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

This matter comes before the Court on plaintiffs' Motion [3] for a Preliminary Injunction. Previously, this Court dismissed this case for lack of standing and denied plaintiffs' motion for a preliminary injunction as moot. Plaintiffs appealed. On appeal, plaintiffs argued that plaintiffs Drs. Sherely and Diesher had competitor standing and conceded that other plaintiffs lacked standing. The Court of Appeals reversed, holding that plaintiffs Sherley and Diesher have standing, and remanded the matter to this Court for consideration of plaintiffs' motion for a preliminary injunction. The mandate from the Court of Appeals was filed in this Court this date.

For the reasons set forth below, the Court will GRANT plaintiffs' motion and issue a preliminary injunction.

II. BACKGROUND

A. Procedural History

Plaintiffs Drs. James L. Sherley and Theresa Deisher, Nightlight Christian Adoptions ("Nightlight"), Embryos, Shayne and Tina Nelson, William and Patricia Flynn, and Christian

Medical Association ("CMA") brought this suit for declaratory and injunctive relief to prevent defendants' Guidelines for Human Stem Cell Research ("Guidelines") from taking effect. (Compl.¶¶ 4, 6-12.) Specifically, plaintiffs sought "an order (a) declaring that the Guidelines are contrary to law, were promulgated without observing the procedures required by law, and constitute arbitrary and capricious agency action; and (b) enjoining [d]efendants from applying the Guidelines or otherwise funding research involving the destruction of human embryonic stem cells." (*Id.* ¶ 4.) On October 27, 2009, this Court dismissed plaintiffs' suit, finding that plaintiffs lacked standing, and denied plaintiffs' motion for a preliminary injunction as moot. *Sherley v. Sebelius*, 686 F. Supp. 2d 1, 5-7 (D.D.C. 2009). Plaintiffs appealed.

The Court of Appeals reversed, concluding that Drs. Sherley and Deisher had standing under the competitor standing doctrine. *Sherely v. Sebelius*, – F.3d –, 2010 WL 2540358, *5 (D.C. Cir. 2010). Because the Nightlight, the Embryos, the Nelsons, the Flynns, and CMA did not contest this Court's finding that they lacked standing, the Court of Appeals treated "their lack of standing as conceded." *Id.* at *2. The Court of Appeals then remanded this matter back to this Court for consideration of plaintiffs' motion for a preliminary injunction. *Id.* at *6.

B. Stem Cell Research

Stem cell research has the potential to produce medical breakthroughs in the treatment of many life-threatening diseases and conditions that have resisted traditional methods of treatment. (Pls.' Mot. [3] for Prelim. Inj. at 2; Defs.' Opp'n [22] at 2.) There are three types of stem cells available for research: adult stem cells ("ASCs"), induced pluripotent stem cells ("IPSCs"), and human embryonic stem cells ("ESCs"). (Pls.' Mot. [3] for Prelim. Inj. at 2.) Each type of stem cell possesses unique capabilities and limitations. (Def.'s Opp'n [22] at 3.) As a result, many

scientists believe that research should be conducted on each type of stem cell. (*Id.* (citing Nat'l Insts. of Health, *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp).) Other scientists, however, believe that research should be conducted only on ASCs and IPSCs because ESC research has not produced positive results and is morally objectionable. (Pls.' Mot. [3] for Prelim. Inj. at 2-3.)

ESCs have been available for research since 1998, when Dr. James Thomson of the University of Wisconsin discovered a process for deriving stem cells from an embryo. (*Id.* at 3.) ESCs are pluripotent, *i.e*, they have "the capability to give rise to any of the approximately 200 types of cells in the human body." (Def.'s Opp'n [22] at 3.) Once they are derived from an embryo, ESCs may be maintained indefinitely. *See* Nat'l Insts. of Health, *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp.

