

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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| DR. JAMES L. SHERLEY, et al., |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| |) | |
| v. |) | Civil Action |
| |) | No. 09-CV-01575-RCL |
| |) | |
| |) | |
| KATHLEEN SEBELIUS, et al., |) | |
| |) | |
| |) | |
| Defendants. |) | |
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**MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION TO STAY
PRELIMINARY INJUNCTION PENDING APPEAL**

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INTRODUCTION

Defendants' motion to stay pending appeal effectively asks this Court to reconsider its August 23, 2010, decision granting Plaintiffs' motion for a preliminary injunction. Because that ruling was correct, and because nothing material has changed in the week since it was issued, Defendants' motion for a stay should be denied.

Defendants' claims of irreparable harm absent a stay rest on speculation, misinformation, and hyperbole. At every turn, Defendants present this case as a choice between spending federal dollars on human embryonic stem cell research—funding that this Court previously determined has only speculative benefits and likely violates federal law—or nothing at all. To the contrary, the preliminary injunction frees up millions in limited grant dollars that the National Institutes of Health (“NIH”) can now award to projects that promise more tangible medical benefits, raise fewer ethical issues, and comport with the law, including adult and induced pluripotent stem cell research.

The administrative record before the NIH when it promulgated the Guidelines demonstrated the overwhelming scientific and ethical advantages of adult and induced pluripotent stem cell research over embryonic stem cell research. Even NIH Director Dr. Francis S. Collins, however, effectively admits in his declaration that adult stem cells have proven to date to have more practical medical applications, such as “FDA-approved treatments that reconstitute the immune system after leukemia, lymphoma, and various blood or autoimmune disorders have been treated with chemotherapy.” Declaration of Francis S. Collins ¶ 7 (Aug. 31, 2010) (hereinafter “Collins Decl.”). The most Dr. Collins can muster in claiming irreparable injury is that embryonic stem cell research “offer[s] hope” to patients suffering from diseases and that beneficial treatments are “possible” in the future. *Id.* ¶ 5. Likewise, with respect to proposed or ongoing experiments that

may be temporarily delayed due to this Court’s preliminary injunction, Dr. Collins again resorts to conjecture that the experiments “may” take a long time to restart and that researchers “may” move to other countries in the meantime. *Id.* ¶ 12.¹ This falls far short of the *imminent* and *irreparable* injury that the law requires; mere speculation or hope cannot support a finding of irreparable harm. *Sherley v. Sebelius*, Civ. No. 1:09-cv-1575 (RCL), 2010 U.S. Dist. LEXIS 86441, at *20-22 (D.D.C. Aug. 23, 2010).

By contrast, both this Court and the D.C. Circuit have acknowledged the importance of the competitive injuries that scientists like Plaintiffs suffer immediately when they have to compete with illegal research proposals for a limited pool of federal dollars. Moreover, this Court’s August 23 order left no room for serious doubt that Plaintiffs will prevail on the merits of their claim—*i.e.*, that the Guidelines violate the Dickey-Wicker Amendment, which “unambiguously” prohibits federal funding of the destruction of human embryos. *See id.* at *18; *see also id.* at *19 (“[B]y allowing federal funding of ESC research, the Guidelines are in violation of the Dickey-Wicker Amendment.”). Due to this holding, the Court did not even reach Plaintiffs’ argument that the Guidelines violate the Administrative Procedure Act (“APA”), which is an independent basis why Plaintiffs prevail on the merits, and is not even addressed in Defendants’ brief. There is nothing to be gained by staying this Court’s order for a temporary period pending appeal of the preliminary injunction order, when there is every reason to expect that Plaintiffs will soon obtain permanent injunctive or declaratory relief invalidating the Guidelines. A stay will only result in

¹ In addition, the Collins declaration is replete with exaggerations and factual mischaracterizations. *See generally* Exhibit A, Declaration of Dr. Theresa Deisher (Sept. 3, 2010). In particular, the declaration repeatedly overstates the promise of embryonic stem cell research, while downplaying the discoveries made through adult stem cell research. *See id.* ¶¶ 9, 12.

further injury to Plaintiffs and additional waste of taxpayer dollars being poured into an illegal, unethical, and scientifically speculative enterprise.

For these reasons, Defendants' request for a stay pending appeal should be denied.

ARGUMENT

To obtain a stay pending appeal of a decision on a motion for a preliminary injunction, the moving party must show "(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction is not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction." *Mylan Labs., Inc. v. Leavitt*, 495 F. Supp. 2d 43, 46 (D.D.C. 2007) (quoting *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (internal citations omitted)). For the reasons set forth in this Court's August 23 opinion and in Plaintiffs' motion for a preliminary injunction, and as further explained below, Defendants cannot meet any of the factors of this test.

