IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. JAMES L. SHERLEY; DR. THERESA DEISHER; NIGHTLIGHT CHRISTIAN ADOPTIONS, individually and as next friend for PLAINTIFF EMBRYOS; SHAYNE AND TINA NELSON; WILLIAM AND PATRICIA FLYNN; CHRISTIAN MEDICAL ASSOCIATION, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services; DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. FRANCIS S. COLLINS, in his official capacity as Director of the National Institutes of Health; NATIONAL INSTITUTES OF HEALTH, Defendants.	Civil Action No. ____

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Thomas G. Hungar, D.C. Bar No. 447783
Bradley J. Lingo, D.C. Bar No. 490131
Ryan G. Koopmans, D.C. Bar No. 986233
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500

Samuel B. Casey, Cal. Bar No. 76022
Law of Life Project
ADVOCATES INTERNATIONAL
8001 Braddock Road, Suite 300
Springfield, VA 22151
(703) 894-1076

Blaine H. Evanson, Cal. Bar No. 254338
Alison E. Klingel, Cal. Bar No. 258194
GIBSON, DUNN & CRUTCHER LLP
333 S. Grand Avenue
Los Angeles, CA 90071
(213) 229-7000

Steven H. Aden, D.C. Bar No. 466777
ALLIANCE DEFENSE FUND
801 G. Street N.W., Suite 509
Washington, D.C. 20001
(202) 393-8690

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES

This Court should enjoin Defendants from taking any further actions to implement or apply the guidelines for public funding of research involving stem cells derived from human embryos ("Guidelines") promulgated by National Institutes of Health ("NIH"). 74 Fed. Reg. 32,170 (July 7, 2009) (attached to Decl. of Bradley J. Lingo in Support of Pls.' Mot. for Prelim. Inj. ("Lingo Decl."), Exh. A). Each of the well-established requirements for a preliminary injunction—likelihood of success on the merits, irreparable harm to the plaintiffs, the balance of hardships, and public-interest considerations—weighs strongly in favor of an injunction.

Plaintiffs have a high likelihood of success on the merits of their claims. To begin, the Guidelines violate federal law, which prohibits funding of "research in which" a human embryo is "destroyed, discarded, or knowingly subjected to risk of injury or death." Omnibus Appropriations Act of 2009, Pub. L. 111-8, § 509(a)(2), 123 Stat. 803 (2009). It is indisputable that research involving human embryonic stem cells necessarily and inevitably involves the destruction of human embryos. (Lingo Decl., Exh. B at 5 [Comments of Do No Harm et al.].) Thus, Defendants' actions are clearly contrary to law, and are therefore invalid under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A).

In addition, the Guidelines should be set aside because in deciding to fund embryonic stem cell research, NIH failed to explain how such funding will fulfill the Guidelines' stated purpose to support "ethically responsible" and "scientifically worthy" research and failed to address substantial evidence in the administrative record showing that federal funding of such research will in fact have the opposite effect. 74 Fed. Reg. 32,170. Scientific discoveries in *adult* stem cell research have made it unnecessary to engage in research that destroys a human embryo. NIH's failure to explain its decision to fund embryonic stem cell research in light of less morally problematic alternatives—and to nevertheless promulgate ethically dubious guidelines funding

scientifically obsolete research—is arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A). Finally, by giving interested parties a mere 34 days to comment on this important issue and refusing to consider comments by those asking NIH to reconsider its decision to fund embryonic stem cell research, NIH has failed to follow the procedures in the Administrative Procedure Act, 5 U.S.C. § 553.

This case provides the quintessential grounds justifying a preliminary injunction: Once destroyed, an embryo cannot be revived. NIH began accepting embryonic stem cell research funding applications even before the Guidelines took effect on July 7, 2009. Absent injunctive relief, many embryos will be destroyed in federally funded research, and this irreparable harm to Plaintiffs far outweighs any conceivable harm to Defendants or others in maintaining the *status quo*. Given the significant moral, ethical, and scientific concerns at stake, injunctive relief is also necessary to further the public interest.

FACTUAL BACKGROUND

I. The Use Of Stem Cells To Treat Medical Illness

Stem cell research holds the potential to treat many diseases that have long resisted traditional methods. But it is important to understand that, from both scientific and moral standpoints, not all stem cells are created equal. There are three general types of stem cells: embryonic, adult, and induced pluripotent. While embryonic stem cells have received much of the public and media attention, scientists have been making dramatic breakthroughs in the use of adult and induced pluripotent stem cells, and these latter and less morally objectionable research methods have generated the vast majority of medical progress.

Embryonic stem cells—as the name implies—are found in the inner cell mass of a living embryo. Because these cells are the building blocks of the human organism, they have the po-

tential to turn into any type of cell in the human body. In 1998, Dr. James Thomson, a professor at the University of Wisconsin, discovered a process for deriving stem cells from embryos. Despite the ethical concerns of engaging in research that causes the death of a human embryo, many researchers hailed the discovery and predicted that embryonic stem cell research would lead to the cure of many diseases such as Parkinson's, Alzheimer's, and diabetes. Those predictions have not come to pass. In fact, rather than treating a patient's disease, research shows that embryonic stem cells would likely form tumors when injected into the body. (Lingo Decl., Exh. B at I-1, I-2.) In addition, because embryonic stem cells do not come from the patient, they would likely be rejected by the patient's immune system. (*See* Lingo Decl., Exh. B at G-8.) Thus, not only have embryonic stem cells failed to demonstrate the miracle-working potential that some had forecasted, research shows they have the potential to cause harm.

Adult stem cells are cells found in the body and in tissues normally discarded after birth (such as umbilical cord blood and the placenta) that have the potential to generate most or all of the different tissues in the human body. (*Id.* at G-1.) And, unlike embryonic stem cells, adult stem cells have shown tremendous promise in treating disease. As former NIH head Dr. Bernadine Healy stated earlier this year, adult stem cells "have become stars" representing "most of the stem cell triumphs that the public hears about." Bernadine Healy, M.D., *Why Embryonic Stem Cells Are Obsolete*, U.S. News & World Report, March 4, 2009, *available at* http://health.usnews.com/blogs/heart-to-heart/2009/03/04/why-embryonic-stem-cells-are-obsolete.html. Indeed, adult stem cells have verifiably treated countless individuals suffering from a wide variety of diseases including, but not limited to, ovarian cancer, retinoblastoma, brain tumors, testicular cancer, chronic and acute leukemias, breast cancer, renal cell carcinoma, anemias, Crohn's disease, rheumatoid arthritis, and juvenile diabetes. (Lingo Decl., Exh. B at G-

5–G-7.) In addition, adult stem cells do not present a risk of tumor formation, and because adult stem cells often come from the patient's own body, there is less risk of immune rejection. (*Id.* at G-8.)

Induced pluripotent stem cells (commonly known as iPS cells or iPSCs), are adult cells that have been genetically reprogrammed such that they are virtually identical to embryonic stem cells. The process of replicating embryonic stem cells from human adult cells was discovered less than two years ago by a group of researchers, including Dr. Thomson. (Lingo Decl., Exh. B at H-2–H-3.) This discovery was a dramatic leap forward in developmental biology, hailed by the journal *Science* as last year's leading scientific breakthrough in any field. Gretchen Vogel, *Breakthrough of the Year: Reprogramming Cells*, 322 Science 1766 (2008). These cells "meet the defining criteria [that were] originally proposed for human [embryonic stem] cells, with the significant exception that the [induced pluripotent stem] cells are not derived from embryos." Junying Yu et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 Science 1917 (2007). In addition, unlike embryonic stem cells, NIH has stated that "tissues derived from [induced pluripotent stem cells] will be a nearly identical match to the cell donor and thus probably avoid rejection by the immune system." Nat'l Institutes of Health, *Stem Cell Basics* 14 (2009), *available at* http://stemcells.nih.gov/staticresources/info/basics/ SCprimer2009.pdf.

For these reasons, Dr. Thomson—the pioneer of embryonic stem cell research—has publicly recognized that the availability of induced pluripotent stem cells will soon make research using embryonic stem cells an anachronism. *See* G. Kolata, *Man Who Helped Start Stem Cell War May End It*, N.Y. Times, Nov. 22, 2007, *available at* http://www.nytimes.com/2007/11/22/science/22stem.html (quoting Dr. Thomson as saying, "[i]sn't it great to start a field

and then to end it"). Others have similarly recognized that induced pluripotent stem cells offer all of the scientific possibilities of embryonic stem cells—and more. For instance, Professor Ian Wilmut—whose research brought about the first cloned sheep, Dolly—has declared that the induced pluripotent "technique to obtain stem cells is now the most efficient technique for researchers" and that "[induced pluripotent] cells are more useful than embryonic cells." (Lingo Decl., Exh. B at H-3.)