ESCs may be used to treat diseases in two ways. First, researchers can transplant ESCs into patients. (*See* Defs.' Opp'n [22] at 3.) To transplant ESCs, researchers must guide the differentiation of ECSs into certain kinds of cells. (*Id.*) Differentiation of ESCs reduces the risk of benign tumor forming after the ESCs are transplanted. (*Id.* (citing Nat'l Acads., *Understanding Stem Cells: An Overview of the Science and the Issues from the National Academies* at 5 (2009)).) Second, ESCs may be used to "study disease mechanisms that cannot be studied in the human body, and to develop other, non-stem-cell based therapies for these conditions." (Defs.' Opp'n [22] at 4.) Recent studies employing both methods of treatment suggest that ESCs will contribute to the development of medical knowledge in the future. (*See id.*)

ASC research, in which Drs. Sherley and Deisher specialize, is approximately fifty years

old and began with the discovery of hematopoietic stem cells. (*Id.*) ASCs are found in tissues that are normally discarded after birth, such as the umbilical cord, and in the body. (Pls.' Mot. [3] for Prelim. Inj. at 3.) Because researchers have been able to study ASCs for decades, they have been able to develop treatments for numerous diseases with ASCs. (*Id.*; Defs.' Opp'n [22] at 5.) ASCs, however, are limited because, unlike ESCs, they are multipotent, not pluripotent. (Defs.' Opp'n [22] at 5 (citing Nat'l Insts. of Health, *Hematopoietic Stem Cells*, http://stemcells.nih.gov/info/scireport/chapter5.asp).) As a result, ASCs cannot differentiate into the 200 types of cells in the human body. (*Id.*) Nevertheless, ASC research remains of great importance in the treatment of disease. (*Id.* at 6.)

IPSC research is the newest form of stem cell research. Discovered in 2007, IPSCs "are adult stem cells that have been genetically reprogrammed such that they are virtually identical to embryonic stem cells." (Pls.' Mot. [3] for Prelim. Inj. at 4.) Because research involving IPSCs is at such an early stage, its full potential is unknown. (Defs.' Opp'n [22] at 5.) Some researchers, however, believe that IPSCs offers the most promise for advancements in medical research and treatment. (Pls.' Mot. [3] for Prelim. Inj. at 4-5.)

C. Regulatory Background

In 1996, Congress enacted the Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996). The Balanced Budget Downpayment Act contained a rider, known as the Dickey-Wicker Amendment, which prohibited the use of federal funds for "(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" applicable federal regulations.

Id. Congress has included the Dickey-Wicker Amendment in every appropriations bill for Health and Human Services ("HHS") since 1996 without substantive alteration. *See* Omnibus Appropriations Act 2009, Pub. L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803 (2009).

In 1999, defendants determined that the Dickey-Wicker Amendment was not applicable to ESC research because ESCs are not embryos as defined by statute. (*See* Lingo Decl. Ex. D.) Specifically, defendants recognized a distinction between deriving ESCs from an embryo, which is prohibited by the Dickey-Wicker Amendment because it results in the destruction of the embryo, and research on ESCs, which does not result in the destruction of an embryo. *See* Nat'l Insts. of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170, 32173 (July 7, 2009). Defendants have maintained this interpretation of the Dickey-Wicker Amendment since 1999. (*Id.*) Congress, however, has not altered the Dickey-Wicker Amendment in response. (Defs.' Opp'n [22] at 9-10.)

On August 9, 2001, President Bush announced a policy statement on stem cell research that limited federal funding for research on ESCs. *See* Address to Nation on Stem Cell Research From Crawford Texas, 37 Weekly Compl. Pres. Doc. 1149 (Aug. 9, 2001). Specifically, the President prohibited federal funding for research on ESCs that were created after the date of the policy statement. (*Id.*) Federal funding remained available, however, for research on ESCs that were created by private researchers prior to his policy statement. (*Id.*) The President formalized this policy statement in Executive Order No. 13,435, which provided federal funding for IPSC research and left the limitations on ESC research unchanged. *See* Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007).

On March 9, 2009, President Obama, by executive order, removed President Bush's

limitations on ESC research in order "to expand NIH support" for human stem cell research and "to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." Executive Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009) As a result, the National Institutes of Health ("NIH") "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem research, to the extend permitted by law." *Id.* To achieve that end, the President directed NIH to review the existing stem cell research guidelines and "issue new NIH guidance on such research that is consistent with this order." *Id.*

In response to President Obama's executive order, NIH published draft guidelines entitled "National Institutes of Health Guidelines for Human Stem Cell Research." 74 Fed. Reg. 18,578 (Apr. 23, 2009). The draft guidelines allowed "funding for research using human embryonic stem cells that were derived from human embryos created by *in vitro* fertilization (IVF) for reproductive purposes and were no longer needed for that purpose." *Id.* NIH received approximately 49,000 comments, including plaintiffs' submission, on the draft guidelines during the comment period. 74 Fed. Reg. at 32,170. After reviewing the comments, NIH published its final Guidelines on human stem cell research on July, 7 2009.