I. This Court Has Already Decided The Issues Presented In Defendants' Motion In Plaintiffs' Favor.

As an initial matter, this Court's August 23, 2010 order granting Plaintiffs' motion for a preliminary injunction has already resolved all of the issues raised by Defendants' motion to stay. The motion should be denied for that reason alone.

As the D.C. Circuit and this Court have frequently observed, the standards governing a motion for a preliminary injunction and a motion for a stay pending appeal are the same. *See, e.g., Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977); *Mylan Labs.*, 495 F. Supp. 2d at 46 ("The court analyzes motions for a stay pending appeal under the same factors that it considers for motions for a preliminary injunction."). Indeed, the two forms of relief serve the same purpose—to prevent irreparable harm pending the out-

come of litigation. Defendants provide no compelling reason why this Court should revisit its recent decision, made after full briefing and oral argument, which held that a preliminary injunction is necessary to prevent Plaintiffs from suffering further illegal competitive injury by virtue of NIH's consideration of illegal embryonic stem cell research grant applications. "Most of [Defendants'] arguments—if not all of them—are simply repetitions of points made before. They were not considered persuasive then, and they are not persuasive now." *Brown v. Artery Org., Inc.*, 691 F. Supp. 1459, 1461 (D.D.C. 1987) (denying motion for a stay pending appeal of order granting preliminary injunction); *cf. Abdulla Thani Faris Al-Anazi v. Bush*, 370 F. Supp. 2d 188, 199 n.11 (D.D.C. 2005) ("[I]f the petitioners cannot meet the prerequisites of a motion for preliminary injunction (as the Court concludes), it is unlikely that they should receive that same relief through the backdoor of a stay [pending appeal].").

Moreover, "because [the Court] has previously considered the precise legal issue on appeal, the movant's showing of likelihood of success must be impressive." *Mylan Labs.*, 495 F. Supp. 2d at 47 (ruling on a motion to stay following ruling on motion for preliminary injunction). "The law-of-the-case doctrine, which prevents a court from revisiting an issue it has already decided, reinforces this conclusion." *Id.* (citing *LaShawn v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996)). Under the law-of-the-case doctrine, "the *same* issue presented a second time in the *same case* in the *same court* should lead to the *same result*." *Barry*, 87 F.3d at 1393 (emphases in original).

Defendants cannot clear the high hurdle necessary for this Court to reconsider its recent decision and lift the preliminary injunction pending appeal. Among other reasons, this Court has correctly concluded that Plaintiffs have "a strong likelihood of success" on the merits of their claims, because the NIH Guidelines violate an "unambiguous" statutory provision expressly pre-

cluding any funding for research in which embryos are injured or destroyed. *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *14, *18-19. There is no reason for this Court to allow illegal federal funding for embryonic stem cell research to continue, even for a brief period pending appeal, when those projects are likely to be terminated if and when this Court grants Plaintiffs permanent relief. Conversely, there is no reason to impede for another day meritorious grant proposals from adult stem cell researchers (and other NIH applicants) who have illegally been forced to compete with embryonic stem cell researchers for scarce federal funding.

II. This Court's Preliminary Injunction Order Is Not Overly Broad.

Nor is it necessary for this Court to narrow or otherwise amend its August 23 preliminary injunction order. Defendants devote the lion's share of their motion to challenging the scope of that order, reciting a parade of horrors that will supposedly follow should the order remain in place without modification.

Defendants' concerns are misplaced. A reasonable reading of the Court's order reveals that it either does not apply to the activities that Defendants describe or that Defendants mischaracterize the harm that will allegedly result from the order:

- **Funds Already Awarded to Third Parties for "Extramural" Projects.** Defendants express concern about possible application of the preliminary injunction to third-party grantees that received funds from NIH prior to this Court's August 23 order, but on its face, the Court's order applies only to Defendants and their agents, not to third parties.
- **Research on Stem Cell Lines Approved By Bush Administration.** Defendants also claim that this Court's order prohibits federal funding of research involving stem cell lines in existence prior to August 9, 2001, although such funding was allowed under the prior Administration's policies. The Court's order that Defendants not "tak[e] any action whatsoever pursuant to the . . . Guidelines . . . or otherwise," however, is limited by the phrase, "funding research involving human embryonic stem cells *as contemplated in the Guidelines*." (Emphases added). The order itself thus does not address the prior and much narrower (and since rescinded) NIH policy, or whether NIH could return to that pre-Guidelines policy pursuant to appropriate procedures and federal law.

