# Exhibit B

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Client Matter No.
04949-00003

**VIA ELECTRONIC SUBMISSION AND E-MAIL**
NIH Stem Cell Guidelines
MSC 7997
9000 Rockville Pike
Bethesda, MD 20892-7997

**Re: Draft NIH *Guidelines* for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009); Comment Period Ending: May 26, 2009**

To Dr. Raynard S. Kington:

Do No Harm: The Coalition of Americans for Research Ethics, molecular biologists and stem cell researchers Dr. Theresa Deisher and Dr. James L. Sherley, the Family Research Council, Concerned Women for America, the Christian Medical Association, Advocates International, and the Alliance Defense Fund (collectively "Do No Harm *et al*." or "Commentators"), whose interests are more fully described in Appendix A, hereby respectfully submit the following comments (including the accompanying attachments) on the above-referenced "Draft NIH Guidelines for Human Stem Cell Research" ("Guidelines"). We request that this letter and each of its appendices be made part of the public record of the proceedings and that NIH consider this letter and its appendices as relevant matter to be taken into account in any statement of the basis and purpose of this rulemaking action under 5 U.S.C. § 553.

## GENERAL COMMENTS

The Guidelines were purportedly drafted "to help ensure that NIH-funded research in [the area of human embryonic stem cells] is ethically responsible, scientifically worthy, and conducted in accordance with applicable law." Guidelines, Summary, 74 Fed. Reg. 18578. As proposed, however, the Guidelines fail to achieve even one of these goals. For the scientific, legal, and ethical reasons set forth below, we respectfully request that the NIH decide not to issue

the proposed Guidelines and take no further steps to fund research involving "human embryonic stem cells," other than the ongoing research on the stem cell lines in the NIH's Human Embryonic Stem Cell Registry permitted under the NIH's current guidelines, as set forth in NIH Notice Number NOT-OD-09-085. Any federal funding of research on the basis of the proposed Guidelines at this time:

(1) Is illegal.

(a) Federal funding of human embryonic stem cell research violates the plain language and clear intent of applicable federal law.[1]

(b) This federal funding also promotes the destruction of human embryos in a manner that may violate applicable state law.[2]

(2) Is unnecessary and inappropriate due to several advances in scientific research and medical understanding that promise to achieve each of the stated purposes for the proposed Guidelines without violating the legal and ethical boundaries implicated by the use of human embryonic stem cells:

(a) Scientific developments achieved utilizing adult stem cells provide or promise to provide actual cell-based therapies that will lead to beneficial results for patients suffering from the diseases and conditions amenable to such therapies noted in the proposed Guidelines.

(b) Recent scientific developments provide the ability to create induced human pluripotent stem cells already approved for funding by NIH, which

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[1] The current funding ban is found in the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009, Pub. L. No. 110-329, Division A (2008) (incorporating by reference, and continuing the effectiveness of, Consolidated Appropriations Act of 2008, Pub. L. No. 110-161, § 509, 121 Stat. 1844 (2007)) (hereinafter "Dickey-Wicker" or "Federal Funding Ban"). It provides that "none of the funds made available in 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. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." *Id.*

[2] Part II.B.7.h of the Guidelines requires that the donor(s) be issued a "statement as to whether or not information that could identify the donor(s) would be retained prior to the derivation or the use of the human embryonic stem cells." The Guidelines cite OHRP's *Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles*. This document provides that HHS-conducted or supported research involving human cell lines where donor(s) may be identified constitutes human subject research that is subject to the consent requirements in 45 C.F.R. 46. *Id*. at p. 3. As discussed *infra*, Comments 9-11, it is impossible to follow the consent procedures when deriving human embryonic stem cells, because that process necessarily results in the destruction of the human embryo, which is a unique human individual. As a result, in order to avoid application of the consent procedures, researchers will undoubtedly strip the embryonic stem cells of all identifiers associated with the embryo. This means that it will be impossible to prove that any particular stem cell line was not derived from the destruction of a human embryo in violation of state law.

offer an ethical, viable alternative to embryonic stem cell research. Such cells are fully capable of achieving the Guidelines' stated desires "to test new drugs" and obtain "a better understanding of the genetic and molecular controls" involved in serious medical conditions such as cancer and birth defects, which arise due to abnormal cell division and differentiation. Guidelines, Supplementary Information.

(c) The body of scientific evidence indicates that human embryonic stem cells are abnormal, tumor-producing cells that cannot achieve the very purposes for embryonic stem cell research that are offered in the proposed Guidelines.

(3) Lacks necessary and sufficient "conflicts of interest" safeguards because:

(a) The proposed Guidelines do not prohibit contractual, agency or corporate relationships between the IVF clinic that creates and then cryogenically stores the human embryo, the researchers (a/k/a the "derivers") who kill that human embryo to harvest its stem cells, and the researchers (a/k/a the "users") who will be funded by NIH to continue the research process with respect to these human embryo stem cells. Indeed, it appears that the Guidelines do not even prohibit the deriver and the user from being the *very same person*. *See* Guidelines, Part II.B.6.

(b) The proposed 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 judgment of the legally incompetent human embryo to withhold essential life-supporting medical care from the human embryo, thereby assuring that their embryonic child will surely die. Not only is state law on this point far from settled, but the parents' moral and ethical authority to do so is far from accepted. At a bare minimum, *as a prerequisite for funding*, the Guidelines should require a judicial proceeding, in which the human life interests of the human embryo(s) in question are represented by a court-appointed attorney pro vita (for life), and court approval before such a parental "donation" would be deemed lawful under state law and free of the obvious conflicts of interest presented when the parents of an offspring initially conceived to be their child are now proposing to terminate its life solely for medical research purposes supported by federal tax dollars, particularly when there has been no showing that: (1) other more life-preserving options have been explored for the embryonic child and reasonably excluded; and (2) the federally financed researcher has established that a compelling governmental interest exists to perform the research, which interest cannot otherwise be satisfied without destroying

the lives of these human embryos.[3]

(4) Lacks necessary and sufficient "informed consent" safeguards because the proposed Guidelines do not even *require* the parents of the human embryos (a/k/a "the potential donors") to be informed that:

(a) *Scientifically speaking*, each of their human embryos is a living human being;

(b) *Legally speaking*, many states hold that human life begins at conception. In these states, the "donation" of human embryos for research may be deemed to be the taking of human life.[4] In multiple states, research involving human embryos is effectively banned.[5]

(c) Insofar as each of these human beings is "no longer needed," Guidelines, Supplementary Information at 18579, it is now possible for the parents to place each embryo up for adoption as an alternative to having the human embryo killed for research purposes.[6]

## SPECIFIC COMMENTS

1. It is axiomatic that regulations of a federal agency cannot violate an applicable federal statute.[7] The proposed Guidelines violate an applicable federal statute. Current federal law

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[3] For a thoughtful analysis of the substituted judgment rule and the inherent conflicts of interests involved in health care decisions terminating life, *see* Walter Weber, *Substituted Judgment Doctrine: A Critical Analysis*, 1 Issues L. & Med. 131 (1985).

[4] For an analysis of state law protecting human life from conception, see the accompanying **Appendix B**. Part I of Appendix B lists states' fetal homicide statutes that apply without regard to gestational age. Part II lists wrongful death statutes that apply without regard to the state of gestation or development. Finally, Part III identifies courts that have rejected constitutional challenges to fetal homicide statutes that apply without regard to the age of the unborn child.

[5] *See* **Appendix C**, *The Legal Consensus on the Beginning of Life*.

[6] For a legal analysis of the adoption alternative that legally and ethically should be part of any informed consent procedure involving frozen embryos in excess of clinical need, see the accompanying **Appendix D**, *The Frozen Embryos: The Adoption Solution*.

[7] The Administrative Procedure Act declares it "unlawful" for "agency action, findings, and conclusions . . . to be . . . contrary to constitutional right, power, privilege, or immunity [or] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706; *see also Iowa Telecomms. Servs., Inc. v. Iowa Utils. Bd.*, 545 F. Supp. 2d 869 (S.D. Iowa 2008) (Agencies only possess powers conferred by statute; they do not possess inherent powers); *Agro Dutch Indus. Ltd. v. United States.*, 508 F.3d 1024 (Fed. Cir. 2007) (An agency literally has no power to act unless and until Congress confers power upon it.); *Portland Gen.Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009 (9th Cir. 2007) (Regardless of how serious the problem an

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prohibits federal funding of any "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Federal Funding Ban, subsection (a)(2). The proposed Guidelines (including in particular Part II.B, authorizing federal funding for embryonic stem cell research) would infringe this and other current laws and regulations protecting the human embryo from harmful experiments at federal expense, because the research to be funded by the Guidelines necessarily involves and entails the destruction of human embryos. Indeed, human embryonic stem cell research cannot be conducted *without* destroying the human embryos involved, and thus the clear and inevitable purpose and effect of the Guidelines is to necessitate and encourage the destruction of human embryos for research in direct violation of the Federal Funding Ban. Such a purpose and effect is contrary to Congress' clear intent to maintain the *status quo* by re-enacting the current ban on federal funding for destructive human embryonic research. As one legal commentator has explained that legislative history:

> *The history behind federal funding of human embryo research evinces uneasy disapproval of this type of experimentation.* Since 1980, the federal government has withheld funding for human embryo research by de facto moratorium. Until 1993, [45 C.F.R. § 46.204(d)] authorized federal funding of embryo research subject to approval of such projects by a Department of Health and Human Services Ethical Advisory Board ("EAB"). The first—and only—EAB appointed to evaluate embryo research concluded that it was ethical as a theoretical matter for the purpose of developing IVF techniques. Despite this approval, the NIH neither took action on a specific project nor appointed additional EAB's, and funding was never allocated for projects involving embryo research.
>
> The National Institutes of Health Revitalization Act of 1993 eliminated the EAB approval requirements of 45 C.F.R. § 46.204(d). . . .
>
> Before allocating any funds, however, the NIH convened the Human Embryo Research Panel. The Panel gathered nineteen participants with expertise in clinical research, ethics, law, social science, public health, and public policy to consider the moral and ethical implications of human embryo research, and to develop funding Guidelines for that research.

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administrative agency seeks to address, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law, because an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.); *Elec. Power Supply Ass'n v. F.E.R.C.*, 391 F.3d 1255 (D.C. Cir. 2004) (When an agency acts in violation of an express congressional mandate, its motives are irrelevant); *In re Sealed Case*, 237 F.3d 657 (D.C. Cir. 2001) (Agencies are not empowered to carve out exceptions to statutory limits on their authority); *Birth Hope Adoption Agency, Inc. v. Arizona Health Care Cost Containment Sys.*, 218 F.3d 1040 (9th Cir. 2000) (The scope of an agency's power is measured by statute and may not be expanded by agency fiat); *United States v. Amdahl Corp.*, 786 F.2d 387 (Fed. Cir. 1986) (Administrative actions taken in violation of statutory authorization or requirement are of no effect).

After listening to testimony from more than forty witnesses and reviewing correspondence from 30,000 individuals, *the Panel [affirmed the NIH's prior recommendation] that embryo research should be funded by the federal government.* The members found that human embryo experimentation would generate significant advances in scientific research—particularly in the areas of infertility, genetic defects, and disease therapy. The Panel struggled, however, with the ethical implications of research conducted with deliberately fertilized embryos. While they did not define the precise moral or legal status of the embryo, they attempted to design their recommendations with "respect" for the embryo as a symbol of human life. The Panel believed that their Guidelines and corresponding public funding would also stimulate ethical and scientific review of privately funded embryo research. . . .

The Advisory Committee to the Director of the NIH ("ACD") approved all of the Panel's recommendations—including the one permitting deliberate creation of research embryos—and passed the recommendations on to the NIH Director, Harold Varmus, for the ultimate funding decision. Within hours of that vote, however, President Clinton stated: "I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that the NIH not allocate any resources for such research." William Galston, deputy director of Clinton's Domestic Policy Council, later confirmed that the Clinton administration had decided even before the ACD's meeting that deliberate creation of human embryos for experimentation exceeded the public's tolerance for "exotic" research.

The President's announcement did not prevent Varmus from implementing the NIH Panel's other recommendations--such as . . . funding for experimentation on "surplus" embryos. *Congress, however, has since passed broader restrictions. Under Public Law 105-78 [continued under Pub. L. No. 110-329], federal funds are presently unavailable not only for the creation of research embryos, but also for any type of research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death. In effect, the moratorium on federally-funded embryo research continues. No federal legislation, however, exists to regulate embryo research conducted in the private sector.*[8]

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[8] *See* Christine L. Feiler, *Note: Human Embryo Experimentation: Regulation and Relative Rights*, 66 Fordham L. Rev. 2435, 2459–61 (1998) (emphasis added). The current funding ban, found in the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009, Pub. L. No. 110-329, Division A (2008) (incorporating by reference, and continuing the effectiveness of, Consolidated Appropriations Act of 2008, Pub. L. No. 110-161, § 509, 121 Stat. 1844 (2007)), provides that "none of the funds made available in 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. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." The standard of risk referenced in 45 C.F.R. § 46.204(b) limits in utero fetal research to that where the "risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk

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The foregoing legislative history makes clear that the purpose of the Federal Funding Ban was to prevent NIH from implementing the very strategy that the Guidelines are now being proposed to implement—federal funding for experimentation on "surplus" human embryos. Given the nature of the living human embryo, any human stem cell research is, in the words of the Federal Funding Ban, a type of "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death. . . ." It is patently impossible for NIH, in good conscience, to promulgate these Guidelines and begin funding human embryo research without knowing that such funding means that human embryos are thereby being "*subjected to risk of injury or death*" in patent violation of the Federal Funding Ban—a risk that would not exist were it not for the incentives to destroy embryos created by the availability of NIH funding.[9] There will be no way for NIH to wash its hands of its complicity in the destruction of human embryos involved in the research projects it funds; the funding proposed in the Guidelines can serve only to create the very "risk of injury or death" prohibited by the Federal Funding Ban. Indeed, the Guidelines confirm this understanding, because they directly regulate the manner in which consent for embryo destruction is obtained from the parents and determine the categories of embryos that should be destroyed for federally funded research projects. *See* Guidelines, Part II.B. Moreover, such funding plainly contradicts NIH's prior pronouncement that the early human embryo "warrants serious moral consideration as developing form of human life." NIH, *Final Report of the Human Embryo Research Panel*, Page 2 (1994). Killing a defenseless human being, then asking every taxpayer to pay for research on that human being's cells, is the exact opposite of "moral consideration"—it is callous inhumanity.

2. This Federal Funding Ban has been in place since 1996, and its meaning has not changed. There is no justification for ignoring the plain language of the Federal Funding Ban. Any research involving cells derived through the destruction of human embryos is *necessarily* research "in which a human embryo" is destroyed. Indeed, HHS itself has acknowledged that, in order for any guidelines to comply with the Federal Funding Ban, it is critical that "human embryonic stem cell research [be] limited to a discrete set of stem cell lines with respect to which

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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 other means." The term "minimal risk" is defined at 45 C.F.R. § 46.102(i) as "mean[ing] that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." The standard of risk referenced in section 498(b) of the Public Health Service Act (42 U.S.C. § 289g(b)) provides that "[i]n administering the regulations for the protection of human research subjects [at 45 C.F.R. 46] . . . the Secretary [of Health and Human Services] shall require 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." *See also* **Exhibit E**, Samuel B. Casey, *Legislative & Administrative History of the Federal Funding Ban on Destructive Human Embryo Research* (May 26, 2009).

[9] The Federal Funding Ban (*see supra*, fn. 1) defines an embryo as "any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means. . . ." This provision proceeds to require that this embryo be treated *exactly like* other protected human subjects, by extending to the embryo in the laboratory the protective standard already in effect for all fetuses *in utero*.

the life and death decision has been made prior to the announcement of the policy . . . [which would] provide[] no incentives for the destruction of additional embryos."[10]

3. By necessarily entailing, promoting, and encouraging the destruction of human embryos, the federally funded research envisioned by the Guidelines also potentially violates various state laws and policies, without even considering, let alone justifying, these intrusions on state law and policy.[11] For example, 21 states have fetal homicide statutes that apply without regard to gestational age. *See* Appendix B, Part I. Eight states have wrongful death statutes that apply regardless of gestational age. *Id*. at Part II.

Still other states explicitly proclaim that life begins at conception.[12] The overwhelming majority of medical authorities equate the terms "conception" and "fertilization." For example, a medical text commonly used near the time these definitions were adopted stated:

> The term *conception* refers to the union of the male and female pronuclear elements of procreation from which a new living being develops. It is synonymous with the terms *fecundation*, *impregnation*, and *fertilization*.

J. Greenhill and E. Friedman, *Biological Principles and Modern Practice of Obstetrics*, 17 (1974) (emphasis in original).[13] This usage continues to the present day, as the majority of medical dictionaries now in use follow the American Medical Association in defining conception as "[t]he fertilization of an egg by a sperm that initiates pregnancy." *AMA Complete Medical*

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[10] A copy of the HHS Legal Memorandum re Compliance of the President's Embryonic Stem Cell Decision with the Dickey Amendment for Fiscal Year 2002, dated January 11, 2002, is attached as **Appendix F**.

[11] *See* **Appendix C**, The Legal Consensus on the Beginning of Life.

[12] *See id*.

[13] This use of "conception" clearly refers to fertilization, not implantation. At least seven medical dictionaries published at or near the time the General Assembly defined conception as fertilization. *See Butterworth's Medical Dictionary* 400 (2d ed. 1978) (conception: "1. The act of becoming pregnant. 2. The fertilization of the ovum by a spermatazoon and the beginning of the growth of the embryo."); *Blakiston's Gould Medical Dictionary* 305 (4th ed. 1979) (conception: "the fertilization of the ovum by the spermatazoon"); *Black's Medical Dictionary* 217 (33rd ed. 1981) ("Conception signifies the complex set of changes which occur in the ovum and in the body of the mother at the beginning of pregnancy. The precise moment of conception is that at which the male element, or spermatazoon, and the female element, or ovum, fuse together."); *Urdang Dictionary of Current Medical Terms* 91 (1981) (conception: "1. (in gynecology) the start of pregnancy when a male germ cell (sperm) fertilizes a female germ cell (ovum) in the fallopian tube."); *Mosby's Medical and Nursing Dictionary* 258 (1983) (conception: "1. the beginning of pregnancy, usually taken to be the instant that a spermatazoon enters an ovum, 2. the act or process of fertilization"); *Taber's Cyclopedic Medical Dictionary* 368 (15th ed. 1984) (conception: "2. fertilization"); *Melloni's Illustrated Medical Dictionary* 108 (2d ed. 1985) (conception: "2. The fertilization of an ovum or the act of becoming pregnant.").

*Encyclopedia* 392 (2003).[14] In those states that acknowledge and protect life from the moment of fertilization or conception, "donation" of human embryos for the purpose of destruction is properly viewed as a state criminal violation. The Guidelines fail even to consider this possibility, and improperly seek to encourage and fund potentially illegal activity.

4. As further discussed below, adult stem cell research has already provided a wide array of vastly important real-world medical benefits and promises future advances of similar quality. It is, therefore, a worthy scientific priority meriting federal funding so long as it is pursued in a lawful, ethical and scientifically appropriate fashion on the basis of broad public consensus as to what is socially acceptable for American taxpayers to fund. The public generally supports *adult* stem cell research that does no harm to anyone, but many millions of American taxpayers oppose research like human embryo stem cell research that relies on destroying one human life in the speculative (and illusory) hope of perhaps making another human being's life better somehow, some day. Under these circumstances it would be arbitrary and capricious for the NIH to force every American taxpayer to pay for research that is scientifically unnecessary and that many Americans believe to be unethical, particularly where alternative research avenues exist for pursuing the same goals in a more uncontroversial, lawful, and ethical fashion.

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 (Type I) diabetes.[15] Adult stem cells also present the following benefits that embryonic stem cells ("ESCs") cannot:[16]

- Adult stem cells provide a readily available and flexible source of stem cells for the treatment of disease.
- Adult stem cells can be harvested from various tissue sources, including virtually all body tissues, as well as tissues normally discarded after birth (umbilical cord blood, placenta).
- Adult stem cells can be harvested as well as grown in numbers sufficient for patient treatments.
- Adult stem cells can provide matched tissue transplants, especially in the majority of cases where the patient's own cells are used, and also in donor transplants.

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[14] *See also*, R. Jones & K. Lopez, *Human Reproductive Biology* 23 (3d ed. 2006) ("The process of *fertilization*, or *conception*, involves fusion of the nucleus of a male gamete (sperm) and a female gamete (ovum) to form a new individual.") (emphasis in original); *id*. at 540 ("Conception[:] See Fertilization."); G. Thibodeau & K. Patton, *Anatomy & Physiology* 1167 (6th ed. 2007) (equating conception with fertilization).

[15] *See* **Appendix G-5** through **G-7** for a more detailed discussion of adult stem cell success stories, and accompanying references.

[16] *See* **Appendix G** for a thorough discussion on the benefits of adult stem cell research.

- Adult stem cells do not present a risk of tumor formation, making these cells a safe therapeutic strategy.

- Adult stem cells show some ability to home to sites of tissue damage, and the homing ability can be further enhanced to increase efficacy and delivery.

- Adult stem cells have shown efficacy at repairing damaged and diseased tissue in numerous animal models of disease and injury.

- Adult stem cells have already demonstrated their efficacy in improving the health and saving the lives of thousands of patients.

5. Not only has adult stem cell research progressed in recent years, so has human induced pluripotent stem cell ("iPSC") research. This research provides an ethical alternative to human embryonic stem cell research. Accordingly, even if NIH had reason to believe that research involving human embryonic stem cells would be as valuable from a scientific and medical standpoint as research involving human adult stem cells (which it does not), it would be arbitrary and capricious for NIH to fund embryonic stem cell research when it could achieve the same scientific and medical goals through research involving human induced pluripotent stem cells that does not pose the same moral and ethical problems. Below is a summary of the advantages of iPSCs:[17]

- Induced pluripotent stem cells ("iPSCs") are a substitute for embryonic stem cells (ESCs), and have additional advantages over ESCs.

- iPSCs are indistinguishable from ESCs in their morphology and cellular behavior.

- iPSCs can be created through reprogramming of virtually any somatic cell type.

- iPSC lines can be created more easily and less expensively than ESC lines.

- iPSC creation does not require use of embryos, eggs, or nuclear transfer (organismal) cloning, thus bypassing ethical concerns associated with use of embryos, eggs, and cloning in stem cell research.

- iPSC lines can be created from a specific individual, allowing creation of patient-specific cell lines. 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. There is also the potential that such lines would provide cells that would not be rejected if transplanted into the same individual from whom they were derived.

6. In addition to the facts that adult stem cell research has made significant strides, provides

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[17] *See* **Appendix H** for a thorough discussion on iPSC research, with supporting authorities.

a wide array of life-saving treatments, and offers the prospect of many further medical and scientific advances, recent scientific research suggests that human embryonic stem cells ("hESCs") can never be transplanted into children or adults as a safe and effective therapeutic. In fact, research suggests that hESCs will not lead to safe and effective human therapeutics—thus obviating the need for human embryonic stem cell research at all, since, as the Guidelines recognize, the very purpose of this research is to develop cures or treatments for various diseases. Guidelines, Supplementary Information, 74 Fed. Reg. 18578.

Human embryonic stem cells ("hESCs") will not lead to safe human therapeutics and are therefore inappropriate federal funding targets for the following reasons:[18]

**A. ESCs are not normal cells**.

1. While the cells of the inner cell mass give rise to the organism during normal embryonic development, the derivation of embryonic stem cells ("ESCs") from the inner cell mass generates cells that exhibit epigenetic changes and that form tumors in vivo, even after in vivo tetraploid fetus derivation. The formation of tumors by hESCs is an essential characteristic used to identify a cell as a pluripotent hESC, and is a quality control test used by commercial suppliers of hESCs. Additionally, the formation of tumors after in vivo injection of ESCs is a uniform event in animal models of sufficient duration when adequate quantities of ESCs have been injected to achieve long term ESC survival.

2. Clonal analysis of ESC-generated tumors reveals that the tumor is not clonal, demonstrating that tumor formation is not the product of a single aberrant ESC. Rather, tumor formation is an inherent property of all ESC injections, which explains the development of polyclonal tumors.

3. This quality of ESCs cannot be dismissed as a normal characteristic of a pluripotent cell removed from its endogenous environment. The use of hESCs for medical therapy does not imagine the re-introduction of hESCs into a normal embryonic environment, but rather the injection of hESCs into a non-embryonic recipient, and science teaches us that the clinical result will be tumor formation.

**B. ESCs do not differentiate into desired adult phenotype cells, but to fetal, immature phenotype cells.**

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[18] For a more detailed explanation of the reasons why stem cells can never be transplanted into children or adults as a safe and effective therapeutic, and citations to supporting authority, see **Appendix I**.

1. Both in vitro and after in vivo injection, ESCs differentiate into fetal or immature cell phenotypes, rather than into fully functioning adult phenotype cells needed for therapeutic treatments. When attempts are made to differentiate ESCs in vitro prior to in vivo injection, in order to reduce tumor formation, the ESCs do not then differentiate into adult cell phenotypes in vivo, and actually do not survive long term in the in vivo environment.

2. Experience has taught us that in vivo use of fetal tissue or cells leads to dangerous, uncontrolled cell growth and tumor formation.

3. Fetal cells are not adequate cell replacements for lost adult cells. Fetal insulin-producing cells do not produce therapeutically effective levels of insulin.

**C. ESCs are neither useful nor required for research using other pluripotent cells such as spermatogonial stem cells (SSCs) or induced pluripotent stem cells (iPSCs).**

1. The quality assurance test used by commercial suppliers of ESCs as well as by research laboratories to demonstrate cellular pluripotency is tumor formation. This test to determine whether other cell types are pluripotent does not require ESCs at any step.

2. If pluripotent cells will have any therapeutic utility they must be differentiated into adult, functional phenotype cells. This requires the use of the desired adult cell type as an in vitro and in vivo comparator. Because the only possible comparator is adult stem cells, ESCs are neither required nor useful at any step of these comparative tests.

**D. hESCs will not cure the targeted diseases listed in the Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice.**

1. Complex, polygenic, autoimmune diseases such as Parkinson's Disease, amyotrophic lateral sclerosis, diabetes and arthritis are not amenable to stem cell therapy because hESCs will not address the pathology underlying these diseases.

2. Effective treatment of these types of diseases requires medical intervention to significantly dampen if not eradicate the autoimmune attack prior to any attempt to regenerate tissue.

3. Stem cell therapy in the environment of autoimmune activity will not lead to long term functional recovery, as any tissue replacement will eventually suffer the same autoimmune attack and destruction.

4. Clinical studies using this approach have demonstrated that autoimmune blockade or eradication can be sufficient to allow endogenous tissue regeneration to occur leading to profound clinical benefits in patients suffering from rheumatoid arthritis, type I diabetes, multiple sclerosis and osteoporosis.

Because the Guidelines fail to make any showing that human embryonic stem cell research is currently necessary and sufficient to accomplish vitally important research that cannot otherwise be accomplished through the use of adult stem cells and/or iPSCs, NIH should not promulgate the Guidelines and should instead withdraw the notice of proposed rulemaking.

