IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DR. JAMES L. SHERLEY, DR. THERESA DEISHER, NIGHT-LIGHT 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, 200 Independence Avenue, S.W., Washington, D.C. 20201; DEPARTMENT OF HEALTH AND HUMAN SERVICES; DR. FRANCIS S. COLLINS, in his official capacity as Director of the National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892; NATIONAL INSTITUTES OF HEALTH, Defendants.	Filed: August 19, 2009 CIVIL ACTION NO. 1:09-CV-1575 Assigned To: Lamberth, Royce C. Assigned Date: 8/19/2009 Description: TRO/PI

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, by their attorneys, allege as follows:

I. INTRODUCTION

1. For over 13 years, Congress has explicitly prohibited the use of federal monies to fund research in which embryos are destroyed or knowingly subjected to harm. *See* Balanced Budget Downpayment Act, Pub. L. No. 144-99, § 128, 110 Stat. 26, 34 (1996). This prohibition

on the use of federal funds for embryonic stem cell research remains in place today. *See* Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009) ("Federal Funding Ban" or "Dickey-Wicker Amendment"). Despite the explicit federal ban on funding embryonic stem cell research, on July 7, 2009, Defendants promulgated the Guidelines for Human Stem Cell Research ("Guidelines"). 74 Fed. Reg. 32,170. These Guidelines authorize public funding of research that depends upon and, indeed, requires the destruction of living human embryos. As a result, these Guidelines violate the Federal Funding Ban, and are therefore invalid. *See* 5 U.S.C. § 706(2)(A).

2. Furthermore, in promulgating the Guidelines, Defendants failed to follow the procedures required by the Administrative Procedure Act. *See* 5 U.S.C. § 706(2)(D). Contrary to the rulemaking procedures set forth in 5 U.S.C. § 553, Defendants entered the rulemaking proceedings with an unalterably closed mind, having prejudged the relevant issues; did not allow a sufficient time period for commenting on the draft guidelines, proposed on April 23, 2009, 74 Fed. Reg. 18,578 ("Draft Guidelines"); refused to respond to or even consider comments asking NIH to reconsider its decision to fund embryonic stem cell research; and did not properly consider or respond to the more than 49,000 comments that were submitted regarding the Draft Guidelines.

3. The implementation of the Guidelines also constitutes arbitrary and capricious agency action under 5 U.S.C. § 706(2)(A) because the Defendants have repeatedly and improperly dismissed or ignored substantial scientific research that demonstrates that adult stem cells and induced pluripotent stem cells ("iPSCs") provide ethically and medically superior alternatives to medical experimentation on stem cells derived from human embryos; the Guidelines fail to implement proper and necessary safeguards ensuring that embryo donors give truly informed con-

sent; the Guidelines fail to protect against conflicts of interest among the fertility clinic that creates the embryo, the destroyer of the embryo, and the recipient of federal funding; and the Defendants have failed to take into account long-established state laws and policies protecting human embryos.

4. For these reasons, Plaintiffs bring this action against Defendants Kathleen Sebelius, in her official capacity as Secretary of the Department of Health and Human Services ("HHS"), HHS, Dr. Francis S. Collins, in his official capacity as Director of the National Institutes of Health ("NIH"), and NIH (collectively, the "Defendants"), and seek 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 Defendants from applying the Guidelines or otherwise funding research involving the destruction of human embryonic stem cells.

II. JURISDICTION AND VENUE

5. This action arises under 5 U.S.C. § 706(2) and the Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009), and therefore presents a federal question, giving this Court jurisdiction over the matter pursuant to 28 U.S.C. § 1331. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States, defendant HHS resides in this judicial district, defendant Kathleen Sebelius performs her official duties in this judicial district, and a substantial part of the events or omissions giving rise to this action occurred in this judicial district.

III. PARTIES

A. Plaintiffs

6. Plaintiff Dr. James L. Sherley is a senior scientist currently working at the Boston Biomedical Research Institute where he and his research team are pursuing the study of normal

molecular and biochemical processes in adult stem cells that are involved in cancer initiation and contribute to aging. Dr. Sherley, a Massachusetts resident, received his B.A. in Biology from Harvard University, and his M.D. and Ph.D. in Molecular Biology from John Hopkins University. Prior to joining the Boston Biomedical Research Institute, Dr. Sherley worked in the Department of Molecular Oncology at the Fox Chase Cancer Center in Philadelphia, Pennsylvania, and served as an associate professor in the Department of Biological Engineering at the Massachusetts Institute of Technology. Dr. Sherley does not conduct research on embryonic stem cells. His research focuses on improving methods for identifying adult stem cells and producing them in large numbers for therapeutic development. Dr. Sherley has received funding from NIH for research aimed at developing new methods for identification and production of human adult stem cells that have the potential for human cell therapy. Since 1999, Dr. Sherley has applied for NIH funding approximately 41 times. Twelve of these proposals have received NIH funding, and one proposal is currently pending. Dr. Sherley will continue to seek NIH funding for adult stem cell research in the future. The Guidelines, which unlawfully authorize federal funding of research using stem cells derived from human embryos, will result in increased competition for limited federal funding and will thereby injure Dr. Sherley's ability to compete successfully for the NIH stem cell research funds that he seeks.