- **Administrative and Regulatory Activities.** Defendants seek clarification as to whether this Court’s order prevents NIH from doing peer review of applications for human embryonic stem cell research or from maintaining or processing applications for the Human Embryonic Stem Cell Registry. The Registry and the peer review processes, of course, are integral parts of the mechanism whereby embryonic stem cell research proposals are submitted and approved for NIH funding in violation of federal law. Therefore, the processing of additional Registry and grant applications contributes directly to the competitive injuries to Plaintiffs (and other scientists) that the preliminary injunction was designed to prevent, and was properly enjoined. But to the extent that the NIH seeks merely to conduct document or website preservation, or activities that are related solely to adult or induced pluripotent stem cell research, the Court’s order plainly does not apply.
- **“Intramural” NIH Research.** Finally, Defendants argue that this Court’s order should exempt so-called “intramural” NIH projects—that is, research carried out onsite by NIH employees—because Plaintiffs supposedly do not compete with NIH researchers for federal dollars. The only evidence that Defendants submit to support this proposition, however, is Dr. Collins’s carefully qualified statement that “[f]unds for intramural and extramural research are specifically budgeted each fiscal year and are not *readily* interchangeable.” Collins Decl. ¶ 4 (emphasis added). Congress imposes no such limitation, instead allocating funds to each NIH institute as a whole, so any funds freed up by the prohibition on illegal intramural research could be used to fund additional legal extramural research. *See Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, div. D, tit. II, 123 Stat. 3034, 3243 (2009); Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, div. F, tit. II, 123 Stat. 524, 767 (2009).*

For these reasons, Defendants’ requests for clarification or modification of the Court’s preliminary injunction order are without merit. And for the reasons explained below, Defendants should also remain enjoined from funding new or existing “extramural” proposals for embryonic stem cell research.

III. This Court’s Prior Decision Was Correct On The Merits.

A. Defendants Are Unlikely To Prevail on the Merits of Their Claims

Although the Court need not retread this well-known territory, its August 23 order and decision were also correct on the merits.

1. The Guidelines Violate The Plain Language Of The Dickey-Wicker Amendment.

As this Court explained, Plaintiffs are likely to succeed on their claims for declaratory and permanent injunctive relief because the NIH Guidelines violate the plain language of the

Dickey-Wicker Amendment, which strictly prohibits the funding of “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death.” *See Sherley*, 2010 U.S. Dist. LEXIS 86441, at *15. The Court left little doubt that Plaintiffs would ultimately prevail; it “conclude[d] that, by allowing federal funding of ESC research, the Guidelines are in violation of the . . . Amendment.” *Id.* at *19.

For all of the reasons set forth in Plaintiffs’ motion for a preliminary injunction, *see* D.E. 3, Pls.’ Mot. for a Prelim. Inj., at pp. 7-16, this conclusion is undoubtedly correct. Defendants ask this Court to reconsider its ruling for three principal reasons, but none is persuasive.

First, Defendants acknowledge that, under applicable regulations, the term “research” under the Amendment is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.102(d) (2010). Defendants argue, however, that the derivation of embryonic stem cells from embryos for the very purpose of experimenting on them is somehow not part of the same “systematic investigation” as the actual use of those cells. According to Defendants, the word “systematic” means “having, showing, or involving a system, method, or plan,” and therefore a research project does not need to “include within its scope all steps . . . that made the research possible.” Defs.’ Mot. to Stay, at 10.

Defendants are incorrect. Under Defendants’ own definition, the test is not whether the term “research” includes all “steps that made the research possible,” but whether the derivation process is part of the researcher’s “system, method or plan.” Under that test, the derivation of a stem cell from an embryo is undoubtedly part of the “system, method, or plan” of a researcher who is experimenting on embryonic stem cells. Defendants’ interpretation of the statute also ig-

nore its prohibition of funding “research” in which human embryos “are . . . *discarded*.” (Emphasis added.) Defendants’ view leads to the absurd conclusion that merely “discard[ing]” an embryo would constitute its own, standalone “research” project. To the contrary, the Amendment plainly prohibits funding for any “systematic investigation” that entails, as one part of the overall “system, method, or plan” of research, the discarding or destruction of an embryo.

Second, Defendants claim that the words “in which” and “are destroyed” limit Dickey-Wicker’s scope to that part of the research process that involves deriving an embryonic stem cell from an embryo, resulting in its destruction. Defendants’ counsel are correct, of course, when they assert that the words “in which” are necessarily limiting. Without a subordinate clause the statute would prohibit *all* NIH funding. This tells us nothing, however, about *what* the statute prohibits.