Until the publication of these Guidelines, it has been NIH's position that human embryos are to be used for research only if "the research goals cannot otherwise be accomplished" by other means. NIH, *Final Report of the Human Embryo Research Panel* (1994), at page 3. More recently, the National Bioethics Advisory Commission said that the derivation of stem cells from embryos is justifiable "only if no less morally problematic alternatives are available for advancing the research." NBAC, *Ethical Issues in Human Stem Cell Research* (Rockville, MD: September 1999, Volume I, at page 53.) Given what we know about the progress of adult stem cell and iPSC research, NIH should not promulgate the Guidelines and should instead continue to fund only the latter types of research as the "less morally problematic" alternatives to achieve the same medical and scientific goals.

7. The Guidelines are also problematic to the extent they do not prevent conflicts of interest between the reproductive facility and the research facility. By virtue of these Guidelines, NIH directs how embryos are obtained for destruction, regulates the process for obtaining consent from the parents, and determines which categories of embryos may be destroyed for the federally funded research project. The Guidelines clearly establish that the process of destroying the embryo for its stem cells is an integral and federally regulated part of the research project receiving federal funds. But under the Guidelines, the person or organization destroying the embryos can even be the same person who then uses the stem cells thus obtained—simply using different funds for the two activities. Indeed, so long as the "attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells [is not] one and the same person" "*where practicable*," nothing prevents an IVF facility from being both the human embryo killer and the human embryo stem cell researcher. *See* Guidelines, Part II.B.6. Thus, the overly vague Guidelines allow the unacceptable "conflicts of interest" that the proponents of these Guidelines state they were trying to avoid.

8. These Guidelines only set the stage for further abuses by limiting federal funding to cell lines that are derived from embryos that are "no longer needed" for reproductive purposes. 74 Fed. Reg. 18579. But the distinction between "spare" embryos that are "no longer needed" and those specially created for research is easy to evade: Infertility clinics can simply create more embryos at the outset, ostensibly for fertility treatment, so they will have more "spares" left for research. Ironically, the funding separation attempted by these Guidelines, requiring the NIH to accept at face value the assurances provided by researchers regarding their use of private funds to obtain and destroy embryos, makes it even less likely that such abuses will be detected or

stopped. Thus, the Guidelines tend to encourage, not avoid, the very sort of abuses that will degrade public trust in the entire enterprise.[19]

9. The Guidelines purport to implement "ethically responsible" research procedures, but it is not ethically responsible to ignore the humanity of the human embryo. By restricting human embryonic stem cell research to cell lines derived from human embryos that were "donated" for research, and providing that the living human embryo's parents are to think of themselves only as "donors," the Guidelines completely disregard the unique status, worth, and life of human embryos. Guidelines, Part II.B. It is unseemly for NIH, at the taxpayers' expense, to state in federal regulations that living human beings can and ought to be "donated" by their legal guardians "for research" in this country. Human embryos are not mere tissue, nor are they personal property. Under the terms of the Federal Funding Ban, they are living human beings deserving of the same respect due to other protected *human* subjects under 45 C.F.R. 46. *See* Federal Funding Ban. Since 1975, embryos in the womb at this same stage of development (about a week old) have been seen by the federal government as "human subjects" to be protected from harmful research (*see* 45 CFR § 46.201 et seq.). Yet the NIH now proposes to fund research that necessarily entails the destruction and exploitation of identical human embryos *in vitro*. Even NIH's own Human Embryo Research Panel in 1994, and President Clinton's National Bioethics Advisory Commission in 1999, admitted that a human embryo is a developing form of human life that deserves considerably more respect than would be accorded the human embryo in the Guidelines.

10. The Guidelines ought to afford living human embryos more respect than the requirement "that researchers may not create embryos solely for research purposes." Samuel B. Casey and Nathan A. Adams, *Specially Respecting the Living Human Embryo by Adhering to Standard Human Subject Experimentation Rules*, 2 Yale J. Health Pol'y, L. & Ethics 111, 119 (2001). Under the proposed Guidelines, embryos are deemed eligible for destructive research if they were originally created for reproductive purposes but are now "no longer needed for this purpose" (*i.e.*, are unwanted by the parents). But current federal law on embryo research was

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[19] The NIH is no stranger to the damage to public confidence such abuses engender. In January 1997, media controversy erupted when NIH-supported geneticist and former HERP panelist Mark Hughes from Georgetown University was found to have violated the restrictions governing the use of human embryos. Hughes had included Federal equipment and personnel in lab experiments on prenatal embryo diagnosis, violating strict segregation rules designed to implement the Federal Funding Ban. NIH Director Harold Varmus severed ties with the scientist and told a Congressional committee investigating the incident that NIH had taken "several steps to further diminish the risk of subsequent violations." *See* Rick Weiss, *Georgetown Geneticist Admits Disobeying Test Ban on Embryos,* WASH. POST, Jan. 15, 1997, at 3; Testimony of Harold E. Varmus, M.D., Director, NIH, Before the Subcommittee on Oversight and Investigations Committee on Commerce, United States House of Representatives, June 19, 1997 (Serial No. 105-26; ISBN 0-16-055330-X). At that time, Dr. Varmus testified that Dr. Hughes' pre-implantation genetic diagnostic research of human embryos using federal equipment and funds violated "[federal] appropriations laws prohibited the use of federal resources for human embryo research." *Id.* at 3-4; Congressional Statement at 2; *and* Letter from John J. Callahan, Assistant Secretary for Management and Budget, DHHS, to DHHS Institutional Officials (February 1997) (reinforcing the legal requirements of the Federal Funding Ban). If the Hughes incident, which did not even result in the deaths of any human embryos, violated the Federal Funding Ban, the Guidelines clearly do so as well.

clearly designed to extend the same protection to these embryos that is now provided for the unborn child in the womb.[20] That law prohibits any effort to select an unborn child for risky or lethal research because he or she is "unwanted" and slated for a future abortion. Because that principle is ignored here, the Guidelines should be deemed to be contrary to the plain meaning and intent of the Federal Funding Ban.

11. The Guidelines create further conflicts of interest by erroneously presupposing, without explanation, that due to the obvious incompetence of the human embryo to speak for itself, the biological parents of the human embryos are legally and morally empowered to substitute their judgment for that of the human embryo in consenting to the destruction of the human embryo. Guidelines, Part II.B. In recent years, courts have encountered, with increasing frequency, requests for permission to withhold life-supporting medical treatment from incompetent individuals. Some courts have employed the so-called doctrine of substituted judgment to decide cases where the surrogate decision-maker's motives are not self-interested and can be further shown to reflect the true intentions of the incompetent patient, particularly where the imminent terminal outcome for the patient can be shown or safely presumed regardless of the medical care provided. However, any application of that doctrine in the instant situation to be regulated by the Guidelines suffers from theoretical incoherence and practical un-workability where a terminal outcome for the human embryo can be readily avoided by cryopreservation and implantation in adoptive mothers,[21] and the surrogate decision-makers must be presumed to have an exclusively self-interested motive to always destroy the human embryo because the Guidelines presume the parents will only be asked to "donate" human embryos "no longer needed" for their reproductive purposes. Guidelines, Part II.B.

Given the lack of legal and moral support for NIH's unjustified assumption that the parents of a human embryo *ex utero* can or ought to be so authorized to speak for the human embryo under these circumstances, the Guidelines should, at the very least, be revised to provide that such authority will be legally recognized only when the human embryo's interests are represented by a court-appointed guardian, rather than merely by his or her parents. Surely, if the interests of science are as great as the Guidelines suggest, the cost of requiring these judicial proceedings would be a small price to pay for the certainty that the decision to kill the human embryos was made by a neutral third party in conformance with applicable state law, untainted by conflicts of interest, and in a fully informed fashion.

Moreover, the Guidelines should not presume that the parents of the human embryo *ex utero* can legally and morally substitute their judgment for that of their incompetent human embryos who find themselves in the unfortunate position of being "no longer needed." As one commentator has suggested under these circumstances:

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[20] *See supra* Comment 1.

[21] 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/.

> [P]erhaps the best way to preclude the exploitation of the relative defenselessness of incompetents would be to set up a standard whereby incompetents would be treated as if they were competent individuals desiring life. Such a standard would not require the application of useless treatments, since these are irrelevant to a human embryo's desire and ability to live. Nor would this standard mandate a life-at-all-costs approach: if a given treatment option would not be open to a competent individual (whether because of expense or impracticability, or because the requisite resources are already occupied elsewhere), it would also not be available to the incompetent. But this approach would require that an incompetent not be denied beneficial treatments solely on the basis of his incompetence to choose them.
>
> This approach, which might be denominated the presumptions approach, seeks to strain out improper decisional bases. The notion that some classes of humans have less value before the law, for example, might otherwise serve as an implicit or explicit basis for decision-making.
>
> The presumptions approach also serves to check motivations originating in third party selfishness. The strong presumption against the wishes of parental "donors" provides a stronger safeguard for the incompetent than does a standard which too readily accedes to the [parents'] requests. Those who seek the court's aid often want desperately to believe that they are acting for the incompetent's good, and not just their own convenience. Presumptions to the contrary test this belief and force its reexamination by both the court and, ideally, the parties seeking relief.[22]

12. The Guidelines fail to require that parents receive sufficient information to be able to give truly *informed* consent. The Guidelines require only that "[i]nformation about what would happen to the embryos in the derivation of human embryonic stem cells for research" be provided to the parents, Guidelines, Part II.B(d), but that information, standing alone, fails to inform the donor(s) clearly and explicitly that the embryo will be destroyed. The National Bioethics Advisory Commission has recommended that such information *"make clear that the research will involve the destruction of the embryos."* NBAC, *Ethical Issues in Human Stem Cell Research* (Rockville, MD: September 1999, Volume I, at page 72.)

13. The Guidelines are also inadequate in terms of "informed consent" because they fail to require that the embryo's parents be informed that the "donation" will "terminate the life of a whole, separate, unique, living human being." *Planned Parenthood v. Rounds*, 530 F.3d 724, 726 (8th Cir. 2008). Without the vital information that the human embryo is a living, unique human individual, the embryo's parents have not been fully informed before consenting to the destruction of the human embryos.

14. Attached as Appendix J is The Founding Statement of Do No Harm: The Coalition of

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[22] Walter Weber, *Substituted Judgment Doctrine: A Critical Analysis*, 1 Issues L & Med. 131, 154-54 (1985).

Americans for Research Ethics (July 1, 1999). The Statement, which has been signed by a growing group of several hundred doctors, medical researchers, nurses, bio-ethicists, law professors, attorneys, and theologians, makes the following points, all of which support our request to withdraw the notice of proposed rulemaking and not issue the Guidelines:[23]

> Recent scientific advances in human stem cell research have brought into fresh focus the dignity and status of the human embryo. . . . [H]uman stem cell research requiring the destruction of human embryos is objectionable on legal, ethical, and scientific grounds. Moreover, destruction of human embryonic life is unnecessary for medical progress, as alternative methods of obtaining human stem cells and of repairing and regenerating human tissue exist and continue to be developed.

Do No Harm's Statement makes the following points, which the Guidelines fail to adequately consider or address:

**A. Human embryonic stem cell research violates existing law and policy: *States*:** Homicide laws in all 50 states protect human life and the dignity of every human being—especially the vulnerable. In addition, a number of states already specifically protect vulnerable embryonic human beings outside the womb, while others prohibit destructive human embryo and human fetal research.

***National*:** The present Congressional ban on federally funded human embryo research explicitly excludes "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death"; existing laws requiring separation between the death of an unborn child in abortion and research objectives using the unborn child's tissues preclude the destruction of human embryos as a means of achieving research objectives. "Obviously, Congress' intent here was not merely to prohibit the use of federal funds for embryo destruction, but to prohibit the use of such funds for research dependent in any way upon such destruction. Therefore, the opinion of HHS that human embryonic stem cell research may receive federal funding clearly violates both the language of and intention behind the existing law. Congress and the courts should ensure that the law is properly interpreted and enforced to ban federal funding for research which harms, destroys, or is dependent upon the destruction of human embryos."

***International*:** Documents such as the Nuremberg Code, the World Medical Association's Declaration of Helsinki, and the United Nations Declaration of Human Rights reject the use of human beings in experimental research without their informed consent, and permit research on incompetent subjects only if there is a legal surrogate, minimal risk, and therapeutic benefit for the human subject.

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[23] For the full Statement and other information, *see* DO NO HARM-THE COALITION OF AMERICANS FOR RESEARCH ETHICS, *available at* http://www.stemcellresearch.org/statement/statement.htm.

**B. Human embryonic stem cell research is <u>unethical</u>:**

- Recent history provides tragic examples of attempts to justify gross violations of the rights of human beings in medical research on the utilitarian basis of "social and medical benefit": the Tuskegee experiments on African Americans, U.S. government-sponsored radiation research; the Nazi medical war crimes, etc.

- Good ends (e.g., health) do not justify the use of unethical means (e.g., killing human beings).

- Scientifically, the international consensus of embryologists is that human beings begin at fertilization (or cloning)—i.e., when their genetic code is complete and operative; even before implantation they are far more than a "bunch of cells" or merely "potential human beings."

**C. Human embryonic stem cell research is <u>scientifically unnecessary</u>:**

- Other research methods which use stem cells from adults to develop treatments for many diseases have recently been shown to be quite promising. *See* Appendix G.

- The use of a patient's own stem cells is even preferable to using embryonic stem cells because it avoids the problem of the body rejecting cells other than its own.

- Other new methods such as somatic cell gene therapy are increasingly successful in tissue regeneration and otherwise treating disease.

15. The NIH has provided the public with insufficient time to meaningfully comment on the Draft Guidelines. A mere 34-day comment period does not afford interested parties an adequate opportunity to comprehensively review and comment on the Guidelines—especially given the scientific complexity and ethical ramifications of the Guidelines. 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 60-day period was inadequate because, inter alia, the issue involved "such great numbers of interested persons and organizations . . . [that would need] to go through their own bureaucratic processes to arrive at their comments"). Moreover, the inadequate comment period precludes the NIH from having sufficient information to engage in informed rulemaking.

Making matters worse, the NIH has failed even to create an *appearance* that it will thoroughly consider, with an open mind, the comments submitted within the 34-day window. Indeed, a full week prior to publishing the Draft Guidelines, the NIH had already announced that it was accepting applications for human embryonic stem cell research, reflecting an obvious decision to authorize such research regardless of the comments received. *See* Implementation of Executive Order on Removing Barriers to Responsible Scientific Research Involving Human

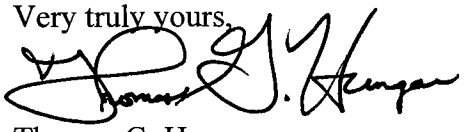
Stem Cells, NOT-OD-09-085 (Apr. 17, 2009), available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html ("NIH will accept applications for research proposing to use human embryonic stem cells during the period of Guidelines development . . . .").

16. Acting Director Raynard Kington should be excluded from crafting and approving the final guidelines because he has made clear that his mind is made up about the merits of the policy and the formulation of the guidelines. In *Association of National Advertisers, Inc. v. FTC*, the D.C. Circuit held that an agency member should be excluded from a rulemaking proceeding when there is a "clear and convincing showing that the agency member has an unalterably closed mind on matters critical to the disposition of the proceeding." 627 F.2d 1151, 1170 (D.C. Cir. 1979). The member need not be excluded because of a "mere discussion of policy or advocacy on a legal question." *Id.* at 1171. But, when a decision maker enters a rulemaking proceeding with an unalterably closed mind about the merits of the proposed rule, the effect is to entirely deprive interested parties of the required opportunity to comment. *See Nehemiah Corp. of America v. Jackson*, 546 F. Supp. 2d 830, 847 (E.D. Ca. 2008) (holding that HUD Secretary Jackson should have been excluded after stating that HUD "intend[ed] to approve the new rule by the end of the year even if the agency receive[d] critical comments").

Like Secretary Jackson, Acting Director Kington has made clear his views on the funding of embryonic stem cell research. Indeed, 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 Street Journal, Apr. 17, 2009, http://online.wsj.com/article/SB123999343505429693.html. Furthermore, Kington and the NIH have demonstrated their judgment of the merits of the proposed Guidelines by allowing applications for funding of hESC research to be submitted even before final promulgation of the Guidelines. *See* Implementation of Executive Order on Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html (last visited May 22, 2009). Kington's statement and this action goes beyond a "mere discussion of policy" and demonstrates that Kington (and potentially other NIH officials as well) has an "unalterably closed mind" in regards to the merits of the NIH Guidelines. Thus, because Acting Director Kington has demonstrated clearly by both his words and his actions that he has prejudged the merits of the Guidelines proposed by the NIH, he should be excluded from the decision-making process, together with any other NIH officials who share his unalterably close-minded approach to this issue.

Thank you for your consideration of these comments.

Very truly yours,



Thomas G. Hungar
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## APPENDIX A

# Statement of Interests

**DO NO HARM: The Coalition of Americans for Research Ethics**
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Do No Harm: The Coalition of Americans for Research Ethics (www.stemcellresearch.org) is composed of a growing coalition of more than 350 scientists, researchers, bioethicists, medical academic and other professionals, patient advocates and concerned individuals who advocate the ethical pursuit of stem cell research and regenerative medicine in general.

Do No Harm has reviewed the Draft National Institutes of Health (NIH) Guidelines for Human Stem Cell Research (the "Guidelines") as published on April 23, 2009 in the Federal Register (74 Fed Reg. 18578), as well Executive Order 13505 issued by President Obama on March 9, 2009, directing the Director of NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." Do No Harm joins in the accompanying joint comments because, for the reasons set forth in the accompanying comments, Do No Harm believes the federal funding of human embryonic stem cell research as proposed in the Guidelines is neither responsible, scientifically worthy or even permitted by existing federal law.

Since issuing its founding statement in 1999, Do No Harm has opposed stem cell research that relies on the destruction of human life and on human cloning and supports such alternatives as adult and cord blood stem cell research and the more recent advances involving induced pluripotent stem cells (iPSCs). The coalition is non-sectarian and not affiliated with any religious denomination or church.

Do No Harm's opposition to human embryonic stem cell research arises from the serious ethical concerns about the commodification of human life represented by such research. This type of research destroys a human life by turning it into raw research material. This concern is even more urgent because proponents of embryonic stem cell research admit that creating new human embryos by cloning is the only way that this type of research can advance. Thus human life becomes a mere commodity to be created, manipulated and destroyed as a means to another's end. This destruction—and now creation—of new human life is at the heart of the controversy over embryonic stem cell research. The coalition maintains that human life must never be reduced to a mere commodity, to be created and destroyed at will, in the name of scientific advancement. The coalition maintains that science does not need to kill in order to cure. This is a position that a person of any faith or no faith at all can share.

From a practical point of view, to date, no human patient has been successfully treated with embryonic stem cells for any disease or condition, and their success in animal models has been very limited. One thing embryonic stem cells have been shown to do well is to produce tumors; in fact in several animal studies, the animals being treated with embryonic stem cells died from tumors produced by them. . . .

Nor was human embryonic stem cell research in any way instrumental in leading to the iPSC breakthrough of 2007. Japan's Shinya Yamanaka is the scientist credited with the original iPSC breakthrough in animal models, and one of two scientists to develop human iPSC (the other being James Thomson of the University of Wisconsin, who was also the first to isolate human embryonic stem cells). Both scientists worked independently and published their results in November, 2007. According to Yamanaka, human embryonic stem cells (hESCs) were not crucial to his work. Yamanaka's initial work in reprogramming utilized mice, not human, embryonic stem cells and he used the same method for human iPSC production. According to him, "[n]either eggs nor embryos are necessary. I've never worked with either." (Nature, June 7 2007, p. 618). In fact, it was precisely Yamanaka's ethical concerns to avoid lethal experiments with human embryos that led to his breakthrough. Recalling looking at a human embryo through a microscope several years earlier, Yamanaka said: "When I saw the embryo, I suddenly realized there was such a small difference between it and my daughters. . . . I thought, we can't keep destroying embryos for our research. There must be another way." ("Risk Taking in His Genes," The New York Times, 12/11/07.)

James Thomson, the stem cell pioneer from the University of Wisconsin who was the first to grow human embryonic stem cells in 1998, is also an independent co-discoverer of human induced pluripotent (iPS) stem cells along with Japanese scientists. Already these reprogrammed cells have eclipsed the value of those harvested from embryos, Dr. Thomson has said, because of significantly lower cost, ease of production, and genetic identity with the patient. They also bring unique application to medical and pharmaceutical research, because cells cultivated from patients with certain diseases readily become laboratory models for developing and testing therapy. That iPS cells overcome ethical concerns about creating and sacrificing embryos is an added plus.

Finally, for the many reasons set forth in Appendix I of the accompanying comments, Do No Harm submits that human embryonic cells will not, in all likelihood, lead to safe human therapies, including therapies for the various diseases identified by NIH in the proposed Guidelines as a purpose for such hESC research.

Given this poor record for human embryonic stem cell research, Do No Harm maintains that resources are far better used to support those areas of stem cell research, such as adult and cord blood, that have actually demonstrated benefits for human patients.

Thus, along with opposition to destructive human embryonic stem cell research, Do No Harm actively advocates for increased public awareness and support for ethically non-contentious avenues of stem cell research such as research using adult and cord blood stem cells (well documented in the accompanying Appendix G), as well as the more recent advances in the

creation of iPCs (well documented in the accompanying Appendix H). In contrast to human embryonic stem cells, adult and cord blood stems have and are continuing to provide therapeutic benefits to human patients for at least 73 diseases and conditions including diabetes, multiple sclerosis, heart disease, spinal cord injury, Parkinson's, lupus and others (see: http://www.stemcellresearch.org/facts/treatments.htm). Adult stem cells have been used for corneal regeneration (one Japanese group used stem cells from lining of mouth to make corneal cells and transplant onto patients' eyes); liver repair; wound and bone repair; growing new bladders; and in a fairly recent development, growing a new windpipe from bone marrow. These are not yet "cures," but according to the peer-reviewed literature, as Do No Harm noted in two letters published in Science, they are applications that have provided "observable and measurable benefit to patients, a necessary step toward formal FDA approval and what is expected of new, cutting-edge medical applications." (SCIENCE 19 January 2007: Vol. 315. no. 5810, p. 328; *see also*, SCIENCE 8 June 2007: Vol. 316. no. 5830, pp. 1422 – 1423.)

This is a proven track record for adult and cord blood stem cells, and in the interests of putting patients first, any guidelines involving federal funding for stem cell research should give priority to research that is actually improving their lives today.

Do No Harm maintains that the proposed Guidelines are little more than an attempt to put an ethical gloss on an inherently unethical avenue of research. By its very nature, human embryonic stem cell research requires the destruction of human life. By its very nature, human embryonic stem cell research commodifies human life, declares some life more valuable than others, and reduces some human life to a mere means to another's ends. This violates all international standards for the conduct of medical research involving human subjects and also U.S. law, which under the Federal Funding Ban, prohibits federal funding of research in which embryos are even "subjected to risk of injury or death." It also violates America's foundational commitment to the worth and human dignity of every human being.

As then-candidate, now-President Obama famously said during the recent presidential campaign, "you can put lipstick on a pig—but it's still a pig." The NIH may attempt to propose guidelines to make destructive embryonic stem cell research appear ethical, but as Do No Harm has been saying for years, it still remains an inherently unethical enterprise that actually violates President Obama's Order because, in the very words of that Order, quoted in the proposed Guidelines, hESC research is neither "responsible," "scientifically worthy" of taxpayer support, nor permitted by the "existing" federal "laws" and the "laws" of many states barring such research.

**Dr. James L. Sherley, M.D., Ph.D.**
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Dr. James L. Sherley, M.D., Ph.D., 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 that contribute to aging. Adult stem cells are rare tissue cells that continuously replace expired tissue cells. Investigations of their specialized properties will yield new therapies for injured, diseased, and aging tissue cells. Dr. Sherley employs an integrated approach, incorporating both basic and applied research strategies, to elucidate novel mechanisms of adult stem cell-specific functions and apply the knowledge to improve methods for identifying adult stem cells and producing them in large number for therapeutic development.

Dr. Sherley has been the recipient of many awards and recognitions in his field of molecular biological research, including the NIH Director's Pioneer Award and the honor of testifying before the Australian Parliament in 2006 on the current state of stem cell science.

Prior to his current position on the faculty of BBRI, Dr. Sherley served as an Associate Professor in the Department of Biological Engineering at the Massachusetts Institute of Technology. Prior to that appointment, Dr. Sherley was an associate member of the staff working in the Department of Molecular Oncology, Division of Medical Science at the Fox Chase Cancer Center in Philadelphia. Dr. Sherley has his B.A. in Biology from Harvard; his M.D. and Ph.D. in molecular biology from John Hopkins University School of Medicine's Department of Molecular Biology and Genetics, and he did his post-doctoral research work at Princeton University's Department of Molecular Biology.

Dr. Sherley has reviewed the Draft National Institutes of Health (NIH) Guidelines for Human Stem Cell Research (the "Guidelines") as published on April 23, 2009 in the Federal Register (74 Fed Reg. 18578), as well Executive Order 13505 issued by President Obama on March 9, 2009, directing the Director of NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." Dr. Sherley joins in the accompanying comments submitted by DO NO HARM: The Coalition of Americans for Research Ethics *et al.* because, for the reasons set forth in the accompanying comments, he believes the federal funding of human embryonic stem cell research as proposed in the Guidelines is neither responsible, scientifically worthy nor even permitted by existing federal law.

Dr. Sherley is most centrally concerned that the proposed Guidelines fail to acknowledge that the scientific fact that human embryos are living human beings. The President's Executive Order 13435 that purportedly seeks to "remove barriers to responsible scientific research involving human stem cells" fails to acknowledge this scientific truth, and previous NIH documents, including the proposed Guidelines, omit it as well; and the two most quoted leaderships of scientific organizations (NAS and ISSCR) omit it too. Therefore, Dr. Sherley is concerned that the proposed Guidelines for human embryonic stem cell (hESC) research are publicly deceptive in the same manner as the recently issued respective recommendations from the U.S. National Academy of Sciences (NAS), headquartered in Washington, D.C., and the International Society for Stem Cell Research (ISSCR), headquartered in Boston.

Like the NAS and ISSCR documents, the proposed Guidelines consider ethical treatment only from the perspective of so-called "donors" of human embryos for research. In fact, the "human research subjects," who are due ethical protection under the NIH's existing regulations

for human research studies, are the human embryos, not their biological parents who are donating these human subjects for research.

Existing regulations for research studies with human subjects require a clear statement of the eligibility criteria for participants, including their state of well-being. Like the NAS and ISSCR documents, the NIH guidelines do not acknowledge the scientific fact that embryos are living human beings and, as such, are due the same protections. Along with this omission, they falsely represent embryos as "human materials" obtained from protected donors. The language of the Guidelines falsely equates living human embryos with tissues obtained from donors for induced pluripotent stem cell (iPSC) research. The NIH does this with full expert knowledge that, whereas tissue material harvested for iPSC research has the same human genome as its donor, because it is the donor's own tissue, embryos have a different and unique genome. Embryos are not tissues harvested from consenting donors. They are non-consenting, distinct human individuals, and they deserve the same protections for human subjects research as any other human subject. Using embryos for hESC research is equivalent to injurious research with children, which is not permitted.