7. Plaintiff Dr. Theresa Deisher, a resident of the State of Washington, is the founder, managing member, and research and development director of AVM Biotechnology. Dr. Deisher received her B.A. in Human Biology and Ph.D. in Molecular and Cellular Physiology from Stanford University. Dr. Deisher has seventeen years of experience in scientific and corporate leadership positions involving research, discovery, production, and commercialization of human therapeutics. After obtaining her Ph.D., Dr. Deisher was employed by Repligen Cor-

poration as a Research Scientist where she managed a staff of associates and scientists and directed the development of research and clinical tests in support of Phase I and Phase II clinical trials for various Repligen developmental efforts. Thereafter, Dr. Deisher served as Senior Scientist of Cardiovascular Biology at ZymoGenetics, Inc., Senior Staff Scientist of Vascular Biology at Immunex, and Principal Scientist at Amgen, Inc. Most recently, Dr. Deisher served as Vice President of Research and Development for Cellcyte Genetics Corp., a post she held prior to founding AVM Biotechnology in 2007. Dr. Deisher does not conduct research using embryonic stem cells. She specializes in adult stem cell therapies and regenerative medicine, and her research has resulted in the issuance of twenty-three patents. In order to continue her research, Dr. Deisher and AVM Biotechnology will require federal funding, and are in the process of applying for NIH grants for research on adult stem cells. The Guidelines, which unlawfully authorize federal funding of research using stem cells derived from human embryos, will result in increased competition for limited federal funding and will thereby injure Dr. Deisher's ability to successfully compete for the NIH stem cell research funds that she requires.

8. Plaintiff Nightlight Christian Adoptions ("Nightlight") is a non-profit, licensed adoption agency located in the States of California and South Carolina that is dedicated to protecting human embryos conceived through *in vitro* fertilization. Through its "Snowflakes" Program, Nightlight enables adoptive parents to adopt human embryos that are being stored in fertilization clinics. Nightlight has assisted many adoptive parents in successfully adopting and implanting these embryos, resulting in numerous births. Nightlight currently has a waiting list of families seeking to adopt embryos, and often these families must wait several months. The Guidelines permit federal funding for research on stem cells that are derived from embryos that, while no longer needed for the donors' reproductive purposes, could have been donated to an

adoption agency such as Nightlight. Therefore, the Guidelines, in unlawfully utilizing federal monies to fund human embryonic stem cell research, decrease the number of embryos available for adoption. The Guidelines pose a recurring threat to embryos that adoption agencies such as Nightlight could otherwise place for adoption with waiting families, and impose a consequent burden on the resources that Nightlight devotes to facilitating embryo adoption. Moreover, by perpetuating the myth that embryos are a more promising source of human therapies and cures than adult stem cells, Defendants effectively discourage families with frozen embryos from considering embryo donation and adoption because they are led to believe that there is a high moral purpose in donating the embryos for research. Nightlight brings this action on behalf of itself and, pursuant to Fed. R. Civ. P. 17(c), as guardian ad litem of the Plaintiff Embryos, who are minor persons that qualify for representation under Rule 17(c).

9. Plaintiff Embryos include all individual human embryos that are or will be "created using in vitro fertilization (IVF) for reproductive purposes and [are] no longer needed for these purposes." 74 Fed. Reg. at 32,171. The Embryos are persons that qualify for representation under Fed. R. Civ. P. 17(c). NIH's violation of the Federal Funding Ban will place the lives of these Embryos under a recurring risk of destruction.

10. Plaintiffs Shayne and Tina Nelson, residents of the State of Utah, are clients of Plaintiff Nightlight. The Nelsons have two children, both adopted embryos, and are currently seeking to adopt additional embryos for implantation. Defendants' promulgation of the Guidelines in violation of federal law jeopardizes the likelihood that embryos will become available in a timely manner for adoption and implantation.

11. Plaintiffs William and Patricia Flynn, residents of the State of Massachusetts, are clients of Plaintiff Nightlight. The couple have one child, an adopted embryo, and seek to adopt

additional human embryos. Defendants' promulgation of the Guidelines jeopardizes the likelihood that human embryos will become available for Mr. and Mrs. Flynn to adopt in the future.