Defendants’ entire argument, therefore, rests on the slender reed of Congress’s use of the present tense in describing embryos that “*are*” destroyed or discarded, which Defendants view as restricting the statute to the specific act a researcher is performing at a given moment in time. Defendants’ argument, however, divorces the verb “are” from the subject “research.” The statute bans the destruction of embryos as part of a “research” project, which is a *continuing* or *systematic* process. Because the destruction of embryos is an essential aspect of the embryonic stem cell research process, it is only logical to speak of the destruction as an event that is concurrent with the “research.” Moreover, the implications of Defendants’ arguments are absurd. If the Dickey-Wicker Amendment prohibited only the funding of present destruction of human embryos, as Defendants now argue, then NIH could fund even the already-completed—and hence past tense—act of destroying human embryos that was necessary to produce stem cell lines for which researchers “are” now seeking NIH approval. Not even Defendants take that position, in-

stead conceding that they cannot fund such destruction (even though it has by definition already occurred with respect to any NIH-approved stem cell lines). *See* NIH Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,175 (Jul. 7, 2009) (“NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research.”). In short, Defendants’ argument based on verb tense must be rejected as inconsistent with the NIH’s own interpretation of the statute.

Third, Defendants rely on snippets of legislative history to argue that Congress somehow accepted or acquiesced in the validity of the Guidelines under the Dickey-Wicker Amendment. *See* Defs.’ Mot. to Stay, at 11-12. Reference to legislative history is inappropriate, however, when as here the text of a statute is unambiguous. *Dep’t of Hous. & Urban Dev. v. Rucker*, 535 U.S. 125, 132 (2002). Moreover, the legislative history in this case also contains statements by the Amendment’s co-author, Congressman Jay Dickey, and others that support Plaintiffs’ reading of the statute.² The history is therefore even less helpful than usual, because it “supports conflicting inferences and provides scant illumination.” *Carter v. United States*, 530 U.S. 255, 271 n.9 (2000). This only “further confirms the wisdom of relying on the *legislative text* to de-

² Dickey explained that federal funding of embryonic stem cell experiments that incentivizes the destruction of human embryos “undermines the spirit and letter of the law.” *Special Hearing on Stem Cell Research: Hearing before the Subcomm. on Labor, Health, and Education of the S. Comm. on Appropriations*, 106th Cong. 9-10 (Nov. 4, 1999); *see also* Statement of Senator Brownback, 147 Cong. Rec. S6393, 6394 (June 19, 2001) (placing in the record a letter from twenty Senators to NIH urging the agency to withdraw the “Clinton-era guidelines which call for the destruction of human embryos for the purpose of subsequent federal funding for the cells that have been derived through the process of embryo destruction” because they were “contrary to the law and Congressional intent,” and stating that “[c]learly, the destruction of human embryos is an integral part of the contemplated research, in violation of the law”).

termine the purpose of [the statute].” *Nat’l Ass’n of Mfrs. v. Taylor*, 582 F.3d 1, 13 (D.C. Cir. 2009) (emphasis added).

Even if Defendants’ warped reading of the term “research” were correct, moreover, the funding they propose would still be illegal, because Dickey-Wicker’s prohibition also encompasses research in which embryos are “knowingly subjected to risk of injury or death.” Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 803. In order to give any meaning to the phrase “knowingly subjected to risk of injury or death,” Defendants must be prohibited from funding research that they know will place additional human embryos at substantial risk of destruction. The NIH, of course, is well aware that the stem cell derivation process necessarily destroys an embryo. By creating a financial incentive for embryonic stem cell research—an incentive that by NIH’s own admission involves investments of “hundreds of millions of dollars”—and by specifying the precise means by which embryos must be destroyed in order to qualify for federal funding, the NIH necessarily and knowingly subjects embryos to a substantial risk of injury or death.

2. The Guidelines Are Arbitrary And Capricious And Therefore Invalid Under The Administrative Procedure Act.

Although this Court did not reach the issue, Defendants are also unlikely to succeed on appeal because the NIH Guidelines are arbitrary and capricious under the APA. In their motion for a stay pending appeal, Defendants do not even address Plaintiffs’ APA arguments, but they cannot establish likelihood of success on appeal unless they show they will likely prevail on *both* sets of issues. Because Defendants have made no such showing, their motion should be denied.

As Plaintiffs have demonstrated at length elsewhere (*see* D.E. 3, Pls.’ Mot. for Prelim. Inj., at pp. 16-33), they are highly likely to succeed on their APA challenge to the Guidelines.