The Guidelines set forth eligibility requirements to determine which ESC lines "could be used in research funded by NIH." (Defs.' Opp'n [22] at 8.) If a research applicant proposes research on ESCs derived after the effective date of the Guidelines, the applicant must use either ESCs that are posted on the NIH registry, or submit an assurance of compliance with requirements contained within Section II(A) of the Guidelines. 74 Fed. Reg. at 32,174. Section II(A) requires that research involves only ESCs that were derived from human embryos that

"were created using *in vitro* fertilization for reproductive purposes and were no longer needed for this purpose" and "were donated by the individuals who sought reproductive treatment . . . and who gave voluntary written consent for the human embryos to be used for research purposes." *Id.* Section II(A) further requires documentation of the following: (a) that "[a]ll options available in the health care facility where treatment was sought pertaining to the embryos no longer needed for reproductive purposes were explained to the individual(s) who sought reproductive treatment"; (b) that no payments were offered for the embryos; (c) that the health care facility has procedures in place to ensure that the quality of care provided to potential donors would not be affected by their consent or refusal to donate embryos; (d) that there was a "clear separation" between the donor's decision to create the embryos for reproductive purposes and the donor's decision to donate the embryos for research; and (e) that donors were provided with certain information during the consent process. *Id.*

If a research applicant proposes research on ESCs derived before the effective date of the Guidelines, the applicant must use either ESCs that are posted on the NIH registry, or establish funding eligibility in one of two ways: the applicant may either comply with Section II(A), or submit materials to a Working Group of the Advisory Committee to the Director of NIH, which will make recommendations regarding funding eligibility. *Id.* at 32,175. If an applicant submits materials to the Working Group, the applicant must demonstrate that the ESCs were derived from embryos that were created using *in vitro* fertilization, that the embryos were no longer needed for reproductive purposes, and that the donors gave voluntary written consent that their embryos could be used for research. *Id.* In addition, the Working Group will consider the factors contained in Section II(A). *Id.*

Finally, the Guidelines provide that "NIH funding of the derivation of stem cells from human embryos is prohibited by" the Dickey-Wicker Amendment. *Id.* Thus, according to defendants, the Guidelines "recognize the distinction . . . 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 hESCs that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted." *Id.* at 32,173.

III. LEGAL STANDARD

A preliminary injunction is "an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion. *Cobell v. Norton*, 391 F.3d (251, 258 (D.C. Cir. 2004). A party carries this burden of persuasion by establishing: (1) that there is a substantial likelihood of success on the merits; (2) that the plaintiff would suffer irreparable injury absent an injunction; (3) that an injunction would not substantially injure other interested parties; and (4) that an injunction would further public interest. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)).

The Court evaluates these factors on a "sliding scale." *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009). Under this approach, the Court balances the factors against each other to determine whether the plaintiff has shown that "all four factors, taken together, weigh in favor of the injunction." *Id.* at 1292. Thus, a particularly strong showing on one factor may offset a weaker showing on another factor. *See id.* at 1291-92 ("If the movant makes an unusually strong showing on one of the factors, then it does not necessarily have to make as strong a showing on another factor."). The plaintiff, however, must show at

least some injury to warrant the preliminary injunction because "the basis for injunctive relief in the federal courts has always been irreparable harm." *CityFed Fin. Corp.*, 58 F.3d at 747.

IV. ANALYSIS

The Court finds that the likelihood of success on the merits, irreparable harm to plaintiffs, the balance of hardships, and public interest considerations each weigh in favor of a preliminary injunction. *See Winter v. Natural Res. Def. Counsel, Inc.*, 129 S. Ct. 365, 374 (2008). Accordingly, the Court will GRANT plaintiffs' motion and issue the preliminary injunction.

A. Likelihood of Success

Plaintiffs assert two independent arguments as to why they are likely to succeed on the merits. First, they argue that the Guidelines violate the plain language of the Dickey-Wicker Amendment. Second, they contend that, in promulgating the Guidelines, defendants violated the Administrative Procedure Act ("APA"). Because the Court concludes that plaintiffs have demonstrated a strong likelihood of success that the Guidelines violate the Dickey-Wicker Amendment, the Court need not address whether defendants violated the APA.