12. Plaintiff Christian Medical Association ("CMA") is located in Bristol, Tennessee. CMA is a non-profit association of doctors that is dedicated to improving the ethical standards of health care in the United States and abroad. CMA is opposed to federal funding of human embryonic stem cell research, and expends approximately $300,000 a year in an ongoing effort to promote high ethical standards in the field of medical research, to assist its members in dealing with the issues posed by the development of medical practice and research, and to encourage legal reform. If Defendants are not enjoined from illegally funding research using stem cells derived from human embryos, the Guidelines will frustrate CMA's purpose and require CMA to devote significant resources to address and counteract the grave ethical problems posed by illegal public funding of embryo research.

B. Defendants

13. Defendant Kathleen Sebelius is the Secretary of HHS. She was confirmed by the Senate and sworn in as Secretary on April 28, 2009. Her official address is 200 Independence Avenue, S.W., Washington, D.C. 20201. She is sued in her official capacity. In this capacity, Secretary Sebelius has overall responsibility for the operation and management of HHS, of which NIH is an agency. Ms. Sebelius exercises cabinet-level oversight and supervisory authority over the management and policy of NIH. Ms. Sebelius is thus responsible, in her official capacity, for NIH's unlawful promulgation of the Guidelines and for related acts and omissions alleged herein.

14. Defendant HHS is, and was at all times relevant hereto, an executive agency of the U.S. government subject to the Administrative Procedure Act. *See* 5 U.S.C. § 551(1). HHS is located at 200 Independence Avenue, S.W., Washington, D.C. 20201.

15. Defendant Dr. Francis S. Collins is the Director of NIH and has served in that position since August 7, 2009. Dr. Collins is sued in his official capacity. His official address is 9000 Rockville Pike, Bethesda, MD 20892. Dr. Collins has the overall responsibility for the operation and management of NIH.

16. Defendant NIH is, and was at all times relevant hereto, an agency within HHS subject to the Administrative Procedure Act. *See* 5 U.S.C. § 551(1). NIH conducts, regulates, and supports federally funded biomedical scientific research. NIH is responsible for issuing and administering the Guidelines that are the subject matter of this suit. NIH is located at 9000 Rockville Pike, Bethesda, MD 20892.

17. Defendants, and those subject to their supervision, direction, and control are responsible for the actions complained of herein. The relief requested in this action is sought against each Defendant, as well as against each Defendant's officers, employees, and agents, and against all persons acting in cooperation with Defendant(s), under their supervision, at their direction, or under their control.

IV. BACKGROUND

A. Congress's Ban On The Federal Funding Of Human Embryo Research

18. For more than a decade, Congress has explicitly banned federal funding of research in which embryos are destroyed or knowingly subject to harm. *See* Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009). This prohibition was a direct response to efforts on the part of NIH to begin funding stem cell research that utilized human embryos. Specifically, in early 1993, NIH Director Harold Varmus convened the Human Embryo Research Panel, which recommended that NIH fund research using "surplus" human embryos. 59 Fed. Reg. 28,874, 28,875 (June 3, 1994). The Human Embryo Research Panel submitted its report to the NIH Advisory Committee to the Director, and the report was subse-

quently transmitted to NIH Director Varmus, who approved implementing the Panel's recommendations.

19. Before any grants were made under NIH's new standards, however, Congress enacted an appropriations rider to override Director Varmus's decision and prevent federal funding of human embryo research. *See* Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996). The rider provided in relevant part: "None 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 42 U.S.C. 289g(b)."

20. This congressional prohibition on the use of HHS funds for human embryo[1] research has been renewed every year since the enactment of the initial rider. Most recently, Congress renewed the rider, without any material change, in the HHS appropriations bill that was signed into law on March 11, 2009. *See* Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509, 123 Stat. 524, 803 (2009).[2]

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1 The Federal Funding Ban defines "human embryo" as "any organism, not protected as a human subject under 45 C.F.R. 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

2 The new version of the rider cross-references 45 C.F.R. § 46.204(b), which requires that any research-related risk to a human fetus be "caused solely by interventions or procedures that hold out the prospect of direct benefit for . . . the fetus; or if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means," and 42 U.S.C. § 289g(b), which demands that the "risk standard . . . be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term."

21. Under the Human Subject Protection Regulations—cited 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). And according to HHS's own guidance, an institution that receives federal funding is generally engaged in human subjects research "even where all activities involving human subjects are carried out by agents of another institution." Final Guidance on Engagement of Institutions in Human Subjects Research, 73 Fed. Reg. 63,151 (Oct. 23, 2008).

22. The rider therefore evinces a clear congressional intent to prohibit federal funding for research that is dependent on harming or destroying human embryos. Because the process by which human embryonic stem cells are extracted from human embryos necessarily destroys the embryos, the Federal Funding Ban expressly prohibits federal funding of human embryonic stem cell research.

23. In addition, the Federal Funding Ban prohibits "knowingly subject[ing embryos] to risk of injury or death." Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509(a)(2). Because funding and conducting embryonic stem cell research will inevitably create a substantial risk—indeed, a virtual certainty—that more human embryos will be destroyed in order to derive embryonic stem cells for research purposes, the Federal Funding Ban clearly prohibits the federal government from knowingly funding and/or conducting such research.