NIH issued the Guidelines pursuant to President Obama’s Executive Order 13,505, which provided that the agency “may support and conduct responsible, scientifically worthy human

stem cell research, including human embryonic stem cell research, to the extent permitted by law.” Exec. Order No. 13,505, 74 Fed. Reg. 10,667, 10,667 (Mar. 9, 2009). In promulgating the Guidelines, however, the NIH refused to consider or address the thousands of comments it received (roughly 60 percent of 49,015 public comments) that opposed federal funding of embryonic stem cell research. Those comments demonstrated, among other things, that embryonic stem cell research is ethically problematic and shows no signs of leading to effective medical treatments, whereas adult and induced pluripotent stem cell research deliver far greater scientific and medical benefits, are ethically responsible, and comport with the law. *See* D.E. 3, Pls.’ Mot. for Prelim. Inj., Declaration of Bradley J. Lingo, Exs. B, C (hereinafter “Lingo Decl.”). Inexplicably, however, the agency failed to make *any* attempt to explain its *sub silentio* rejection of those highly relevant categorical objections to funding embryonic stem cell research. NIH thus failed to “examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *U.S. Telecom Ass’n v. FCC*, 227 F.3d 450, 461 (D.C. Cir. 2000) (internal quotation marks omitted). In addition, NIH’s stated criteria in the Guidelines established that it could fund only “ethically responsible” and “scientifically worthy” research. NIH Guidelines, 74 Fed. Reg. at 32,170. The administrative record establishes that adult and induced pluripotent stem cell research are categorically superior to embryonic stem cell research under NIH’s own stated criteria, because they offer greater scientific and medical promise than human embryonic stem cell research and are ethically superior alternatives. Defendants thus disregarded their own stated criteria and failed to justify their decision to fund embryonic stem cell research in light of those criteria. An agency’s disregard of its own stated criteria is the essence of arbitrary and capricious decisionmaking. *See, e.g., Am. Equity Inv. Life Ins. Co. v. SEC*, 572 F.3d 923, 934 (D.C. Cir. 2009) (an agency “must defend its

analysis before the court upon the basis it employed in adopting that analysis”—even if “the [agency] was not required” by statute to base its decision on those grounds).

Defendants’ only proffered justification for their failure to consider the comments is that the President’s Executive Order purportedly left the agency with no discretion not to fund embryonic stem cell research. That claim is patently incorrect. The language of the executive order itself—which uses the permissive language “*may* support and conduct”—defeats that argument. In any event, even if the Order did require the NIH to fund embryonic stem cell research, the President cannot direct an agency to disregard the requirements of the APA.

For these reasons, and those set forth more fully in Plaintiffs’ motion for a preliminary injunction, Defendants are unlikely to prevail on appeal.

B. Defendants Will Not Be Irreparably Harmed By Denial Of A Stay.

Defendants next sound a jeremiad that this Court’s preliminary injunction order, if kept in place for the brief period while an appeal is pending, will waste millions of dollars in federal grant money, terminate ongoing scientific experiments, and prevent discovery of potentially life-saving cures to debilitating illnesses. This analysis cannot withstand scrutiny.³

First, the harms that Defendants allege all flow from the approval and funding of research prohibited by federal law, as indicated by this Court’s finding that Plaintiffs have “a strong likelihood of success.” *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *14. Because Defendants have violated the law, they cannot seek equitable relief on the basis that their actions were meritorious or could lead to beneficial results.

³ As an initial matter, Defendants’ claims of urgency are belied by the fact that they did not file their “emergency” motion for a stay and for expedited briefing until August 31, over a week after this Court issued its order and decision.

Second, the preliminary injunction that the Court has issued will necessarily be of “short duration.” *Hoffman-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978). Because the core of this case is a legal rather than a factual dispute, this Court can proceed expeditiously to judgment on the merits of Plaintiffs’ claims.⁴ Defendants’ pending appeal of the preliminary injunction order in the D.C. Circuit could also proceed on an expedited basis. In such circumstances, “[i]ssuance of a preliminary injunction—especially one of the short duration contemplated here—will not substantially harm defendants” *Id.*

Third, despite the claims made in Defendants’ motion about the economic harm that would befall them from the preliminary injunction, Defendants provide little (if any) tangible evidence that any such harm is “certain and great,” and “of such imminence that there is a clear and present need for equitable relief,” as required by the governing standard. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (emphasis and internal quotation marks omitted). Dr. Collins cites purely speculative injuries that may (or may not) occur at some point while the appeal is pending, such as the possible death of lab animals or the loss of researchers to opportunities in other countries. *See Collins Decl.* ¶¶ 12, 14.⁵ On the issue of whether biological resources (such as cell cultures) would be lost if research were temporarily halted, Dr. Collins repeatedly hedges his conclusions, and states in general and cryptic terms that “it *may* take months or years

⁴ Plaintiffs intend to file a motion for summary judgment, seeking permanent injunctive and declaratory relief, by September 10, and would not object to expedited consideration of the motion.