Although the NIH guidelines acknowledge the priority of the Federal Funding ban, which prohibits federal funding of research in which human embryos are injured, more is needed for adequate protection of human embryos. The NIH's recommendation of research with existing hESC lines will motivate private funding of the federally prohibited research. Surely, NIH scientists must recognize that promoting the use of existing hESC lines, while at the same time prohibiting the production of new ones, is an ethically conflicted policy.

Dr. Sherley insists that NIH revise its existing guidelines to meet its own regulations for ethical treatment of human research subjects. For any chance of validity, the Guidelines must state that "human embryos are living human beings" that cannot properly give consent; and NIH must adopt an ethically consistent policy that disallows both the unethical production of hESCs going forward and the use of existing cell lines that were produced in the past in violation of NIH regulations for ethical treatment of human research subjects.

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Dr. Deisher, an internationally renowned expert in the field of adult stem cell therapies and regenerative medicine, brings 17 years of experience in scientific and corporate leadership positions involving research, discovery, production and commercialization of human therapeutics. Dr. Deisher's penchant for groundbreaking scientific discovery and her distinguished scientific research has resulted in 23 patents issued. She has published numerous

scientific manuscripts and is a frequent invited lecturer and guest speaker in the area of stem cell technology and regenerative medicine.

Throughout her career, Dr. Deisher has been recruited by some of the country's top biotechnology companies, including Genentech, Repligen, ZymoGenetics, Immunex and Amgen. She has managed and mentored undergraduate honors students, post-doctoral fellows, scientific executives and over 20 research assistants/scientists at all levels of responsibility.

Dr. Deisher graduated with honors and distinction from Stanford University, and obtained her Ph.D. in Molecular and Cellular Physiology from Stanford University.

Subsequent to obtaining her Ph.D. from Stanford, Dr. Deisher was recruited by Repligen Corporation (Cambridge, MA) and accepted a position as Research Scientist where she managed a staff of associates and scientists and directed the development of research and clinical assays in support of Phase I and Phase II clinical trials for various Repligen developmental efforts. Additionally, Dr. Deisher was selected by Senior Management to participate in strategic alliance initiatives, including serving on the Repligen / Eli Lilly joint development committee.

Dr. Deisher has reviewed the Draft National Institutes of Health (NIH) Guidelines for Human Stem Cell Research (the "Guidelines") as published on April 23, 2009 in the Federal Register (74 Fed. Reg. 18578), as well as Executive Order 13505 issued by President Obama on March 9, 2009, directing the Director of NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." Dr. Deisher joins in the accompanying comments submitted by DO NO HARM: The Coalition of Americans for Research Ethics *et al.* because, for the reasons set forth in the accompanying comments, she believes the federal funding of human embryonic stem cell research as proposed in the Guidelines is neither responsible, scientifically worthy nor even permitted by existing federal law.

For the ample reasons based upon the published data set forth in the accompanying Appendix I she has prepared, Dr. Deisher is most concerned that the human embryonic stem cell research being proposed in the Guidelines cannot possibly be useful for any of the potential purposes cited for funding such research in the proposed Guidelines. Dr. Deisher believes that the human stem cell research using adult stem cells and induced pluripotent stem cells already permitted under federal law and fundable under existing NIH Guidelines is more than sufficient to accomplish all the necessary scientific investigation and work on the development of the various therapies mentioned in the proposed Guidelines.

**Christian Medical Association**
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The 15,000 members of the Christian Medical Association (CMA) include thousands of physicians committed to the Hippocratic tradition of medicine that requires physicians to "first, do no harm." In accordance with this tradition and a commitment to biblical principles, CMA members have officially adopted the following ETHICAL STATEMENT ON HUMAN STEM CELL RESEARCH AND USE:

> "The field of stem cell research offers great promise for the advancement of medical science. Adult stem cells are presently being used to treat a variety of illnesses. However, the isolation of human embryonic stem cells in 1998 and resultant research have raised moral concerns because current methods of procuring embryonic stem cells require the destruction of human life.
>
> **"CMA recognizes the potential value of stem cell technology:**
>
> - We endorse the goals of stem cell research to treat human illness and relieve human suffering.
> - We endorse retrieval and use of adult stem cells from a variety of sources – umbilical cord blood, placenta, amniotic fluid, adult organs, etc.
> - We endorse human adult stem cell research and use if it is safe for human subjects.
> - We endorse animal stem cell research provided it is not cruel to experimental animals.
>
> **"CMA has moral concerns regarding embryonic human stem cell research and use. We recognize the sacred dignity and worth of human life from fertilization to death.**
>
> - The destruction of nascent individual human life even for the benefit of others is immoral.
> - We condemn specious arguments that "excess" embryos may be used as a source for embryonic stem cells, "because they would have been destroyed anyway and that good may come." There is a moral difference between intentionally taking a human being's life and the embryo dying a natural death.
> - We are concerned that stem cell research will involve exploitation of women (especially poor women) by using them to produce the eggs necessary for stem cell research, thereby subjecting them to the risk of attendant procedures and potential complications.
> - We are concerned that the instrumental production, use, commodification or destruction of any human being will coarsen our society's attitude toward human life itself.
>
> **"CMA advances the following moral guidelines to direct stem cell research and therapy:**

- No human life should be produced by any means for primarily utilitarian purposes – no matter how noble the ends or widespread the benefit.
- Technology and research must not involve the abuse or destruction of human life.
- We encourage the careful and ethical development of alternative methods for procuring stem cells that do not involve the destruction of human life.

**"CMA encourages life-honoring stem cell research for the advancement of medical science and the benefit of all patients.**

In this pursuit, CMA advocates the protection of all human life, for humans are made in the Image of God."

Besides following the principles expressed in the above ethics statement, CMA physicians do not want to advance a path of research that is unlikely to produce useable therapies for patients in the near future or at all. CMA physicians believe that stem cell research should focus on the ethical path that has most clearly and substantially contributed to therapies for real patients, and that path is non-destructive adult stem cell research. For these reasons and the additional reasons set forth in separate comments submitted by CMA, the 15,000 members of the Christian Medical Association urge the withdrawal of the proposed Guidelines and the continuance of NIH's existing stem cell research guidelines permitting federal funding for human stem cell research using adult stem cells and induced pluripotent stem cells that do not require or depend upon the destruction of human embryos.

**Family Research Council**

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Since 2004, Dr. David Prentice has served as Senior Fellow for Life Sciences at Family Research Council (FRC). While advances in science, medicine, and technology may hold promises of improved health and well-being, FRC believes such advances may also devalue human life and human dignity. Stem cells, cloning, genetic engineering, and other new technologies need to be evaluated carefully within both a scientific and an ethical framework. FRC opposes research that destroys, harms, or manipulates an embryonic human being. However, FRC vigorously supports research and therapies using "adult" stem cells (such as from bone marrow and umbilical cord blood), which is not ethically problematic and has already resulted in useful therapies in human patients. FRC opposes all forms of human cloning, whether "reproductive" to bring an infant to term, or "therapeutic," to destroy the cloned embryo for experiments. FRC believes that good science is also ethical science, and supports biotechnologies that advance scientific knowledge and medical treatments, while valuing all human life and maintaining human dignity.

Prior to joining FRC in July 2004, Dr. Prentice spent almost 20 years as Professor of Life Sciences, Indiana State University, and Adjunct Professor of Medical and Molecular Genetics, Indiana University School of Medicine. He received his Ph.D. in Biochemistry from the University of Kansas, and was at Los Alamos National Laboratory and the University of Texas Medical School-Houston before joining Indiana State University, where he served as Acting Associate Dean of Arts and Sciences, Assistant Chair of Life Sciences, and was recognized with the University's Distinguished Teaching Award and Distinguished Service Award.

Dr. Prentice is a Founding Member of Do No Harm: The Coalition of Americans for Research Ethics, a Fellow of the Wilberforce Forum Council for Biotechnology Policy, a Fellow of the Institute on Biotechnology and the Human Future, and an Advisory Board Member for the Center for Bioethics and Human Dignity. He received the 2007 Walter C. Randall Award in Biomedical Ethics from the American Physiological Society, given for promoting the honor and integrity of biomedical science through example and mentoring in the classroom and laboratory.

Dr. Prentice's research interests encompass aspects of cell growth; one major focus is adult stem cells. Dr. Prentice is an internationally-recognized expert on stem cells and cloning, and has testified before the U.S. Congress, numerous state legislatures, the U.S. National Academy of Sciences, the President's Council on Bioethics, European Parliament, British Parliament, Canadian Parliament, Australian Parliament, German Bundestag, French Senate, Swedish Parliament, the Vatican, and the United Nations. Dr. Prentice was selected by the U.S. President's Council on Bioethics to write their comprehensive review of adult stem cell research. His defense of Adult Stem Cell Treatments with extensive literature documentation was published by Science in January 2007.

Dr. Prentice has reviewed the Draft National Institutes of Health (NIH) Guidelines for Human Stem Cell Research (the "Guidelines") as published on April 23, 2009 in the Federal Register (74 Fed Reg. 18578), as well as Executive Order 13505 issued by President Obama on March 9, 2009, directing the Director of NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." On behalf of FRC, Dr. Prentice joins in the accompanying comments submitted by Do No Harm: The Coalition of Americans for Research Ethics *et al.* because, for the reasons set forth in the accompanying comments, he believes the federal funding of human embryonic stem cell research as proposed in the Guidelines is neither responsible nor scientifically worthy, and is questionable under existing federal law.

As demonstrated by the extensive documented evidence set forth in accompanying Appendices G and H, Dr. Prentice is particularly concerned that NIH acknowledge and the American public realize that taxpayer-funded human stem cell research using adult stem cells and induced pluripotent stem cells, as currently authorized under existing federal law and eligible for funding under existing NIH guidance, is more than sufficient to satisfy all the purposes offered by NIH in its proposed Guidelines to needlessly extend such funding to embryonic stem cells.

**Concerned Women for America**
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The vision of CWA is for women and like-minded men, from all walks of life, to come together and restore the family to its traditional purpose and thereby allow each member of the family to realize their God-given potential and be more responsible citizens. CWA supports the protection of all innocent human life from conception until natural death. While CWA believes in seeking medical cures for debilitating diseases with which we or our loved ones might suffer, America, particularly at the expense of millions of taxpayers who object to unethical research, must not seek such cures at the much dearer expense of innocent human life, including all human embryos in vivo or in vitro.

Stem cell science is not controversial. Killing living human embryos is. Only research that requires the destruction of a human embryo is objectionable to CWA. What the media and proponents of embryonic stem cell research ignore is that embryonic stem cells have not cured any diseases or successfully treated a single patient. In fact, embryonic stem cell research has yielded only unstable, deadly tumors and patient immune rejection.

CWA believes that the good news is that there are ethical alternatives to embryonic stem cell research that are working, treating and curing without the destruction of the tiniest human life. Skin cells that are reprogrammed to act like embryos—induced pluripotent stem cells—hold the same research potential as stem cells from embryos. The induced pluripotent stem cells can be created from the body cells of anyone, so the ensuing stem cell lines are plentiful and avoid the high risk of tissue rejection. They have already been used to make heart muscle, brain neurons, motor neurons, blood and insulin-secreting cells.

One of the researchers who discovered the induced pluripotent stem cell alternative and the researcher to first to identify embryonic stem cells confirms CWA's concerns. Dr. James Thomson, a University of Wisconsin stem cell scientist, states: "If embryonic stem cell research does not make you at least a little bit uncomfortable, you have not thought about it enough." CWA is further confirmed by Dr. Mehmet Oz, a cardiovascular surgeon at Columbia University, who recently appeared on the Oprah Winfrey Show, and in the presence of Oprah and Michael J. Fox declared that the "stem cell debate is dead" because of the successes using adult stem cells and induced pluripotent stem cells.

CWA's views are further confirmed by an article in the March 4 issue of U.S. News and World Report titled "Why embryonic stem cells are obsolete," wherein Dr. Bernadine Healy, the former head of the NIH, wrote that "adult stem cell research successes have 'diminished' the prospect that embryonic stem cell research is the future of regenerative medicine."

CWA acknowledges that all leading science textbooks on the subject clearly state that human life begins at conception when the human egg is fertilized. Life at that moment receives

its entire DNA, all its genetic makeup, its gender, hair color, etc. This is a point from which we all began. To devalue life at this point is comparable to saying that the life of a toddler is of less worth than that of a young adult simply because of her size or because she is not as developed. Should we relegate a toddler to research material to benefit the young adult?

Human embryos are not simply tissue to be researched. The underlying utilitarian belief that some humans need to be sacrificed for the betterment of others is morally and ethically wrong. Experimentation on human embryos contradicts existing federal law and all applicable medical codes of ethics involving experimentation on human subjects, including the Nuremberg Code, ethical guidelines established after World War II, which prohibits such experimentation that knowingly causes injury or death to humans.

CWA has reviewed the Draft National Institutes of Health (NIH) Guidelines for Human Stem Cell Research (the "Guidelines") as published on April 23, 2009 in the Federal Register (74 Fed. Reg. 18578), as well as Executive Order 13505 issued by President Obama on March 9, 2009, directing the Director of NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law." CWA joins in the accompanying comments submitted by Do No Harm: The Coalition of Americans for Research Ethics et al. because, for the reasons set forth in the accompanying comments, CWA believes the federal funding of human embryonic stem cell research as proposed in the Guidelines is neither responsible, scientifically worthy nor even permitted by existing federal law.

CWA is particularly concerned that the informed consent provisions in Part II.B.7 of the proposed Guidelines are wholly inadequate to properly inform the donors what they are doing and what they are giving up. Moreover, no donor has the right to sacrifice the live of another living human being for any purpose, much less unnecessary human experimentation that provides no benefits to the human being so sacrificed.

**Advocates International**
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Advocates International ("AI") is an international organization of attorneys and other public policy advocates in over 150 nations that seeks to do justice with compassion including, through its Global Task Force on Life, protecting or defending in all available legal fora the inalienable right to life and dignity of every human being from his or her biological conception *in vitro* or *vivo* to natural death. AI does not object to all human pluripotent stem cell research, however. Human pluripotent stem cells can be obtained from three four sources: living human embryos, fetal tissue derived from aborted deceased pre-born children, human adult stem cells, and induced pluripotent stem cells. As is currently permitted under federal law and NIH guidance, AI supports federal funding for stem cell research using human adult stem cells and

induced pluripotent stem cells. As yet, there is no reported scientific evidence that types of stem cells, along with the stem cells in the NIH's Human Stem Cell Registry already approved by Congress for research under the Dickey-Wicker Amendment will not be sufficient to accomplish the basic scientific research and achieve all of the medical therapies that is currently being offered as the excuse for ignoring all of the legal and ethical barriers and other scientific reservations involved in human embryo stem cell research.

**Alliance Defense Fund**
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The Alliance Defense Fund ("ADF") is a legal alliance defending the sanctity of human life, religious freedom, marriage and the family. ADF is involved in direct litigation and *amicus* briefing throughout the United States to defend the right to life of preborn children and the right of the government to protect the unborn and specifically to defend the personhood of human embryos. ADF helped fund the 2002 lawsuit *Nightlight Christian Adoptions v. Thompson*, 1:01-cv-502-RCL (D.D.C. filed Mar. 8, 2001), which challenged the Clinton-era NIH's proposed policy to fund human embryo research according to a questionable interpretation of the Dickey-Wicker amendment that was subsequently withdrawn by the NIH. ADF has supported several state court cases involving questions of the humanity of preborn children, including an amicus brief in the Texas embryo custody appeal *Roman v. Roman*, 193 S.W.3d 40 (Tex. Ct. App. 2006). ADF also funded litigation in Missouri to protect the right of voters to propose a ban on cloning without having their proposal deceptively characterized on the ballot by the Secretary of State. ADF submitted written comments to HHS in September 2008 discussing the federal legal status of the pre-implantation human embryo in general and as it relates to regulations that implement federal laws that prohibit fund recipients violating the religious beliefs of pro-life medical providers. ADF also submitted comments in 2007 in the United Kingdom analyzing the Human Tissue and Embryos Draft Bill, which proposed allowing the creation of human-animal hybrid and chimera embryos.

## Appendix B

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

### Part I: Fetal Homicide Statutes that Apply Without Regard to Gestational Age

*Alabama*: 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 unborn child in utero at any stage of development, regardless of viability").

*Arizon*a: ARIZ. REV. STAT. ANN. §§ 13-1102(A), (B) (negligent homicide), 13-1103(A)(5), -(B) (manslaughter), 13-1104(A), (B) (second degree murder), 13-1105(A)(1), -(C) (first degree murder) (West Supp. 2005).

*Idaho*: IDAHO CODE § 18-4016 (definition of human embryo and fetus); §§ 18-4001 (definition of murder), 18-4006 (definition of manslaughter) (2004).

*Illinois*: 720 ILCS §§ 5/9-1.2 (intentional homicide of an unborn child), 5/9-2.1 (voluntary manslaughter of an unborn child), 5/9-3.2 (involuntary manslaughter or reckless homicide of an unborn child) (West 2002).

*Indiana*: IND. CODE ANN. § 35-42-1-6 (Michie 2004) (feticide).

*Kentucky:* KY. REV. STAT. § 507A.010 *et seq*. (Michie Supp. 2005) (fetal homicide).

*Louisiana*: LA. REV. STAT. ANN. § 14:2(11) (West 1997) (definition of "unborn child"); § 14:32.5 (definition of "feticide"), §§ 14:32.6 (first degree feticide), 14:32.7 (second degree feticide), 14:32.8 (third degree feticide) (West 1997 & Supp. 2006).

*Michigan*: MICH. COMP. LAWS ANN. § 750.90a *et seq*. (West 2004).

*Minnesota*: MINN. STAT. ANN. §§ 609.266 (definition of unborn child), 609.2661 (first degree murder of an unborn child), 609.2662 (second degree murder of an unborn child), 609.2663 (third degree murder of an unborn child), 609.2664 (manslaughter of an unborn child in the first degree), 609.2665 (manslaughter of an unborn child in the second degree), 609.268(1) (felony murder of an unborn child), 609.21 subd. 3 (vehicular homicide of an unborn child) (West 2003 & Supp. 2006).

*Mississippi*: MISS. CODE ANN. § 97-3-37(1) (2005) (homicide and assault offenses).

*Missouri*: MO. ANN. STAT. §§ 565.020 subd. 1 (first degree murder), 565.021 subd. 2 (second degree felony murder), and 565.024 (involuntary manslaughter) (West 1999), interpreted in light of § 1.205 (West 2000); *see State v. Knapp*, 843 S.W.2d 345 (Mo. 1992); *State v. Holcomb*, 956 S.W.2d 286 (Mo. Ct. App. 1997); *State v. Rollen*, 133 S.W.3d 57 (Mo. Ct. App. 2003), *transfer denied*, May 25, 2004 (Missouri Supreme Court).

*Nebraska*: NEB. REV. STAT. ANN. § 28-388 *et seq*. (Michie 2003).

*North Dakota*: N.D. CENT. CODE § 12.1-17.1-01 *et seq*. (1997).

*Ohio*: Under Ohio law, "the unlawful termination of another's pregnancy" may be punished as aggravated murder, murder, voluntary manslaughter, involuntary manslaughter, reckless homicide, negligent homicide or aggravated vehicular homicide, vehicular homicide or vehicular manslaughter, *see* OHIO REV. CODE ANN. §§ 2903.01(A), -(B), 2903.02(A), -(B), 2903.03(A), 2903.04(A), -(B), 2903.041(A), 2903.05(A), 2903.06(A) (Anderson 2003 & Supp. 2005). "Unlawful termination of another's pregnancy" is defined as "causing the death of an unborn member of the species homo sapiens, who is or was carried in the womb of another, as a result of injuries inflicted during the period that begins with fertilization and that continues unless and until live birth occurs." OHIO REV. CODE ANN. § 2903.09(A), -(B) (Anderson 2003).

*Oklahoma:* OKLA. STAT. ANN. tit. 21, § 713 (West Supp. 2006) (killing an unborn child), interpreted in light of the definition of "unborn child" in tit. 63, § 1-730(2) (West 2004).

*Pennsylvania*: 18 PA. CONS. STAT. ANN. § 1102 (West 1998), § 2601 *et seq*. (1998) (homicide).

*South Dakota*: S.D. CODIFIED LAWS § 22-17-6 (Michie 1998) (intentional killing of human fetus); §§ 22-16-1 (defining homicide), 22-16-1.1 (fetal homicide) (Michie 1998), read in conjunction with § 22-1-2(31) (definition of "person") (Michie Supp. 2003), and § 22-1-2(50A) (Michie Supp. 2003) (definition of unborn child).

*Texas*: TEX. PENAL CODE § 1.07(a)(26) (West Supp. 2005) (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*: UTAH CODE ANN. § 76-5-201(1)(a) (2003) (when referring to the victim of a criminal homicide, the term "another human being" includes "an unborn child at any stage of its development").

*West Virginia*: W. VA. CODE § 61-2-30 (2005) (recognizing an embryo or fetus as a distinct unborn victim of certain crimes against the person, including homicide).

*Wisconsin*: WIS. STAT. ANN. § 939.75(1) (West 2005) (defining unborn child as "any individual of the human species from fertilization until birth that is gestating inside a woman"); §§ 940.01(1)(b) (first degree intentional homicide), 940.02(1m) (first degree reckless homicide), 940.05(2g) (second degree intentional homicide), 940.06(2) (second degree reckless homicide), 940.08(2) (homicide by negligent handling of a dangerous weapon, explosive or fire), 940.09(1)(c), -(cm), -(d), -(e) (homicide by intoxicated use of a vehicle), 940.09(1g)(c), (1g)(cm), -(d) (homicide by intoxicated use of a firearm), 940.10(2) (homicide by negligent operation of a vehicle) (West 2005); WIS. STAT. ANN. § 940.04(1) (West 2005) (intentional destruction of the life of an unborn child).

## Part II: Wrongful Death Statutes That Apply Without Regard to the State of Gestation or Development

*Illinois*: 740 ILCS § 180/2.2 (West 2002) (right to maintain a wrongful death action is not foreclosed by "[t]he state of gestation or development of a human being").

*Louisiana*: *Danos v. St. Pierre*, 402 So.2d 633, 639 (La. 1981) (rejecting any gestational requirement to maintain wrongful death action); LA. CIV. CODE ANN. art. 26 (West 1999) (codifying holding in *Danos*).

*Michigan*: MICH. COMP. LAWS ANN. § 600.2922a (West Supp. 2006) (amending statute to provide liability for "a wrongful or negligent act [committed] against a pregnant individual . . . if the act results in a miscarriage or stillbirth by that individual, or physical injury to or the death of the embryo or fetus").

*Missouri*: *Connor v. Monkem*, 898 S.W.2d 89 (Mo. 1995) (interpreting statute setting forth rule of construction).

*Nebraska*: NEB. REV. STAT. § 30-809(1) (Supp. 2005) (amending wrongful death statute to include "an unborn child in utero at any stage of gestation").

*South Dakota*: S.D. CODE LAWS ANN. § 21-5-1 (1987) (amending wrongful death statute to include "an unborn child").

*Texas*: TEX. CIV. PRAC. & REM. CODE ANN. § 71.001(4) (West Supp. 2006) (defining "individual" in wrongful death statute to include "an unborn child at every stage of gestation from fertilization until birth").

*West Virginia*: *Farley v. Sartin*, 466 S.E.2d 522 (W. Va. 1995) (interpreting wrongful death statute).

**Part III: Courts Rejecting Constitutional Challenges to Fetal Homicide Statutes That Apply Without Regard to the Age of the Unborn Child**

*People v. Campos*, 227 Ill. App. 3d 434, 451-52, 592 N.E.2d 85, 97 (1992) (twenty and one-half weeks pregnant), *appeal denied*, 146 Ill. 2d 635 (1992).

*United States. ex rel Campos v. Peters*, 827 F. Supp. 1359 (N.D. Ill. 1993) (denying *habeas corpus* relief to the defendant in the *Campos* case), *affirmed without opinion*, 37 F.3d 1501 (7th Cir. 1994), *cert. denied,* 514 U.S. 1024 (1995).

*People v. Ford*, 221 Ill. App. 3d 354, 366-73, 581 N.E.2d 1189, 1197-1202 (1991) (five and one half months), *appeal denied*, 143 Ill. 2d 642 (1992) *Ford v. Ahtow*, 104 F.3d 926 (7th Cir. 1997) (denying *habeas corpus* relief in the previously cited cased).

*State v. Bauer*, 471 N.W.2d 363, 365-66 (Minn. Ct. App. 1991), *review denied*, July 24, 1991 (Minnesota Supreme Court).

*State v. Merrill*, 450 N.W.2d 318, 321-24 (Minn. 1990) (twenty-eight days), *cert. denied*, 496 U.S. 931 (1990).

*State v. Rollen*, 133 S.W.3d 57, 63 (Mo. Ct. App. 2003) (sixteen weeks pregnant), *transfer denied*, May 25, 2004 (Missouri Supreme Court).

*State v. Holcomb*, 956 S.W.2d 286, 289-93 (Mo. Ct. App. 1997) (twenty-six to twenty-eight weeks), *transfer denied*, Dec. 23, 1997 (Missouri Supreme Court).

*State v. Knapp*, 843 S.W.2d 345, 349 (Mo. 1992) (six months pregnant).

*State v. Alfieri*, 724 N.E.2d 477, 481-84 (Ohio Ct. App. 1998) (six months pregnant), *appeal denied*, 709 N.E.2d 849 (Ohio 1999).

*State v. Moore*, Ohio Ct. App. (Second District), Oct. 30, 1998, slip op. at 2-5, 1998 WL 754603, 1998 Ohio App. Lexis 5040 (six months pregnant).

*State v. Coleman,* 705 N.E.2d 419, 420-22 (Ohio Ct. App. 1997) (age of unborn child not indicated), *appeal denied*, 691 N.E.2d 1058 (Ohio 1998).

*Coleman v. DeWitt*, 282 F.3d 908 (6th Cir. 2002) (denying *habeas corpus* relief in the previously cited cased).

*Commonwealth v. Bullock*, 868 A.2d 516, 521-25 (Pa. Super. Ct. 2005) (22 to 23 weeks pregnant), *allocatur allowed*, 885 A.2d 40 (Pa. 2005).

*State v. MacGuire*, 84 P.3d 1171, 1174-78 (Utah 2004) (thirteen to fifteen weeks).

**Courts Recognizing that *Roe v. Wade* Does Not Prevent States from Providing Liability under Wrongful Death Statutes for Prenatal Injuries Resulting in the Death of Unborn Children Prior to Viability**

*Santana v. Zilog, Inc*. 95 F.3d 780, 784-85 n. 4 (9th Cir. 1996) ("In the wrongful death context, *Roe's* use of viability to denote when the balance of competing interests shifts is simply irrelevant.").

*Summerfield v. Superior Court*, 698 P.2d 712, 723 (Ariz. 1985) ("*Roe v. Wade* balances the rights of the fetus against the rights of its mother and concludes that the latter's right to privacy outweighs the former's right to life in the first trimester of pregnancy; it 'neither prohibits nor compels' the inclusion of a fetus as a person for the purposes of other enactments") (citation omitted).