24. Researchers conducting embryonic stem cell research know that embryos were destroyed as a necessary part of the research process needed to create the stem cells.

25. In funding the research, Defendants know that they are creating incentives for and acting as the direct and foreseeable cause of the destruction of embryos. Indeed, the Guidelines function to regulate the process by which these embryos will be destroyed.

B. The NIH's 2000 Funding Guidelines

26. Despite the Federal Funding Ban, in 2000 NIH nonetheless issued guidelines that would permit the federal funding of human embryonic stem cell research. On December 2, 1999, NIH published a Notice of its Draft Guidelines for Research Involving Human Pluripotent Stem Cells in the Federal Register and invited public comment for a period of 60 days. *See* 64 Fed. Reg. 67,576 (Dec. 2, 1999). NIH received approximately 50,000 comments from members of Congress, patient advocacy groups, scientific societies, religious organizations, and private citizens. The vast majority of these comments were opposed to the draft guidelines.

27. NIH finalized and made effective "Guidelines for Research Using Human Pluripotent Stem Cells" ("2000 Guidelines") on August 25, 2000. 65 Fed. Reg. 51,976. The 2000 Guidelines "appl[ied] to the expenditure of [NIH] funds for research using human pluripotent stem cells derived from human embryos." *Id.* at 51,979. Contrary to Congress's plainly expressed intent, the 2000 Guidelines, like the current Guidelines, would have allowed federal funding of research using embryonic stem cells derived from the destruction of human embryos.

C. NIH's Withdrawal Of The 2000 Guidelines

28. In 2001, NIH delayed implementation of the 2000 Guidelines pending a review of their legality under federal law. As a result of that review, NIH issued new guidelines that provided funding to researchers who either already had derived "stem cell lines" from human embryos, or who proposed to use such existing stem cell lines in their own research. NIH determined that this approach complied with the Dickey-Wicker Amendment because with respect to those cell lines, the life and death decision had already been made, leaving no incentive to de-

stroy more embryos. But NIH withdrew the 2000 Guidelines and refused to fund research on those "excess" embryos that were cryopreserved in *in vitro* fertilization banks. 66 Fed. Reg. 57,107 (Nov. 14, 2001).

29. NIH has acknowledged the benefits of medically and ethically superior alternatives to human embryonic stem cells and appropriately allocated federal funds to the research and development of such alternatives. On June 22, 2007, then-President Bush issued Executive Order 13,435, which expressed a policy of "expanding approved stem cell lines in ethically responsible ways" to include "alternative sources of pluripotent stem cells" that were "derived without creating a human embryo for research purposes or destroying, discarding, or subjecting to harm a human embryo or fetus." 72 Fed. Reg. 34,591. Such "alternative sources" included induced pluripotent stem cells ("iPSCs")—pluripotent cells (or cells that are able to develop into most cell types) that are derived from adult stem cells and reprogrammed in such a way as to achieve the characteristics of embryonic stem cells. In 2007, NIH characterized the research advances relating to iPSCs as "very exciting." National Institutes of Health, Plan for Implementation of Executive Order 13,435: Expanding Approved Stem Cell Lines in Ethically Responsible Ways, Sept. 18, 2007, *available at* http://stemcells.nih.gov/staticresources/policy/eo13435.pdf. By federally funding iPSC research and other alternatives to human embryonic stem cell research that would not result in the destruction of human embryos, NIH supported the most current and promising science while adhering to the mandate of the Federal Funding Ban.

D. The NIH's New Funding Guidelines

30. On March 9, 2009, President Obama issued Executive Order 13,505, which required that "within 120 days . . . the Secretary [of HHS], through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell re-

search . . . and issue new NIH guidance on such research that is consistent with [the] order." Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

31. Additionally, Executive Order 13,505 revoked, without explanation, Executive Order 13,435, which had expanded approved stem cell lines to include iPSCs. As a result, there is no longer any guarantee that federal funds will be allocated to alternative sources of stem cells that do not require the creation or destruction of embryos.

32. After the issuance of Executive Order 13,505, but even before the issuance of the Draft Guidelines or the public comment period, Defendants evinced a preconceived intent to expand federally funded stem cell research to include newly derived human embryonic stem cells. For instance, after the issuance of Executive Order 13,505, on April 17, 2009, then-acting Director Raynard S. 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). Additionally, even prior to issuing the Draft Guidelines, NIH announced that it would begin accepting applications for grants funding human embryonic stem cell research. *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. Such actions demonstrate that Defendants entered the rulemaking process having already prejudged the merits of human embryonic stem cell research, thus limiting or foreclosing their ability to fully and fairly consider the comments they received.