⁵ Contrary to what Dr. Collins’s speculation may suggest, countries on the other side of the Atlantic lead the Americas in certain therapeutic uses of *adult* stem cell research. For example, nearly half (48%) of transplants performed using hematopoietic (blood-forming) adult stem cells in patients with blood disorders and malignancies were performed in Europe, as opposed to 36% in all of the Americas. *Deisher Decl.* ¶ 20.

to recreate” undefined “unique materials” and “reagents” used in current experiments. *Id.* (emphasis added).

Defendants make no showing that preservation of existing cell lines is impossible under this Court’s order. To the contrary, when the NIH recently instructed researchers to halt “intramural” experiments on embryonic stem cells, it also directed that “[p]rocedures that will conserve and protect the research resources should be followed.”⁶ In short, there is no evidence that Defendants would be unable to resume their current research projects at a later date if the D.C. Circuit lifted the Court’s preliminary injunction.

Fourth, Defendants’ claim that a brief interruption in research could delay scientific discoveries that could benefit people with debilitating illnesses is, as this Court previously held, purely “speculative.” *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *22. Dr. Collins refers often to the promise of embryonic stem cell research, but concedes that the discovery of cures through such research is a mere possibility and has not yet been established. *See Collins Decl.* ¶¶ 5, 7.⁷ If anything, the administrative record that the NIH had before it when it issued the Guidelines (including many critical comments that the agency never considered) showed that the promise of embryonic stem cell research is even more limited. That record establishes the serious risks associated with human embryonic stem cell treatments, as well as the inherent limitations on those

⁶ Jocelyn Kaiser, *NIH Orders Immediate Shutdown of Intramural Human Embryonic Stem Cell Research*, Science Insider (Aug. 30, 2010), available at <http://news.sciencemag.org/scienceinsider/2010/08/nih-orders-immediate-shutdown.html>.

⁷ Dr. Collins’ statement that a clinical trial involving human embryonic stem cells has been approved tells nothing about the likelihood that that trial will succeed or lead to tangible medical benefits. *See Deisher Decl.* ¶ 11. Similarly, his statement that “differentiated cells derived from hESC are already successfully being used to develop new therapeutic drugs” (*Collins Decl.* ¶ 6) is unsupported by any facts and does not define what “used to develop” means. *See id.* ¶ 9.

cells' therapeutic potential. *See* D.E. 3, Lingo Decl. Exs. B, C. It also details the substantial and verifiable medical results already delivered by adult stem cells, and other characteristics that render adult stem cells a superior scientific and ethical alternative. *Id.*; *see also* Deisher Decl. ¶ 12 (noting that, unlike embryonic stem cells, adult stem cells have “already produced published positive therapeutic benefits for spinal cord injury patients”) (emphasis omitted). Thus, the loss of grant money for embryonic stem cell research that violates federal law will actually *further* scientific advances and future medical cures by freeing up additional funds for more promising grant proposals—such as adult stem cell research.

In short, Defendants' claims of irreparable harm assume (wrongly) that dollars not spent on embryonic stem cell research will simply disappear into the ether. To the contrary, the Court's order makes those dollars available for other, more promising and less ethically fraught medical research projects. In addition, given the fact that Plaintiffs are likely to obtain permanent injunctive and declaratory relief in the future, a stay is likely to cause Defendants *additional harm* in the long run. If federal funding resumed, NIH would spend additional federal dollars on embryonic stem cell research and initiate new projects. If this Court later issued a final judgment invalidating the Guidelines, all interested parties—the NIH, scientists, and taxpayers—would face additional purported losses of the type claimed by Defendants. Federal dollars should not be spent in so reckless a manner. Rather, the prudent course is to keep the preliminary injunction in place until this Court and the D.C. Circuit have had the opportunity to reach a final resolution of the important legal issues raised by this case.

C. A Stay Pending Appeal Would Cause Substantial Harm To Plaintiffs And Other Interested Parties.

In contrast to a temporary delay in illegal funding for research that raises grave ethical issues and has not proven to yield tangible medical benefits, Plaintiffs and other interested parties

(including adult stem cell researchers and other NIH grant applicants generally) would suffer irreparable competitive injuries from a stay of the preliminary injunction.