*Wiersma v. Maple Leaf Farms*, 543 N.W.2d 787, 790 n. 2 (S.D. 1996) ("Nothing in *Roe* prohibits the Legislature from including a nonviable fetus in its definition of a person under our State's wrongful death act.").

*Farley v. Sartin*, 466 S.E.2d 522, 534 (W. Va. 1995) ("Our definition of 'person' within the confines of the wrongful death statute neither affects nor interferes with the constitutional protection afforded a woman who chooses to have an abortion, as was set forth originally in *Roe v. Wade*.") (citation omitted).

## APPENDIX C

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

# The Legal Consensus on the Beginning of Life

[*See generally* Elizabeth Spahn and Barbara Andrade, *Mis-Conceptions: The Moment of Conception in Religion, Science and Law*, 32 U.S.F.L.Rev. 261 (1998); Paul B. Linton, *PLANNED PARENTHOOD v. CASEY: The Flight From Reason in the Supreme Court* 13 St. Louis U. Pub. L. Rev. 15 9 (1993)]

**Alabama:**

*Trent v. State*, 73 So. 834, 836 (Ala. Civ. App. 1916) (interpreting state abortion law) ("does not the new being, from the first day of its uterine life, acquire a legal and moral status that entitles it to the same protection as that guaranteed to human beings in extra-uterine life?") (quoting from the 1911 Transactions of the Medical Association of Alabama).

*Wolfe v. Isbell*, 280 So.2d 758, 761 (Ala. 1973) (rejecting viability requirement in wrongful death action where death occurs after live birth):

> [T]he more recent authorities emphasize that there is no valid medical basis for a distinction based on viability, especially where the child has been born alive. These [decisions] proceed on the premise that the fetus is just as much an independent being prior to viability as it is afterwards, and that from the moment of conception, the fetus or embryo is not a part of the mother, but rather has a separate existence within the body of the mother.

Alabama Constitutional Convention Call (S.J. Res. 9, 1980 Ala. Acts 396):

> [A]pplies to the Congress . . . to call a convention for the sole and exclusive purpose of proposing an amendment to the Constitution that would protect the lives of all human beings including unborn children at every stage of their biological development and providing that neither the United States nor any state shall deprive any human being, from the moment of fertilization, of the right to life without due process of law, nor shall any state deny any human being, from the moment of fertilization, the equal protection of the laws, except where pregnancy results from rape or incest; or where abortion is necessary to save the life of the mother; or where testing revealed abnormality or deformity of the fetus.

**Arizona:**

*Nelson v. Planned Parenthood Ctr. of Tucson*, 505 P.2d 580, 586 (Ariz. Ct. App. 1973) (construing state abortion law):

> One cannot gainsay a legislative determination that an embryonic or fetal organism is "life." Once begun, the inevitable result is a human being, barring prior termination of the pregnancy.

ARIZ. REV. STAT. ANN. § 13-1103(A)(5) (1989) (defining offense of manslaughter to include "[k]nowingly or recklessly causing the death of an unborn child at any stage of its development by any physical injury to the mother of such child which would be murder if death of the mother had occurred").

**Arkansas:**

ARK. CONST. amend. 68, § 2 ("[t]he policy of Arkansas is to protect the life of every unborn child from conception until birth, . . .")

Arkansas Constitutional Convention Call (Res. of Feb. 17, 1977, H.R.J. Res. 2):

> Requests Congress to call a convention to propose a constitutional amendment which would provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled 'to the right of life; provides that Congress and the states shall have concurrent powers to enforce such an amendment.

**California:**

CAL. PENAL CODE, § 187(a) (West 1988) ("[m]urder is the unlawful killing of a human being, or a fetus, with malice aforethought").

*Scott v. McPheeters*, 92 P.2d 678, 681 (Cal. App. 1939) (it is "an established and recognized fact by science and by everyone of understanding" that "an unborn child is a human being separate and distinct from its mother").

**Connecticut:**

*Simon v. Mullin*, 380 A.2d 1353, 1357 (Conn. Supp. l977) (rejecting viability requirement in wrongful death action where death occurs after live birth) ("[t]he development of the principle of law that now permits recovery by or on behalf of a child born alive for prenatal injuries suffered at any time after conception, without regard to the viability of the fetus, is a notable illustration of the viability of our common law").

**Delaware:**

*Scott v. State*, 117 A.2d 831, 835-36 (Del. 1955) (characterizing abortion law as one that defines an offense against the lives and persons of individuals).

Delaware Constitutional Convention Call (Res. of May 23, 1978, H.R. Con. Res. 9):

Requests Congress to call a convention to propose a constitutional amendment that would protect the lives of all human beings, including unborn children at every stage of their biological development.

**District of Columbia:**

*Bonbrest v. Kotz*, 65 F. Supp. 138, 140 (D.D.C. 1946) (recognizing cause of action for prenatal injuries) ("[f]rom the viewpoint of the civil law and the law of property, a child en ventre sa mere is not only regarded as [a] human being, but as such from the moment of conception--which it is in fact").

**Florida:**

*Day v. Nationwide Mut. Ins. Co.*, 328 So.2d 560, 561 (Fla. Dist. Ct. App. 2d Dist. 1976) (rejecting viability requirement in case of prenatal injuries) (quoting with approval WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS §55, at 336 (4th ed. 1971)):

> Viability of course does not affect the question of the legal existence of the foetus, and therefore of the defendant's duty; and it is a most unsatisfactory criterion, since it is a relative matter, depending on the health of mother and child and many other matters in addition to the stage of development. Certainly the infant may be no less injured; and all logic is in favor of ignoring the stage at which it occurs.

**Georgia:**

*Hornbuckle v. Plantation Pipe Line Co.*, 93 S.E.2d 727, 728 (Ga. 1956) (rejecting viability requirement in case of prenatal injuries) ("[i]f a child born after an injury sustained at any period of its prenatal life can prove the effect on it of a tort, it would have a right to recover") (a dissent characterized majority opinion as holding, in effect, "that an infant becomes a 'person' from the moment of conception, with the right to sue for a tortious injury after its birth"); id. at 729.

*Morrow v. Scott*, 7 Ga. 535, 537 (1849) ("[i]n . . . general, a child is to be, considered as in being, from the time of its conception, where it will be for the benefit of such child to be so considered").

**Idaho:**

*Nash v. Meyer*, 31 P.2d 273, 280 (Idaho 1934) (construing state abortion law) (criminal abortion statute intended "to discourage abortions because thereby the life of a human being, the unborn child, is taken").

*Blake v. Cruz*, 698 P.2d 315, 323 (Idaho 1984) (Bistline, J., concurring in part and dissenting in part) ("[t]his Court recently committed itself to the proposition that an unborn child is a person in being," citing *Volk v. Baldazo*, 651 P.2d 11 (Idaho 1982) (rejecting live birth requirement in wrongful death action where death occurs after viability)).

Idaho Constitutional Convention Call (S. Con. Res. 132, 45th Legis. 2d Sess., 1980 Idaho Sess. Laws 1005):

[R]equest[s] that the Congress . . . call a constitutional convention for the specific and exclusive purpose of proposing an amendment . . . [to provide that]:

(a) From the moment of conception a person shall be guaranteed all personal rights extended to all individuals under the constitution and laws of the United States of America and the state or states of residence and only under extreme circumstances shall it be otherwise; namely, to save the life of the mother, or other extenuating circumstances where at least two consulting physicians, one not having previously been involved in the case, and after due and thorough consultation with all persons having the legal right to be involved, find it is necessary and just that the life of the unborn shall be terminated.

(b) Provide that the several states shall have the power to enforce such an amendment, and establish priority of life by appropriate legislation.

**Illinois:**

720 ILL. COMP. STAT. ANN. § 510/1 (Smith-Hurd 1993) (preamble to Illinois Abortion Law of 1975):

> [T]he General Assembly of the State of Illinois do solemnly declare and find in reaffirmation of the longstanding policy of this State, that the unborn child is a human being from the time of conception and is, therefore, a legal person for purposes of the unborn child's right to life and is entitled to the right to life from conception under the laws and Constitution of this State.

740 ILL. COMP. STAT. ANN. § 180/2.2 (Smith-Hurd 1993) (amending wrongful death statute to allow wrongful death action to be brought on behalf of an unborn child without regard to the stage of pregnancy when the child is injured or

whether there is a live birth).

720 ILL. COMP. STAT. ANN. § 5/9-1.2(b)(1) (Smith-Hurd 1993) (defining "unborn child" as "any individual of the human species from fertilization until birth").

720 ILL. COMP. STAT. ANN. §§ 5/9-1.2, 5/9-2.1, 519-3.2, 5/12- 3.2, 5/12-4.4 (Smith-Hurd 1993) (amending criminal code to define broad range of crimes, including homicide, that can be committed against unborn child, regardless of gestational age).

**Indiana:**

*Cheaney v. State*, 285 N.E.2d 265, 268 (1972) cert. denied, 410 U.S. 991 (1973) (construing state abortion law) ("[i]t is now established that some sort of independent life begins at conception," rejecting quickening and viability as outdated and arbitrary distinctions).

**Kansas:**

*City of Wichita v. Tilson*, Case No. 91 MC 108 (Sedgwick County Court, July 21, 1991) (accepting necessity defense) (slip op. at 22) ("the medical and scientific communities . . . are of the opinion that life in homo sapiens begins at conception"), appeal sustained without discussion of this point, 855 P.2d 911, 918 (Kan. 1993), cert. denied, Nov. 16, 1993, 62 U.S. L. W. 3348 (Docket 93-467).

*State v. Harris*, 136 P. 264, 267 (Kan. 1913) (construing state abortion law):

> The arbitrary refusal of the common law to regard the foetus as alive . . . until quick[ening] was based on no sound physiological principle . . . . [T]he movement recognized by the mother, and which is supposed to prove that her unborn child is alive, is merely one evidence of life, whereas unless life had existed long before the most disastrous consequences to the mother must have already been suffered . . . .
>
> For many purposes the law regards the infant as alive from its conception.

**Kentucky:**

KY. REV. STAT. ANN. § 311.710(5) (Michie/Bobbs-Merrill 1990):

> If . . . the United States constitution is amended or relevant judicial decisions are reversed or modified, the declared policy of this Commonwealth to recognize and to protect the lives of all human beings regardless of their degree of biological development shall be fully restored.

KY. REV. STAT. ANN. §§ 311.720(5), (6) (Michie/Bobbs-Merrill 1990) (abortion regulations) (defining "fetus" as "a human being from fertilization until birth" and "human being" as "any member of the species homo sapiens from fertilization until death").

*Hollis v. Commonwealth*, 652 S.W.2d 61, 66-67 (Ky. 1983) (Wintersheimer, J., dissenting) (noting that "[b]iologically speaking, human life begins at the moment of conception" and that "[m]edical authority has long recognized that the child is in existence from the moment of conception").

Kentucky Constitutional Convention Call (H.R. Res. 7, 1978 Gen. Assembly, Reg. Sess., 1978 Ky. Acts 1401):

> [R]equest[s] the Congress . . . to call a convention for the sole purpose of proposing the following article as an amendment to the Constitution ...:
>
> Section 1. With respect to the right to life, the word person as used in this article and in the Fifth and Fourteenth Articles of Amendment to this Constitution applies to all human beings irrespective of age, health, function, or condition of dependency, including their unborn offspring at every stage of their biological development.
>
> Section 2. No unborn person shall be deprived of life by any person, provided, however, that nothing in this article shall prohibit a law permitting only those medical procedures required to prevent the death of the mother.
>
> Section 3. The Congress and the several states shall have the power to enforce this article by appropriate legislation.

**Louisiana:**

LA. REV. STAT. ANN. § 14:2(7) (West 1986) (defining "person" for purposes of criminal code to include "a human being from the moment of fertilization and implantation").

LA. REV. STAT. ANN. §§ 14:32.5-32.8 (West 1992 Supp.) (defining fetal homicide offenses).

*Danos v. St. Pierre*, 383 So. 2d 1019, 1027 (La. Ct. App. 1980), *aff'd*, 402 So. 2d 633 (La. 1981) (Lottinger, J., concurring):

> This definition [LA. REV. STAT. ANN. § 14:2(7) (West 1986)] added to the Criminal Code in 1976, reflects a legislative intent to classify an unborn child as a "person" for purposes of violent criminal conduct like homicide and battery. The definition reveals an express recognition by the

> legislature that life begins at the moment of conception and that this form of life can indeed be the victim of a harm, i.e., a murder or battery.

1991 La. Acts. § 1, No. 26 (amending state abortion law):

> It is declared to be the public policy of the state of Louisiana that it has a legitimate compelling interest in protecting, to the greatest extent possible, the life of the unborn from the time of conception until birth. We also affirm our belief that life begins at conception and that life thereafter is a continuum until the time of death.

*Johnson v. New Orleans Light & Traction Co.*, Docket 9048 (La. App. Orl. Dec. 10, 1923) (rejecting live birth and viability requirements in cause of action for wrongful death) (quoted with approval in Danos v. St. Pierre, 402 So. 2d 633, 639 (La. 1981)):

> The argument of the defendant is that the infant before it is born is not a child, not a human being, that it is only a thing, a part of the anatomy of the mother, as are her organs. We cannot accept that theory. We believe the infant is a child from the moment of conception although life may be in a state of suspended animation, the-subject of love, affection and hope and that the injury or killing of it in its mother's womb is covered by the [wrongful death statute] and gives its bereaved parents to a right of action against the guilty parties for their grief and mental anguish.

*Danos v. St. Pierre*, 383 So. 2d 1019, 1029 (La. Ct. App. 1980), *aff'd*, 402 So. 2d 633 (La. 1981) (rejecting live birth requirement in action for wrongful death of a viable unborn child) (Lottinger, J., concurring):

> Viability has not been the controlling factor in some previous Louisiana cases allowing recovery [for wrongful death of a stillborn child], and there is no need to make it a controlling factor in this decision. Just as live birth is an arbitrary cutoff point for wrongful death purposes, viability is equally arbitrary in deciding whether the fetus is a "person" whose wrongful killing is compensable.

Louisiana Constitutional Convention Call (Res. of July 16, 1976, S. Con Res. 70):

Requests Congress to call a convention to propose a constitutional amendment extending the term "person" in the Fifth and Fourteenth amendments to apply to all human beings "irrespective of age, health, function or condition of dependency, including unborn offspring at every stage of their biological development;" permits states to adopt laws necessary to preserve the woman's life; requests state legislative bodies to apply to Congress to call a convention to

propose this constitutional amendment; grants Congress and the states the power to enforce the amendment.

**Maryland:**

*Damasiewicz v. Gorsuch*, 79 A.2d 550, 559 (Md. 1951) (recognizing cause of action for prenatal injuries) ("from a medical point of view, a child is alive within the mother before the time arrives when it can live apart from her"), *id.* at 560 (theory that "an unborn child is a part of the mother" is "an outworn point of view, now rejected by modern medicine").

*Group Health Ass'n v. Blumenthal*, 453 A.2d 1198, 1207 (Md. 1983) ("a cause of action lies for the wrongful death of a child born alive who dies as a result of injuries sustained while en ventre sa mere") (rejecting viability requirement).

**Massachusetts:**

*Commonwealth v. Cass*, 467 N.E.2d 1324, 1325 (Mass. 1984) (viable fetus is a "person" within meaning of vehicular homicide statute):

> In keeping with approved usage, and giving terms their ordinary meaning, the word "person" is synonymous with the term "human being." An offspring of human parents cannot reasonably be considered to be other than a human being, and therefore a person, first within, and then in the normal course outside, the womb . . . . By the use of the term[] "person" . . . the Legislature has given no hint of a contemplated distinction between pre-born and born human beings.

*Torigian v. Watertown News Co.*, 225 N.E.2d 926, 927 (Mass. 1967) (rejecting viability requirement in wrongful death action where death follows live birth).

Massachusetts Constitutional Convention Call (Act of June 8, 1977, H.R. 5984):

Requests Congress to call a convention to propose a constitutional amendment extending the term "person" in the Fifth and Fourteenth amendments to apply to all human beings "irrespective of age, health, function or condition of dependency, including unborn offspring at every stage of their biological development;" permits states to adopt laws necessary to preserve the woman's life; grants Congress and the states the power to enforce the amendment.

**Michigan:**

*Womack v. Buchhorn*, 187 N.W.2d 218, 222 (Mich. 1971) (recognizing cause of action for prenatal injuries and rejecting viability requirement because "a child has a legal right to begin life with a sound mind and body").

*O'Neill v. Morse*, 188 N.W.2d 785 (Mich. 1971) (recognizing cause of action for wrongful death of a viable stillborn child).

*Larkin v. Cahalan*, 208 N.W.2d 176, 179 (Mich. 1973) (construing state abortion law) ("statutes proscribing manslaughter by abortion are designed to protect human life and carry the necessary implication that that life, the destruction of which is punishable as manslaughter, is human life").

**Minnesota:**

MINN. STAT. ANN. §§ 609.266, 609.2661–609.2665, 609.267, 609.2671, 609.2672, 609.268 (West 1987 & 1992 Supp.) (amending criminal code to include a broad range of crimes, including homicide, that can be committed against an unborn child, regardless of gestational age).

*Verkennes v. Corniea*, 38 N.W.2d 838, 840 (Minn. 1949) (rejecting live birth requirement in wrongful death action) (quoting with approval federal district court opinion in *Bonbrest v. Kotz*, 65 F. Supp. 138, 140 (D.D.C. 1946), where court said "[f]rom the viewpoint of the civil law and the law of property, a child en ventre sa mere is not only regarded as [a] human being, but as such from the moment of conception--which it is in fact").

**Missouri:**

MO. ANN. STAT. § 1.205.1(1) (Vernon Supp. 1992) (preamble to Missouri Abortion Law) ("[t]he life of each human being begins at conception").

MO. ANN. STAT§ 188.015(8) (Vernon Supp. 1992) (abortion regulations) (defining "unborn child" as, "the offspring of human beings from the moment of conception until birth and at every stage of its biological development, including the human conceptus, zygote, morula, blastocyst, embryo, and fetus").

*Rodgers v. Danforth*, 486 S.W.2d 258, 259 (Mo. 1972) (construing criminal abortion law) (accepting stipulation that "unborn children have all the qualities and attributes of adult human persons differing only in age or maturity" and that "[m]edically, human life is a continuum from conception to death").

Missouri Constitutional Convention Call (Res. of Apr. 24, 1975, S. Con. Res. 7):

Requests Congress to call a convention to propose a constitutional amendment extending the term "person" in the Fifth and Fourteenth amendments to apply to all human beings "irrespective of age, health, function, or condition of dependency, including unborn offspring at every stage of their biological development;" permits states to adopt laws necessary to preserve the woman's life; grants Congress and the states the power to enforce the amendment.

**Montana:**

MONT. CODE ANN. § 50-20-102 (1993) (statement of legislative purpose and intent--abortion regulations):

> The legislature reaffirms the tradition of the state of Montana to protect every human life, whether unborn or aged, healthy or sick. In keeping with this tradition and in the spirit of our constitution, we reaffirm the intent to extend the protection of the laws of Montana in favor of all human life.

MONT. CODE ANN. § 41-1-103 (1993) ("[a] child conceived but not yet born is to be deemed an existing person, so far as may be necessary for its interests in the event of its subsequent birth").

**Nebraska:**

Nebraska Constitutional Convention Call (Res. of Apr. 21, 1978, Legis. Res. 152): "Legislature . . . petition[s] . . . Congress . . . to call a convention for the sole purpose of proposing the following article as an amendment to the Constitution of the United States."

ARTICLE

> Section 1. With respect to the right to life, the word person as used in this article and in the Fifth and Fourteenth Articles of Amendment to this Constitution applies to all human beings irrespective of age, health, function, or condition of dependency, including their unborn offspring at every stage of their biological development.
>
> Section 2. No unborn child shall be deprived of life by any person, provided, however, that nothing in this article shall prohibit a law permitting only those medical procedures required to prevent the death of the mother.
>
> Section 3. The Congress and the several states shall have the power to enforce this article by appropriate legislation.

**Nevada:**

*White v. Yup*, 458 P.2d 617, 623 (Nev. 1969) (recognizing cause of action for prenatal injuries and for the wrongful death of a viable, stillborn child) (proposition that "[a]n unborn child is a part of its mother until birth and thus has no juridical existence" "has no scientific or medical basis in fact").

Nevada Constitutional Convention Call (S.J. Res. 27, 60th Legis., 1979 Nev. Stat. 2014):

> [L]egislature requests . . . Congress . . . to call a convention limited to proposing an amendment to the Constitution . . . to protect human life by restricting abortion [subject to exceptions in cases where the pregnancy results from rape or incest and where continuation of the pregnancy would seriously endanger the life of the mother].

**New Hampshire:**

*Bennett v. Hymers*, 147 A.2d 108, 110 (N.H. 1958) (rejecting viability requirement in cause of action for prenatal injuries) ("[w]e adopt the opinion that the fetus from the time of conception becomes a separate organism and remains so throughout its life").

*Wallace v. Wallace*, 421 A.2d 134, 136 (N.H. 1980) (wrongful death action) ("[t]o deny a nonviable fetus a [wrongful death] cause of action is not to deny that life begins with conception").

**New Jersey:**

*Smith v. Brennan*, 157 A.2d 497, 502 (N.J. 1960) (rejecting viability requirement in cause of action for prenatal injuries) ("[m]edical authorities have long recognized that a child is in existence from the moment of conception, and not merely a part of its mother's body"):

> We see no reason for denying recovery for a prenatal injury because it occurred before the infant was capable of separate existence. In the first place, age is not the sole measure of viability, and there is no real way of determining in a borderline case whether or not a fetus was viable at the time of the injury, unless it was immediately born. Therefore, the viability rule is. impossible of practical application . . . . In addition, . . . medical authority recognizes that an unborn child is a distinct biological entity from the time of conception, and many branches of the law afford the unborn child protection throughout the period of gestation. The most important consideration, however, is that the viability distinction has no relevance to the injustice of denying recovery for harm which can be proved to have resulted from the wrongful act of another. Whether viable or not at the time of the injury, the child sustains the same harm after birth, and therefore, should be given the same opportunity for redress.

*Id.* at 504.

*Gleitman v. Cosgrove*, 227 A.2d 689, 696 n.3 (1967) (Francis, J., concurring) (rejecting cause of action for wrongful life) ("[i]t was noted 30 years ago that the

increase in knowledge of embryology had revealed that the child has separate existence from the moment of conception"), overruled, Bermarr v. Allan, 404 A.2d 8 (N.J. 1979) (reorganizing action).

New Jersey Constitutional Convention Call (Act of Apr. 21, 1977, S. 1271):

Requests Congress to call a convention to propose a constitutional amendment which would provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right to life; provides that Congress and the states shall have concurrent powers to enforce such an amendment.

**New York:**

*New York City Health & Hosp. Corp.*, 286 N.E.2d 887, 888 (N.Y. 1972), appeal dismissed, 410 U.S. 949 (1973) (rejecting challenge to pre-Roe abortion law which allowed abortion on demand through the twenty-fourth week of gestation but recognizing that human life begins at conception):

> It is not effectively contradicted, if it is contradicted at all, that modern biological disciplines accept that upon conception a fetus has an independent genetic "package" with potential to become a full-fledged human being and that it has an autonomy of development and character although it is for the period of gestation dependent upon the mother. It is human, if only because it may not be characterized as not human, and it is unquestionably alive.

*Kelly v. Gregory*, 125 N.Y.S.2d 696, 697 (N.Y. App. Div. 1953) (rejecting viability requirement in cause of action for prenatal injuries) ("legal separability should begin where there is biological separability" and "separability begins at conception"):

> The mother's biological contribution from conception on is nourishment and protection; but the foetus has become a separate organism and remains so throughout its life. That it may not live if its protection and nourishment are cut off earlier than the viable stage of its development is not to destroy its separability; it is rather to describe conditions under which life will not continue. Succeeding conditions exist, of course, that have that result at every stage of its life, postnatal as well as prenatal.

*Id*. at 697.

**North Carolina:**

*DiDonato v. Wortman*, 358 S.E.2d 489, 496 (N.C. 1987) (recognizing cause of action for wrongful death of a viable unborn child) ("[t]he public policy of this

state as expressed by the legislature in our statutes recognizes that an unborn infant is a person") (Martin, J., concurring in part and dissenting in part).

*Corkey v. Edwards*, 322 F. Supp. 1248, 1252 (W.D.N.C. 1971), vacated and remanded, 410 U.S. 950 (1973) (construing criminal abortion statute):

> Apart, the sperm and the unfertilized egg will die; neither has the capacity to grow and develop independently as does the fertilized egg. During fertilization, sperm and egg pool their nucleii and chromosomes. Biologically, a living organism belonging to the species homo sapiens is created out of this organization. Genetically, the adult man was from such a beginning all that the essentially has become in every cell and human attribute.

**North Dakota:**

N.D. CENT. CODE §§ 12.1-17.1-02 through 12.1-17.1-06 (Supp. 1991) (amending criminal code to define broad range of crimes, including homicide, that can be committed against unborn child, regardless of gestational age).

Statute providing that "[a] child conceived but not born is to be deemed an existing person so far as may be necessary for its interests in the event of its subsequent birth" was intended "to ensure and to protect the interests of a child subsequent to its conception but prior to its birth," *Hopkins v. McBane*, 359 N.W.2d 862, 864 (N.D. 1984).

**Ohio:**

*Steinberg v. Brown*, 321 F. Supp. 741, 746 (N.D. Ohio 1970) (construing criminal abortion law) (holding that human life is entitled to federal constitutional protection from conception) ("a new life comes into being with the union of human egg and sperm cells" and "[s]uch terms as 'quick' or 'viable', which are frequently encountered in legal discussion, are scientifically imprecise and without recognized medical meaning").

*Williams v. Marion Rapid Transit*, 87 N.E.2d 334, 340 (Ohio 1949) (recognizing cause of action for prenatal injuries):

> To hold that the plaintiff in the instant case [a viable unborn child] did not suffer an injury in her person would require this court to announce that as a matter of law the infant is part of the mother until birth and has no existence in law until that time. In our view such a ruling would deprive the infant of the right [to a remedy] conferred by the [Ohio] Constitution upon all persons, by the application of a time worn fiction not founded on fact and within common knowledge untrue and unjustified.

The court also quoted with approval WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 31, 189 (1941). Professor Prosser stated, "So far as duty is concerned, if existence at the time [of injury] is necessary, medical authority has recognized long since that the child is in existence from the moment of conception, and for many purposes its existence is recognized by the law." *Id*. at 339.

**Oklahoma:**

OKLA. STAT. ANN. tit. 63, § 1-730(2) (West 1997) (abortion regulations) (defining "unborn child" as "the unborn offspring of human beings from the moment of conception, through pregnancy, and until live birth including the human conceptus, zygote, morula, blastocyst, embryo and fetus . . . .").

*Evans v. Olson*, 550 P.2d 924, 926 (Okla. 1976) (rejecting viability requirement in cause of action for prenatal injuries and live birth requirement in wrongful death actions) ("there is no medical or scientific basis" for the proposition that "an unborn child has no judicial existence apart from its mother").