1. The Dickey-Wicker Amendment Is Unambiguous

Defendants argue that the Dickey-Wicker Amendment is ambiguous. Specifically, they argue that the term "research" is ambiguous, and that, as a result, their interpretation of research should be entitled to *Chevron* deference. *See Chevron U.S.A., Inc., v. Natural Resources Defense Counsel, Inc.*, 467 U.S. 837, 843 (1984). Defendants' argument fails.

Under *Chevron*, the Court must first ask whether Congress has "directly spoken to the precise question at issue." *Id.* at 842. If it has, the Court must "give effect to the unambiguously expressed intent of Congress." *Id.* at 843. If, however, the "the statute is silent or ambiguous

with respect to the specific issue," then the Court defers to the NIH's interpretation provided it is "based on a permissible construction of the statute." *Id.*

Congress has spoken to the precise question at issue—whether federal funds may be used for research in which an embryo is destroyed. The Dickey-Wicker Amendment provides that *no* federal funds shall be used for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 C.F.R. § 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Pub. L. No. 111-8, § 509(a)(2). Thus, as demonstrated by the plain language of the statute, the unambiguous intent of Congress is to prohibit the expenditure of federal funds on "research in which a human embryo or embryos are destroyed." *Id.*

Contrary to defendants' argument, the term "research" as used in the Dickey-Wicker Amendment has only one meaning, *i.e.*, "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d); *see also* Random House Dict. (listing the first definition of research as "diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc."). This is the most common definition of research, and no other definition of research is supported by the language of the statute.

The language of the statute does not support defendants' alternative definition of research as "a piece of research." (Def.'s Opp'n [22] at 31 (citing RANDOM HOUSE DICT. (2009).) Indeed, the Dickey-Wicker Amendment does not contain any language to support such a limited definition of research. Rather, the language of the statute reflects the unambiguous intent of Congress to enact a broad prohibition of funding research in which a human embryo is destroyed.

This prohibition encompasses *all* "research in which" an embryo is destroyed, not just the "piece of research" in which the embryo is destroyed. Had Congress intended to limit the Dickey-Wicker to only those discrete acts that result in the destruction of an embryo, like the derivation of ESCs, or to research on the embryo itself, Congress could have written the statute that way. Congress, however, has not written the statute that way, and this Court is bound to apply the law as it is written. Accordingly, this Court must "give effect to the unambiguously expressed intent of Congress" to prohibit federal funding of research in which a human embryo is destroyed. *Chevron*, 467 U.S. at 843.

2. The Guidelines Violate the Dickey-Wicker Amendment

Having concluded that the Dickey-Wicker Amendment is unambiguous, the question before the Court is whether ESC research is research in which a human embryo is destroyed. The Court concludes that it is.

Defendants argue that the ESC research is not research in which a human embryo is destroyed because ESC research does not involve embryos nor result in their destruction. This argument rests on defendants' interpretation of "research," as used in the Dickey-Wicker Amendment, to mean "a piece of research." (Defs.' Opp'n [22] at 31 (citing RANDOM HOUSE DICT. (2009).) This interpretation allows defendants to define ESC research and the derivation of ESCs from embryos as separate and distinct "pieces of research." Thus, the Guidelines, according to defendants, are consistent with Dickey-Wicker Amendment because the Guidelines only allow funding of ESC research, and not the derivation of ESCs, which results in the destruction of an embryo.

Defendants' argument is unavailing. Their entire argument assumes that the Dickey-

Wicker Amendment is ambiguous and that, as a result, they are entitled to *Chevron* deference. As discussed above, defendants' assumption is incorrect. The Dickey-Wicker Amendment unambiguously prohibits the use of federal funds for all research in which a human embryo is destroyed. It is not limited to prohibit federal funding of only the "piece of research" in which an embryo is destroyed. Thus, if ESC research is research in which an embryo is destroyed, the Guidelines, by funding ESC research, violate the Dickey-Wicker Amendment.

ESC research is clearly research in which an embryo is destroyed. To conduct ESC research, ESCs must be derived from an embryo. The process of deriving ESCs from an embryo results in the destruction of the embryo. Thus, ESC research necessarily depends upon the destruction of a human embryo.