33. Defendants promulgated the Draft Guidelines for Human Stem Cell Research on April 23, 2009, 74 Fed. Reg. 18,578, and invited public comment. The comment period, howev-

er, lasted for a mere 34 days, which 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 of the issues raised by the Draft Guidelines. This was in violation of 5 U.S.C. § 553.

34. After receiving 49,015 comments, Defendants issued the final Guidelines only six weeks after the close of the comment period, on July 7, 2009. 74 Fed. Reg. 32,170. This time period did not allow Defendants adequate time to consider fully and respond appropriately to the vast number of comments they received during the comment period.

35. In order to fit within this rushed timeframe, Defendants disregarded *more than 60 percent* of the public comments on the Guidelines. *See* 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 (reporting that NIH's Acting Director admitted the agency ignored approximately 30,000 comments as "unresponsive" to the Guidelines because NIH "did not ask the public whether we should fund research on human embryonic stem cells. We asked the public how we should fund human embryonic stem cell research.").

36. Even before submitting the Guidelines for notice and comment, Defendants had prejudged the issues involved in funding embryonic stem cell research. Specifically, Defendants had already decided, before considering the comments, that they would fund hESC research. *See id.* This pre-judgment allowed Defendants to label approximately 60 percent of the comments to the Guidelines unresponsive, but it did not satisfy their burden to consider any comments with an open mind.

37. Defendants also failed to respond adequately—or respond at all—to many significant comments received in opposition to the Guidelines. NIH's response to the nearly 50,000 comments is contained in a mere 3.5 pages of text. *See* 74 Fed. Reg. 32,170, 32,170–74.

38. This meager response did *not*: provide a rational connection between the facts found and the choice to fund embryonic stem cell research to the detriment of adult stem cell research; consider viable alternatives such as induced pluripotent stem cell research; take into account relevant considerations such as the inherent flaws of embryonic stem cells; consider the effects of the Guidelines on state statutory regimes; cogently justify the provisions addressing conflicts of interest and informed consent; or fulfill Defendants' responsibility to respond to significant arguments made during the public comment period.

39. Because the Guidelines permit federal funds to be used for research in which embryos are destroyed, Defendants' actions to implement the Guidelines violate federal law.

40. 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. As described by NIH, the Guidelines purport to fund only "ethically responsible" research and explicitly fund only research for cells that were "created . . . for reproductive purposes" and "were no longer needed for this purpose." 74 Fed. Reg. at 32,170, 32,174. But notwithstanding the serious ethical concerns associated with embryonic stem cell research, the Guidelines require merely that "[t]he attending physician responsible for reproductive clinical care and the research deriving and/or proposing to utilize hESCs should not have been the same person *unless separation was not practicable.*" *See id.* at 32,174 (emphasis added). This makes it possible for the *in vitro* fertilization facility to create and destroy the embryo, and then utilize the derived embryonic stem cell as a research subject. 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 allow researchers to evade the substantive requirements by creating more embryos at the outset to ensure that there are "spares" left for research. This risk was made known to NIH during the public comment period, but NIH nonetheless failed to explain how the Guidelines' conflict of interest provisions can possibly ensure that federally funded embryonic stem cell research is conducted in an ethical manner.

41. The Guidelines do not ensure that potential donors will be adequately informed of the relevant scientific, legal, and practical implications of donating human embryos for research purposes. Potential donors are not told that many scientists believe that human embryos are human life or that many States hold that human life begins at conception. *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 . . . ."); La. Rev. Stat. Ann. § 14:2(7) (defining "person" for purposes of criminal code to include "a human being from the moment of fertilization and implantation"). Indeed, in some of these States, the "donation" of human embryos for research may be deemed a criminal action, and the potential donor is left without any knowledge of this fact. A researcher is required to include only 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.

42. Finally, the informed consent procedures fail to notify potential donors that to the extent the embryos are no longer needed, it is now possible for them to place each embryo up for adoption as an alternative to having the human embryo destroyed for research purposes. *See, e.g.*, Natalie Lester, *Embryo Adoption Becoming the Rage*, Wash. Times, Apr. 19, 2009, *available at* http://washingtontimes.com/news/2009/apr/19/embryo-adoption-becoming-rage.

E. Current Scientific Knowledge About Stem Cell Research

43. NIH's decision to use federal funds to support research that destroys human embryos is unethical, scientifically unnecessary, fiscally irresponsible, and counterproductive. Although the Guidelines purport to "ensure that NIH-funded research in this area is ethically responsible [and] scientifically worthy," 74 Fed. Reg. at 32,170, the Guidelines' true effect is to divert limited federal dollars away from the most ethically responsible and scientifically promising forms of stem cell research—without even explaining such an irrational decision. Indeed, not only is embryonic stem cell research ethically problematic, it has shown no promise of safe, effective human therapies.