**Oregon:**

*State v. Ausplund*, 167 P. 1019, 1022-23 (Or. 1917) (construing criminal abortion law):

> The statute refers to "any woman pregnant with a child" without reference to the stage of pregnancy. When a virile spermatozoon unites with a fertile ovum in the uterus, conception is accomplished. Pregnancy at once ensues, and under normal circumstances continues until parturition. During all this time the woman is "pregnant with a child" within the meaning of the statute. She cannot be pregnant with anything else than a child. From the moment of conception a new life has begun, and is protected by the enactment. The product of conception during its entire course is imbued with life, and is capable of being destroyed as contemplated by the law. By such destruction the death of a child is produced and often that of its mother as well.

*Mallison v. Pomeroy*, 291 P.2d 225, 228 (Or. 1955) (recognizing cause of action for prenatal injuries) (Thin Oregon we have recognized by statute the separate entity of an unborn child by protecting him in his property rights and against criminal conduct . . . .").

*Libbee v. Permanente Clinic*, 518 P.2d 636 (Or. 1974) (recognizing cause of action for the wrongful death of a viable stillborn child).

**Pennsylvania:**

28 PA. Code § 29.31 (1995) (abortion regulations) (defining "unborn child" as a human being from fertilization until birth and includes a fetus).

*Amadio v. Levin*, 501 A.2d 1085, 1087 (Pa. 1985) (rejecting live birth requirement in wrongful death actions) ("a child en ventre sa mere is a separate individual from the moment of conception'').

*Sinkler v. Kneale*, 164 A.2d 93, 96 (Pa. 1960) (rejecting viability requirement in cause of action for prenatal injuries) (viability has "little to do with the basic right to recover, when the foetus is regarded as having existence as a separate creature from the moment of conception").

Pennsylvania Constitutional Convention Call (H.R. 71, 1978 Gen. Assembly, 1978 Pa. Laws 1431):

> [A]pplication to the Congress . . . to call a convention for drafting and proposing an amendment to the Constitution . . . to guarantee the right to life to the unborn fetus by doing the following:
>
> (a) With respect to the right to life guaranteed in the United States Constitution, provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right to life.
>
> (b) Provide that Congress and the several states shall have concurrent powers to enforce such an amendment by appropriate legislation.
>
> ***
>
> (d) Nothing in this article shall prohibit a law permitting only those medical procedures required to prevent the death of the mother.

**Rhode Island:**

*Sylvia v. Gobeille*, 220 A.2d 222, 223-24 (R.I. 1966) (rejecting viability requirement in cause of action for prenatal injuries) (noting "the medical fact that a fetus becomes a living human being from the moment of conception" and rejecting viability as a "decisive criterion" because "there is no sound reason for drawing a line at the precise moment of the fetal development when the child attains the capability of an independent existence").

*Presley v. Newport Hosp.*, 365 A.2d 748, 751 (R.I. 1976) (rejecting live birth requirement in wrongful death of a viable unborn child) (citing with approval the civil law proposition that "from the moment of conception a separate organism with its own identity comes into existence" and the medical proposition that "an ovum, once it is fertilized, is a separate living entity"):

> [V]iability is a concept bearing no relation to the attempts of the law to provide remedies for civil wrongs. If we profess allegiance to reason, it would be seditious to adopt so arbitrary and uncertain a concept as viability as a dividing line between those persons who shall enjoy the protection of our remedial laws and those who shall become, for most intents and purposes, nonentities. It seems that if live birth is to be characterized, as it so frequently has been, as an arbitrary line of demarcation, then viability, when enlisted to serve that same purpose, is a veritable non sequitur.

*Id*. at 753-54 (dicta in plurality opinion) (disapproved *Miccolis v. Amica Mutual Ins. Co.*, 587 A.2d 611 (R.I. 1991)).

Rhode Island Constitutional Convention Call (Act. of Apr. 21, 1977, H.R. 5150):

Requests Congress to call a convention to propose a constitutional amendment which would provide that every human being subject to the jurisdiction of the United States or any state shall be deemed from the moment of fertilization to be a person and entitled to the right to life; provides that Congress and the states shall have concurrent power to enforce such an amendment.

**South Dakota:**

*State v. Munson*, 201 N.W.2d 123, 126 (S.D. 1972), vacated and remanded, 410 U.S. 950 (1973) (construing criminal abortion law) (citing with approval holding in Steinberg v. Brown, 321 F. Supp. 741 (N.D. Ohio 1970), that human life is entitled to federal constitutional protection from conception).

S.D. CODIFIED LAWS ANN. § 21-5-1 (1987) (amending wrongful death statute to include "an unborn child" without regard to gestational age).

S.D. CODIFIED LAWS ANN. § 22-17-6 (1988) ("[a]ny person who intentionally kills a human fetus by causing an injury to its mother . . . is guilty of a Class 4 felony").

S.D. CODIFIED LAWS ANN. § 26-1-2 (1992) ("[a] child conceived, but not born, is to be deemed an existing person so far as may be necessary for its interests in the event of its subsequent birth").

**Texas:**

*Thompson v. State*, 493 S.W.2d 913, 918 (Tex. Crim. App. 1971) vacated and remanded, 410 U.S. 950 (1973) (construing criminal abortion law):

> The State of Texas is committed to preserving the lives of its citizens so that no citizen "shall be deprived of life, . . . except by the due course of the law of the land." [Citation omitted]. [The

> Texas abortion law] is designed to protect fetal life . . . and this justifies prohibiting termination of the life of the fetus or embryo except for the purpose of saving the life of the mother.

*Leal v. C.C. Pitts Sand & Gravel, Inc.*, 419 S.W.2d 820, 822 (Tex. 1967) (recognizing cause of action for wrongful death for prenatal injuries where death occurs after live birth), *rev'g* 413 S.W.2d 825 (Tex. Civ. App. 1967) (denying cause of action) and *app'g* dissenting opinion of Justice Cadena, 413 S.W.2d at 828 ("medical science . . . consider[s] that life begins at conception"), *id*. at 829 ("legalistic concept that the unborn child is but a part of its mother" is "contrary to scientific fact and common sense").

*Witty v. Am. Gen. Capital Distrib., Inc.*, 727 S.W.2d 503, 505 (Tex. 1987) (denying cause of action for wrongful death of viable child who was stillborn but recognizing "the fetus as having an existence separate from its mother").

*Delgado v. Yandell*, 468 S.W.2d 475 (Tex. Civ. App. 1971), *writ ref'd n.r.e.* 471 S.W.2d 569 (Tex. 1971) (per curiam) (rejecting viability requirement in cause of action for prenatal injuries).

**Utah:**

UTAH CODE ANN. § 76-7-301.1(2): "The state of Utah has a compelling interest in the protection of the lives of unborn children."

UTAH CODE ANN. § 76-5-201(1) (1992 Supp.) (defining offense of criminal homicide as causing "the death of another human being, including an unborn child at any stage of its development").

Utah Constitutional Convention Call (H.R.J. Res. 28, 42nd Legis., Reg. Sess., 1977 Utah Laws 1317, 1318):

> [A]pplies to the Congress . . . to call a convention for the purpose of drafting and submitting for ratification by the states, . . . an amendment to the Constitution that will guarantee to every human life, from the moment of fertilization throughout its natural existence, in every state, territory, and possession of the United States, the full protection of all laws respecting life, excepting an unborn child whose mother's life would otherwise be lost.

**Virginia:**

*Kalafut v. Gruver*, 389 S.E.2d 681, 683-84 (Va. 1990) (rejecting viability rule in cause of action for prenatal injuries or for wrongful death following live birth) (noting "developments in medical science, especially in the field of embryology," court held that "an action may be maintained for recovery of damages for any injury occurring after conception, provided the tortious conduct and the proximate

cause of the harm can be established").

**Wisconsin:**

WIS. STAT. ANN. § 940.04(6) (West 1982) (criminal abortion statute defining "unborn child" as "a human being from the time of conception until it is born alive")

*Puhl v. Milwaukee Auto. Ins. Co.*, 99 N.W.2d 163, 170 (Wis. 1959) (rejecting viability requirement in cause of action for prenatal injuries), *overruled on other grounds*, *In re Estate of Stromsted*, 299 N.W.2d 226 (Wis. 1980):

> The viability theory has been challenged as unrealistic in that it draws an arbitrary line between viability and nonviability, and fails to recognize the biological fact there is a living human being before viability. A child is no more a part of its mother before it becomes viable than it is after viability. It would be more accurate to say that the fetus from conception lives within its mother rather than as a part of her. The claim of a child injured before viability is just as meritorious as that of a child injured during the viable stage.

*Kwaterski v. State Farm Mut. Auto. Ins. Co.*, 148 N.W.2d 107, 111 (Wis. 1967) (rejecting born alive requirement in wrongful death actions) (assertion that "[a] child has no juridical existence apart from its mother" has "no scientific or medical basis in fact").

## APPENDIX D

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

# Frozen Embryos:

## The Adoption Solution

RONALD L. STODDART, ESQ.© (November 5, 1999), as updated May 22, 2009

## THE BACKGROUND

The increase in the use of "reproductive technology" has resulted in the birth of children through an alphabet soup of conception techniques. For those families who have gone through infertility treatment, terms such as IVF, GIFT, ZIFT, AHA, etc. sometimes obscure the fact that achieving a pregnancy and having a family is the goal. But while pursuing the goal, families find themselves creating new issues as frequently as they resolve existing ones.

For example, one of the by-products of in-vitro fertilization of eggs is the creation of embryos which are not immediately implanted. Where economics and technology clash, the economy of scale has typically prevailed and left the "fertility challenged" parents with "extra" embryos that can be frozen and stored for later implantation. Whether the first implantations are unsuccessful or the parents desire additional children, the availability of stored embryos is an attractive service offered by the fertility physicians.

By some estimates, there are hundreds of thousands of frozen embryos currently in storage in the United States. A recent report indicated that there were over 25,000 frozen embryos being stored in Massachusetts, alone, due to their favorable health insurance coverage requirements for infertility procedures.

Eventually the genetic parents will be confronted with the need to make a decision on the future of their stored embryos when they have completed their own family. The three choices they are given are (1) to donate the embryos for implantation, (2) to donate the embryos for research or (3) to have the embryos destroyed. Physicians, bioethicists, social workers, clergy and other "experts" have weighed in on these choices with arguments reminiscent of the Pro-Life -Pro-Choice debate. Although I am strongly Pro-Life, this issue is largely irrelevant when dealing with the focus of this article, the adoption of frozen embryos.

For the record, however, I would like to state the fundamental argument for "adopting" frozen embryos rather than transferring them through some other contractual means. A frozen embryo is a pre-born child with the potential for development into a viable fetus and ultimately a new born baby. Regardless of the debate surrounding the creation of the embryos that are now frozen and stored, the movement to offer the genetic parents the full rights of birth parents in an adoption proceeding recognizes the deep emotional bonds that exist between genetic parents and their children - regardless of how they come to be born.

## THE LAW

As one might imagine, the law has lagged far behind reproductive technology and generally responds to disputes that test the wisdom of Solomon. In California, the Penal Code has brought the transfer of embryos under the common law Statue of Frauds by requiring a written agreement. The further regulation of such transfers, however, are woefully lacking any specifics or protections for either party to the written agreement, other than those provided by the Health & Safety Code sections dealing with tissue transfer and health issues.

California Penal Code Section 367(b) provides the legal basis for the formalities required in an embryo transfer as follows:

> "It shall be unlawful for anyone to knowingly implant sperm, ova, or embryos, through the use of assisted reproduction technology, into a recipient who is not the sperm, ova, or embryo provider, without the signed written consent of the sperm, ova, or embryo provider and recipient."

There are certainly clinics and physicians that are transferring embryos with the most abbreviated consent forms imaginable. To those families who are comfortable with the designation "provider" and "recipient", perhaps such informality is sufficient. But the law has always treated the adoption of human beings with a bit more respect.

Seven states have laws in effect which provide some general guidance for embryo donation or adoption. With the exception of statutes in Louisiana, most statutes are geared toward the respective rights of those donating and receiving embryos, rather than the embryos themselves. With the exception of Louisiana and Florida, four states solely use the term embryo donation as opposed to embryo adoption.

1. CALIFORNIA

a. California civil law provides that each individual undergoing fertility treatment must be informed of all possible options for unused embryos. It also details possible dispositions for embryos belonging to individuals or couples who die, separate, divorce, or fail to pay storage fees. CAL HEALTH & SAFETY CODE §12315 (2007).

b. California criminal law prohibits the use of embryos for anything other than that to which the embryo provider consents. Cal. Penal Code § 367g (2007).

2. FLORIDA

Florida law provides that donors of embryos relinquish all parental rights with respect to the donation of embryos or the resulting children. FLA. STAT. § 742.14 (2007). Additionally, embryo adoption is included in a listing of fertility techniques. FLA. STAT. § 63.213 (2007).

3. LOUISIANA

Louisiana law provides for a wide range of embryo protection, stating that an embryo is a juridical person (not fully human under the law, but deserving of some rights), and has a legal status in which it is recognized as a separate entity apart from the physician or the sperm and egg donors. Embryos may not be intentionally destroyed. Louisiana also allows for embryo adoption if IVF patients renounce parental rights. LA. REV. STAT. ANN. §§ 9:122-130 (2007).

4. OHIO

Ohio law provides that a woman who gives birth to a child as the result of embryo donation will be regarded as the natural mother and establishes that embryo donors have no parental rights or responsibilities. OHIO REV. CODE ANN. §§ 3111.97 (2007).

5. OKLAHOMA

Oklahoma law provides basic guidelines for human embryo transfer and donation and establishes that donors of embryos relinquish all parental rights with respect to the donation or any resulting children. OKLA. STAT. ANN. tit. 10, § 556 (2007).

6. TEXAS

Texas law includes embryo donation in the definition of assisted reproduction technology (ART). TEX. FAM. CODE ANN. § 160.102 (2007).

7. GEORGIA

Georgia law, enacted April 3, 2009, called the Option of Adoption Act, specifically provides procedures for genetic parents to relinquish their rights to embryos before birth and allow the recipient intended parents to be the legal parents of the child that may be born as a result of the embryo transfer. Additionally, the bill changes the definition of "child" to include an in vitro human embryo and offers the same legal rights to adoption as an *in utero* or already born human being.

**ADOPTION LAW**

The basic elements of an adoption, even ignoring the considerable evidence supporting the importance of "open adoption", include:

1. Complete and thorough advisement of legal rights to the birth parent(s), generally accompanied by psychological counseling.

2. Complete and thorough screening and education of the adopting parent(s), generally through the home study process.

3. Formal execution of consent documents by both birth parents and adopting parents.

4. Court decree recognizing the sufficiency of the process and-the protection of the best interests of the child.

5. Promulgation of a new birth certificate reflecting the legal status of adopting parents and child.

When dealing with embryo adoptions, the first three elements of an adoption can be satisfied, and should be satisfied for the protection of the child and the adult parties to the adoption. As will be shown below, the need for a new birth certificate is obviated in an embryo adoption and there is no statutory basis for an adoption decree (although some courts may be willing to issue ceremonial decrees).

## DEFINING THE ROLES

As with any new area of the law, defining the roles of the participants - and the terminology applied to them - is often the first hurdle to overcome. To ease the understanding of the roles - both emotionally and legally - of the parties we have adopted the following definitions.

**Genetic Parents:** The genetic parents fill the role most commonly associated with "birth parents" in adoptions. The frozen embryo is the pre-born child of the genetic parents. The genetic parents have the legal right to custody and control of the frozen embryos, which custody has generally been assigned temporarily to a fertility clinic or cryobank laboratory. With some exceptions, the law recognizes this right of custody more as an ownership interest than parental rights and obligations.

For purposes of this article, the genetic parents are assumed to have been the source of the eggs and sperm used to create the embryos. In the case where donor eggs or donor sperm were used, the genetic parents are the individuals with the legal right to determine the future of the frozen embryos.

**Pre-born Child:** A frozen embryo is a pre-born child, subject to many of the same risks of survival as any pre-born child. Our purpose in emphasizing the personhood of the frozen embryo is not to subject the genetic parents to a moral and religious argument for not destroying the embryo - although certainly that is our unequivocal position. Rather, it is easier to understand and plan for the future emotional needs of the "adopted" embryo by recognizing its identity at the earliest possible time.

**Adopting Parents:** The adopting parents are the recipients of the frozen embryo and therefore the child's "birth parents" under the law. The frozen embryo would be implanted in the adopting mother after it has been legally "relinquished" or transferred to the adopting parents. No additional legal proceedings would be necessary for the adopting parents/birth parents to secure full legal and physical custody to the child.

**Relinquishment:** The term relinquishment, rather than donation, legal transfer or gift, is used to describe the procedure for the genetic parents to terminate their legal rights to the frozen

embryo. It is important that this be accomplished with the same safeguards as are found in a more traditional adoption in order to best prepare and educate all of the parties involved. It is also important that the relinquishment be accomplished prior to the implantation of the frozen embryo into the adopting mother so that there is no later dispute as to the legal roles of the parties.

**Genetic Siblings:** One of the little noticed, but important factors in treating the transfer of a frozen embryo to another family as an "adoption" is to safeguard the later needs of the genetic family, including genetic siblings. Unlike other forms of in-vitro fertilization used in infertility cases, the placement of frozen embryos for adoption generally involves genetic parents who have already been successful in giving birth to children using the contemporaneously created embryos.

## ADVANTAGES OF EMBRYO ADOPTION

There are a number of advantages to embryo adoption to all of the parties involved. Let's review what some of those advantages might be.

*1. Advantages to Genetic Parents*

As was discussed earlier, once genetic parents have completed their families and have no further desire to give birth to additional children, the decision as to the future of any remaining frozen embryos must be made. Regardless of the medical status of the embryo, which may be as few as 4 cells, the genetic parents are frequently emotionally invested in the future of "all" of their children, even those that carry the label "potential" children. For those genetic parents who believe that the embryos are more than tissue, and who would like to give each embryo a fair chance at life, adoption is the most satisfying answer.

Mere release of the embryos for implantation in unknown parents is similar to the old "closed adoption" system that left birth mothers grieving for far too long when simple information as to the child's welfare would have been a healing balm. Like birth mothers in an open adoption, genetic parents can be as involved or uninvolved in the selection of adopting parents as they choose. In addition, they can maintain the security of knowing that the genetic siblings of their own children will always be known in the event of medical emergencies or to later answer imponderable questions.

*2. Advantages to Adopting Parents*

For infertile couples, it was thought that the closest experience to giving birth was adopting a new born baby and taking the baby home directly from the hospital. Although some women who have experienced labor and delivery may disagree, the opportunity to become pregnant with your adopted child, carry the child to term and then give birth to your adopted child truly maximizes the parenting experience. For those experts who extol the virtues of "pre-natal bonding", frozen

embryo adoption is the great equalizer.

## MODEL EMBRYO ADOPTION PROGRAM

*I. Services to the Genetic Parents*

Similar to traditional adoptions, genetic parents should be offered counseling as to all of the options available to them. Adoption of the frozen embryos should be described as a lifelong commitment to the children who may be born from the implantation of the embryos in an adopting mother. As with open adoption, genetic parents should be encouraged to participate in the establishment of criteria for the adopting parents and even in the actual selection of parents.

Genetic parents will provide complete medical information, including recent HIV test results. Such information must be disclosed to the adopting parents and the physician assisting with the embryo implantation.

Post-adoption services, including counseling must also be made available to genetic parents. Every effort should be made to maintain contact through the agency involved with the genetic parents.

*II. Services to Adopting Parents*

Potential adopting parents should complete a home study as would any other adopting parents. It is important that the family be counseled as to the life long issues of adoption, even though they will be giving birth to their adopted child. To try to ignore the fact that the child is adopted could result in emotional upheaval for the child later in life. Although the way of explaining to a birthed child that the child is adopted may seem bizarre to us now, children will soon find the realities of reproductive technology very common place. Education and support will be as important in frozen embryo adoptions as they are in other more traditional adoptions.

Potential adopting mothers must also show, through recommendations from her physician, that she is capable of carrying a child to term even though she may suffer from other infertility problems. It is also highly desirable that the adopting parents have the willingness to provide continuing information on their child(ren) to the agency and genetic parents. It should be remembered that the tie between genetic parents and adopting parents is particularly strong when the presence of genetic siblings are recognized.

*III. The Role of the Adoption Agency*

The role of the adoption agency is critical to the future of frozen embryo adoptions. Without the recognition that adoptions of frozen embryos are entitled to the same safeguards and protections as other adoptions, the potential for a "market" in frozen embryos being created is very real. Just as the law regulates

who may act as an intermediary in traditional adoptions (either the birth parent(s) directly or a licensed adoption agency), it is equally important to regulate who may act as an intermediary in a frozen embryo adoption. It should also be noted that even when birth parent(s) place a child directly with adopting parents, the law still requires a home study and court approval of the adoption.

In the case of frozen embryo adoption, until the law catches up with the science, the appropriate adoption expertise to apply to frozen embryo adoption will come from licensed agencies. The agency can offer the counseling, screening, education and formal relinquishment services that should be the hallmarks of a frozen embryo adoption. Until the legislature or courts provide for other formalities or protections, the adoption community should encourage, even advocate, for the necessity of such an adoption model.

## CONCLUSIONS

Although many physicians and facilitators may point to the success of their myriad varieties of egg, sperm and embryo transfers, at some point the treatment of embryos must conform to that afforded children rather than property. To wait until we have a generation of displaced children, with little knowledge or understanding of their roots, crying for "open records" and their "right to know" their history, would reflect too little appreciation for the 'past errors of adoption practice. The time to develop a progressive and thoughtful approach to dealing with the futures of the hundreds of thousands of stored frozen embryos is now.

There are more than 10 million infertile couples in the U.S. In the last decade, the infertility industry has grown from about 30 to over 300 clinics earning revenues in excess of 1 billion dollars. It is estimated that 11-25% of couples who experience difficulty conceiving or carrying a pregnancy to term consider adoption. The National Adoption Information Clearinghouse reports that about 200,000 couples are actively seeking to adopt each year. It is estimated that in the U.S. in 2007, about 1% of the live births (or more than 42,000 infants) will be born as a result of IVF – about the same number that will be available through traditional unrelated infant adoption. At the same time, more than 400,000 human embryos are now frozen, suspended in liquid nitrogen tanks on the premises of IVF clinics (with more than 19,000 frozen embryos estimated to be added to each year). While many proponents of embryonic stem cell research claim that these 400,000 frozen embryos are "unwanted leftovers" that ought to be used for research, the facts prove otherwise. According to the most definitive 2003 Rand Corporation study, only 2.8% (or about 11,000) of the frozen embryos are "designated for research" by their biological parents, 88.2% are designated by the biological families for their own "family-building," 2.3% (or about 9,200) for donation or "adoption by others," 2.2% are to be "discarded," and 4.5% have experienced "lost contact with biological 'patients,' patient death, abandonment or divorce." Thus, aside from the unethical nature of destructive human embryo research, there are not even enough human embryos designated for research to create the number of genetically diverse stem cell lines demanded by embryonic research proponents

Although the program developed by Christian Adoption & Family Services (called Snowflakes) is certainly a "work in progress", it does recognize the unique nature of each

embryo and the real needs of the genetic parents in planning for their future.[1]

[1] It is existing federal policy to promote human embryo adoption as currently authorized by Congressional appropriations and implemented by HHS. For updated information on the federally-funded Embryo Adoption Awareness Campaign see www.embryoadoption.org/. Biological and adoptive parents interested in human embryo adoption can also obtain additional information from Nightlight Christian Adoptions (www.nightlight.org/snowflake adoption.htm), the National Embryo Donation Center (www.embryodonation.org), Embryos Alive (www.embryosalive.com) and Miracles Waiting (www.miracleswaiting.org).

## APPENDIX E

# *Legislative and Administrative History of the Federal Funding Ban on Destructive Human Embryo Research*

May 26, 2009

by
Samuel B. Casey,[1] *General Counsel*
ADVOCATES INTERNATIONAL

The federal funding ban on destructive human embryo research [popularly known as the "Dickey-Wicker Amendment" after its original sponsor, former Cong. Jay. Dickey (R-AK) and current Senator Roger Wicker (R-MS) who was then a member of the House of Representatives)], included in every Health and Human Services ("HHS") appropriations bill since 1995,[2] states, "None of the funds made available by this Act may be used for . . . research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero*. . . ." Interpreting this language, then-HHS General Counsel Harriet S. Rabb issued a memorandum on January 15, 1999, cleverly claiming that the Dickey-Wicker Amendment bans federal funding of the

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[1] Mr. Casey was co-counsel for plaintiffs in *Nightlight Christian Adoptions et al. v. Thompson* (Civil Action No. 1.01CV00502-RCL, U.S. District Court, District of Columbia, hereafter "Nightlight"), the case that ultimately dismissed without prejudice when the Bush Administration agreed to withdraw the HHS regulations issued by the Clinton Administration (65 F.R. 51976 et seq.).

[2] The current funding ban is found in the CONSOLIDATED SECURITY, DISASTER ASSISTANCE, AND CONTINUING APPROPRIATIONS ACT OF 2009, Pub. L. No. 110-329, Division A (2008) (incorporating by reference, and continuing the effectiveness of, CONSOLIDATED APPROPRIATIONS ACT OF 2008, Pub. L. No. 110-161, § 509, 121 Stat. 1844 (2007)) (hereinafter "Dickey-Wicker" or "Federal Funding Ban").For earlier legislation containing the same amendment, see e.g. BALANCED BUDGET DOWNPAYMENT ACT, Pub. L. No. 104-99, 110 Stat. 26, 34, Title I, § 128 (January 26, 1996); Omnibus Bill, Pub. L. No. 104-208 § 512 (Sept. 30, 1996); Labor/HHS/Education Appropriations Act, Pub. L. No. 105-78 § 513 (Nov. 13, 1997); Omnibus Bill, Pub. L. No. 105-277 § 511 (Oct. 21, 1998); Omnibus Bill, Pub. L. No. 106-113 § 510 (Nov. 29, 1999); Omnibus Consolidated Appropriations Act of 2001, Pub L. No. 106-554 § 510 (December 21, 2000); Labor/HHS/Education Appropriations Act; H.R. 3061/S. 1536, 107th Cong. (2001) (conference report approved by both houses on 12-20-01); Omnibus Bill. Pub. L. No. 107-116, § 510 (January 22, 2002).

***derivation*****n** of embryonic stem cells – a euphemism for the procedure killing the living human embryo – but not research ***utilizing*** the derived embryonic stem cells.[3]

On August 25, 2000, based almost exclusively on the 'derivation' vs. 'use' distinction in the Rabb memorandum, NIH published and made effective its "GUIDELINES FOR RESEARCH USING HUMAN PLURIPOTENT STEM CELLS." 65 Fed. Reg. 51976 (hereafter the "*Clinton Guidelines*"). Contrary to HHS's decades-long practice of refusing to fund research that threatens or destroys human embryos, and in direct contradiction of Congress's plainly expressed intent, the Clinton Guidelines allowed federal funding of research using embryonic stem cells derived from the destruction of human embryos by others not funded by the federal government. The Clinton Guidelines were never implemented due to the end of the Clinton Administration, litigation in the *Nightlight Adoption* case staying their enforcement, and their ultimate withdrawal by the National Institutes of Health (NIH) on November 7, 2001, based upon the President's Executive Statement of August 9, 2001.[4]

In January 2002, following President Bush's August 9, 2001 announcement of his administration's stem cell research policy, the Bush Administration formally withdrew the Clinton Guidelines and issued its own guidance in the following documents (hereafter the Bush Guidelines) that remain the law today, subject to the NIH review ordered by President Obama in his March 11, 2009 Executive Order 13505[5]:

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[3] *See* 65 Fed. Reg. 51796 (2000).