II. Public Funding And Embryonic Stem Cell Research

In 1996, Congress enacted an appropriations rider that prohibits federal funding of research in which human embryos are harmed or destroyed. The rider, commonly known as the Dickey-Wicker Amendment, provides in relevant part that: "(a) [n]one of the funds made available by this Act may be used 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 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. § 289g(b))." Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996). The Dickey-Wicker Amendment has been included in every Health and Human Services ("HHS") appropriations bill since 1996, and has not been altered in any material respect.[1] *See* Omnibus Appropriations Act of 2009, Pub. L. 111-8, § 509(a)(2), 123 Stat. 803.

---

[1] In 2005, the citation in the rider was changed from 45 C.F.R. § 46.208(a)(2) to 45 C.F.R. § 46.204(b). Whereas the old regulation allowed only minimal risk in every case, the new regulation appears to allow risk that is greater than minimal, as long as that risk "is caused solely by interventions or procedures that hold out the prospect of direct benefit" for the fetus.

From the time Congress passed the Dickey-Wicker Amendment, no federal money has been spent on research that depended on the further destruction of human embryos. Nevertheless, on July 7, 2009—in the face of the federal ban and the ever-accumulating evidence that embryonic stem cells are scientifically obsolete—NIH issued "Guidelines For Human Stem Cell Research" that broadly promise federal funding for embryonic stem cell research that will necessarily involve the destruction of now-living embryos. 74 Fed. Reg. 32,174. These Guidelines mark the first use of federal funds in a way that will incentivize and cause the destruction of human embryos for research.

ARGUMENT

The NIH Guidelines violate a clear statutory provision that expressly precludes any funding for research in which embryos are injured or destroyed, and were in any event invalidly promulgated because NIH ignored numerous comments it received setting forth effective alternatives to embryonic stem cell research and numerous scientific and ethical problems with funding research in which embryos are injured and destroyed. And because the implementation of the Guidelines risks the destruction of the embryos, there is unquestionably a risk of irreparable harm if NIH is not enjoined from further implementing the Guidelines. Thus, as set forth below, each of the well-established requirements for a preliminary injunction—likelihood of success on the merits, irreparable harm to the plaintiffs, the balance of hardships, and public-interest considerations—weighs strongly in favor of an injunction. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998).

I. Plaintiffs Are Likely To Prevail on the Merits of Their Claims

The Guidelines must be set aside for two compelling reasons. First, the 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." Second, in promulgating the Guidelines NIH ignored scores of comments detailing the scientifically and ethically superior alternatives to embryonic stem cell research. Indeed, NIH ignored more than 60 percent of the public comments because those comments did not support the agency's preconceived decision to fund embryonic stem cell research. In so doing, NIH rushed to a predetermined judgment that is not only scientifically and ethically flawed, but also legally invalid.

A. The Guidelines Violate The Dickey-Wicker Amendment By Funding Research In Which An Embryo Is Destroyed.

1. The Clear Text And Structure Of The Dickey-Wicker Amendment Preclude The NIH Guidelines.

The NIH Guidelines violate Congress's unambiguous prohibition against federal funding of "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death." Pub. L. No. 111-8, § 509(a)(2). The ban on research that involves the destruction of embryos is broad; funding is prohibited for the actual destruction of embryos, and also for any "research in which . . . embryos are destroyed." *Id.* Because it is indisputable that human embryonic stem cell research involves injury to and destruction of human embryos, the text of the Dickey-Wicker Amendment plainly precludes federal funding for such research.

NIH seeks to avoid Congress's unambiguous ban on destructive embryo research by asserting that the funding ban applies only to the act of deriving the stem cells from the embryos, but not to subsequent experiments on those cells. 74 Fed. Reg. 32,173. But this distinction ignores the plain text of the statute, which not only prohibits funding for discrete acts that destroy human embryos, but also for all "*research in which*" an embryo is "destroyed, discarded or knowingly subjected to risk of injury or death." Pub. L. No. 111-8, § 509(a)(2) (emphasis added).

Indeed, the Amendment contains two subsections: It prohibits the use of 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 45 C.F.R. § 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. § 289g(b))."[2] *Id*. By its terms, subsection (1) prohibits funding for the *specific act* of creating a human embryo for research purposes, while subsection (2) prohibits funding for all "*research in which*" a human embryo is destroyed or knowingly threatened. NIH's interpretation renders this two-section format nonsensical: If Congress intended to forbid only the use of federal funds for specific acts that destroy human embryos, it could have done so in a far simpler and more straightforward way by utilizing the format of subsection (1) to prohibit funding for specific acts that destroy human embryos. *See Ali v. Fed. Bureau of Prisons*, 128 S. Ct. 831, 840 (2008) (rejecting petitioner's interpretation of a statute, in part because "[h]ad Congress intended to limit [the statute's] reach as petitioner contends, it easily could have written [it that way]").

Congress instead chose to protect human embryos by enacting a much broader ban. Rather than banning funding only for specific acts that destroy human embryos, Congress banned funding for any "*research in which* a human embryo or embryos are destroyed" or are "knowingly subjected to risk of injury or death." Pub. L. No. 111-8, § 509(a)(2) (emphasis added). Both

---

[2] The cross-referenced regulation, when incorporated into the appropriations rider, effectively provides as follows: "No [human embryo] may be involved as a subject in any activity covered by this subpart unless: . . . the risk to the [human embryo] imposed by the research is not greater than minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by any other means." 45 C.F.R. § 46.204(b).

by its terms and by necessary implication, that prohibition bans the funding of research, such as embryonic stem cell research, that is dependent upon and induces the destruction of human embryos. NIH's contrary reading improperly ignores the important differences in the way Congress structured its ban on funding for the creation of human embryos, on the one hand, and its ban on all research that destroys or threatens embryos, on the other. *See Russello v. United States*, 464 U.S. 16, 23 (1983) (holding that where Congress uses different language in proximate subsections of the same statute, courts must construe the statute to give effect to those differences in language); *Harbor Gateway Commercial Prop. Owners' Ass'n v. EPA*, 167 F.3d 602, 606 (D.C. Cir. 1999) ("We see no reason to depart from the usual canon that when Congress uses different language in different sections of a statute, it does so intentionally.").

Common sense dictates that this language was chosen to ensure that embryos are not destroyed to support federally funded experiments. Clearly, Congress did not enact the funding ban because it was trying to save taxpayer money or reduce the deficit. It enacted the ban because it was concerned with the moral costs of research involving the destruction of human embryos. NIH's interpretation would make the Dickey-Wicker Amendment a hollow accomplishment.

2. NIH's Interpretation Of The Dickey-Wicker Amendment Is Untenable And Is Incompatible With NIH's Own Understanding Of "Research."

NIH's supposed distinction between "research" with stem cells and "derivation" of stem cells is also untenable on its face. As an initial matter, NIH itself has recognized that "research" is not task specific. Under the Human Subject Protection Regulations—incorporated by Congress in the Dickey-Wicker Amendment—"research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d). In other words, research is a systematic process

involving multiple steps and procedures with the overall purpose of advancing knowledge. Derivation of human embryonic stem cells for scientific inquiry thus constitutes an integral part of the research being conducted under NIH's own regulations. Moreover, the Department of Health and Human Service's ("HHS") own guidance on these regulations provides that an institution that receives federal funding is generally engaged in human subjects research "*even where all activities involving human subjects are carried out by employees or agents of another institution*." Department of Health and Human Services, *Guidance on Engagement of Institutions in Human Subjects Research* (Oct. 16, 2008), available at http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html (emphasis added). Thus, NIH's artificial division of labor between deriving stem cells from human embryos and using those cells is inconsistent with its own interpretation of the term "research," which recognizes that such activities constitute parts of an overall research project.

NIH's overly narrow interpretation of the funding ban's use of the term "research" is also inconsistent with courts' use of that term. For instance, in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis added), the Supreme Court, in analyzing the scope of the research exemption under the patent statute, acknowledged that "research" is a multi-phase process rather than a single experiment: "There is simply no room in the statute for excluding certain information from the exemption on the basis of *the phase of research* in which it is developed or the particular submission in which it could be included." *See also Nat'l Ctr. for Mfg. Sciences, Inc. v. City of Ann Arbor*, 563 N.W.2d 65, 68 (Mich. Ct. App. 1997) (agreeing that "research is not limited to a specific experiment" but includes "other critical steps in the research process [such as] the definition of the research agenda, raising the money to perform the necessary experiments, and the monitoring and evaluation of the results").