Despite defendants' attempt to separate the derivation of ESCs from research on the ESCs, the two cannot be separated. Derivation of ESCs from an embryo is an integral step in conducting ESC research. Indeed, it is just one of many steps in the "systematic investigation" of stem cell research. 45 C.F.R. § 46.102(d). Simply because ESC research involves multiple steps does not mean that each step is a separate "piece of research" that may be federally funded, provided the step does not result in the destruction of an embryo. If one step or "piece of research" of an ESC research project results in the destruction of an embryo, the entire project is precluded from receiving federal funding by the Dickey-Wicker Amendment. Because ESC research requires the derivation of ESCs, ESC research is research in which an embryo is destroyed. Accordingly, the Court concludes that, by allowing federal funding of ESC research, the Guidelines are in violation of the Dickey-Wicker Amendment.

* * *

In sum, plaintiffs have demonstrated a strong likelihood of success on the merits. The Dickey-Wicker Amendment is unambiguous. It prohibits research in which a human embryo is destroyed, discarded, or knowingly subject to risk of injury or death greater than that allowed under applicable regulations. The Guidelines violate that prohibition by allowing federal funding of ESC research because ESC research depends up on the destruction of a human embryo.

B. Irreparable Injury

This Circuit has established a high standard for irreparable injury . *Chapliancy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). First, a plaintiff must allege an injury that is "both certain and great; it must be actual and not theoretical." *Id.* (quoting *Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). The alleged injury must be "of such *imminence* that there is a 'clear and present' need for equitable relief to prevent irreparable harm." *Id.* (citation omitted). Second, the plaintiff's alleged injury "must be beyond remediation." *Id.* Plaintiffs Sherley and Deisher have met this high burden.

Plaintiffs are researchers who work exclusively with ASCs. They seek funds for their research projects from defendants and allege "that obtaining NIH funding is *necessary* for their continued research." (Pls.' Mot. [3] at 44.) The Guidelines, by allowing federal funding of ESC research, increases competition for NIH's limited resources. This increased competition for limited funds is an actual, imminent injury. *See Sherely*, 2010 WL 2540358 at *5 (explaining that the increased competition that plaintiffs face is "substantial enough to deem the injury to them imminent"). There is no after-the-fact remedy for this injury because the Court cannot compensate plaintiffs for their lost opportunity to receive funds. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (quoting *Hoffman-Laroche Inc. v. Califano*, 453 F.

Supp. 900, 903 (D.D.C. 1978) (stating that even if an injury is economic in nature, the injury may be irreparable if "there is 'no adequate compensatory or other corrective relief' that can be provided at a later date"). Accordingly, plaintiffs would suffer irreparable injury in the absence of the injunction.

C. Balance of Hardships

The balance of hardships weighs in favor of an injunction. Defendants argue that two interested parties would be injured if the Court issues an injunction: ESC researchers and individuals who suffer from diseases that may be treatable in the future as a result of ESC research. The Guidelines give ESC researchers, like plaintiffs, the opportunity to compete for NIH funding. The injunction, however, would not seriously harm ESC researchers because the injunction would simply preserve the *status quo* and would not interfere with their ability to obtain private funding for their research. In addition, the harm to individuals who suffer from diseases that one day may be treatable as a result of ESC research is speculative. It is not certain whether ESC research will result in new and successful treatments for diseases such as Alzheimer's and Parkinson's disease.

Plaintiffs' injury of increased competition, however, is not speculative. It is actual and imminent. Indeed, the Guidelines threaten the very livelihood of plaintiffs Sherley and Deisher. Accordingly, the irreparable harm that plaintiffs would suffer absent the injunction outweighs the harms to interested parties.

D. Public Interest

Finally, the public interest weighs in favor of a preliminary injunction. "It 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 Pharms. Inc. v. Shalala*, 81 F. Supp. 2d 30, 45 (D.D.C. 2000). Here, the will of Congress, as expressed in the Dickey-Wicker Amendment, is to prohibit federal funding of research in which human embryos are destroyed. Accordingly, it is in the public interest to enjoin defendants from implementing the Guidelines because the Guidelines allow federal funding of ESC research, which involves the destruction of embryos.

V. CONCLUSION

Plaintiffs have established that the preliminary injunction factors—the likelihood of success on the merits, irreparable injury, the balance of hardships, and the public interest—weigh in favor of a preliminary injunction. Accordingly, the Court will GRANT plaintiffs' motion [3] for a preliminary injunction. A separate order shall issue this date.

Signed by Royce C. Lamberth, Chief Judge, on August 23, 2010.