[4] This legal history is summarized in the attached legal memorandum to NIH's Acting Director, Dr. Ruth Kirchstein, from Alex M. Azar, II, NIH's General Counsel, dated January 11, 2002, **Appendix F**.

[5] As recently as June 14, 2004, Associated Press reports that the Bush Administration is rejecting calls by former President Reagan's family to change its policy on stem cell research. Press Secretary Scott McClellan reportedly said, "[t]he policy remains the same." He adds: "We are looking at other ways to combat disease." On June 22, 2007, President Bush issued his Executive Order 13435 reaffirming his presidential policy decision of August 9, 2001 and "expanding the approved stem cell lines in ethically responsible ways" to include "alternative sources of pluripotent stem cells" that are "derived without creating a human embryo for research purposes or destroying, discarding or subjecting to harm a human embryo or fetus." 72 Fed. Reg. 34591. President Bush's Order sought to explore the "potential of pluripotent stem cells…without violating human dignity or demeaning human life." *Id*. Section 2 of the Order set forth the following ethical principles: (b) it is critical to establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity; (c) the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another; (d) human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold; and (e) the Federal Government has a duty to exercise responsible stewardship of taxpayer funds, both supporting important medical research and respecting ethical and moral boundaries. On March 11, 2009, President Obama issued his Executive Order 13505 that "revoked" Executive Order 13435. 74 Fed. Reg. 10667.

1. HHS General Counsel Memorandum, January 11, 2002, Alex M. Azar II to Dr. Ruth Kirchstein, Acting Director, NIH

2. Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry, November 7, 2001, NOT-OD-02-005, Office of the Director, NIH (http://grants.nih.gov/grants/gu ide/notice-files/NOT-OD-02-006.html; see generally http://stemcells.nih.gov/).

All research involving human embryonic stem cells necessarily entails extraction of stem cells from living human embryos. The process by which human embryonic stem cells are extracted from human embryos necessarily destroys the human embryos. Accordingly, research using embryonic stem cells necessarily involves the destruction or discarding of embryos and/or places such embryos at more than a minimal risk, without biomedical necessity. The proposed NIH Guidelines nevertheless provide for federal funding of research involving human embryonic stem cells, so long as the funds are not directly used to pay for the act of extracting the stem cells from the human embryos for research.

The proposed NIH Draft Guidelines on Human Embryonic Stem Cell Research, as published by NIH for comment on April 23, 2009 (77 Fed. Reg. 18578-18580)(the "proposed 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. Similarly, the proposed Guidelines fail to account for longstanding ethical norms that protect human life from medical exploitation and experimentation.

The proposed Guidelines cannot be justified by any attempt to resurrect the thinking originally set forth in a single legal memorandum, dated January 15, 1999, issued by HHS General Counsel Harriett S. Rabb (the "Rabb memo"). *See* 65 Fed. Reg. 51796. The Rabb memo claimed that despite the federal funding ban, federal funds could still be used to pay for research involving stem cells obtained by deliberately destroying human embryos so long as the federal funds do not pay for the specific procedure by which the stem cells are extracted from the living human embryos.

In attempting to justify the purported legality of federally funding human embryonic stem cell research, the Rabb memo concluded that research on embryonic stem cells "would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such stem cells are not human embryos." In support of this conclusion, the Rabb memo asserted that human embryonic stem cells "are not organisms and do not have the capacity to develop into an organism that could perform all the life functions of a human being – in this sense they are not even precursors to human organisms." Further, the Rabb memo stated that human embryonic "stem cells do not have the capacity to develop into a human being, even if transferred into a uterus." In support of these assertions, the Rabb memo mischaracterized testimony before a Senate Subcommittee's Hearings, ignored other critical testimony provided during the course of

those same hearings, and failed to discuss scientific evidence suggesting that the conclusions stated in the Rabb memo are inaccurate.

In a letter dated February 11, 1999, approximately 75 members of Congress requested that then-Secretary Shalala correct the HHS General Counsel's misinterpretation of the federal funding ban on destructive embryo research.

On February 12, 1999, seven United States Senators signed and delivered a letter to Secretary Shalala expressing "deep[] concern[]" over certain testimony by then-NIH Director Varmus suggesting the NIH's willingness to fund embryonic stem cell research. The Senators expressly disagreed with Director Varmus's "contention . . . that once the stem cells are derived, federal funding of research which directly relies on such destruction is acceptable." The Senators made clear that "Congress never intended for the National Institutes of Health to give incentives for the killing of human embryos for the purpose of stem cell research." The letter also expressed concern over Director Varmus's sworn testimony admitting that he was "unsure" whether so-called "pluripotent stem cells may come together in culture to begin developing as an embryo." The Senators noted that if, as some researchers have found, such development is possible, then even under the reasoning employed in the Rabb memo, embryonic stem cell research would unquestionably violate Congress's ban on any research that destroys, discards, or places human embryos at risk.

Despite these congressional warnings, the NIH, on December 2, 1999, 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. 67576 (Dec. 2, 1999). The NIH subsequently extended the original 60-day comment period for an additional 28 days. The comment period ended on February 22, 2000.

The 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 Guidelines.

The Clinton Guidelines allowed for funding of research involving human embryonic stem cells "only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment." 65 Fed. Reg. 51979. The Clinton Guidelines also "prescribe the documentation and assurances that must accompany requests for NIH funding for research using human [embryonic] stem cells from: (1) Awardees who want to use existing funds; (2) awardees requesting an administrative or competing supplement; and (3) applicants or intramural researchers submitting applications or proposals." 65 Fed. Reg. 51979.

The Clinton Guidelines provided no scientific, or any other, support for the primary premise upon which NIH relied and apparently still relies in the proposed Guidelines, namely, its assumption that human embryonic stem cells are not protectable as human embryos. Rather, the Guidelines merely repeated HHS General Counsel Rabb's unscientific and unfounded assertion

that "[a]lthough human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos." 65 Fed. Reg. 51979.

In responding to numerous comments objecting to the Clinton Guidelines on the ground that NIH funding for human embryonic stem cell research plainly violates HHS appropriations law, NIH merely cited HHS General Counsel Rabb's unsupported assertion 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.'" 65 Fed. Reg. 51976. NIH asserted without explanation that these comments "did not present information or arguments that justify reconsideration of the [HHS General Counsel's] conclusion." *Id.*

NIH defended its decision to fund embryonic stem cell research, rather than relying on adult stem cell research, on the grounds that "[i]t is *possible* that no single source of stem cells is best or even suitable/usable for all therapies," and that "[d]ifferent types or sources of stem cells *may be optimal* for treatment of specific conditions." 65 Fed. Reg. 51976 (emphases added). Those speculative and unsubstantiated assertions, however, fell far short of Congress's requirement that embryonic research can be conducted only if, in addition to not posing a non-minimal risk to the human embryo, "the purpose of the activity is the development of *important* biomedical knowledge *which cannot be obtained by other means*." 45 C.F.R. § 46.208(a)(2) (emphases added); Pub. L. No. 106-554, Omnibus Consolidated Appropriations Act of 2001, § 510.

On March 8, 2001, the *Nightlight* plaintiffs sued HHS to prevent implementation of the Clinton Administration's Rabb-influenced Guidelines for Research Involving Pluripotent Stem Cells,[6] because this interpretation flatly contradicted legislative history through 2000, and the original purpose for passing the Dickey-Wicker Amendment: to prevent destructive human embryo research.[7] Until 1994, a *de facto* federal ban on human embryo research existed.[8] The Clinton Administration took steps to reverse this ban, pursuant to the recommendation of an *ad*

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[6] *Nightlight Christian Adoptions et al. v. Tommy G. Thompson*, Civil Action No. 1.01CV00502-RCL, U.S. District Court, District of Columbia (March 8, 2001).

[7] *See* Appendix A. *See also* Samuel B. Casey and Nathan A. Adams, IV, *Specially Respecting the Living Human Embryo by Adhering to Standard Human Subject Experimentation Rules*. YALE J. HEALTH, POL'Y, L & ETHICS (forthcoming).

[8] Although federal funding for IVF research projects was permissible, it required the approval of an Ethical Advisory Board ("EAB"). 45 C.F.R. § 46.204(d), nullified by section 121(c) of the NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122, June 10, 1993. HHS declined to direct an EAB to perform any funding review of a proposed IVF research project until September 1978. That board concluded that certain funding was theoretically ethical, but NIH declined to take any action on this conclusion. In early-1993, the Clinton Administration proposed, and Congress subsequently passed, legislation intended to eliminate the EAB approval prerequisite, as well as the executive moratorium on fetal tissue research. Pub. L. No. 103-43.

*hoc* advisory committee, the Human Embryo Research Panel ("HERP"),[9] while still prohibiting the creation of embryos for research purposes.[10] In testimony before the House Appropriations Committee, NIH Director Varmus stated that he "firmly agree[d]" with several portions of the HERP report, and told the Committee that NIH was currently deciding whether to go forward with funding.[11]

Before NIH could approve any grants, Congress passed the Dickey-Wicker Amendment for the first time.[12] Opponents of the amendment objected to it on the grounds that it would foreclose action on the HERP report and "segregate [human embryo] research into private laboratories, which are not subject to any set scientific or ethical guidelines."[13] Sen. Boxer agreed that the Dickey-Wicker Amendment amounted to "a *total prohibition* of Federal funding for human embryo research."[14] That first year, the House Appropriations Committee rejected an alternative rider offered by Rep. John Porter (R-IL), which would have codified President Clinton's directive by prohibiting only the funding of the *creation* of embryos for research purposes.[15]

During the 1997 reauthorization cycle, the full House roundly rejected (167-256) an amendment identical to the Porter Amendment offered by Rep. Lowey (D-NY).[16] Again, the proponents and opponents of embryo research operated on the same premise; *i.e.*, that the Dickey-Wicker Amendment banned federal funding of *all* research dependent upon the

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9 NIH, Report of the Human Embryo Research Panel, Vol. I at 49 (1994) ("HERP Report"); *see also* id. at xvii, 2, 8, 26-27, 47, 49, 50, 76 (recommending federal funding for human embryonic stem cell research using "spare" embryos from IVF clinics).

10 30 Weekly Comp. Pres. Doc. 2459 (December 2, 1994)

11 Department of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 1996: Hearings Before a Subcomm. of the House Comm. on Appropriations, 104th Cong., 1st Sess. 139, 144 (1995); *see also* NIH, *Background Information on the Impact of the Human Embryo Research Amendment* at 2 (June 30, 1996) (NIH would have funded six out of nine applications for grants involving embryo-related research "if the NIH had been able to proceed according to the [Human Embryo Research Panel's] recommendations and the President's directive.")

12 H.R. Rep. No. 104-209, at 384 (emphasis added).

13 Id. at 385.

14 142 Cong. Rec. S429, S433 (1996) (emphasis added).

15 H.R. Rep. No. 104-209, at 213-14 (1995).

16 Id. at H7364; 142 Cong. Rec. H7339 (July 11, 1996).

destruction of an embryo.[17] Rep. Porter argued, for example, that repeal of the Dickey-Wicker Amendment was necessary, because federal funding of research "could also lead to breakthroughs *in the use of embryonic stem cells*."[18] No further attempts were made to modify the Dickey-Wicker Amendment until the 2001 reauthorization cycle.

In 2001, the House reauthorized the amendment without change, with a statement in the House report describing its action as consistent with the announced Bush Administration stem cell policy as articulated by President Bush on August 9, 2001.[19] Rep. McDermott and Sen. Arlen Specter proposed amendments permitting liberal embryonic stem cell research.[20] Both failed, with the Specter bill defeated due to the Bush Administration's public opposition.[21] The resulting Amendment is not a vindication of the Rabb memo's derivation-versus-use dichotomy. Nor is it a vindication of the limited protection that President Clinton, Reps. Lowey, Porter, and McDermott, and Sen. Specter offered (*i.e.*, prohibiting the funding merely of the *creation* of embryos for research purposes).

Rather, the resulting amendment is at most a vindication of the principles permitting research on already dead fetuses. President Bush refused to justify research on living human embryos based on the derivation-versus-use dichotomy; he authorized research only on embryos terminated before August 9, 2001, without creating federal incentives to kill more.

On January 14, 2002, without waiver of the right to re-file the case should circumstances change, the *Nighlight* case was voluntarily dismissed by the plaintiffs because the objectives of the injunctive relief action they had filed in federal court the prior March against the Department of Health & Human Services and the National Institutes of Health – enjoining destructive human embryo research – have been achieved by two actions taken by the Bush Administration: (1) the

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17 Id. at H7339-43.

18 Id. at H7340 (emphasis added).

19 The House report language states: "The committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President." H.R. REP. NO. 107-229, § 510 (2001).

20 H.R. 2059, 107th Cong. (2001) (killed in committee); S. 723, 107th Cong. (2001) (killed in committee); S. 1536, 107th Cong. § 510 (2001) (adding to the Dickey-Wicker Amendment part (c) "Federal dollars are permitted, at the discretion of the President, solely for the purpose of 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.")

21 Office of Management and Budget, Statement of Administration Policy (October 30, 2001), available on the web at www.whitehouse.gov/omb/legislative/sap/107-1/S1536-s.html.

President's action the prior week signing the 2002 Labor/HHS Appropriations Act (H.R. 3061) that continues the complete federal funding ban on destructive human embryo research; and (2) the action of the HHS General Counsel on January 11, 2002 issuing his legal memorandum to NIH confirming that HHS and NIH will now properly interpret the law to completely ban any federal funding for destructive human embryo research.[22]

Since that time federal law and policy has firmly prohibited the federal funding of destructive human embryonic stem cell research. In President Bush's words when he signed the 2002 Labor/HHS Appropriations Act (H.R. 3061:

> "*I am pleased that the final version of the [Labor/HHS Appropriations] bill retains the prohibition against research in which human embryos are destroyed, and reinforces my determination on August 9, 2001, to support federally funded stem cell research in an ethical manner."*

According to the HHS General Counsel's January 11, 2002 legal opinion supporting the President's action:

> *"Under the President's policy, federal funding for human embryonic stem cell research is limited to a discrete set of stem cells with respect to which the life and death decision had been made prior to the announcement of his policy. The President's policy provides no incentives for the destruction of additional embryos….So limited, the President's policy does not provide federal funding for research in which (during the course of, during or part of the act or process of, or within the category of class of] embryos are destroyed, discarded, or knowingly subjected to risk of injury or death….within the ordinary, common usage of those terms. The policy is, thus, consistent with the second restriction of the [2002 Labor/HHS Appropriations Act].*

Viewed in this perspective, the proposed Guidelines violate the intent of federal funding ban because by their terms they are not "*limited* to a discrete set of stem cells with respect to which the life and death decision had been made *prior* to the announcement [of their new] policy and they *do* "provide incentives for the destruction of additional embryos" in the form of federal research dollars. Indeed, the proposed Guidelines detailed protocol for how to regulate the

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[22] The lawsuit dismissed in 2002 was originally commenced by a group of plaintiffs, including the Nightlight Christian Adoption Agency that (through its "Snowflakes" program, www.snowflakes.org) successfully arranges for infertile couples to adopt human embryos stored at *in vitro* fertilization clinics; the Christian Medical Association (www.cmdahome.org), a national association of doctors ethically opposed to the destructive human experimentation on human embryos, several couples who desire to adopt human embryos; and Dr. David Prentice, a researcher specializing in research using stem cells derived from adults without the loss of human life.

consent process and obtain embryos for destruction is best described as the initial phase of a larger research project which will receive funds from the federal government and must be viewed as a blatant attempt to violate the existing federal law set forth in the federal funding ban and for the first time illegally authorize the use of federal funds in the precise case prohibited by the federal funding ban, that is "research in which" human embryos are "harmed, destroyed or subjected to risks" not permitted for unborn children in the womb.

Indeed, interpreting paragraph (2) of the federal funding ban to cover only the act of destruction itself would violate two principles of statutory construction applicable to the federal funding ban.

*First*, a statute must be construed to avoid rendering any of its word superfluous. *Walters v. Metropolitan Educational Enterprises*, 519 U.S. 202, 209-210 (1997); *United States v. Menasche*, 348 U.S. 528, 538-539 (1955). While the NIH in the proposed Guidelines acknowledges the existence of federal funding ban, it fails to give any legal basis for the proposed Guidelines other than the Executive Order that merely instructs it to "support and conduct responsible scientifically worth human stem research…to the extent permitted by law." Nonetheless, the unspoken interpretation apparently used by the NIH in the proposed Guidelines would render the words in paragraph (2) of the federal funding ban "research in which" superfluous.

*Second,* when Congress chooses different language in proximate subsections of the same statute – one narrow, the other broad – the statute must be construed to give effect to those differences. *Russello v. United States*, 464 U.S. 16, 23 (1983) and cases cites therein. Thus, NIH is correct when it says that the federal funding ban in the Dickey-Wicker Amendment prohibits "NIH funding of the derivation of stem cells from human embryos." Guidelines, IV.A., 74 Fed. Reg. at 18580. But its proposed Guidelines violate the federal funding ban by failing to acknowledge that it prohibits more than that, and also prescribes "research in which" human embryos are "harmed, destroyed or subjected to risks" not permitted for unborn children in the womb.

**U.S. Department of Justice**

Civil Division

*Office of the Assistant Attorney General* *Washington, D.C. 20530*

## APPENDIX F

### HHS General Counsel Memorandum, January 11, 2002
### Alex M. Azar II to Dr. Ruth Kirchstein, Acting Director, NIH

January 11, 2002

Via Facsimile

Thomas G. Hungar, Esq.
Gibson, Dunn & Crutcher, LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036

Re: Nightlight Christian Adoption, et al., Civil No. 01-0502 (RCL) (DDC)

Dear Mr. Hungar:

On November 7, 2001, Defendants in the above-referenced case gave notice that they had completed their review of the National Institutes of Health ("NIH") Guidelines for Research using Human Pluripotent Stem Cells, 65 Fed. Reg. 51976 (Aug. 25, 2000) ("Guidelines"), which review had resulted in withdrawal of those Guidelines and issuance of a Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry announcing new criteria that must be met to allow Federal funds to be used for research on human embryonic stem cell lines.

As you know, NIH plans soon to initiate federal funding of research on existing human embryonic stem cells in accordance with the policy announced by the President on August 9, 2001. For your information, please find enclosed a Memorandum dated January 11, 2002 from Alex M. Azar II, General Counsel at the Department of Health & Human Services, to Dr. Ruth Kirchstein, Acting Director of NIH, concluding that the President's policy with respect to embryonic stem cell research comports with the so-called Dickey Amendment.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

/s/ *Robert D. McCallum, Jr.*

Robert D. McCallum, Jr.
Assistant Attorney General

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

January 11, 2002

MEMORANDUM

TO: Dr. Ruth Kirchstein
Acting Director, National Institutes of Health

FROM Alex M. Azar II
General Counsel

SUBJECT: Compliance of the President's Embryonic Stem Cell Decision with the Dickey Amendment for Fiscal Year 2002

The National Institutes of Health plan soon to initiate federal funding of research on existing human embryonic stems cells in accordance with the policy announced by the President on August 9, 2001. Prior to the initiation of such funding, you have asked the Office of the General Counsel to provide advice on the legality of the President's policy under the Dickey Amendment to Public Law Number 107-116 (signed Jan. 10, 2002), the appropriations act funding the Department of Health & Human Services (the "Department") for fiscal year 2002.

It is our conclusion that the President's policy comports with the plain language of the Dickey Amendment. This reading is further buttressed by Congress's recent reenactment of the Dickey Amendment and, hence, ratification of the President's policy and by the legislative history accompanying the most recent reenactment of the Dickey Amendment.

**The President's Policy**

On August 9, 2001 at 9:00 p.m. EDT, President George W. Bush announced his decision to allow federal funds to be used for research on existing human embryonic stem cell lines as long as, prior to his announcement, (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated, and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being.

As the President noted, "the life and death decision ha[d] already been made" with respect to those "existing human embryonic stem cell lines." This decision, as the President stated, "allows us to explore the promise and potential of stem cell research without crossing a fundamental

moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life." Remarks by the President on Stem Cell Research, Aug. 9, 2001, http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html.

The President established the following additional criteria that had to be met for embryonic stem cell research to receive federal funding: (1) the stem cells must have been derived from an embryo that was created for reproductive purposes; (2) the embryo was no longer needed for such purposes; (3) informed consent must have been obtained for the donation of the embryo; and (4) no financial inducements were provided for donation of the embryo. Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry, Nov. 7, 2001, NOT-OD-02-005, Office of the Director, NIH, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html; NIH Human Embryonic Stem Cell Registry, http://escr.nih.gov. Pursuant to the President's policy, federal funds will not be used for (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose. Fact Sheet, Embryonic Stem Cell Research, Aug. 9, 2001, http://www.whitehouse.gov/news/release/2001/08/print/20010809-1.html.

Pursuant to the President's policy, on August 27, 2001, Secretary Thompson announced the creation of a registry of the embryonic stem cell lines meeting the President's eligibility criteria, such that research on stem cell lines listed on the Registry would be eligible for federal funding. He stated that:

> [t]he NIH wants to expedite this work and is aggressively pursuing several initiatives to facilitate research on all forms of stem cells. The NIH is creating a registry of the embryonic stem cell lines that meet the eligibility criteria so that researchers can contact the owners and gain access to them. The registry will contain basic information about the cells, a unique identifier, the name of the company or laboratory that derived the cells, and contact information about that company or lab. The registry will list these 10 laboratories as well as any other owners of stem cell lines meeting the eligibility criteria who come forward in the future.

Statement by Tommy G. Thompson, Secretary of Health & Human Services, Aug. 27, 2001, http://www.hhs.gov/new/press/2001pres/20010827a.html; *see also* Tommy G. Thompson, Secretary of Health & Human Services, Testimony before the Senate Committee on Health, Education, Labor & Pensions, Sept. 5, 2001, at 4 (discussing NIH's development of "a stem cell registry" and the intent to "mak[e] it available so scientists know exactly what lines are eligible and who they can approach for access" and to post the registry on the NIH website),

http://www.hhs.gov/news/speech/2001/010905.html.

In an NIH Update, the NIH noted that the laboratories or companies that derived the cells listed on the registry that it was creating would provide "a signed assurance that the derivation process

was initiated prior to 9:00 p.m. EDT on August 9, 2001, informed consent was obtained for the donation of the embryo, the cells were derived from an excess embryo that was created for reproductive purposes, and there were no financial inducements for the donation of the embryo for research." NIH Update on Existing Human Embryonic Stem Cells, Aug. 27, 2001, at 2-3, http://www/nih.gov/news/stemcell/082701list.html. Shortly thereafter, the NIH entered into a memorandum of understanding with one of the entities that possesses such embryonic stem cell lines, to permit access to those lines by NIH scientists to conduct research and to permit scientists pursuing research funded by the NIH to negotiate access to those lines under the same terms and conditions. *See* NIH Press Release, National Institutes of Health and WiCell Research Institute, Inc. Sign Stem Cell Research Agreement, Sept. 5, 2001, http://www.nih.gov/news/pr/sep2001/od-05.html; Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service, US Department of Health & Human Services, effective as of Sept. 5, 2001, http://www.nih.gov/news/stemcell/WicellMOU.pdf; *see also* Tommy G. Thompson, Secretary of Health & Human Services, Testimony before the Senate Committee on Health, Education, Labor & Pensions, Sept. 5, 2001, at 4 (announcing negotiation of the memorandum of understanding permitting research use of WiCell's "five existing stem cell lines that meet the eligibility criteria"), http://www.hhs.gov/news/speech/2001/010905.html.

On November 7, 2001, the NIH posted the Registry of embryonic stem cell lines that comply with the President's policy as announced on August 9, 2001. *See* NIH Human Embryonic Stem Cell Registry, http://escr.nih.gov; Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry, Nov. 7, 2001, NOT-OD-02-005, Office of the Director, NIH, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.

**The Dickey Amendment**

In construing the meaning of a statute, the starting point of the analysis is the language of the statute. *See, e.g., Central Bank of Denver NA v. First Interstate Bank of Denver NA*, 511 U.S. 164, 173 (1994) (the statutory language is "'the starting point in every case involving construction of a statute'"); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 409 (1993) ("The starting point in interpreting a statute is its language, for '[i]f the intent of Congress is clear, that is the end of the matter.'"); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 197 (1976) ("'The starting point in every case involving construction of a statute is the language itself.'"); *Kaiser Aluminum & Chem. Corp. v. Bonjorno*, 494 U.S. 827, 834-44 (1990) (same); *Meredith v. Federal Mine Safety & Health Review Comm'n*, 177 F.3d 1042, 1053 (D.C. Cir. 1999) ("As always, the starting point of analysis is the text of the statute.").

Since 1995, the Dickey Amendment has been enacted in each of the annual appropriations acts for the Department. For fiscal year 2002, the Amendment provides:

> (a) None of the funds made available in 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 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
>
> (b) For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Pub. L. No. 107-116 § 510. This language is unchanged from the fiscal year 2001 Dickey Amendment.

The President's policy is consistent with the plain language of the Dickey Amendment. The Dickey Amendment contains two basic restrictions. The first prohibits the use of federal funds for "the creation of a human embryo or embryos for research purposes." *See* Pub. L. No. 107-116, § 510(a)(1). It is clear that, under the President's policy, no federal funds will be used for the creation of human embryos for research purposes. *See* Fact Sheet, Embryonic Stem Cell Research, Aug. 9, 2001, http://www.whitehouse.gov/news/release/2001/08/print/20010809-1.html (federal funds will not be used for "creation of any human embryos for research purposes"). Thus, the President's policy comports with the first restriction contained in the Dickey Amendment.

The second restriction of the Dickey Amendment prohibits the use of federal funds for "*research in which* a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . . ." H.R. 3061, § 510(a)(2) (emphasis added). The term "research in which" is not defined in the statute, and our research has not located any cases in which such a term is defined. As such, it is appropriate to look to ordinary and common usage when interpreting those terms. *See FDIC v. Meyer*, 510 U.S. 471, 476 (1994) ("In the absence of such a definition [in the act], we construe a statutory term in accordance with its ordinary or natural meaning."). The word "which," when "[u]sed as a relative pronoun preceded by *that* or a preposition in a clause that defines or restricts the antecedent" means "[t]he thing, animal, group of people, or event previously designated or implied, specifically." *See* The American Heritage Dictionary, New College Edition 1459 (1976). Dictionaries define "in" as meaning "within the confines of; inside"; "within the area covered by"; "during the course of or before the expiration of"; "during or part of the act or process of"; "within the category or class of." *See id*. at 663; *see also* Black's Law Dictionary 683 (5th ed. 1979) (a preposition "expressing relation of presence, existence, situation, inclusion, action, etc.; inclosed or surrounded by limits . . .; also meaning for, in and about, on, within etc.; and is synonymous with expressions 'in regard to', 'respecting', 'with respect to', and 'as is'"). Under the President's policy, federal funding for human embryonic stem cell research is limited to a discrete set of stem cell lines with respect to which the life and death decision had been made prior to the announcement of his policy. The President's policy provides no incentives for the destruction of additional embryos. Moreover, these derivation processes were not funded

with federal dollars. So limited, the President's policy does not provide federal funding for "research in which [during the course of, during or part of the act or process of, or within the category or class of] embryos are destroyed, discarded, or knowingly subject to risk of injury or death greater than that allowed for research on fetuses in utero" within the ordinary, common usage of those terms. The policy is, thus, consistent with the second restriction of the Dickey Amendment.