The Guidelines themselves acknowledge that research involving embryonic stem cells is inextricably intertwined with, and indeed includes, the act of destroying human embryos. The Guidelines demand that NIH-funded researchers delve into the matter of derivation to ensure that the process by which the embryos were selected for destruction was in accordance with the Guidelines. *See* 74 Fed. Reg. 32,170 (noting that "the Guidelines pertain primarily to the donation of embryos for the derivation of [human embryonic stem cells]"). NIH cannot plausibly contend that the embryonic stem cell research that it proposes to fund is wholly separate and legally distinct from the destruction of human embryos while also mandating that individuals donating "human embryos for *research* purposes" be informed of "[w]hat would happen to the embryos in the derivation of [the stem cells]." 74 Fed. Reg. 32,174 (emphasis added).

To demonstrate the implausibility of NIH's interpretation of "research in which," consider that the Guidelines do not even prohibit funding to a researcher who both derives stem cells from an embryo and then uses the cells in federally funded activities. Indeed, far from prohibiting such funding, the Guidelines actually contemplate that the deriver and user may be the same person. The Guidelines state that when it is "practicable," the physician responsible for fertility treatments should not have been the same person as "the researcher deriving *and/or* proposing to utilize [human embryonic stem cells]." 74 Fed. Reg. 32,174 (emphasis added). The obvious implication of the "and/or" construction is that a *single researcher* can both derive the cells and use federal money for subsequent experiments on those cells. It defies common sense to suggest that a federal grant recipient is not engaged in "research in which" a human embryo is destroyed when the researcher is conducting a multi-phase study of stem cells and he derives the stem cells—and thereby destroys an embryo—at phase one of the research effort. *See Harbor Gateway*, 167 F.3d at 606 (rejecting the EPA's interpretation of an appropriations rider because "there

is no reason to mistrust the common sense understanding of the statutory language" (internal quotation omitted)).

3. The Language And Purpose Of The Dickey-Wicker Amendment Have Not Changed.

NIH also contends that Congress—by passing the Dickey-Wicker Amendment each year without change—has "accepted" its "consistent" and "long-standing" interpretation. 74 Fed. Reg. 32,173. This argument is baseless, however, because HHS has *not* consistently interpreted the funding ban. In addition, NIH has never funded research that was dependant on the further destruction of human embryos, belying the notion that Congress has acquiesced in such conduct.

In 1999, HHS General Counsel Harriet S. Rabb issued a memorandum ("Rabb Memorandum") in which she concluded that embryonic stem cells are not "embryos" under the Dickey-Wicker Amendment. (Lingo Decl., Exh. D [Rabb Memorandum].) From that premise, she reasoned that NIH could legally fund experiments on the stem cells after those cells had been derived with private funds. Despite the fact that the Rabb Memorandum said *nothing* about the scope of the word "research," and was merely an opinion of agency counsel rather than a formal interpretation by the agency head, NIH cited the Memorandum in promulgating its first guidelines involving human embryonic stem cells. 65 Fed. Reg. 51,976 (adopting the Rabb Memorandum's conclusion that "federally funded research that utilizes [human embryonic stem cells] would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such cells are not human embryos").

These guidelines were never implemented, however. They were initially stayed due to litigation, and in November 2001, NIH formally withdrew the guidelines (66 Fed. Reg. 57,107) after then-President Bush instituted a new policy to limit funding of embryonic stem cell research to "existing stem cell lines where the life and death decision has already been made."

Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), *available* at http://www.whitehouse.gov/the_press_office/Fact-Sheet-on-Presidential-Executive-Order/. By withdrawing the guidelines, NIH also withdrew its reliance on the Rabb Memorandum.

After NIH withdrew the guidelines, on January 11, 2002, HHS General Counsel Alex M. Azar II issued a memorandum ("Azar Memorandum") concluding that the new policy comported with the federal funding ban. (Lingo Decl., Exh. B at F-1–F-8.) This time, HHS General Counsel focused on the meaning of "research in which." The Azar Memorandum concluded that funding of experiments on "a discrete set" of existing stem cell lines for which the life-and-death decision had already been made did not violate the Dickey-Wicker Amendment because such funding "provides no incentives for the destruction of additional embryos." In other words, because the "life and death decision" had already been made prior to the funding announcement, there was no causal link between the federally funded research and the destruction of the embryos.

The Azar Memorandum's recognition of the need to consider whether NIH was creating an incentive for the further destruction of embryos represented a shift in HHS General Counsel's interpretation of the Dickey-Wicker Amendment. Under the Rabb Memorandum's earlier derivation-versus-use interpretation, the question whether federal funding created an incentive for researchers to derive more stem cells was irrelevant. Thus, even leaving aside the fact that both memoranda were merely opinions of counsel rather than interpretations by the NIH Director, NIH's contention that it has "consistently" interpreted the Dickey-Wicker Amendment since 1999 is simply not true.

Even the members of Congress who support embryonic stem cell research have recognized that NIH's current interpretation does not comport with the plain terms of the Dickey-Wicker Amendment. For this reason, in 2001, an additional subsection was introduced in the Senate version of the Dickey-Wicker Amendment that would allow funding of all "stem cell research, on embryos that have been created in excess of clinical need and will be discarded, and donated with the written consent of the progenitors." S. 1536, 107th Cong. § 510(c) (2001). The Executive Branch "strongly oppose[d] the Senate version" because it modified the existing language and "would signal a weakening of the Federal Government's commitment to protecting human embryos," and "strongly support[ed] the House version" which retained the existing language. Office of Management and Budget, Statement of Administrative Policy (Oct. 30, 2001), *available at* http://www.whitehouse.gov/omb/legislative/sap/107-1/S1536-s.html. Congress agreed and ultimately rejected the Senate version. Absent Congressional adoption of such statutory language, the Dickey-Wicker Amendment must be construed—consistent with its plain terms—to prohibit NIH from funding research in a manner that causes and incentivizes the destruction of human embryos.

* * *

The conclusion that the NIH Guidelines violate Congress's funding ban is inescapable. The Guidelines—which expressly regulate and induce the destruction of human embryos—plainly allow funding for research in which embryos are destroyed. NIH's contrary interpretation is implausible: It ignores the common usage of the term "research," the structure of the funding ban, and Congress's purpose in avoiding the taxpayers' complicity in the sacrifice of human embryos.

B. The Guidelines Violate The Dickey-Wicker Amendment Even Under NIH's Implausible Interpretation Of "Research."

Contrary to NIH's implicit assumption, moreover, the funding ban extends beyond research in which embryos are destroyed: It also prohibits funding for research in which human embryos are "*knowingly* subjected to risk of injury or death." Pub. L. No. 111-8, § 509(a)(2) (emphasis added). It is indisputable that those funding and conducting embryonic stem cell research knowingly subject human embryos to substantial risk of injury or death. Thus, even assuming NIH's implausible, task-specific interpretation of "research," NIH cannot escape the conclusion that the Guidelines violate the funding ban.

A person does not need to *intend* a consequence in order to act "knowingly"—he need only set in motion a chain of events that ultimately leads to a foreseeable result. *See, e.g.*, *H.A.L. v. Foltz*, 551 F.3d 1227, 1230 (11th Cir. 2008) (holding that a state employee "*knowingly subjected* [foster children] to a substantial risk of victimization" by placing another child with a history of aggressive sexual behavior in the same home (emphasis added)); *United States v. Walters*, 997 F.2d 1219, 1223 (7th Cir. 1993) (stating that a person "knowingly causes" the use of the mails when he "acts with the knowledge that the use of the mails will follow in the ordinary course of business, or where such use can reasonably be foreseen" (internal quotation omitted)). Under NIH's Guidelines, grant-awarding officials and federally funded researchers will "knowingly subject" human embryos "to risk of injury or death" by funding and conducting embryonic stem cell research that inevitably creates a substantial risk—indeed, a virtual certainty—that more human embryos will be destroyed in order to derive more embryonic stem cells for research purposes. If a private scientist, who derives and studies embryonic stem cells without use of public money, destroys an embryo in order to satisfy a request for embryonic stem cells from a federally funded scientist—a practice allowed under NIH's Guidelines—the public scientist

knows that his request, which is an integral part of his research, will subject living human embryos "to risk of injury or death." The public scientist could work in the same laboratory, refer to himself as a collaborator, and even watch as his request is carried out. In fact, as already explained, the Guidelines do not even prohibit the deriver and the user from being the very same person, in which case the federally funded scientist would be absolutely certain that his research subjects human embryos to death.