44. Only research with adult stem cells has yielded any successes in the treatment of human disease. Moreover, even if NIH had reason to believe that research involving human embryonic stem cells ("hESCs") would be as valuable as research involving adult stem cells, it has not offered an adequate explanation for choosing not to focus funds on iPSC research, which offers the same benefits without the ethical difficulties.

1. Scientific Evidence In The Administrative Record Shows That Embryonic Stem Cell Research Cannot Develop Safe Or Effective Human Therapies

45. Human embryonic stem cells are neither required nor useful components of modern scientific research aimed at discovering "new ways to prevent and/or treat illness." 74 Fed. Reg. at 32,174. hESCs are plagued by a multitude of shortcomings that limit their scientific efficacy and potential to be used successfully and safely in human therapies. Indeed, even NIH recognizes that embryonic stem cells are "not currently being used clinically." 74 Fed. Reg. at 32,172–74. Indeed, hESCs have never been utilized in human therapy, let alone successfully treated human disease. In promulgating the Guidelines, NIH ignored evidence in the Administrative Record about these shortcomings, ignored the advantages of non-hESC research, and has

therefore failed to consider adequately that federal funds would be better utilized in research that does not present the same problems.

46. The problems associated with hESC research are a function of the fact that hESCs are inherently abnormal cells. hESCs are derived from the inner cell mass of an early stage embryo. Typically, the cells of this inner cell mass would give rise to a fetus during normal embryonic development. However, the removal of the inner cell mass generates cells—the hESCs—that are not normal. The cells, for instance, universally exhibit genetic instability. *See* Comments of Do No Harm et al. at I-1, *available at* http://www.advocatesinternational.org/sites/www.advocatesinternational.org/files/webfm/DoNoHarm_20090526.pdf ("Comments").

47. This genetic instability is an inherent characteristic of hESCs, and one that inevitably causes hESCs injected into organisms to cause tumors. Scientists have been unable to develop methods to prevent this tumor formation. *Id.* at I-2. Research indicates that the tumor-causing characteristics of hESCs cannot be dismissed as a normal quality of a pluripotent cell removed from its endogenous environment. *Id.* at I-1. As a result of these abnormalities, hESCs have not shown promise of offering a safe or effective component of human therapy or medical treatments. Defendants have failed to address this defect inherent in hESC therapy.

48. Embryonic stem cells are also problematic candidates for safe and effective human therapies because they do not come from the patient, and are often rejected by the patient's immune system. *See* Comments, at G-8. iPSCs do not pose this problem.

49. The therapeutic utility of other pluripotent cells does not require the use of hESCs. Specifically, hESCs are not needed in order to test the pluripotent properties of other stem cells, such as iPSCs. The only test needed to establish the pluripotency of a stem cell is the tumor-forming test—hESCs are not needed at any step in the process. Moreover, in testing the

differentiation capacity of other pluripotent stem cells, adult stem cells—and not hESCs—are required. Thus, hESCs cannot contribute to the development of research that utilizes other types of pluripotent stem cells. *Id.* at I-3.

50. In promulgating the Guidelines, Defendants ignored important information on the promise and utility of hESC research that was contained in the Administrative Record. The Guidelines, the product of this uninformed and arbitrary decisionmaking process, will result in the allocation of fewer resources to research that utilizes more promising alternatives, including adult stem cells and induced pluripotent stem cells, while devoting scarce public resources to research that will not yield effective medical treatment, thereby defeating the very goals that Defendants claim to advance.

2. Defendants Ignored Evidence In The Administrative Record That Adult Stem Cell Research Is Scientifically And Ethically Superior To Embryonic Stem Cell Research

51. Adult stem cells do not possess hESCs' inherent shortcomings, and are therefore superior to hESCs. The Guidelines, by permitting federal funding of hESC research, unnecessarily direct resources away from the more scientifically promising adult stem cell research.

52. Unlike embryonic stem cells, adult stem cells provide a readily available, flexible, and safe source of stem cells for the treatment of diseases. They can be harvested from various tissue sources, including virtually all body tissues, as well as tissues normally discarded after birth. In addition, adult stem cells can be harvested and grown in numbers sufficient for patient treatment. *See* Comments, at G-2.

53. Unlike the transplantation of hESCs, which carries with it the risk of immune rejection, re-transplantation of a patient's own adult stem cells does not pose the same risks because the patient's own cells can be used. Adult stem cells also avoid tumor formation. And

adult stem cells have shown an ability to home in on damaged tissue, allowing the development of minimally invasive administration techniques. *Id.* at G-8.

54. Adult stem cells are currently being used to treat clinically many diseases in human patients. Successful clinical trials include the use of adult stem cells, in conjunction with chemotherapy or radiation, in treatments for various cancers, including ovarian cancer, brain tumors, testicular cancer, breast cancer, and various lymphomas. Similar methodology has utilized adult stem cells in treatments for sickle cell anemia and Fanconi's anemia. Adult stem cells have also successfully been used to treat patients with certain autoimmune diseases, including multiple sclerosis, systemic lupus, Crohn's disease, rheumatoid arthritis, and juvenile diabetes. *Id.* at G-4–G-8.