**Congressional Ratification of the Legality of the President's Policy**

This plain meaning reading of the Dickey Amendment is bolstered by Congress's reenactment of the Dickey Amendment in identical form after the President's announcement on August 9, 2001. As discussed below, Congress was fully aware of the President's policy decision and the Secretary's steps in implementing that decision. With that knowledge, Congress reenacted the Dickey Amendment in identical form, clearly evidencing its concurrence that the President's policy is consistent with the Dickey Amendment. *See Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."); *Central Bank of Denver*, 511 U.S. at 185-86 ("When Congress reenacts statutory language that has been given a consistent judicial construction, we often adhere to that construction in interpreting the reenacted statutory language."); *Pierce v. Underwood*, 487 U.S. 552, 567 (1988) (same); *City of Pleasant Grove v. United States*, 479 U.S. 462, 468 (1987) ("Congress was aware of the Attorney General's view . . . and implicitly approved it, when it reenacted the Voting Rights Act . . . ."); *San Huan New Materials High Tech, Inc. v. International Trade Comm'n*, 161 F.3d 1347, 1355 (Fed. Cir. 1998) ("The legislative history shows that Congress was fully aware of the agency regulations and practices [regarding consent decrees] at the time of legislating in their area, and absent some special circumstances the failure to change or refer to existing practices is reasonably viewed as ratification thereof.").

**Legislative History of the Dickey Amendment Contained in Pub. L. No. 107-116**

The legislative history of the current reenactment of the Dickey Amendment in the appropriations act providing funding for Department for fiscal year 2002 further confirms that Congress understood the contours of the President's policy and believed that the policy complies with the requirements of the Dickey Amendment.

The Committee Report on H.R. 3061, the House version of the Act, published exactly two months after the President's announcement states:

> *Human Stem Cell Research*- The Committee received testimony from NIH institute and center directors, representatives of scientific and medical societies, and members of voluntary health organizations about the potential of both adult and embryonic stem cells for improving the lives of those who suffer with a host of disorders, including diabetes, Alzheimer's, Parkinson's, and cardiovascular disease. The Committee understands that a great deal of basic research is required to determine whether this potential can be realized.

> *It is the Committee's intent, that the NIH move ahead expeditiously to implement the President's policy concerning support of scientifically meritorious research involving both adult and human embryonic stem cells.* The Committee commends the NIH for moving quickly to negotiate material transfer agreements *with holders of existing embryonoc [sic] cell lines.* The Director is requested to keep the Committee apprised of program initiatives as well as research progress concerning both adult and embryonic stem cells.

H.R. Rep. 107-229, at 98 (Oct. 9, 2001) (emphases added). In addition, the Committee noted in connection with section 510, the Dickey Amendment, the following:

> Sec. 510. The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, *this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President.*

H.R. Rep. 107-229, at 180 (Oct. 9, 2001) (emphasis added). The Joint Explanatory Statement of the Committee of Conference directed that "in implementing this agreement [on appropriations], the Departments and agencies should comply with the language and instructions set forth in House Report 107-229 and Senate Report 107-84." *See* Joint Explanatory Statement of the Committee of Conference, H.R. Rep. 107-342, Conference Report on H.R. 3061, at 55 (Dec. 19, 2001). Thus, it would be appropriate to accord to H.R. Rep. 107-229 the weight customarily given to conference committee explanatory statements. *See Northern Colorado Water Conservancy Dist. v. Federal Energy Regulatory Comm'n*, 730 F.2d 1509, 1518-19 (D.C. Cir. 1984) ("Statements in a conference report, because commended to the entire Congress, carry greater weight than comments from floor debates by individual legislators."); *Vitrano v. Marshall*, 504 F. Supp. 1381, 1383 (D.D.C. 1981) ("Perhaps the most useful document illuminating Congressional purpose is a Conference Report which bears on the final draft that is used by the conferees in explaining to the entire Congress why the bill should pass.")

As a whole, this legislative history expresses the Congress's support for the President's policy and unambiguously confirms that the President's decision is consistent with the Dickey Amendment. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 209 (1994) ("The legislative history of the Mine Act confirms this interpretation."); *see also San Huan New Materials*, 161 F.3d at 1355 ("The legislative history leaves no doubt that Congress was aware of, and approved of, the Commission's consent order procedure as it existed at the time of the 1988 amendments.").

In sum, whatever legal challenges might be brought, the President's policy is consistent with the Dickey Amendment as evidenced by the plain language of the statute, Congress's reenactment ratification of the President's policy, and the legislative history reflecting Congress's full understanding of the precise contours of the President's policy and that policy's compliance with the Dickey Amendment.

As we move forward with implementation of the President's decision, it should be noted that federal funding of research in the following areas remains barred: (1) the derivation of new stem cells from human embryos; (2) research in which human embryonic stem cells are used to create or contribute to a human embryo; (3) research in which human embryonic stem cells are derived, using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (4) research using human embryonic stem cells that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (5) research in which human embryonic stem cells are combined with an animal embryo; and (6) research in which human embryonic stem cells are used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human. *See* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, Part III ("Areas of Research Involving Human Pluripotent Stem Cells that are Ineligible for NIH Funding", listing the above categories of research), 65 FR 51976 (effective Aug. 25, 2000), corrected, 65 FR 69951 (Nov. 21, 2000), www.nih.gov/news/stemcell/stemcellguidelines.html, withdrawn as to those sections pertaining to research involving human pluripotent stem cells derived from human embryos that are the result of in vitro fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed, Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells, Nov. 7, 2001, NOT-OD-02-007, Office of the Director,

NIH, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-007.html; NIH Office of Extramural Research, Implementation Issues for Human Embryonic Stem Cell Research Frequently Asked Questions, Nov. 16, 2001, http://grants.nih.gov/grants/stem_cell_faqs.html.

## APPENDIX G

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

# Adult Stem Cell Research

**By: David A. Prentice, Ph.D.**

Only adult stem cells—not embryonic stem cells—have shown any successes in therapeutic applications. A wealth of published scientific papers document that adult stem cells are a much more promising source of stem cells for regenerative medicine. Some adult stem cells actually do show pluripotent flexibility in generation of tissues, meaning that they can generate most or all of the different tissues of the body. In 2001, researchers found that *one* adult bone marrow stem cell could form not only marrow and blood, but also form liver, lung, digestive tract, skin, heart, muscle.[1] Other researchers have found pluripotent ability of adult stem cells from various sources, including bone marrow,[2,3,4] peripheral blood,[5] inner ear,[6] umbilical cord blood,[7,8] nasal mucosa,[9] amniotic fluid,[10,11] and placental amniotic membrane.[12]

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Indeed, a report from researchers at Wake Forest[11] that amniotic fluid and placenta contains stem cells that can be easily harvested, show extended growth in culture, show similar flexibility to form other tissues of the body, and can be transplanted without tumors, emphasizes the range of abilities that adult and tissue stem cells have without the negatives associated with embryonic stem cells. Furthermore, testicular biopsies have shown that animal and human pluripotent stem cells can be obtained from this tissue source.[13,14,15]

The true test of the usefulness of any stem cell is not its pluripotency, but rather its ability for use in regenerative medicine, repairing damaged and diseased tissue and improving health. Pre-clinical results provide voluminous evidence that adult stem cells are effective in treating animal models of disease, including examples such as diabetes,[16] stroke,[17] spinal cord injury,[18] Parkinson's disease,[19] retinal degeneration,[20] ALS,[21] and cardiac damage.[22]

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More importantly, adult stem cells are already being used clinically to treat many diseases in human patients. While it is true that bone marrow transplants have been used successfully in patients since the 1960's and the first successful cord blood transplant was in 1988,[23] the human bone marrow stem cell was not actually isolated until 1992.[24] Thus, it is only in recent times that a real focus on adult stem cells as a separate cell type and not an unidentified entity or phenomenon within a tissue has been possible. Given this recent development makes it all the more amazing that clinical applications have moved ahead as rapidly as they have done so. There has also been a bias against adult stem cells as a reparative stem cell with multipotent capabilities. This is exemplified in a statement from the National Institutes of Health in its 2001 review of stem cell science:

> It was not until recently that anyone seriously considered the possibility that stem cells in adult tissues could generate the specialized cell types of another type of tissue from which they normally reside—either a tissue derived from the same embryonic germ layer or from a different germ layer.[25]

A search of clinicaltrials.gov shows well over 2,000 clinical trials currently with adult stem cells, and the number grows weekly. The published successful results with patients continue to pour forth with increasing frequency. Early successes and many of the continuing results use adult stem cells, most often from bone marrow or umbilical cord blood, in conjunction with chemotherapy or radiation, in treatments for various cancers, including ovarian cancer,[26] retinoblastoma,[27] amyloidosis,[28] brain tumors,[29] Merkel cell carcinoma,[30] mantle cell

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lymphoma,[31] testicular cancer,[32] various lymphomas including Hodgkin's lymphoma[33] and Non-Hodgkin's lymphoma,[34] chronic[35] and acute[36] leukemias, breast cancer,[37] renal cell carcinoma,[38] and numerous other cancers (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). Similar methodology has utilized adult stem cells in treatments for various anemias, including sickle cell anemia[39] and Fanconi's anemia[40] (for a

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representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). In the last decade, this technique has also been used successfully to treat patients with various autoimmune diseases, including multiple sclerosis,[41] systemic lupus,[42] Crohn's disease,[43] rheumatoid arthritis,[44] and juvenile (Type I) diabetes[45] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). Various immunodeficiencies including SCID have been treated successfully as well[46] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). Adult stem cells have also shown success in protocols to ameliorate the effects of various genetic metabolic disorders such as Hurler's syndrome,[47] Krabbe's leukodystrophy,[48] and other genetic disorders (for a representative list of

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references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf ). These life-saving treatments continue to improve and to increase with further federally-funded clinical trials.

The utility of adult stem cells to save lives and improve health is not, however, limited to use as an adjunct or rescue technique to chemotherapy. Published patient results have also shown their abilities for repair of acute and chronic cardiac damage[49] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf ). Adult stem cells have also been used to grow new corneas to restore sight to blind patients[50] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf ). Successful results have also been obtained for treatment of limb ischemia and wounds[51] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). Early, ongoing trials have shown evidence of successful amelioration of the effects of stroke[52] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). Early results with adult stem cells show effectiveness at treating liver disease[53] (for a representative list of references, please see: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 and http://stemcellresearch.org/facts/asc-refs.pdf). An early clinical trial has shown effectiveness of

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the patient's own adult stem cells at treating Parkinson's disease.[54] Several reports now document clinical improvement using adult stem cells for treatment of spinal cord injury.[55]

Adult stem cells have also already shown their utility in tissue engineering applications to treat patients, including growth of functional bladders[56] and a published case of a new windpipe.[57]

Adult stem cells have distinct advantages over other stem cell types. In most cases the patient's own stem cells can be used for the treatment, circumventing problems of immune rejection. Adult stem cells do not have the problem of tumor formation that is associated with embryonic stem cells. Adult stem cells also show a homing ability to damaged tissue, allowing development of minimally invasive administration techniques.

The citations given above for adult stem cells are only a sampling. Adult stem cells already show ability to deliver therapeutic benefit to countless patients suffering from a wide array of diseases, and the greatest possible resources should be devoted to improving current adult stem cell therapies and developing the full promise of these useful cells.

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## APPENDIX H

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

# Human Induced Pluripotent Stem Cell Research

**By: David A. Prentice, Ph.D.**

Induced pluripotent stem (iPS) cells provide a relatively easy method for creation of embryonic stem cells (ESC) directly from virtually any tissue source or individual. These cells were first developed in 2006 in mice by the Japanese scientist Shinya Yamanka.[1] Several groups have now verified the ability to produce embryonic-like iPS cells from mice.[2] In November 2007, Yamanaka's lab and the lab of Thomson in the U.S. showed that this same technique could work for human cells as well, easily producing human iPS cells directly from human tissue.[3] The straightforward technique involves "reprogramming" the genetic expression of a cell, similar to reprogramming a computer to run a different program. The technique essentially reverses the developmental clock of the cell, inducing it to behave as if it was an ESC. The original Yamanaka reprogramming technique involved adding four genes directly to a human cell such as a fibroblast (e.g., skin) cell, with the genes added using a viral vector. While there was initial concern over possible cancers because at least one of the genes used (c-*Myc*, which is an oncogene) and because the original viral vector (retroviruses) have cancer-causing potential, subsequent work has shown that reprogramming can proceed without the need for c-*Myc*,[4] the number of genes necessary for reprogramming has been reduced, sometimes by combining the

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genetic signal with chemical compounds,[5] safer viral vectors have been developed,[6] as well as vectors that do not require viruses.[7] Additional work has also demonstrated the ability to completely remove any residual genetic sequences that were added to reprogram the iPS cells.[8] Reprogramming of iPS cells has now been accomplished completely without the use of added DNA sequences, by using added protein reprogramming factors.[9]

Using numerous tests, the characteristics of iPS cells have been shown to be virtually indistinguishable from ESC. For example, the telomeres of iPS cells acquire the same characteristics as those found in ESC.[10] Thomson's group in their first paper showing production of human iPS cells noted:

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[5] Kim JB *et al.*, Pluripotent stem cells induced **from adult neural stem cells** by reprogramming **with two factors**, *Nature* 454, 646-650, 31 July 2008; published online 29 June 2008; Eminli S *et al.*, Reprogramming of **neural progenitor cells** into induced pluripotent stem cells in the **absence of exogenous Sox2** expression, *Stem Cells* 26, 2467-2474, October 2008; published online 17 July 2008; Huangfu D *et al.*, Induction of pluripotent stem cells from primary **human** fibroblasts with **only *Oct4* and *Sox2***, *Nature Biotechnology* 26, 1269-1275, published online 12 October 2008; Shi Y *et al.*, Induction of pluripotent stem cells from mouse embryonic fibroblasts by **Oct4 and Klf4 with small-molecule compounds**, *Cell Stem Cell* 3, 568-574, 6 November 2008

[6] Stadtfeld M *et al.*, Induced pluripotent stem cells generated **without viral integration**, *Science* 322, 945-949, 7 November 2008; published online 25 Sept 2008; Sommer CA *et al.*, iPS Cell Generation **Using a Single Lentiviral Stem Cell Cassette**, *Stem Cells* 27, 543-549, March 2009; Chang C-W *et al.*, Polycistronic Lentiviral Vector For **Hit and Run Reprogramming** Of Adult Skin Fibroblasts To Induced Pluripotent Stem Cells, *Stem Cells* 27, 1042-1049, May 2009, published online 12 February 2009

[7] Okita K *et al.*, Generation of mouse induced pluripotent stem cells **without viral vectors**, *Science* 322, 949-953, 7 November 2008

[8] Kaji K *et al.*, **Virus-free induction of pluripotency** and **subsequent excision of reprogramming factors**, *Nature* 458, 771-775, 9 April 2009, published online 1 March 2009; Woltjen K *et al.*, **piggyBac** transposition **reprograms fibroblasts to induced pluripotent stem cells**, *Nature* 458, 766-770, 9 April 2009, published online 1 March 2009; Yu J *et al.*, **Human** induced pluripotent stem cells **free of vector and transgene sequences**, *Science* 324, 797-801, 8 May 2009, published online 26 March 2009; Yusa K *et al.*, **Generation of transgene-free** induced pluripotent mouse stem cells by the *piggyBac* transposon, *Nature Methods* published online 31 March 2009

[9] Zhou H *et al.*, Generation of Induced Pluripotent Stem Cells **Using Recombinant Proteins**, *Cell Stem Cell* 4, 381-384, 8 May 2009, published online 23 April 2009

[10] Marion RM *et al.*, **Telomeres acquire embryonic stem cell characteristics in induced pluripotent stem cells**, *Cell Stem Cell* 4, 141-154, 6 February 2009

> The human iPS cells described here meet the defining criteria we originally proposed for human ES cells, with the significant exception that the iPS cells are not derived from embryos.[11]

Hearing of the impending announcement of the first human iPS cells, Prof. Ian Wilmut, cloner of Dolly the sheep, publicly forsook cloning technology to work on the new iPS cell technology.[12] Wilmut has noted that "the technique of cloning is no longer applicable;" "The de-differentiation of somatic cells didn't require the use of human embryos as, technically speaking, it wasn't necessary. The first iPS cells were produced and identified through studies on mouse embryos;" "The iPS technique to obtain stem cells is now the most efficient technique for researchers, in particular for research on inherited diseases;" and "iPS cells are more useful than embryonic cells."[13]

The iPS cells from mice have already been used in proof-of-principle experiments to ameliorate disease in mouse models of sickle cell anemia,[14] Parkinson's disease,[15] and murine hemophilia.[16]

iPS cells can be created from virtually any cell type. Besides common fibroblast cells, human iPS cells have been generated from plucked human hair[17] and from human blood cells.[18]

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[11] Yu J *et al.*, Induced pluripotent stem cell lines derived **from human somatic cells**, *Science* 318, 1917-1920, 21 December 2007, published online 20 November 2007

[12] Roger Highfield, Dolly creator Prof Ian Wilmut shuns cloning, The Telegraph, November 16, 2007

[13] "Interview du professeur Ian WILMUT par Gènéthique", accessed at: http://www.genethique.org/tribunes_mensuelles/mai_2009.asp ; for English translation, see: http://ethicalstemcellresearch.blogspot.com/2009/05/read-this-wilmut-king-of-cloning-says.html

[14] Hanna J *et al.*, **Treatment of sickle cell anemia mouse model** with iPS cells generated from autologous skin, *Science* 318, 1920-1923, 21 December 2007

[15] Wernig M *et al.*, Neurons derived from reprogrammed fibroblasts functionally integrate into the fetal brain and **improve symptoms of rats with Parkinson's disease**, *Proc. Natl. Acad. Sci. USA* 105, 5856-5861, 15 April 2008

[16] Xu D *et al.*, Phenotypic **correction of murine hemophilia A** using an iPS cell-based therapy, *Proc. Natl. Acad. Sci. USA* 106, 808-813, 20 January 2009

[17] Aasen T *et al.*, **Efficient and rapid generation** of induced pluripotent stem cells **from human keratinocytes,** *Nature Biotechnology* 26, 1276-1284, November 2008; published online 17 October 2008

[18] Loh Y-H *et al.*, Generation of induced pluripotent stem cells **from human blood**, *Blood* published online 18 March 2009, doi: 10.1182/blood-2009-02-204800

The iPS cells have succeeded where cloning had previously failed.[19] Discussing this real advance with iPS cells in mice, the researchers noted:

> This demonstrates that IPS cells have the same potential for therapy as embryonic stem cells, without the ethical and practical issues raised in creating embryonic stem cells," says Jaenisch.[20]

Additionally:

> Townes says he and Jaenisch initially collaborated on a project that used nuclear transfer to make corrected stem cells, a process called therapeutic cloning. But the experiments failed, he says, because nuclear transfer was too inefficient to produce the needed cells. The iPS cell technique "is amazingly efficient," he says.[21]

Thus, iPS cells fulfill the desire to create embryonic-type stem cells, with the potential for transplant match, but do so without the use of embryos, eggs, or cloning.

Due to the ease of preparation, numerous human iPS cell lines have already been created. Within one year after announcement of the first human iPS cell lines, at least 315 human iPS cell lines had been generated, and over 500 total human iPS cell lines have been reported. In addition, iPS cell lines from patients suffering from various diseases have been created, covering 13 different diseases. See Table 1 at the end.

In summary, iPS cells provide all of the characteristics of pluripotent ESC, and also distinct advantages in terms of their ethical creation as well as ease and cost of creation, and production directly from patients.

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[19] Hanna J *et al.*, **Treatment of sickle cell anemia mouse model** with iPS cells generated from autologous skin, *Science* 318, 1920-1923, 21 December 2007, online 6 Dec 2007

[20] Reprogrammed adult cells treat sickle-cell anemia in mice, published 14:10 EST, December 06, 2007, http://physorg.com/news116172622.html

[21] Gretchen Vogel, Reprogrammed Skin Cells Strut Their Stuff, ScienceNOW Daily News, 6 December 2007

**TABLE 1. HUMAN INDUCED PLURIPOTENT STEM (iPS) CELL LINES**

| | Publications—Human iPS Cell Lines | Detailed Lines | Total Lines | Additional Information |
|---|---|---|---|---|
| 1 | Takahashi K *et al. (Yamanaka)*, *Cell* 131, 861-872 published online 20 November 2007 | 3 | 32 | |
| 2 | Yu J *et al.(Thomson)*, *Science* 318, 1917-1920 published online 20 November 2007 | 8 | 62 | |
| 3 | Nakagawa M *et al.*, *Nature Biotechnology* 26, 101-106 published online 30 November 2007 | 7 | 7 | |
| 4 | Park I-H *et al.*, *Nature* 451, 141-147 published online 23 December 2007 | 15 | 15 | |
| 5 | Lowry WE *et al.*, *Proc. Natl. Acad. Sci. USA* 105, 2883-2888 published online 16 February 2008 | 7 | 30 | |
| 6 | Liao J *et al.*, *Cell Research* 18, 600-603 published May 2008 | 1 | 1 | Paper indicates large number of colonies |
| 7 | Mali P *et al., Stem Cells* 26, 1998-2005 published online 29 May 2008 | 15 | 15 | possibly more lines |
| 8 | Park I-H *et al., Nature Protocols* 3, 1180-1186 published online 26 June 2008 | | | protocol for lines as developed in #4 above |
| 9 | Dimos JT *et al.*, *Science* 321, 1218-1221 published online 31 July 2008 | 3 | 8 | **ALS disease-specific lines** |
| 10 | Park I-H *et al.*, *Cell* 134, 877-886 published online 7 August 2008 | 22 | 22 | **21 disease-specific lines, 10 diseases**: ADA-SCID, Gaucher, Duchenne MD, Becker MD, Down's, Parkinson's, Type I Diabetes, Shwachman-Bodian-Diamond, Huntington's, Lesch-Nyhan |
| 11 | Tateishi K *et al.*, *J. Biological Chemistry* 283, 31601-31607 published online 9 Sept 2008 | 9 | 9 | made insulin-secreting islet clusters |

| | | | | |
|---|---|---|---|---|
| 12 | Maherali N *et al.*, *Cell Stem Cell* 3, 340-345<br>11 Sept 2008 | 15 | 15 | possibly more lines |
| 13 | Hockemeyer D *et al.*, *Cell Stem Cell* 3, 346-353<br>11 Sept 2008 | 8 | 8 | |
| 14 | Huangfu D *et al.*, *Nature Biotechnology* 26, 1269-1275<br>published online 12 October 2008 | 9 | 34 | |
| 15 | Aasen T *et al.*, *Nature Biotechnology* 26, 1276-1284<br>published online 17 October 2008 | 8 | 31 | |
| 16 | Zhao Y *et al.*, *Cell Stem Cell* 3, 475-479<br>6 November 2008 | 26 | 26 | possibly more lines |
| | **>>>--<u>One year, at least 315 lines</u>--<<<** | | | |
| 17 | Ebert AD *et al.*, *Nature* 457, 277-280<br>published online 21 December 2008 | 3 | 3 | 2 lines--**Spinal Muscular Atrophy** |
| 18 | Choi K-D *et al.*, *Stem Cells* 27, 559-567<br>published online 8 January 2009 | 3 | 3 | Hematopoietic and Endothelial Differentiation |
| 19 | Li W *et al.*, *Cell Stem Cell* 4, 16-19<br>9 January 2009 | 4 | 4 | possibly more lines |
| 20 | Park TS *et al.*, *Stem Cells* 27, 783-795<br>published online 22 January 2009 | | | used 2 lines from #5 above, Derivation of Primordial Germ Cells |
| 21 | Zhang J *et al.*, *Circulation Research* 104, e30-e41<br>published online 12 February 2009 | | | used lines from #2 above, Functional Cardiomyocytes |
| 22 | Karumbayaram S *et al.*, *Stem Cells* 27, 806-811<br>published online 23 February 2009 | | | used lines from #5 above, Active Motor Neurons |
| 23 | Chambers SM *et al.*, *Nature Biotechnology* 27, 275-280<br>published online 1 March 2009 | 2 | 2 | Neural Conversion |
| 24 | Kaji K *et al.*, *Nature* 458, 771-775<br>published online 1 March 2009 | 3 | 3 | |
| 25 | Woltjen K *et al.*, *Nature* 458, 766-770<br>published online 1 March 2009 | 4 | 4 | |
| 26 | Zhang D *et al.*, *Cell Research* 19, 429-438<br>published online 3 March 2009 | | | used lines from #16 above, pancreatic insulin-producing cells |
| 27 | Soldner F *et al.*, *Cell* 136, 964-977 | 25 | 25 | **23 Parkinson's** |

**Appendix H (cont.)**

| | | | | |
|---|---|---|---|---|
| | 6 March 2009 | | | **lines** |
| 28 | Loh Y-H *et al.*, *Blood* xxx doi: 10.1182/blood-2009-02-204800<br>published online 18 March 2009 | 2 | 8 | |
| 29 | Yu J *et al.*, *Science* 324, 797-801<br>published online 26 March 2009 | 2 | 12 | and at least 24 subclones |
| 30 | Deng J *et al.*, *Nature Biotechnology* 27, 353-360<br>published online 29 March 2009 | | | used lines from #2, #4, and #12 above |
| 31 | Ball MP *et al.*, *Nature Biotechnology* 27, 361-368<br>published online 29 March 2009 | 3 | 3 | |
| 32 | Hotta A *et al.*, *Nature Methods* 6, 370-376<br>published online 26 April 2009 | 6 | 135 | **at least 1 Rett syndrome line** |
| | | | | |
| | | **213** | **517** | |
| | | **Detailed Lines** | **Total Lines** | **13 diseases** |

## APPENDIX I

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

# Human Embryonic Stem Cell Research

**By: Theresa Deisher, Ph.D.**

Human embryonic stem cells (hESCs) will not lead to human therapeutics and are therefore inappropriate federal funding targets for the following reasons: hESCs are not normal cells; hESCs do not differentiate into the desired adult phenotype cells; hESCs are not necessary for pluripotent stem cell research; and hESCs will not provide the over-promised cures for diseases that are per se not amenable to stem cell therapy.