Similarly, by awarding new grants for embryonic stem cell research, NIH officials will set in motion a chain of events that will create demand for additional, newly derived stem cells. In so doing, there can be no question that NIH officials are knowingly subjecting human embryos to risk of death. Indeed, as discussed, the Guidelines—by regulating the process by which researchers destroy those embryos—explicitly contemplate the destruction of additional embryos for purposes of federally funded research. *See* 74 Fed. Reg. 32,174. There can therefore be no doubt that the research which the NIH's Guidelines now promise to fund will involve "knowingly" subjecting embryos to risks of injury and death, and the Guidelines therefore violate the Dickey-Wicker Amendment even under NIH's interpretation of the statutory language.

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

In its too-hasty effort to overturn the previous policy, NIH did not engage in the statutorily required "reasoned decisionmaking": NIH failed to observe the procedures required by the APA, and accordingly it promulgated Guidelines that are arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A). *Cf. Int'l Bhd. of Teamsters v. United States*, 735 F.2d 1525, 1531 (D.C. Cir. 1984). As set forth below, NIH has refused to consider important information about embryonic, adult, and induced pluripotent stem cells, and in order to reach its desired result—and to lighten its intellectual and administrative load along the way—NIH simply disre-

garded *more than 60 percent* of the public comments on the Guidelines. In addition, the Guidelines are at odds with numerous state and federal laws, and the Guidelines' provisions governing conflicts of interest and informed consent procedures are irrational and incomplete.

When taking any final action, an "agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Importantly, courts do not simply "rubber stamp" an agency's decision. *United States v. Garner*, 767 F.2d 104, 116 (5th Cir. 1985). Instead, they undertake a "searching and careful inquiry" to "ensure that the agency engaged in reasoned decisionmaking." *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 815 (D.C. Cir. 1983) (internal quotation omitted). In determining whether an agency has engaged in "reasoned decisionmaking," a court must examine carefully the agency's articulated basis for its decision. *State Farm*, 463 U.S. at 50. A court may neither supply its own rationale nor consider an agency counsel's "post hoc rationalizations" to justify the agency's decision. *Id.* On the basis of the agency's explanation alone, the court must determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* at 43.

The Guidelines cannot survive this review. In its promulgation of the Guidelines, NIH failed to provide a rational connection between the facts found and its choice to fund embryonic stem cell research instead of scientifically and ethically superior adult stem cell research; failed to consider viable alternatives such as induced pluripotent stem cell research; ignored relevant considerations such as the inherent flaws of embryonic stem cells; disregarded the effects of the Guidelines on state statutory regimes; failed to cogently justify the provisions addressing conflicts of interest and informed consent; and abdicated its responsibility to respond to significant

arguments made during the public comment period. The unsurprising result of this flawed decision-making process is an irresponsible set of Guidelines that fund unethical and unnecessary research.

1. NIH Failed To Offer A Rational Connection Between The Facts Found And The Decision To Fund Embryonic Stem Cell Research.

The ostensible purpose of the Guidelines is to ensure that NIH funding is "ethically responsible, scientifically worthy, and conducted in accordance with applicable law." 74 Fed. Reg. at 32,170. This purpose echoes the President's laudable goal of ensuring that "scientific data is never distorted or concealed to serve a political agenda—and that we make scientific decisions based on facts, not ideology."[3] And yet, ironically, NIH did just what the President criticized: It allowed ideology, not facts, to drive its decision to fund research that is morally objectionable and scientifically obsolete.

In contrast to embryonic stem cell research, adult stem cell research delivers far greater medical benefits with fewer disadvantages; is ethically responsible; and comports with the law. (Lingo Decl., Exh. B at 1–19, B-1–B-5, C-1–C-18, E-1–E-9, G-1–G-8, H-1–H-7, I-1–I-11, J-1–J-8.) The administrative record demonstrates these facts, yet NIH has failed even to consider them and accordingly has not fulfilled its statutory duty to establish a "rational connection" between these facts and its choice to fund human embryonic stem cell research. *See, e.g., United States Telecomm. Ass'n v. FCC*, 227 F.3d 450, 461 (D.C. Cir. 2000) ("Fundamental principles of ad-

---

[3] President Barack Obama, Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum.

ministrative law require that agency action be based on a consideration of the relevant factors and rest on reasoned decisionmaking in which the agency must examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." (internal quotation marks omitted)).

NIH claims to be pursuing "scientifically worthy" stem cell research, 74 Fed. Reg. at 32,170, but the administrative record demonstrates that adult stem cell research offers far greater medical benefits than embryonic stem cell research. (Lingo Decl., Exh. B at 9–13, 18, G-1–G-8, H-1–H-7, I-1–I-11.) Unlike embryonic stem cell research, adult stem cell research has already *proven* to be "scientifically worthy." (*Id.*) Indeed, it has improved the health and saved the lives of thousands of patients. (*Id*. at G-4.) Moreover, though one would not know it from reading NIH's Guidelines, adult stem cell research does not suffer from numerous shortcomings of embryonic stem cell research. (*Id*. at G-1–G-8, I-1–I-11.) Because NIH overlooked many of the shortcomings of embryonic stem cells—in their inherent properties, their development, and their potential uses—NIH has failed to consider an important aspect of the problem. *See Arkansas v. Oklahoma*, 503 U.S. 91, 113 (1992) (citing *State Farm*, 463 U.S. at 43). In sum, in light of the successes of adult stem cell research, it simply blinks reality for NIH to claim that it is rationally pursuing "scientifically worthy" research when it is, in fact, dedicating scarce funds to an unproven and inferior alternative.

Embryonic stem cells are inherently flawed because they are not normal cells. (Lingo Decl., Exh. B at I-1.) Indeed, the formation of tumors by human embryonic stem cells is such an essential characteristic of those cells that it is used to identify a cell as a pluripotent human embryonic stem cell and serves as a quality control test used by commercial suppliers of human embryonic stem cells. (*Id.* at I-2.) Research has shown that this propensity to form tumors is not

the product of a single aberrant embryonic stem cell but an inherent property of all embryonic stem cell injections. (*Id.*) Tumor-producing cells are obviously highly flawed as potential medical cures—a fact that NIH does not even acknowledge, much less explain away.

Embryonic stem cells are also flawed in the manner in which they develop because they do not differentiate into the type of cells needed for therapeutic treatments. Embryonic stem cells differentiate only into fetal or immature cell types, rather than into fully functioning adult cells. (*Id.*) And fetal cells are not adequate cell replacements for lost adult cells. Rather, experience shows that *in vivo* use of fetal tissue or cells leads to dangerous, uncontrolled cell growth and tumor formation. (*Id.* at I-2–I-3.) NIH stands mute in the face of these serious problems with embryonic stem cells.

Given the major scientific problems with embryonic stem cell research, it is unsurprising that, although "more than a decade" has passed since the discovery of human embryonic stem cells, they are "not currently being used clinically" and NIH can express only the hope that they will someday deliver a modicum of their supposed "potential." 74 Fed. Reg. 32,173–74. Not only is NIH's hope desperately misplaced, but the agency also elides a critical point: Adult stem cell research offers proven results, not far-off wishes. Adult stem cells have *already* treated countless individuals suffering from a wide variety of diseases including, but not limited to, ovarian cancer, retinoblastoma, brain tumors, testicular cancer, chronic and acute leukemias, breast cancer, renal cell carcinoma, anemias, Crohn's disease, rheumatoid arthritis, and juvenile (Type I) diabetes. (*See* Lingo Decl., Exh. B at G-5–G-8.) Adult stem cells are *currently* being used to clinically treat many diseases in human patients. Successful clinical trials include the use of adult stem cells, in conjunction with chemotherapy or radiation, in treatments for a wide variety of cancers, and adult stem cells have been used in treatments for sickle cell anemia and Fanco-

ni's anemia. In short, it is not rational for NIH to dedicate scarce resources to embryonic stem cell research when adult stem cells are already delivering verifiable medical results, and NIH did not even attempt to explain its contrary conclusion.