55. Preclinical studies also reveal the significant potential of adult stem cells for use in regenerative medicine, repairing damaged and diseased tissue, and improving health. These studies demonstrate that adult stem cells are effective in treating animal models of disease, including diabetes, stroke, spinal cord injury, Parkinson's disease, retinal degeneration, amyotrophic lateral sclerosis, and cardiac damage. *Id.* at G-2.

56. Defendants ignored the voluminous current scientific research record and comments in the Administrative Record indicating the impressive scientific and medical potential of adult stem cell research. Unlike hESCs, adult stem cells have already shown the ability to deliver therapeutic benefit to countless patients suffering from a wide array of diseases.

57. In the interest of improving patient well-being, federal funding should be directed at research that is actually improving the lives of patients. By failing to recognize the comparative strength of adult stem cell research, NIH's decision to direct federal funds toward hESC research is uninformed, misleading, inaccurate, arbitrary, and capricious, and unnecessarily diverts

funding away from more promising alternatives. Defendants abdicated their duty to exercise reasoned decisionmaking and issue fair and informed rules regarding research funding.

3. Defendants Ignored Another Ethically And Scientifically Superior Alternative, Induced Pluripotent Stem Cell Research

58. Similarly, Defendants did not properly consider that induced pluripotent stem cells have the ability to achieve the scientific and medical goals identified in the Guidelines, while avoiding the moral and ethical problems posed by the use of human embryonic stem cells. Within the last several years, scientists discovered how to use adult stem cells to create iPSCs. 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." National Institutes of Health, *Stem Cell Basics* 14 (2009), *available at* http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf.

59. The development of iPSCs essentially eliminates the need for hESCs. Dr. James Thomson, the first scientist to isolate and culture hESCs, was also one of the first scientists to produce iPSCs. In referring to the effect that the discovery of iPSCs will have on hESC research, Dr. Thomson stated: "Isn't it great to start a field and then to end it?" Gina 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?_r=1. 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." Comments, at H-3.

60. Not only do iPSCs offer an ethically superior alternative to hESCs, they also offer scientific advantages. iPSC lines can be created more easily and less expensively than embryonic stem cell lines, and iPSC lines can be derived from virtually any cell type, including human hair and human blood cells. *Id.* at H-3. To date, over 500 human iPSC lines have been created. *Id.* at H-4.

61. Additionally, scientists can create iPSC lines from a specific individual, allowing the creation of patient-specific cell lines. *Id.* Several such lines have already been created from individuals with specific diseases so that the disease mechanism and potential drug-based therapies can be studied in the laboratory. As NIH has recognized, unlike embryonic stem cells, "tissues derived from iPSCs will be a nearly identical match to the cell donor and thus probably avoid rejection by the immune system." National Institutes of Health, *Stem Cell Basics*, *supra*, at 14.

62. Thus, iPSC research offers a superior alternative to embryonic stem cell research and does not require the destruction of human embryos. By failing to consider the scientific and ethical advantages of iPSC research compared to embryonic stem cell research and choosing to fund hESC research, which will necessarily result in less funding available for adult and iPSC research, NIH's decision to make public funds available for embryonic stem cell research is uninformed, arbitrary, and capricious.

F. Defendants Failed To Consider The Guidelines' Effect On State Law And Policy

63. 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 hu-

man embryos from being destroyed or placed at risk for the purpose of medical experimentation. Indeed, state protection of human embryos is pervasive: Numerous States have fetal homicide statutes that apply without regard to gestational age and/or wrongful death statutes that apply regardless of gestational age; various States expressly prohibit nontherapeutic human embryonic stem cell research; still others prohibit the destruction of embryos for any purpose; and a number of state laws provide that life begins at conception. Moreover, under evolving state tort laws, parents or other surrogates in some States have limited capacity to consent to hazardous biomedical experiments on human subjects under their care who are incapable of voluntary consent. Despite the fact that a number of the comments on the Draft Guidelines make this plain, the Guidelines fail to inform potential donors that some States consider embryos to be living human beings, and that donating an embryo for research may constitute criminal conduct under these States' laws.

64. 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 human embryo, which is recognized in some States as an independent human life.

65. Although Defendants have a statutory mandate to "assist States" in the enforcement of state health regulations, 42 U.S.C. § 243(a), the adoption and implementation of the Guidelines will substantially undermine state laws and policies that protect embryonic human life from destruction through medical experimentation. Defendants, however, have wholly failed to consider, address, or acknowledge the effect of authorizing and implementing the Guidelines on these coordinate state laws and policies.