Defendants lampoon the harm suffered by Plaintiffs in this case as merely the need to invest more time in filling out research applications. *See* Defs.' Mot. to Stay, at 21. In reality, the NIH has a limited budget for funding scientific research that could lead to potentially life-saving medical breakthroughs, and Plaintiffs—as well as other adult stem cell researchers and the scientific community as a whole—must compete for those federal dollars. As the D.C. Circuit has recognized, Plaintiffs suffer immediate and legally cognizable injury from being forced to compete with illegal grant applications, and they and other applicants should not have to face such illegal competition for a single additional day. Defendants' claims of harm to third parties (embryonic stem cell researchers and persons seeking medical cures) rest on an utterly false dichotomy, namely the assumption that there is no alternative to funding embryonic stem cell research. As the administrative record makes clear, there are such alternatives, including both adult and induced pluripotent stem cell research, and those *alternatives* are *more* likely to result in cures for debilitating diseases, and thus *more* likely to benefit patients. *See supra* pp. 5-6, 10-11.

As this Court found in its August 23 decision, the Guidelines, “by allowing federal funding of ESC research, increase[] competition for NIH’s limited resources.” *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *21. Therefore, adult stem cell researchers, such as Drs. Sherley and Deisher, would suffer “actual, imminent injury” if federal dollars continued to be diverted to embryonic stem cell research. *Id.*; *see also Sherley v. Sebelius*, 610 F.3d 69, 74 (D.C. Cir. 2010) (find-

ing that Plaintiffs suffer injury “whenever a project involving ESCs receives funding that, but for the broadened eligibility in the Guidelines, would have gone to fund a project of theirs”).⁸

It is well-established that economic losses cause irreparable harm where there is “no adequate compensatory or other corrective relief” that can be provided at a later date.” *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (quoting *Hoffmann-Laroche, Inc. v. Califano*, 453 F. Supp. 900, 903 (D.D.C. 1978)).⁹ That standard is met here because, as this Court found, “[t]here is no after-the-fact remedy for this injury because the Court cannot compensate plaintiffs for their lost opportunities to receive funds.” *Sherley*, 2010 U.S. Dist. LEXIS 86441, at *21; *see also Sherley*, 610 F.3d at 74 (finding that Plaintiffs “are more likely to lose funding to projects involving ESCs than are researchers who do not work with stem cells because [adult stem cells] and ESCs are substitutes in some uses”). The Court’s conclusion was amply supported by the record. *See* D.E. 3, Decl. of Dr. James L. Sherley in Support of Pls.’ Mot. for Prelim. Inj., ¶¶ 3–4; D.E. 3, Decl. of Dr. Theresa Deisher in Support of Pls.’ Mot. for Prelim. Inj., ¶¶ 3–4.

⁸ Defendants’ allege that neither Plaintiff currently has any grant proposals pending that could be affected by funding for embryonic stem cell research. That is mistaken. Dr. Sherley currently has two proposals related to adult stem cell research pending before NIH. *See* Exhibit B, Declaration of Dr. James L. Sherley ¶ 4 (Sept. 2, 2010). Dr. Deisher in turn is in the process of applying for NIH grant money. *See* Deisher Decl. ¶ 4.

⁹ Defendants’ argument that they “will be forced to make payments that will be irrecoverable” in order to bring their (illegal) funding system into compliance with the Court’s order is misplaced. Every dollar spent in violation of Dickey-Wicker is contrary to law and “will be irrecoverable,” which is a significant reason why defendants’ motion should be denied.

The harm that will result from a stay pending appeal is not merely pecuniary and is not limited to the Plaintiffs that appear before the Court.¹⁰ To the contrary, adult stem cell researchers and other NIH grant applicants will lose the opportunity to pursue their own research interests, which could lead to potential cures and other medical and scientific breakthroughs. As Defendants repeat throughout their motion, this Court's decision will have an effect on patients with diseases and society as a whole. But that consideration weighs decisively *against* a stay, because (as shown in the administrative record) adult stem cell research has proven more likely to lead to effective treatments than embryonic stem cell research.

Moreover, a stay would itself cause irreparable harm to American taxpayers and flout the will of Congress. As noted above, the Court's order applies only to Defendants and their agents, not to third parties. As a result, NIH takes the position that awards granted on or before August 23, 2010, "are not affected by the preliminary injunction order, and award recipients may continue to expend the funds awarded to them prior to the date of the injunction."¹¹ If this Court were to grant a temporary stay, Defendants would have every incentive to disburse as much federal money as they could to third party grantees before the Court awarded Plaintiffs permanent relief. Once those millions of dollars are given to third parties and spent (in violation of Dickey-

¹⁰ See, e.g., *Mova Pharm. Corp.*, 140 F.3d at 1066 (standard permits consideration of harm to "other interested parties" in litigation); *Va. Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958) (court may consider harm to "other interested persons").