When one considers the following characteristics of adult stem cells (as NIH should have done), it is no wonder that only adult stem cells—and not embryonic stem cells—have delivered substantial medical results:

- Unlike embryonic stem cells, adult stem cells do not pose a risk of tumor formation. (*Id.* at G-2.)
- Adult stem cells provide a readily available and flexible source of stem cells for the treatment of disease. (*Id.*)
- Adult stem cells can be harvested from virtually all body tissues, as well as tissues normally discarded after birth (*i.e.*, umbilical cord blood and the placenta). (*Id.*)
- Adult stem cells often avoid the problem of immune rejection because, in most cases, a patient's own stem cells can be used for treatment. (*Id.*) This obviously is not true for embryonic stem cell research, which destroys (rather than heals) the human life used to supply the stem cells.
- Adult stem cells have demonstrated the ability to home to sites of tissue damage, allowing for the development of "minimally invasive administration techniques." (*Id.*)
- Adult stem cells have successfully been used to treat patients with certain autoimmune diseases. (*Id.* at G-6.)

With nary a word about why it is ignoring the medical benefits of adult stem cell research, NIH nonetheless decided to fund embryonic stem cell research. In doing so, the agency utterly failed to "examine the relevant data and articulate a satisfactory explanation for its action,

including a rational connection between the facts and the choice made." *United States Telecomm. Ass'n*, 227 F.3d at 461 (internal quotation marks omitted). NIH's conduct in this regard is quintessentially arbitrary and capricious.

2. NIH Failed To Consider Reasonable Alternatives To The Funding Of Embryonic Stem Cell Research.

Even if NIH had rationally chosen to fund embryonic stem cell research instead of pursuing adult stem cell research, the Guidelines would still have to be set aside because NIH failed to consider sufficiently another vastly superior alternative to the funding of embryonic stem cell research—namely, induced pluripotent stem cell research. Human induced pluripotent stem cell research offers all of the potential of embryonic stem cell research, with none of the moral difficulties. Accordingly, even if NIH had reason to believe that human embryonic stem cell research would be as scientifically valuable as adult stem cell research, it would still be arbitrary and capricious for NIH to fund embryonic stem cell research when it could achieve the same scientific goals through the ethically superior alternative of research using human induced pluripotent stem cells.

Induced pluripotent stem cells are a perfectly viable substitute for embryonic stem cells. In fact, they are virtually indistinguishable from embryonic stem cells. (Lingo Decl., Exh. B at H-2.) As explained by Dr. Thomson, a pioneer in the field of embryonic stem cell research, induced pluripotent stem cells "meet the defining criteria [that were] originally proposed for human [embryonic stem] cells, with the significant exception that the [induced pluripotent stem] cells are not derived from embryos." Yu, *supra*, 318 Science 1917. In addition, induced pluripotent stem cell research provides distinct advantages over embryonic stem cells. Because the creation of induced pluripotent stem cells does not require use of embryos, eggs, or cloning, iPSC research avoids the ethical concerns associated with embryonic stem cell research. (Lingo

Decl., Exh. B at H-4.) In addition, induced pluripotent stem cell lines can be created from a specific individual, allowing creation of patient-specific cell lines. (*Id.*) Several such lines have already been created from individuals with specific diseases so that disease mechanisms and potential drug-based therapies can be studied in the laboratory. (*Id.*) Indeed, NIH itself has recognized that, unlike embryonic stem cells, "tissues derived from [induced pluripotent stem cells] will be a nearly identical match to the cell donor and thus probably avoid rejection by the immune system." *Stem Cell Basics*, *supra* at 14.

Induced pluripotent stem cell research is a well-known, viable alternative to embryonic stem cell research. In fact, according to Dr. Thomson, it will not be long before embryonic stem cell research will be obsolete and the stem cell debate "will be just a funny historical footnote." Kolata, *supra*. Induced pluripotent stem cell research was mentioned in the notice announcing the consideration of the Guidelines, 74 Fed. Reg. at 18,578, and the promise and possibilities of the research were explicitly described in the comments received (*see* Lingo Decl., Exh. B), but NIH offered no explanation in the final Guidelines as to why it chose to authorize funding of ethically problematic human embryonic stem cell research rather than focusing on the ethically superior and scientifically equivalent alternative of induced pluripotent stem cell research. Because NIH has offered no adequate explanation for why it chose to fund embryonic stem cell research when research using induced pluripotent stem cells offers the same (or even greater) promise, the Guidelines are arbitrary and capricious. *See, e.g., Int'l Ladies' Garment Workers' Union*, 722 F.2d at 817 (stating that the APA "demands an adequate explanation when [such an alternative is] rejected").

3. Adult Stem Cell Research Is Not Only More Promising, It Also Avoids The Serious Moral Problems Of Research Using Human Embryos.

NIH offers no rational justification for its decision to pursue ethically problematic embryonic stem cell research instead of focusing on adult stem cell research and/or induced pluripotent stem cell research. There is widespread concern over the ethics of human embryonic stem cell research. A deep concern is justified by the fact that human embryonic stem cell research necessarily involves the killing of a human embryo during the harvesting of the embryonic stem cells, and there is a scientific consensus that each such embryo is the "beginning of a new human being." Keith L. Moore & Persaud, T.V.N., *The Developing Human: Clinically Oriented Embryology* 2 (7th ed. 2003). As noted in comments submitted to NIH, "[a]dvisory groups seeking to inform federal policy on human embryo research have consistently acknowledged that fact, and recognized that it has serious moral implications." (Lingo Decl., Exh. C at 2 [Comments of the U.S. Conference of Catholic Bishops].) Indeed, NIH's own Human Embryo Research Panel noted in 1994 that human embryos "warrant serious moral consideration as a developing form of human life." Nat'l Inst. Health, *Report of the Human Embryo Research Panel* 2 (Sept. 1994). Similarly, the National Bioethics Advisory Commission has recognized our society's widespread agreement that "human embryos deserve respect as a form of human life." Nat'l Bioethics Advisory Comm'n, 1 *Ethical Issues in Human Stem Cell Research* ii (Sept. 1999). Given these ethical concerns, it is not surprising that the Commission ultimately concluded that "the derivation of stem cells from embryos remaining following infertility treatments is justifiable *only* if no less morally problematic alternatives are available for advancing the research." *Id.* at 53 (emphasis added).

Because adult and induced pluripotent stem cell research does not involve the killing of human embryos, there are morally superior alternatives. And because embryonic stem cell re-

search is not the "only"—and, indeed, is the worst—alternative, NIH erred in pursuing it. Moreover, NIH also arbitrarily and capriciously disregarded, and failed to justify, its decision in light of the very goal that it explicitly set for itself, namely, that NIH-funded research must be "ethically responsible." 74 Fed. Reg. at 32,170. It is impossible to justify as "ethically responsible" the destruction of human life in order to conduct research that could be conducted as well or better *without* the destruction of human life, and in any event NIH *did not even try* to explain how its funding of human embryonic stem cell research meets its own stated criterion. That is the essence of arbitrary and capricious decision-making. *See Am. Equity Inv. Life Ins. Co. v. SEC*, 2009 WL 2152351, at *10 (D.C. Cir. July 31, 2009) (holding that 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) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)).

4. NIH Disregarded The Possible Effects Of The Guidelines On State Laws.

In addition to ignoring much of the science of human stem cell research, the Guidelines fail to account for, and substantially undermine, the laws of numerous States that protect human life from the moment of conception or otherwise protect human embryos from being destroyed or placed at risk for the purpose of medical experimentation. An agency "must engage in a careful analysis of the possible effects of [agency action] on the functioning and policies of other statutory regimes." *N.Y. Shipping Ass'n v. Fed. Mar. Comm'n*, 854 F.2d 1338, 1365, 1367, 1371 (D.C. Cir. 1988) (citing *McLean Trucking Co. v. United States*, 321 U.S. 67 (1944)). Because NIH disregarded the statutory regimes across several States with which the new Guidelines would be in tension, it has not satisfied this requirement.