While the cells of the blastocyst's inner cell mass give rise to the organism during normal embryonic development, the derivation of ESC from this inner cell mass generates cells that are not normal. The derived hESC cells exhibit epigenetic instability demonstrated by altered methylation patterns (1)[1]. Of great concern are studies demonstrating that this epigenetic instability is independent of hESC isolation methods or hESC culture conditions, indicating that this is a universal characteristic of hESCs (2) (3) (4). Additionally, culture of hESCs leads to well-documented genetic and chromosomal instability (5) (6) (7) (8). However, even in hESC lines that do not exhibit gross evidence of chromosomal instability using standard cytogenetics measures, neoplastic changes are readily apparent, which include high proliferative capacity and growth factor independence (7) (9). The hESC lines studied in a 2009 Nature Biotechnology publication had amplifications, deletions and mosaicism demonstrated by array comparative genomic hybridization. Indeed, genomic amplifications at 20q11 have been associated with oncogenic transformation and most likely provide a selection advantage to hESCs in culture (8).

Scientists who want to continue to derive new hESC lines have argued that this genetic and chromosomal instability is the result of removing the cells from their normal tissue environment, the embryo. However, even when ESCs are re-injected into the natural embryonic development environment, using tetraploid embryo complementation techniques, the resulting fetuses derived solely from the implanted ESC continue to exhibit altered gene methylation and expression patterns and abnormal phenotype (1) (10). There is no evidence to suggest that hESCs will behave otherwise. In fact, merely culturing fertilized embryos in vitro has been shown to lead to epigenetic abnormalities. Epigenetic abnormalities are observed at significantly higher rates in ART (assisted reproductive technology) children than in naturally conceived children (11) (12) (13) (14).

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[1] Citations are to the references attached at the end of this summary.

In addition to concerns about the genetic instability of hESCs, we are also faced with the challenges of overcoming another universal characteristic of hESCs: teratoma, or tumor, formation. In fact, teratoma formation is one of the quality control assays used by commercial suppliers of hESCs lines to validate the identity of their cells as hESCs (15) (16). The ability of hESCs to form teratomas when implanted in mice is the sole quality control assay that demonstrates the pluripotency of these cells. Not only do commercial hESC suppliers rely on the teratoma forming assay to characterize their products, but academic and individual scientists routinely and commonly utilize this assay to demonstrate the pluripotency of their hESC cells. The teratoma formation has been shown to be polyclonal, further evidence that this is an innate characteristic of ESCs and not the result of an aberrant contaminating cell within the ESC culture (17) (18). The anti-apoptotic factor surviving appears to contribute to ESC teratoma formation, and is highly expressed in hESCs and teratomas, but not in the embryoid bodies from which the hESCs are derived (19). Additionally, the teratoma formation cannot be ascribed to culture conditions that include animal cells or animal growth factors, as derivation of new hESC lines in conditions lacking animal cell feeder layers or growth factors produces hESC lines that also form teratomas (20).

Science answered the question of whether ESCs would form teratomas in an organism years ago (18) (21) (22) (23), and acknowledges this insurmountable hurdle by having invested substantial resources into developing sensitive imaging techniques to monitor the formation of teratomas in vivo (24) (25) (26) (27) (28) (16) (29) (30) (18) (31) (7), and into developing methods to prevent teratoma formation, without success (32) (19) (33) (34) (35) (36). One of the attempted means to prevent in vivo teratoma formation in response to ESC treatment has been to differentiate the ESCs in vitro towards a somatic phenotype and then to implant these differentiated cells. Careful assessment of differentiated hESCs demonstrates however, that even differentiated hESCs rapidly formed teratomas (25). Published claims that differentiated ESCs show reduced teratoma formation in in vivo models need to be substantiated by documenting the continued presence of engrafted ESCs in high enough numbers and for substantial periods of time, at least 10-12 months, in order for the claim of no teratoma formation to be made with validity (16). Indeed, engraftment of differentiated ESCs has been demonstrated to be efficient and effective only in immune-compromised rodents such as the SCID mouse or athymic nude rats (37), indicating that life-long immunosuppression would be necessary in humans with its associated severe side effects that can include diabetes, hypertension, and osteoporosis.

Additionally, several therapeutic problems have been routinely observed with the approach of using differentiated ESCs for in vivo therapy. First, the ESC-derived differentiated cells exhibit immature or fetal phenotypes that are not therapeutically useful (23) (38) (39) (40) (19) (41) (35). For instance, several reports claim the derivation of insulin and C-peptide producing cells for the treatment of diabetes, but the derived cells have differentiated only to the fetal stage and do not produce therapeutic levels of insulin (42). Unfortunately, the fetal or immature phenotype cells do not further differentiate toward a fully functioning adult phenotype after being introduced into the organism (35) (37). Furthermore, the ESC-derived differentiated cells do not survive in vivo (23) (39) (43) (37) (34) (44) (35), and have required complex cocktails of gene therapy, in vitro growth factors additives, and in vivo growth factor treatments and immune suppression (44) (36). Of even greater concern is the fact that human experience has already

taught us the hard lesson that the clinical use of fetal cells or tissue leads to uncontrolled cellular growth and tumor formation (45) (46) (47) (48).

In vitro evidence of neoplastic qualities of hESC (7) (8) has been substantiated by in vivo demonstration of hESC formation of malignant tumors in SCID mice, not merely teratoma formation (49). Indeed, both teratoma formation and malignant tumor formation may be intrinsic qualities of pluripotent stem cells (50) that cannot be avoided without also losing the sought-after potency of the cells themselves (16). Again, one cannot ascribe the malignant tumor formation to the situation of removing a pluripotent stem cell from its intrinsic environment. Okita and Yamanaka have shown that chimeric mice derived partially from induced pluripotent cells have a malignant tumor incidence of 29% (50).

The discovery and publication of pluripotent stem cells equivalent to hESCs, induced pluripotent stem cells (iPSCs) and spermatogonial or testicular stem cells (SSCs) eliminates any justification to destroy a human embryo in order to derive pluripotent stem cells. However, scientists continue to argue and publish their perceived need for newly derived hESC lines. They claim that they need to continue to derive new hESC lines in order to use these as a comparator for the pluripotent properties and differentiation capacity of iPSCs or SSCs. The arguments are fallacious for the following reasons. The only, and the sufficient, assay to establish the pluripotency of a stem cell, either in the culture dish or in vivo, is the teratoma-forming assay. The test to determine whether a cell is a pluripotent cell involves injecting the cell in question into an animal, and watching for teratoma formation. While ESCs are, in some instances, the "tested" cell, at no step in this test are ESCs needed or required when other potentially pluripotent cells are being tested. The teratomas are well characterized and therefore the assays do not require ESCs at any step in the process. In regards to differentiation capacity, we have already discussed the tendency of ESCs to differentiate into immature or fetal phenotypes, rather than adult, fully functioning phenotypes. The necessary and sufficient comparators for the differentiation capacity of iPSCs or SSCs are the adult phenotype cells that are the replacement target for in vivo stem cell regenerative therapy. Derivation of new hESCs lines cannot be justified by either of these above arguments.

The targeted diseases listed in the Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice include Parkinson's disease, amyotrophic lateral sclerosis, diabetes and arthritis. These are complex, polygenic diseases with an autoimmune component (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67). Effective treatment of these types of diseases requires medical intervention to significantly dampen if not eradicate the autoimmune attack prior to any attempt to regenerate tissue. Stem cell therapy in the environment of autoimmune activity will not lead to long term functional recovery, as any tissue replacement will eventually suffer the same autoimmune attack and destruction. It is correct that adult stem cell treatment is being investigated, with exciting results, in the context of treating and/or curing type I diabetes, lupus and multiple sclerosis. However, the stem cell treatments utilized in these clinical trials are for the specific purpose of regenerating the blood/marrow systems following non-myeloablative chemotherapy (68) (69) (70) (71) (72). The autoimmune attack is reduced or eliminated by the ablative destruction of the mature self-reactive immune cells. Unfortunately, ablation of the self-reactive immune cells also damages normal blood and

marrow cells, requiring administration of autologous stem cells for marrow rescue to prevent infectious complications and/or death from the ablative therapy. Stem cell therapy will not treat autoimmune disease until the underlying pathological organ or tissue attack is controlled, and therefore, hESCs are improbable, if not absolutely unlikely, candidates for the diseases highlighted in the proposed guidelines.

hESC research proponents also promise cures for the devastating disease of Alzheimer's, again over-promising and over-simplifying a complex, polygenic, poorly understood disease process that is unlikely to be amenable to stem cell therapy (73). More to the point, early Alzheimer's disease appears to be driven by aberrant reactivation of fetal neural synapse pruning processes (74) (75) (76) (77), as well as being driven by an inflammatory/immune component compromising the blood-brain-barrier integrity (78). Delivery of further levels of embryonic or fetal genes and microRNAs to the brain of an Alzheimer's patient by attempting to treat them with embryonic or fetal stem cells would be the last thing one would want to do to a patient with Alzheimer's.

In conclusion, hESCs are not safe for human therapy due to their intrinsic teratoma and neoplastic properties. Nor are the necessary for research using other pluripotent cell lines. Most importantly, hESCs will not treat the myriad of diseases promised by hESC research proponents. In contrast, less pluripotent stem cells, such as those found in the mononuclear fractions of our bone marrow, are safe, affordable, and effectively treating patients in clinic and clinical trials.

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**APPENDIX J**

DO NO HARM *et al.* Comments on Draft NIH ***Guidelines*** **for Human Stem Cell Research, 74 *Federal Register* 18578-18580 (April 23, 2009)**

# DO NO HARM: THE COALITION OF AMERICANS FOR RESEARCH ETHICS

# STATEMENT

## ON HUMAN EMBRYOS AND STEM CELL RESEARCH:

### AN APPEAL FOR LEGALLY AND ETHICALLY RESPONSIBLE SCIENCE AND PUBLIC POLICY

Released July 1, 1999

Recent scientific advances in human stem cell research have brought into fresh focus the dignity and status of the human embryo. These advances have prompted a decision by the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH) to fund stem cell research which is dependent upon the destruction of human embryos. Moreover, the National Bioethics Advisory Commission (NBAC) is calling for a modification of the current ban against federally funded human embryo research in order to permit direct federal funding for the destructive harvesting of stem cells from human embryos. These developments require that the legal, ethical, and scientific issues associated with this research be critically addressed and articulated. Our careful consideration of these issues leads to the conclusion that human stem cell research requiring the destruction of human embryos is objectionable on legal, ethical, and scientific grounds. Moreover, destruction of human embryonic life is unnecessary for medical progress, as alternative methods of obtaining human stem cells and of repairing and regenerating human tissue exist and continue to be developed.

**Human Embryonic Stem Cell Research Violates Existing Law and Policy**

In November 1998, two independent teams of U.S. scientists reported that they had succeeded in isolating and culturing stem cells obtained from human embryos and fetuses. Stem cells are the cells from which all 210 different kinds of tissue in the human body originate. Because many diseases result from the death or dysfunction of a single cell type, scientists believe that the introduction of healthy cells of this type into a patient may restore lost or compromised function. Now that human embryonic stem cells can be isolated and multiplied in the laboratory, some scientists believe that treatments for a variety of diseases–such as diabetes, heart disease, Alzheimer's, and Parkinson's–may be within reach. While we in no way dispute the fact that the ability to treat or heal suffering persons is a great good, we also recognize that not all methods of achieving a desired good are morally or legally justifiable. If this were not so, the medically accepted and legally required practices of informed consent and of seeking to do no harm to the patient could be ignored whenever some "greater good" seems achievable.

One of the great hallmarks of American law has been its solicitous protection of the lives of individuals, especially the vulnerable. Our nation's traditional protection of human life and human rights derives from an affirmation of the essential dignity of every human being. Likewise, the international structure of human rights law–one of the great achievements of the modern world–is founded on the conviction that when the dignity of one human being is assaulted, all of us are threatened. The duty to protect human life is specifically reflected in the homicide laws of all 50 states. Furthermore, federal law and the laws of many states specifically protect vulnerable human embryos from harmful experimentation. Yet in recently publicized experiments, stem cells have been harvested from human embryos in ways which destroy the embryos.

Despite an existing congressional ban on federally-funded human embryo research, the Department of Health and Human Services (HHS) determined on January 15, 1999 that the government may fund human embryonic stem cell research. The stated rationales behind this decision are that stem cells are not embryos (which itself may be a debatable point) and that research using cells obtained by destroying human embryos can be divorced from the destruction itself. However, even NBAC denies this latter claim, as is evident by the following statement in its May 6, 1999 Draft Report on Stem Cell Research:

> Whereas researchers using fetal tissue are not responsible for the death of the fetus, researchers using stem cells derived from embryos will typically be implicated in the destruction of the embryo. This is true whether or not researchers participate in the derivation of embryonic stem cells. As long as embryos are destroyed as part of the research enterprise, researchers using embryonic stem cells (and those who fund them) will be complicit in the death of embryos.

If the flawed rationales of HHS are accepted, federally-funded researchers may soon be able to experiment on stem cells obtained by destroying embryonic human beings, so long as the act of destruction does not itself receive federal funds. However, the very language of the existing ban prohibits the use of federal funds to support "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death...." (Sec. 511(a)(2)). Obviously, Congress' intent here was not merely to prohibit the use of federal funds for embryo destruction, but to prohibit the use of such funds for research dependent in any way upon such destruction. Therefore, the opinion of HHS that human embryonic stem cell research may receive federal funding clearly violates both the language of and intention behind the existing law. Congress and the courts should ensure that the law is properly interpreted and enforced to ban federal funding for research which harms, destroys, or is dependent upon the destruction of human embryos.

It is important to recognize also that research involving human embryos outside the womb–such as embryos produced in the laboratory by *in vitro* fertilization (IVF) or cloning–has never received federal funding. Initially, this was because a federal regulation of 1975 prevented government funding of IVF experiments unless such experiments were deemed acceptable by an Ethics Advisory Board. Following the failure of the first advisory board to reach a consensus on the matter, no administration chose to appoint a new board. After this regulation was rescinded

by Congress in 1993, the Human Embryo Research Panel recommended to the National Institutes of Health (NIH) that certain kinds of harmful nontherapeutic experiments using human embryos receive federal funding. However, these recommendations were rejected in part by President Clinton and then rejected in their entirety by Congress.

Further, it is instructive to note that the existing law which permits researchers to use fetal tissue obtained from elective abortions requires that the abortions are performed for reasons which are entirely unrelated to the research objectives. This law thus prohibits HHS from promoting the destruction of human life in the name of medical progress, yet medical progress is precisely the motivation and justification offered for the destruction of human life that occurs when stem cells are obtained from human embryos.

Current law against funding research in which human embryos are harmed and destroyed reflects well-established national and international legal and ethical norms against the misuse of any human being for research purposes. Since 1975, those norms have been applied to unborn children at every stage of development in the womb, and since 1995 they have been applied to the human embryo outside the womb as well. The existing law on human embryonic research is a reflection of universally accepted principles governing experiments on human subjects–principles reflected in the Nuremberg Code, the World Medical Association's Declaration of Helsinki, the United Nations Declaration of Human Rights, and many other statements. Accordingly, members of the human species who cannot give informed consent for research should not be the subjects of an experiment unless they personally may benefit from it or the experiment carries no significant risk of harming them. Only by upholding such research principles do we prevent treating people as things–as mere means to obtaining knowledge or benefits for others.

It may strike some as surprising that legal protection of embryonic human beings can co-exist with the U.S. Supreme Court's 1973 legalization of abortion. However, the Supreme Court has never prevented the government from protecting prenatal life outside the abortion context, and public sentiment also seems even more opposed to government funding of embryo experimentation than to the funding of abortion. The laws of a number of states–including Louisiana, Maine, Massachusetts, Michigan, Minnesota, Pennsylvania, Rhode Island, and Utah–specifically protect embryonic human beings outside the womb. Most of these provisions prohibit experiments on embryos outside the womb. We believe that the above legally acknowledged protections against assaults on human dignity must be extended to all human beings–irrespective of gender, race, religion, health, disability, or age. Consequently, the human embryo must not be subject to willful destruction even if the stated motivation is to help others. Therefore, on existing legal grounds alone, research using stem cells derived from the destruction of early human embryos is proscribed.

## Human Embryonic Stem Cell Research Is Unethical

The HHS decision and the recommendations of NBAC to federally fund research involving the destruction of human embryos would be profoundly disturbing even if this research could result in great scientific and medical gain. The prospect of government-sponsored experiments to manipulate and destroy human embryos should make us all lie awake at night.

That some individuals would be destroyed in the name of medical science constitutes a threat to us all. Recent statements such as "stem cell research is too promising to be slowed, impeded, or stopped" underscore the sort of utopianism and hubris that could blind us to the truth of what we are doing and the harm we could cause to ourselves and others. Human embryos are not mere biological tissues or clusters of cells; they are the tiniest of human beings. Thus, we have a moral responsibility not to deliberately harm them.

An international scientific consensus now recognizes that human embryos are biologically human beings beginning at fertilization, and acknowledges the physical continuity Of human growth and development from the one-cell stage forward. In the 1970s and 1980s, some frog and mouse embryologists referred to the human embryo in its first week or two of development as a "pre embryo," claiming that it deserved less respect than embryos in later stages of development. However, some embryology textbooks now openly refer to the term "pre-embryo" as a scientifically invalid and "inaccurate" term which has been "discarded" and others which once used the term have quietly dropped it from new editions. Both the Human Embryo Research Panel and the National Bioethics Advisory Commission have also rejected the term, describing the human embryo from its earliest stages as a living organism and a "developing form of human life." The claim that an early human embryo becomes a human being only after 14 days or implantation in the womb is therefore a scientific myth. Finally, the historic and well-respected 1995 Ramsey Colloquium statement on embryo research acknowledges that:

> The [embryo] is human; it will not articulate itself into some other kind of animal. Any being that is human is a human being. If it is objected that, at five days or fifteen days, the embryo does not look like a human being, it must be pointed out that this is precisely what a human being looks like—and what each of us looked like—at five or fifteen days of development.

Therefore, the term "pre-embryo," and all that it implies, is scientifically invalid.

The last century and a half has been marred by numerous atrocities against vulnerable human beings in the name of progress and medical benefit. In the 19th century, vulnerable human beings were bought and sold in the town square as slaves and bred as though they were animals. In this century, the vulnerable were executed mercilessly and subjected to demeaning experimentation at Dachau and Auschwitz. At mid-century, the vulnerable were subjects of our own government's radiation experiments without their knowledge or consent. Likewise, vulnerable African-Americans in Tuskegee, Alabama were victimized as subjects of a government-sponsored research project to study the effects of syphilis. Currently, we are witness to the gross abuse of mental patients used as subjects in purely experimental research. These experiments were and are driven by a crass utilitarian ethos which results in the creation of a "sub-class" of human beings, allowing the rights of the few to be sacrificed for the sake of potential benefit to the many. These unspeakably cruel and inherently wrong acts against human beings have resulted in the enactment of laws and policies which require the protection of human rights and liberties, including the right to be protected from the tyranny of the quest for scientific progress. The painful lessons of the past should have taught us that human beings must not be conscripted for research without their permission–no matter what the alleged justification–

especially when that research means the forfeiture of their health or lives. Even if an individual's death is believed to be otherwise imminent, we still do not have a license to engage in lethal experimentation–just as we may not experiment on death row prisoners or harvest their organs without their consent..

We are aware that a number of Nobel scientists endorse human embryonic stem cell research on the basis that it may offer a great good to those who are suffering. While we acknowledge that the desire to heal people is certainly a laudable goal and understand that many have invested their lives in realizing this goal, we also recognize that we are simply not free to pursue good ends via unethical means. Of all human beings, embryos are the most defenseless against abuse. A policy promoting the use and destruction of human embryos would repeat the failures of the past. The intentional destruction of some human beings for the alleged good of other human beings is wrong. Therefore, on ethical grounds alone, research using stem cells obtained by destroying human embryos is ethically proscribed.

**Human Embryonic Stem Cell Research is Scientifically Questionable**

Integral to the decision to use federal funds for research on human embryonic stem cells is the distinction between stem cells and embryos. HHS has stated that federal funds may be used to support human embryonic stem cell research because stem cells are not embryos. A statement issued by the National Institutes of Health (NIB) regarding this decision asserts that "The congressional prohibition on the use of [government] funds for . . . embryciresearch does not apply to research utilizing human pluripotent stem cells because such cells are not an embryo as defined by statute. Moreover, because pluripotent stem cells do not have the capacity to develop into a human being, they cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term."

It is important to note that the materials used in an experiment, as well as the methods of experimentation, are considered to be part of scientific research. When a scientific study is published, the first part of the article details the methods and materials used to conduct the research. Ethical and scientific evaluation of an experiment takes into account both the methods and materials used in the research process. Therefore, the source of stem cells obtained for research is both a scientifically and ethically relevant consideration.

Research on human embryonic stem cells is objectionable due to the fact that such research necessitates the prior destruction of human embryos; however, the HHS's claim that stem cells are not, and cannot develop into, embryos may itself be subject to dispute. Some evidence suggests that stem cells cultured in the laboratory may have a tendency to recongregate and form an aggregate of cells capable of beginning to develop as an embryo. In 1993, Canadian scientists reported that they successfully produced a live-born mouse from a cluster of mouse stem cells. While it is true that these stem cells had to be wrapped in placenta-like cells in order to implant in a female mouse, it seems that at least some doubt has been cast on the claim that a cluster of stem cells is not embryonic in nature. If embryonic stem cells do indeed possess the ability to form or develop as a human embryo (without any process of activation which affects the transformation of the cell into a human embryo), research on such stem cells could itself involve the creation and/or destruction of human life and would thereby certainly fall under the existing

ban on federally-funded embryo research. It would be irresponsible for the HHS to conduct and condone human embryonic stem cell research without first discerning the status of these cells. Their use in any research in which they could be converted into human embryos should likewise be banned.

## Methods of Repairing and Regenerating Human Tissue Exist Which Do Not Require the Destruction of Human Embryos

While proponents of human embryonic stem cell research lobby aggressively for government funding of research requiring the destruction of human embryos, alternative methods for repairing and regenerating human tissue render such an approach unnecessary for medical progress.

For instance, a promising source of more mature stem cells for the treatment of disease is hematopoietic (blood cell-producing) stem cells from bone marrow or even from the placenta or umbilical cord blood in live births. These cells are already widely used in cancer treatment and in research on treating leukemia and other diseases. Recent experiments have indicated that their versatility is even greater than once thought. For example, given the right environment, bone marrow cells can be used to regenerate muscle tissue, opening up a whole new avenue of potential therapies for muscular dystrophies. In April 1999, new advances were announced in isolating mesenchymal cells from bone marrow and directing them to form fat, cartilage, and bone tissue. Experts in stem cell research believe that these cells may allow for tissue replacement in patients suffering from cancer, osteoporosis, dental disease, or injury.

An enormously promising new source of more mature stem cells is fetal bone marrow, is many times more effective than adult bone marrow and umbilical cord blood. It appears that fetal bone marrow cells do not provoke immune reactions to the same degree as adult or even newborn infant cells. This is true whether the unborn child is the donor or the recipient–that is, fetal cells can be used to treat adults, or adult bone marrow cells can be used to treat a child in the womb without the usual risk of harmful immune reactions. Such cells would not need to be derived from fetuses who were intentionally aborted, but could instead be obtained from spontaneously aborted fetuses or stillborn infants.

In 1999, unprecedented advances were also made in isolating and culturing neural stem cells from living human nerve tissue and even from adult cadavers. Such advances render it quite possible that treatment of neural diseases such as Parkinson's and Alzheimer's, as well as spinal cord injuries, will not depend upon destructive embryo research.

Earlier claims that embryonic stem cells are uniquely capable of "self-renewal" and indefinite growth can also now be seen as premature. For example, scientists have isolated an enzyme, telomerase, which may allow human tissues to grow almost indefinitely. Although this enzyme has been linked to the development of cancer, researchers have been able to use it in a controlled way to "immortalize" useful tissue without producing cancerous growths or other harmful side effects. Thus, cultures of non-embryonic stem cells may be induced to grow and develop almost indefinitely for clinical use.

One of the most exciting new advances in stem cell research is the January 1999 announcement that Canadian and Italian researchers succeeded in producing new blood cells from neural stem cells taken from an adult mouse. Until recently, it was believed that adult stem cells were capable of producing only a particular type of cell: for example, a neural stem cell could develop only into cells belonging to the nervous system. Researchers believed that only embryonic stem cells retained the capacity to form all kinds of tissue in the human body. However, if stem cells taken from adult patients can produce cells and tissues capable of functioning within entirely different systems, new brain tissue needed to treat a patient with Parkinson's disease, for example, might be generated from blood stem cells derived from the patient's bone marrow. Conversely, neural stem cells might be used to produce needed blood and bone marrow. Use of a patient's own stem cells would circumvent one of the major obstacles posed by the use of embryonic stem cells–namely, the danger that tissue taken from another individual would be rejected when transplanted into a patient. Thus, in commenting on this finding, the *British Medical Journal* remarked on January 30, 1999 that the use of embryonic stem cells "may soon be eclipsed by the more readily available and less controversial adult stem cells." Given that the function of the adult stem cells was converted without the cells first having to pass through an embryonic stage, the use of such cells would not be subject to the ethical and legal objections raised by the use of human embryonic stem cells. The Director of the NIH has pointed out that evidence that adult stem cells can take on different functions has emerged only from studies on mice. However, his own claim that human embryonic stem cell research can produce treatments for diabetes and other diseases is also based solely on experimental success in mice.

One approach to tissue regeneration that does not rely on stem cells at all, but on somatic cell gene therapy, is already in use as an experimental treatment. A gene that controls production of growth factors can be injected directly into a patient's own cells, with the result that new blood vessels will develop. In early trials, this type of therapy saved the legs of patients who would have otherwise undergone amputation. It was reported in January 1999 that the technique has generated new blood vessels in the human heart and improved the condition of 19 out of 20 patients with blocked cardiac blood vessels. Such growth factors are now being explored as a means for growing new organs and tissues of many kinds.

The above recent advances suggest that it is not even necessary to obtain stem cells by destroying human embryos in order to treat disease. A growing number of researchers believe that adult stem cells may soon be used to develop treatments for afflictions such as cancer, immune disorders, orthopedic injuries, congestive heart failure, and degenerative diseases. Such researchers are working to further research on adult, rather than embryonic, stem cells. In light of these promising new scientific advances, we urge Congress to provide federal funding for the development of methods to repair and regenerate human tissue which do not require the destruction of embryonic human life. However, even if such methods do not prove to be as valuable in treating disease as are human embryonic stem cells, use of the latter in the name of medical progress is still neither legally nor ethically justifiable for the reasons stated in this document.

## Conclusion

We believe that an examination of the legal, ethical, and scientific issues associated with human embryonic stem cell research leads to the conclusion that the use of federal funds to support any such research that necessitates the destruction of human embryos is, and should remain, prohibited by law. Therefore, we call on Congress to (1) maintain the existing ban against harmful federally-funded human embryo research and make explicit its application to stem cell research requiring the destruction of human embryos and (2) provide federal funding for the development of alternative treatments which do not require the destruction of human embryonic life. If anything is to be gained from the cruel atrocities committed against human beings in the last century and a half, it is the lesson that the utilitarian devaluation of one group of human beings for the alleged benefit of others is a price we simply cannot afford to pay.

For more information visit http://www.stemcellresearch.org
A referenced version is available upon request. If desired, contact The Center for Bioethics and Human Dignity at 847-317-8180.

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