¹¹ "Status of Applications and Awards Involving Human Embryonic Stem Cells, and Submissions of Stem Cell Lines for Eligibility Consideration," National Institutes of Health (Aug. 30, 2010), available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-126.html> (last viewed Sept. 3, 2010).

Wicker), they are irreparably lost to taxpayers and other NIH researchers under the terms of the Court's order.

Finally, the harm to the embryos that would be destroyed if a preliminary injunction were lifted—precisely the harm that the Dickey-Wicker Amendment was enacted to prevent—would be irreversible. “Simply put, absent some form of preliminary relief [the embryos] run[] the real risk of dying and in such circumstances money damages would be wholly useless”

DiDomenico v. Employers Coop. Indus. Trust, 676 F. Supp. 903, 907 (N.D. Ind. 1987).¹²

D. The Public Interest Favors Denial Of A Stay.

Finally, the public interest weighs strongly in favor of denying Defendants' request for a stay. In passing the Dickey-Wicker Amendment, Congress necessarily mandated that the public interest would be served by preventing taxpayer funding of research that entails the destruction of human embryos. It is well-established that “[i]t is in the public interest for courts to carry out the will of Congress and for an agency to implement properly the statute it administers.” *Mylan Pharm., Inc., v. Shalala*, 81 F. Supp. 2d 30, 45 (D.D.C. 2000). By vindicating Congress's prohibition of research that entails the destruction of human embryos, keeping the preliminary injunction in place will serve the public interest. *See Sherley*, 2010 U.S. Dist. LEXIS 86441, at *22-23 (finding preliminary injunction is in public interest because “the will of Congress, as expressed

¹² It makes no difference for purposes of irreparable injury analysis that the embryos in question are not yet mature human beings. On the contrary, courts have recognized that the threat of harm to a human being not yet born can constitute irreparable harm for purposes of determining the propriety of injunctive relief. *See, e.g., Lewis v. Grinker*, 1987 WL 8412, at *6 (E.D.N.Y. Mar. 6, 1987) (finding that denial of Medicare may lead to irreparable harm of unborn child); *Woe v. Perales*, 1987 WL 108983 (W.D.N.Y. Oct. 29, 1987) (finding that denial of prenatal care constitutes irreparable harm “[g]iven the importance of this prenatal care to the health of the fetus and the future health of the yet unborn child”).

in the Dickey-Wicker Amendment, is to prohibit federal funding of research in which human embryos are destroyed”).

Moreover, denial of a stay will serve the public interest by preventing a wasteful diversion of public funds to needless and relatively unpromising research. Because the Guidelines divert funds away from more promising types of research and perpetuate popular misconceptions about the science of embryonic stem cells, a preliminary injunction will serve the interest of the public.

Finally, denial of a stay will also serve the public’s interest by withholding taxpayer dollars from a type of research that many taxpayers and States recognize to be ethically and morally troubling. The laws of numerous States protect human life from the moment of conception or otherwise protect human embryos from being destroyed for the purpose of medical experimentation. *See* Lingo Decl. Ex. B, Appendix C (collecting authorities). The public interest is diserved by federal funding of an immoral and unnecessary research method.

CONCLUSION

In the face of this Court’s holdings that Dickey-Wicker is “unambiguous” and that Plaintiffs therefore have “a strong likelihood of success on the merits,” Defendants’ arguments fall far short of demonstrating that *defendants* have a substantial likelihood of success on the merits. Moreover, for all the above reasons, Defendants are unlikely to succeed on appeal, and neither they nor the public will suffer irreparable harm from the denial of a stay pending appeal. To the contrary, this Court’s preliminary injunction advances the public interest by ensuring that adult stem cell researchers and other meritorious NIH grant applicants can seek federal funding free from competition from illegal, ethically dubious, and scientifically problematic embryonic stem cell research. Defendants’ motion for a stay pending appeal should be denied.

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Respectfully Submitted,

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Certificate of Service

I hereby certify that on September 3, 2010, I caused a true and correct copy of the foregoing Plaintiffs' Opposition to Defendants' Motion To Stay Preliminary Injunction Pending Appeal to be served on Defendants' counsel electronically by means of the Court's ECF system.

/s/ Thomas G. Hungar

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