Congress specifically directed that NIH, when exercising its statutory discretion, must cooperate with state regulatory regimes. *See, e.g.*, 42 U.S.C. § 243(a) (asserting that the HHS Secretary "shall assist States" in the enforcement of state health regulations); *id*. § 284(c)(1) (stating that NIH "shall coordinate" its activities with other public entities). But NIH promulgated the Guidelines without even mentioning—much less attempting to comply with or accommodate—state regulations that ban the destruction of human embryos, even though NIH was informed during the public comment period of the numerous state regulations at issue. This alone is fatal to the Guidelines: Where a statute requires an agency to take into account conflicting or concurrent regulatory schemes, failure to do so is *ipso facto* arbitrary and capricious and an abuse of discretion. *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971) (agency action must take into account factors Congress intended it to consider), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977); *Southern S.S. Co. v. NLRB*, 316 U.S. 31, 37–38 (1942) (failure to take into account conflicting regulatory scheme is an abuse of discretion); *Can-Am Plumbing, Inc. v. NLRB*, 321 F.3d 145, 153–54 (D.C. Cir. 2003) (the National Labor Relations Board "'must . . . minimize[ ]'" and "take into account" the "impact of its actions on the policies of the other [conflicting] statute").

That conclusion is particularly warranted in this case. State protection of human embryos is pervasive. *See generally* Jean R. Schroedel, *Is the Fetus a Person?: A Comparison of Policies Across Fifty States* (Cornell 2000). For example, many States have fetal homicide statutes that apply without regard to gestational age.[4] Some States have wrongful death statutes that apply

---

[4] *See, e.g.*, 2006 Ala. Acts ch. 419 (amending the definition of "person," when referring to the victim of a criminal homicide or assault, to mean "a human being, including an un-
[Footnote continued on next page]

regardless of gestational age.[5] Still other States explicitly proclaim that life begins at conception.[6] (*See also* Lingo Decl., Exh. B at B-1–B-5, C-1–C-18.) Finally—and perhaps most importantly—a number of States explicitly ban or restrict human embryonic stem cell research. *See, e.g.*, La. Rev. Stat. § 9:122; Minn. Stat. § 145.422; N.M. Stat. Ann. §§ 24-9A-1 et.seq.; 18 Pa. C.S. §§ 3203, 3216.

NIH's Guidelines make no attempt to coordinate federal stem cell research with the requirements of state law. Instead, NIH has acted as though the existence of conflicting state regulations is not even a matter of passing concern: Under the Guidelines, neither NIH nor a grant recipient has *any* obligation to guarantee that federally funded research complies with state law. This is no trivial matter: In States that acknowledge and protect life from the moment of fertilization or conception, "donation" of human embryos for the purpose of destruction may be viewed as a state criminal violation. The Guidelines fail even to *consider* this possibility, and improperly seek to encourage and fund potentially illegal activity.

[Footnote continued from previous page]

born child in utero at any stage of development, regardless of viability"); Tex. Penal Code § 1.07(a)(26) (defining the term "individual," as used in the Texas Penal Code, to mean "a human being who is alive, including an unborn child at every stage of gestation from fertilization until birth"); Utah Code Ann. § 76-5-201(1)(a) (stating that when referring to the victim of a criminal homicide, the term "another human being" includes "an unborn child at any stage of its development").

5 *See, e.g.*, Neb. Rev. Stat. § 30-809(1) (amending wrongful death statute to include "an unborn child in utero at any stage of gestation"); S.D. Code Laws Ann. § 21-5-1 (amending wrongful death statute to include "an unborn child").

6 *See, e.g.*, Ark. Const. amend. 68, § 2 ("The policy of Arkansas is to protect the life of every unborn child from conception until birth . . . ."); Mo. Ann. Stat. § 1.205.1(1) ("[t]he life of each human being begins at conception") (preamble).

Because NIH has failed to even consider state regulations, NIH's promulgation of the Guidelines exceeds the scope of its discretion under both its enabling statute and the APA.

5. NIH Failed To Explain Cogently Why It Exercised Its Discretion To Create Inadequate Conflict-of-Interest Provisions And Meaningless Informed-Consent Requirements.

Science and statutory regimes aside, even at the core of the Guidelines, NIH has acted arbitrarily and capriciously. By creating insufficient conflict-of-interest safeguards and inadequate informed-consent standards, the Guidelines evince superficial concern about ethical issues, but do nothing significant to address those concerns. Because NIH did not explain why two important aspects of the Guidelines do not fulfill the purposes they purport to serve, the agency has not satisfied the APA's requirement that an agency "cogently explain why it has exercised its discretion in a given manner." *State Farm*, 463 U.S. at 48; *see also Atchison, T & S.F.R. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 806–07 (1973).

a. The Conflict-Of-Interest Provisions Leave Loopholes That Eviscerate Their Effectiveness.

Although the Guidelines set out to create the appearance of protection against conflicts of interest, the vagueness of the procedural requirements creates an unacceptable risk that these conflicts will survive. The Guidelines claim to fund only "ethically responsible" research using cells that were "created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose." 74 Fed. Reg. at 32,170, 32,174. The loose procedural requirements, however, fail to ensure achievement of this objective. The Guidelines do not prohibit contractual, agency, or corporate relationships between the *in vitro* fertilization clinic that creates and then cryogenically stores the human embryo, the researchers who destroy that human embryo to harvest its stem cells, and NIH-funded researchers who will continue the research process with respect to these human embryonic stem cells. Indeed, the Guidelines do not even prohibit the

deriver and the user from being the very same person. *See* 74 Fed. Reg. at 32,174. By allowing the same person or clinic to be involved in the creation of embryos "for reproductive purposes" and the research using the embryos that are "no longer needed," the Guidelines tempt researchers to evade the Guidelines' requirements and create additional embryos at the outset to ensure that there are "spares" left for research. *See id.* NIH avoided any real analysis of these issues by proclaiming that it "is not always possible" to avoid this situation. *Id.* at 32,173. This *ipse dixit* does not even come close to satisfying NIH's duty to engage in reasoned decisionmaking.

Furthermore, the Guidelines erroneously presume that the parents of the human embryo have the legal right under applicable state law, as well as the moral and ethical authority, to substitute their judgment for the interests and judgment of the legally incompetent human embryo. But parents' moral and ethical authority to do so is far from accepted. Without a judicial proceeding in which the interests of the human embryo in question are represented by a court-appointed attorney pro vita (for life), such a parental "donation" could violate state laws and would create obvious conflicts of interest.

b. The Informed-Consent Requirements Fail To Inform Parents Of The True Nature Of The Procedure To Which They Are Consenting.

The Guidelines fail to describe adequately the true nature of the procedure to which "donors" are consenting. The so-called informed consent provisions are deficient from a scientific, legal, and practical perspective. Scientifically, the informed consent procedures fail to notify potential donors that each of their human embryos is a living human being and that the decision to donate is, in fact, a life-or-death decision. A researcher is required only to include information about "[w]hat would happen to the embryos in the derivation of [human embryonic stem cells] for research." 74 Fed. Reg. at 32,174. The gravity of the decision to donate living human beings for destruction cannot possibly be conveyed in such coy and evasive language. Moreover, the

informed-consent requirements also fail to inform potential donors that many States hold that human life begins at conception, *see, e.g.*, Ark. Const. amend. 68, § 2; La. Rev. Stat. Ann. § 14:2(7), and that in these States, the "donation" of human embryos for research may be deemed to be a criminal act. In addition, the informed consent procedures do not always require donors to be informed that adoption is an alternative to having the human embryo killed for research purposes. 74 Fed. Reg. at 32,174; *see also* Natalie Lester, *Embryo Adoption Becoming the Rage*, Wash. Times, Apr. 19, 2009, http://washingtontimes.com/news/2009/apr/19/embryo-adoption-becoming-rage.

In sum, by including conflict-of-interest and informed-consent requirements, NIH has created the appearance of being concerned about the ethical problems involved with human embryonic stem cell research without taking the appropriate action to address those concerns. Because the agency has not "cogently explain why it has exercised its discretion" in this manner, the Guidelines are arbitrary and capricious.

6. NIH Failed To Respond To Significant Comments That Cast Doubt On The Reasonableness Of The Guidelines.

For no apparent reason, the Executive Branch created a rushed and result-oriented rulemaking process in which it could not and did not respond to the majority of significant comments that it received. *See also* § I.D.1, *infra* (the comment period was of insufficient length); *id.* (NIH's Acting Director had an unalterably closed mind about the rulemaking). 5 U.S.C. § 553(c) of the APA requires the agency to "respond in a reasoned manner to those [comments] that raise significant problems." *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006); *see Am. Mining Congress v. EPA*, 907 F.2d 1179, 1190–91 (D.C. Cir. 1990). NIH utterly failed to do so, and it therefore acted arbitrarily and capriciously. *See id.* at 1191 ("the agency's failure to respond to . . . specific challenges in the record is fatal here, since 'the points raised in

the comments were sufficiently central that agency silence . . . demonstrate[s] the rulemaking to be arbitrary and capricious'").