V. CLAIMS FOR RELIEF

CLAIM ONE: AGENCY ACTION NOT IN ACCORDANCE WITH LAW—5 U.S.C. § 706(2)(A)

66. Plaintiffs repeat and reallege paragraphs 1–65.

67. Defendants' promulgation and implementation of the Guidelines are not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A). Such funding authorizations violate the Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 509 (2009), which prohibits federal funding of "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))."

68. Therefore, the Defendants' actions are contrary to law, and Plaintiffs are entitled to relief pursuant to 5 U.S.C. § 706(2)(A).

CLAIM TWO: AGENCY ACTION NOT IN OBSERVANCE OF PROCEDURES REQUIRED BY LAW—5 U.S.C. § 706(2)(D)

69. Plaintiffs repeat and reallege paragraphs 1–65.

70. The Guidelines were not promulgated in observance of the procedures required by law within the meaning of 5 U.S.C. § 706(2)(D). In violation of 5 U.S.C. § 553(c)'s requirement that an agency "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," Defendants did not permit sufficient time for the submission of comments on the Draft Guidelines.

71. Additionally, in violation of 5 U.S.C. § 553(c)'s requirements that interested persons have the opportunity to comment and that the agency issue a final rule only after it completes a meaningful "consideration of the relevant matter presented," Defendants prejudged the

merits of matters critical to the rulemaking proceeding and did not even consider, much less respond to, the voluminous comments they received in opposition to the proposed Guidelines.

72. Therefore, Defendants have undertaken agency action not in observance with procedures required by law, and Plaintiffs are entitled to relief pursuant to 5 U.S.C. § 706(2)(D).

CLAIM THREE: ARBITRARY AND CAPRICIOUS AGENCY ACTION—
5 U.S.C. § 706(2)(A)

73. Plaintiffs repeat and reallege paragraphs 1–65.

74. Defendants' issuance of the Guidelines was arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A) because the Guidelines lack necessary and sufficient informed consent safeguards, do not adequately prohibit conflicts of interest, and ignore, contradict, or are otherwise inconsistent with scientific knowledge regarding the relative research and therapeutic potential of embryonic, adult, and induced pluripotent stem cells, and with numerous state laws and ethical rules regarding the protection of human embryos. Defendants failed to consider and utilize alternative research methods that offer similar or even superior medical promises without giving rise to the difficult ethical issues posed by hESC research, and failed to respond to evidence in the administrative record demonstrating that hESC research is neither ethically responsible nor scientifically worthy (NIH's stated criteria for funding hESC research).

75. Therefore, Defendants' agency action is arbitrary and capricious, and Plaintiffs are entitled to relief pursuant to 5 U.S.C. § 706(2)(A).

VI. IRREPARABLE INJURY

76. Plaintiffs repeat and reallege paragraphs 1–75.

77. Plaintiffs are now severely and irreparably injured by the Guidelines. Plaintiffs' injuries will be redressed only if this Court declares that the Guidelines are not in accordance

with law, fail to observe procedures required by law, and/or are arbitrary and capricious, and enjoins the Defendants from implementing them.

78. An actual and judicially cognizable controversy exists between Plaintiffs and Defendants regarding whether the Guidelines are not in accordance with law, fail to observe procedures required by law, and/or are arbitrary and capricious. Once an embryo is destroyed it cannot be revived. It is gone forever. Moreover, adult stem cell researchers like Drs. Sherley and Deisher will likely experience increased competition for already-scarce funds for their research, and may be unable to continue their work with adult stem cells. Also as a result of the Guidelines, which will likely cause many more embryos to be donated for research purposes, adoptive parents like Mr. and Mrs. Flynn, and Mr. and Mrs. Nelson, may find it more difficult to secure an embryo for adoption, and Nightlight will likely be less able to match the clients on their waiting list with embryos. Defendants are presently implementing the Guidelines to the detriment of the Plaintiffs.

VII. PRAYER FOR RELIEF

79. WHEREFORE, Plaintiffs pray for an order and judgment:

(a) Declaring that the NIH Guidelines authorizing the funding of research involving human embryonic stem cells are not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A); declaring that the NIH Guidelines authorizing the funding of research involving human embryonic stem cells were promulgated by Defendants without observing procedures required by law within the meaning of 5 U.S.C. § 706(2)(D); declaring that the NIH Guidelines authorizing the funding of research involving human embryonic stem cells are arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A);

(b) Declaring that any action previously taken by Defendants pursuant to the Guidelines is null and void, including any grants of funds for research involving human embryonic stem cells;

(c) Enjoining Defendants and their officers, employees, and agents from implementing, applying, or taking any action whatsoever pursuant to the Guidelines, or otherwise funding research involving human embryonic stem cells as contemplated by the Guidelines;

(d) Awarding Plaintiffs their reasonable costs, including attorney's fees, incurred in bringing this action; and

(e) Granting such other and further relief as this Court deems just and proper.

Dated: August 19, 2009

Respectfully Submitted,

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