem cell research that would ensure that funded projects are ethically responsible and scientifically worthy.

Nor is the NIH's decision to disregard such comments surprising given that President Obama's Executive Order 13,505 required the NIH to promulgate guidelines for funding embryonic stem cell research. The NIH reasonably interpreted the Executive Order to demand new guidelines that would govern the funding of responsible and scientifically worthy embryonic stem cell research projects, and had it adopted the views of the commenters who categorically objected to such funding and banned it altogether, its rule would have violated the law.

As an initial matter, an agency is presumed to have special expertise in interpreting executive orders charged to its administration, and so judicial review must afford considerable deference to agency interpretations of such orders. *Udall v. Tallman*, 380 U.S. 1, 16–17 (1965); *Kester v. Campbell*, 652 F.2d 13, 15–16 (9th Cir. 1981). Therefore, to determine whether the NIH reasonably understood the scope of the rulemaking that led to the final Guidelines requires an examination of the President's Executive Order 13,505. "An executive order is, for many purposes, a form of presidential 'law'." *Meyer v. Bush*, 981 F.2d 1288, 1303 n.6 (D.C. Cir. 1993). A regulation that is inconsistent with an executive order that authorizes its promulgation is unlawful. *Itek Corp. v. First Nat'l Bank of Boston*, 704 F.2d 1, 7 (1st Cir. 1983) (citing *Peters v. Hobby*, 349 U.S. 331, 345–46 (1955)). Since the NIH is an executive agency subject to the President's supervisory authority, if it can lawfully implement an Executive Order, it must do so. *Bldg. & Construction Trades Dep't*, 292 F.3d at 33. Executive Order 13,505 therefore establishes the issues—and comments—relevant to the NIH's promulgation of the Guidelines.

The Executive Order is titled "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells." Exec. Order No. 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 11, 2009) (AR at 12). The Order is short, and has five sections. Section 1 (titled "Policy") explains that human stem cell research, including embryonic stem cell research, may lead to advances in medical science and that the purpose of the Order is to remove limitations placed upon embryonic stem cell research by previous Presidential actions. *Id.* Section 2 (titled "Research") states that the "Secretary of Health and Human Services . . . , through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including embryonic stem cell research, to the extent permitted by law." *Id.* Section 3 of the Order ("Guidance") orders the Secretary to issue new guidance on human stem cell research "that is consistent with this order." Section 4 ("General Provisions") states that the Order "shall be implemented consistent with applicable law," and contains some other provisions. Finally, Section 5 ("Revocations") orders that one of former President Bush's statements on stem cell policy would have no further effect and that one of his executive orders concerning embryonic stem cell research is revoked.

The purpose of President Obama's Order, as it clearly states, "is to remove . . . limitations" on the "authority of the Department of Health and Human Services, including the National Institutes of Health," "to fund and conduct human embryonic stem cell research . . . ." *Id.* The "limitations" President Obama is talking about were the result of "Presidential actions"—specifically, the actions of then-President George W. Bush. President Obama nullified two such actions: (1) President Bush's statement of August 9, 2001, which permitted federal funding only for research using embryonic stem cell lines already in existence at the time of the statement, Address to the Nation on Stem Cell Research from Crawford, Texas, 37 Weekly

Comp. Pres. Doc. 1149 (Aug. 13, 2001), AR at 21; and (2) Executive Order 13,435, 72 Fed. Reg. 34,591, 34,591 (Jun. 20, 2007), which supplemented President Bush's August 9, 2001 statement. *Id.*

It is crucial to note that even President Bush permitted federal funding of embryonic stem cell research. Address to the Nation, AR at 21. He did not categorically ban such funding, finding necessarily that some forms of embryonic stem cell research are ethically responsible and scientifically worthy. However, President Bush specifically limited the availability of federal funds to embryonic stem cell research projects involving stem cell lines that were already in existence and "where the life and death decision has already been made." *Id.*

President Obama's Order removes this specific temporal limitation, thereby permitting funding for embryonic stem cell research projects—whether they involve stem cells from already-destroyed embryos or embryos to be destroyed in the future. The Order was not, as plaintiffs suggest, an invitation from President Obama to adopt a policy even *more* restrictive than his predecessor's by categorically prohibiting funding for any embryonic stem cell research projects. The question of whether embryonic stem cell research should be funded at all was not a question left on the table for the NIH by President Obama's Order. Indeed, had the NIH adopted plaintiffs' views and refused to consider funding any embryonic stem cell research projects, its regulation would have been inconsistent with the Executive Order and unlawful. *See Itek Corp.*, 704 F.2d at 7.

The consequences of President Obama's policy as presented in section 1 of the Executive Order are presented in its subsequent sections. Whereas before the Order issued, the NIH was prohibited from supporting human embryonic stem cell research using stem cell lines created after August 9, 2001 (pursuant to then-President Bush's policy), the NIH was now permitted to

fund such research without regard to President Bush's temporal limitation. As President Obama stated, the "[NIH] may support and conduct responsible, scientifically worthy stem cell research, including human embryonic stem cell research, to the extent permitted by law." Exec. Order No. 13,505, AR at 12. By permitting the NIH to fund "responsible, scientifically worthy . . . human embryonic stem cell research," the Order's language assumes that embryonic stem cell research is, in at least some cases, responsible and scientifically worthy, and grants permission to the NIH to support only such embryonic stem cell research as is "responsible" and "scientifically worthy." *Id.* The Guidelines' embryo-source and informed consent restrictions—alongside its peer-review process—are, of course, the NIH's means of channeling federal funds to "responsible" and "scientifically worthy" embryonic stem cell research projects.

For these reasons, the NIH reasonably interpreted Executive Order 13,505, and operated consistently with both it and the APA's requirements when it disregarded tens of thousands of public comments that sought an outright ban on embryonic stem cell research. The NIH reasonably concluded, as expressed in the notice of proposed rulemaking, that the fundamental policy question of whether to provide federal funds for embryonic stem cell research wasn't a question for it to decide. That policy question is not answered by any Congressional law, and it has fallen on three Presidential administrations to provide an answer. For all three such administrations, Democratic and Republican, the answer has been to permit federal funding. They have differed only as to the path forward.

This conclusion also disposes of plaintiffs' claim that the comments of Acting NIH Director Raynard Kington, before the comment period began, show that the NIH's top executive had an "unalterably closed mind" on a topic central to the rulemaking. Pls.' Mot. Summ J. [55] 32–33. Kington's observation in a newspaper article, following the issuance of President

Obama's Executive Order, that the number of embryonic stem cell lines available to federally funded researchers would increase merely states the obvious. The entire purpose of the Executive Order was to remove President Bush's restrictions on the cell lines for which federal funding was available. The other newspaper remark attributed to Mr. Kington, where he stated that commenters who objected categorically to federal funding of embryonic stem cell research missed the point of the rulemaking, merely indicates Mr. Kington's reasonable understanding of the scope of the rulemaking as specified in Executive Order 13,505.

Therefore plaintiffs' APA claims fail as a matter of law.

V. Conclusion

For the reasons stated above, the Court will grant defendants' Motion [58] for Summary Judgment and deny plaintiffs' Motion [55] for Summary Judgment.

A separate Order consistent with this Memorandum Opinion shall issue this date.

Signed by Royce C. Lamberth, Chief Judge, on July 27, 2011.