NIH received "approximately 49,000 comments" on the Guidelines. 74 Fed. Reg. at 32,170. Many of those comments raised substantial problems with the Guidelines—including all of the arguments made here. (*See, e.g.*, Lingo Decl., Exh. B at 2 (explaining, *inter alia*, that human embryonic stem cell research is "unnecessary and inappropriate" due to the scientific advances in adult and induced pluripotent stem cell research); *id*., Exh. C at 2 (explaining, *inter alia*, that the informed consent protocols are insufficient for the "life-and-death decision" parents are being asked to make).)

Yet, after the comment period ended, NIH had only forty-two days to review the 49,000 comments submitted and respond to the significant arguments presented therein. Even a team of ten people working twelve hours per day for all forty-two days would have only six minutes to devote to each comment. With some comments spanning over 100 pages, the task was unwieldy. And yet, the requirements of the APA do not yield. "That an agency has only a brief span of time in which to comply . . . cannot excuse its obligation to engage in reasoned decisionmaking under the APA." *Am. Mining Cong.*, 907 F.2d at 1191.

NIH's task of reviewing and responding to important comments was made substantially easier by its stunning decision not to consider—much less respond to—more than 60 percent of the comments. NIH received "[a]bout 30,000" comments "debat[ing] whether the NIH should be funding embryonic stem cell research." Jeffrey Young, *Administration Unveils Stem Cell* Rules, The Hill, July 6, 2009, *available at* http://thehill.com/leading-the-news/obama-administration-unveils-stem-cell-rules-2009-07-06.html. But NIH admits that it "disregarded all such comments," and it instead branded such comments with the (ironic) label "unresponsive."

Id. NIH's then-Acting Director offered this feeble *post hoc* excuse: "'[NIH] actually did not ask the public *whether* we should fund research on human embryonic stem cells. [NIH] asked the public *how* we should fund human embryonic stem cell research." *Id.* (emphases added). This illegitimate decision to *assume* the answer to the fundamental question at issue cannot justify the agency's decision to completely ignore the majority of the comments that it received. Indeed, if agencies could proceed in this manner, it would obliterate the purpose of APA's public comment process. NIH's blatant disregard for the statutorily mandated rulemaking process is illegitimate, and its effects can be seen throughout the final version of the Guidelines.

In the Guidelines, NIH did not make *any* attempt to explain its decision to allocate scarce funds to embryonic stem cell research instead of adult stem cell research. Nor did it address the issue whether induced pluripotent stem cells are superior to embryonic stem cells. Consistent with this theme, the agency's response to evidence that embryonic stem cells create tumors was complete silence. And the agency failed to offer any adequate response to concerns about how the Guidelines would conflict with numerous State laws. In the unusual situations where NIH bothered to read and (at least superficially) respond to comments, the agency often offered insufficient categorical statements. For example, when responding to the comment that potential donors should be informed that derivation of embryonic stem cells destroys the embryo, NIH offered nothing but obfuscation. The agency declared that "all necessary details are explained and understood" in the informed consent process, but that it could not require disclosure of information about the destruction of embryos because it did not want to mandate "exact wording for the consent forms." 74 Fed. Reg. at 32,173. This response was entirely inadequate, and indeed, misleading. As NIH well knows, the Guidelines need only modify the substance of the required disclosure, not its "exact wording." In fact, the Guidelines contain an enumerated list of seven

disclosures. Surely one of those could and should reflect—in substance—that the "donated" embryo will be destroyed.

Such categorical—and, ultimately, unresponsive—statements are insufficient to satisfy the APA's requirements. In *American Mining Congress v. EPA*, petitioners submitted comments challenging the agency's listings of the materials as hazardous, including specific evidence that was contrary to the EPA's findings, but the EPA responded with categorical statements rather than empirical analysis. 907 F.2d at 1190–91. As a result, the court held that "the agency's failure to respond to petitioners' specific challenges in the record [was] fatal . . . , since the points raised in the comments were sufficiently central that agency silence . . . demonstrate[d] the rulemaking to be arbitrary and capricious." *Id.* at 1191 (internal quotation marks omitted). That precedent is directly applicable here.

NIH's flagrant disregard for public input has been evident since the inception of this (all too brief) rulemaking process. At bottom, the agency's disregard for important public comments reflects a disregard for a congressionally mandated process that cannot simply be jettisoned in favor of political expediency. That congressionally mandated process requires the agency to consider and respond to important public comments. Because NIH failed to offer more than conclusory statements in response to the significant arguments raised by the comments to the proposed guidelines, it has not engaged in the reasoned decisionmaking required by the APA. Thus, the Guidelines are arbitrary and capricious and must be set aside.

D. The Guidelines Were Not Issued In Accordance With The Procedures Required By Law.

Wholly apart from the arbitrary and capricious nature of the NIH Guidelines, the Guidelines should be set aside because they were issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Agencies participating in rulemaking are required to follow the

procedures set out in 5 U.S.C. § 553. NIH violated these procedures by not allowing enough time for submitting comments and by entering the rulemaking process with an "unalterably closed mind."

Under 5 U.S.C. § 553, agencies participating in rulemaking must publish "general notice of the proposed rule making . . . in the Federal Register," provide "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," and incorporate "a concise general statement of [any adopted rule's] basis and purpose." § 553(b), (c). Although the APA exempts from its notice-and-comment requirement matters "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts," 5 U.S.C. § 553(a)(2), many agencies, including HHS, have specifically waived this exemption. *See* Public Participation in Rule Making, 36 Fed. Reg. 2,532 (Feb. 5, 1971); *see also Abbs v. Sullivan*, 756 F. Supp. 1172, 1188 (W.D. Wis. 1990) (applying the waiver to NIH), *judgment vacated on other grounds*, 963 F.2d 918 (7th Cir. 1992). As the Department explained, the "public benefit" from the "greater participation by the public in the formulation of this Department's rules and regulations . . . outweigh[s] any administrative inconvenience or delay." 36 Fed. Reg. at 2,532.

1. NIH Provided Insufficient Time To Meaningfully Comment On The Draft Guidelines.

In direct contravention of § 553, NIH provided the public insufficient time to meaningfully comment on the Draft Guidelines. NIH issued the Draft Guidelines and request for comment on April 23, 2009, and all comments were due a mere 34 days later. 74 Fed. Reg. at 32,170. This truncated comment period did not afford interested parties an adequate opportunity to comprehensively review and comment on the Draft Guidelines—especially given the scientific complexity and ethical ramifications thereof. *See Fla. Power & Light Co. v. United States*, 846 F.2d

765, 771 (D.C. Cir. 1988) (explaining that a notice of proposed rulemaking must provide "adequate time for comments," and noting that interested parties should be able "to comment meaningfully"); *In re Estate of Smith v. Bowen*, 656 F. Supp. 1093, 1097–99 (D. Colo. 1987) (holding that a sixty-day period was inadequate). Moreover, by short-circuiting the process by which the public provides valuable information, the bobtailed comment period precluded NIH from having sufficient information to engage in informed rulemaking.

2. Former Director Kington Precluded An Effective Comment Period By Participating With An Unalterably Closed Mind.

Unfortunately, it is now clear why NIH was not concerned about providing the public an insufficient comment period: NIH never had any intention of considering the views of those opposed to the federal funding of embryonic stem cell research. Agencies cannot fulfill their duty to consider important comments, *see* 5 U.S.C. § 553(b), when a participating agency member "has 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). Former Director Raynard Kington's mind was "unalterably closed" from the outset.[7]

Agency members need not be excluded because of a "mere discussion of policy or advocacy on a legal question." *Id*. But when an agency member enters a rulemaking proceeding with an "unalterably closed mind," public comments are inevitably ignored. *Id.* In *Nehemiah Corp. of Am. v. Jackson*, 546 F. Supp. 2d 830, 848 (E.D. Cal. 2008), the district court determined that HUD Secretary Jackson entered a rulemaking proceeding with an "unalterably closed mind" about the merits of a proposed rule. During the comment period, a *Bloomberg News* report

---

[7] Kington served as the Acting Director of NIH from October 31, 2008 to August 7, 2009, when the Senate confirmed Dr. Francis Collins as the new Director of NIH.

quoted Secretary Jackson as stating his views on the proposed rule and claiming that HUD "intend[ed] to approve the new rule by the end of the year even if the agency receive[d] critical comments." *Id.* at 847. After setting aside the rule on other grounds, the district court ordered, based on these statements, that Secretary Jackson be excluded from the decision-making process on remand. *Id.* at 848.

Kington's prejudgment of this matter is even more striking. Kington made clear his views on the result of the rulemaking proceeding before the comment period even began. On April 17, Kington reported to the press that NIH "*will* expand greatly the number of cell lines eligible for funding." Guatam Naik, *NIH Offers Rules for Embryonic Stem Cell Research*, Wall St. J., Apr. 17, 2009, *available at* http://online.wsj.com/article/SB123999343505429693.html (emphasis added). Moreover, Kington and NIH demonstrated their prejudgment of this matter by encouraging the submission of applications for embryonic stem cell research even before the issuance of the draft Guidelines. *See* Implementation of Executive Order on Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, NOT-OD-09-085 (Apr. 17, 2009), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html.

Then, after the comment period concluded, Kington made a stunning admission: *He (and the agency) totally ignored all public comments that took a particular side of the central debate in this rulemaking. See* Young, *supra*. Approximately 30,000 of the 49,000 comments addressed the fundamental question "whether the NIH should be funding embryonic stem cell research." *Id.* But Kington utterly refused to consider comments that disagreed with his position, *id.*, that NIH should "expand greatly the number of cell lines eligible for funding," Naik, *supra*. Kington claimed that NIH "did not ask the public" for input on this question. Young, *supra*. But an agency official may not hide an unalterably closed mind by prejudging an issue, ignoring tens

of thousands of comments that address the issue, and then declaring brazenly that he "did not ask," *id.*, for comments that disagreed with his predetermined judgment.

It is beyond dispute that Kington had an "unalterably closed mind" about the merits of the NIH Guidelines. Because the administrative proceeding has now concluded, "the appropriate remedy" is to "vacate and remand the proceeding to be redone without the participation" of Kington. *Nehemiah*, 546 F. Supp. 2d at 847.

II. Absent An Injunction, The Plaintiffs Will Suffer Irreparable Harm.

There can be little doubt that, absent an injunction, the plaintiffs will suffer irreparable injury. Once destroyed, an embryo cannot be revived; it is gone forever. This "injury" is great enough to meet any standard. "This is not a case where plaintiff can wait until trial for a remedy. Simply put, absent some form of preliminary relief, plaintiff runs the real risk of dying and in such circumstances money damages would be wholly useless to plaintiff." *DiDomenico v. Employers Co-Op Indus. Trust*, 676 F. Supp. 903, 907 (N.D. Ind. 1987).[8] In addition, the destruction of the embryo results in irreparable injury for all to whom that embryo holds promise. It is no longer available to parents that might wish to adopt it or adoption agencies that might wish to place it for adoption.[9]

---

[8] It makes no difference for purposes of irreparable injury analysis that the embryos in question are not yet mature human beings. On the contrary, the threat of harm to a human being not yet born constitutes irreparable harm for purposes of deciding the question 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 pre-natal care constitutes irreparable harm "[g]iven the importance of this pre-natal care to the health of the fetus and the future health of the yet unborn child").

[9] Moreover, the Guidelines discourage parents from offering their embryonic children for adoption by perpetuating the myth that embryos are needed for promising medical re-

[Footnote continued on next page]

Apart from the irreversible destruction of human embryos, the Guidelines would irreparably injure researchers who work exclusively with adult stem cells, like Drs. Sherley and Deisher, by illegally diverting scarce federal stem cell funding to embryonic stem cell research. By putting adult stem cell researchers' grant proposals in competition with those of embryonic stem cell researchers, the Guidelines will make it more difficult for the former to obtain federal funding. (Decl. of Dr. James L. Sherley in Support of Pls.' Mot. for Prelim. Inj., ¶¶ 3–4 ("Sherley Decl."); Decl. of Dr. Theresa Deisher in Support of Pls.' Mot. for Prelim. Inj., ¶¶ 3–4 ("Deisher Decl.").) Under the Guidelines, embryonic stem cell research will absorb a significant proportion of total federal stem cell research funding. Given the fixation on embryonic stem cell research that the Guidelines reflect, those working on more promising adult stem cell research will no doubt be deprived of opportunities for funding.

Importantly, those adult stem cell researchers will have no after-the-fact remedy for the loss of this opportunity for federal funding. (Sherley Decl., at ¶ 4; Deisher Decl., at ¶ 3.) In the absence of an adequate remedy, this loss constitutes irreparable injury. *See Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) (finding irreparable harm where there is "no adequate compensatory or other corrective relief" even though harm is economic in nature). But beyond mere pecuniary loss, enforcement of the Guidelines will irreparably harm the research-

---

[Footnote continued from previous page]

> search. Without a preliminary injunction, many embryos will be destroyed as parents are misled into believing that there is a high moral purpose to donating embryos for research. As a result, Plaintiffs who wish to adopt (or place for adoption) these embryos will be irreparably injured. (Decl. of William T. Flynn in Support of Pls.' Mot. for Prelim. Inj., ¶ 4; Decl. of Tina Nelson in Support of Pls.' Mot. for Prelim. Inj., ¶ 4.; Decl. of Ronald L. Stoddart in Support of Pls.' Mot. for Prelim. Inj., ¶ 6.)

ers' personal and professional interests in pursuing their lifelong work while this Court considers this case. (Sherley Decl., at ¶ 4; Deisher Decl., at ¶ 3.) For these reasons, they will suffer irreparable harm.

III. The Balance Of Hardships Heavily Favors Immediate Injunctive Relief

In light of the serious and irreparable harm that Plaintiffs would suffer without a preliminary injunction, the balance of hardships strongly favors immediate injunctive relief. As explained above, Plaintiffs' reproductive choices, lives, and livelihoods will be lost if this Court permits the Guidelines to go into effect during the pendency of their suit. These enduring interests far outweigh any negligible harm to Defendants' interest in enforcing an ethically dubious and scientifically unnecessary government policy during the few months needed to litigate this case.

Neither Defendants nor any other entity will be substantially burdened by a preliminary injunction in Plaintiffs' favor. Federal funds have never before been used to incentivize the destruction of human embryos, and temporarily maintaining the *status quo* will not impose any new burden on Defendants. On the contrary, a system for allocating federal stem cell research funds—the system NIH has used since the current policy was developed in 2001—is already in place. Moreover, embryonic stem cell researchers can continue to access non-federal funding for their work, a prospect with which a preliminary injunction would not interfere.

Courts have been particularly willing to preserve the *status quo* through use of a preliminary injunction where, as here, the contemplated injunction will be of a "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, little discovery will be necessary before this Court can proceed to judgment on the merits. Under these circumstances, "[i]ssuance of a preliminary

injunction especially one of the short duration contemplated here will not substantially harm defendants." *Id.*

IV. The Public Interest Favors A Preliminary Injunction

The public interest strongly favors a preliminary injunction in this case. 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, a preliminary injunction will serve the public interest.

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

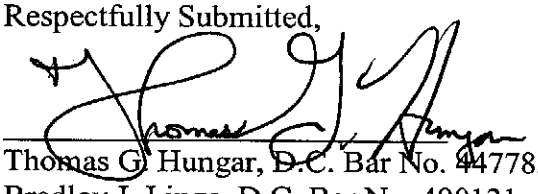
Finally, a preliminary injunction will also serve the public's interest by withholding taxpayer dollars from a type of research that many taxpayers and States recognize to be ethically and morally troubling. The laws of numerous States protect human life from the moment of conception or otherwise protect human embryos from being destroyed for the purpose of medical experimentation. The public interest is disserved by federal funding of an immoral and unnecessary research method.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for a preliminary injunction should be granted.

Dated: August 19, 2009

Respectfully Submitted,



Thomas G. Hungar, D.C. Bar No. 447783
Bradley J. Lingo, D.C. Bar No. 490131
Ryan G. Koopmans, D.C. Bar No. 986233
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500

Blaine H. Evanson, Cal. Bar No. 254338
Alison E. Klingel, Cal. Bar No. 258194
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071
(213) 229-7000

Samuel B. Casey, Cal. Bar No. 76022
Law of Life Project
ADVOCATES INTERNATIONAL
8001 Braddock Road, Suite 300
Springfield, VA 22151
(703) 894-1076

Steven H. Aden, D.C. Bar No. 466777
ALLIANCE DEFENSE FUND
801 G. Street N.W., Suite 509
Washington, D.C. 20001
(202) 393-8690