



## Office of the General Secretary

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May 22, 2009

NIH Stem Cell Guidelines, MSC 7997  
9000 Rockville Pike  
Bethesda, Maryland, 20892-7997

### **Re: Draft Guidelines on Human Embryonic Stem Cell Research**

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (“Conference”), I offer the following comments on draft guidelines proposed by the National Institutes of Health (NIH) to authorize federally funded human embryonic stem cell research, published at 74 *Fed. Reg.* 18578-80 (April 23, 2009) (“Guidelines”).

### **Interest of the United States Conference of Catholic Bishops**

The Conference is a nonprofit corporation organized under the laws of the District of Columbia. All active Catholic bishops in the United States are members of the Conference. The Catholic Church, the largest religious denomination in the United States, has over 67 million adherents in over 18,000 parishes throughout the country. The Conference advocates and promotes the pastoral teaching of the bishops in such diverse areas as education, family life, health care, social welfare, immigration, civil rights, and the economy. The Conference participates in rulemaking proceedings of importance to the Catholic Church and its people in the United States. Rulemaking that concerns the protection of unborn human life and the ethical integrity of medicine is of paramount concern to the Conference.

In the Conference’s view, the dignity and inviolability of human life at every stage of development is a foundational principle of any truly civilized society. The core ethical norms protecting human research subjects, affirmed in the Nuremberg Code and many subsequent documents, reflect this principle. The right not to be subjected to harmful experimentation without one’s express and informed consent is an innate human right, belonging to each and every member of the human family by his or her very nature as a human being. Thus it does not belong to government to recognize this right for some human beings and not for others, or to set aside protection of this right in the name of expanded knowledge or the good of society. Laws or regulations which fail to give full

recognition to this fundamental right do not succeed in nullifying the right in question, but only call into question their own moral legitimacy. It is in light of this moral conviction that we offer the following comments.

### General Comments

The central fact of science relevant to this issue is the fact that the living human embryo at the blastocyst stage – the being who will be destroyed to obtain embryonic stem cells for research funded under these Guidelines -- is a human being at a very early stage of his or her development. As one widely used embryology textbook notes: “The development of a human begins with fertilization, a process by which the *spermatozoon* from the male and the oocyte from the female unite to give rise to a new organism, the *zygote*.”<sup>1</sup> Or to cite another: “A zygote is the beginning of a new human being.”<sup>2</sup>

Advisory groups seeking to inform federal policy on human embryo research have consistently acknowledged this scientific fact, and recognized that it has serious moral implications. The NIH Human Embryo Research Panel of 1994 concluded: “The preimplantation human embryo warrants serious moral consideration as a developing form of human life.”<sup>3</sup> The National Bioethics Advisory Commission appointed by President Clinton noted widespread agreement in our society that “human embryos deserve respect as a form of human life.”<sup>4</sup>

This consensus does not rely on a particular religious view, or a particular theory about “personhood.” It is a basic human insight, a recognition that each one of us began life as an embryo and engaged in continuous development through the stages of fetus, infant, newborn, toddler, etc. to reach maturity. Dr. Shinya Yamanaka, whose discoveries have enabled researchers to reprogram ordinary adult cells into “induced pluripotent stem cells” (iPS cells) without doing any harm to human life, was struck by this insight while looking at a human embryo through a microscope: “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.”<sup>5</sup> The “other way” he developed has been hailed by the journal *Science* as last year’s leading scientific breakthrough in any field.<sup>6</sup> Ethically responsible stem cell research has indeed

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<sup>1</sup> Sadler, T.W. *Langman's Medical Embryology*. 7th edition. Baltimore: Williams & Wilkins 1995, at 3.

<sup>2</sup> Moore, Keith L. and Persaud, T.V.N. *The Developing Human: Clinically Oriented Embryology*. 7th edition. Philadelphia: Saunders 2003, at 2.

<sup>3</sup> National Institutes of Health, *Report of the Human Embryo Research Panel* (Sept. 1994), at 2.

<sup>4</sup> National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* (September 1999), Vol. I, at ii.

<sup>5</sup> Quoted in M. Fackler, “Risk Taking Is in His Genes,” *The New York Times*, December 11, 2007, [www.nytimes.com/2007/12/11/science/11prof.html](http://www.nytimes.com/2007/12/11/science/11prof.html).

<sup>6</sup> See G. Vogel, “Breakthrough of the Year: Reprogramming Cells,” 322 *Science* 1766-7 (19 December 2008).

moved forward, under a federal policy that researchers may not create new cell lines (that is, may not destroy more living human embryos) for federally funded stem cell research.

Yet President Obama's executive order of March 9 not only rescinded that policy, but also rescinded the executive order of 2007 instructing the NIH to thoroughly explore new avenues for obtaining pluripotent stem cells without destroying human embryos.<sup>7</sup> Both science and ethics have been ignored in this decision.

The National Bioethics Advisory Commission did not hold, as we do, that the human embryo has the same inherent human dignity as every other human being. Yet it concluded that because the embryo deserves our "respect," we must ensure that any research requiring the destruction of that embryo is a last resort, to be pursued only after other ways to pursue important research goals have been exhausted:

"In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research."<sup>8</sup>

The Commission added that it did not think these less problematic alternatives were available in 1999, but that this would have to be constantly reassessed as research progressed.

The President's executive order and these Guidelines fail the Commission's test, by failing to require that morally unproblematic avenues for exploring important medical research goals be thoroughly investigated *before* the NIH considers any avenues that require destroying embryonic human life. Avenues of stem cell research which pose no moral problem are now showing great promise. In fact, human patients suffering from *all* the conditions cited by President Obama when he signed his executive order – cancer, juvenile diabetes, Parkinson's disease, spinal cord injury, heart disease – have been shown in peer-reviewed studies to benefit from clinical trials using human stem cells.<sup>9</sup> And *in every case*, the benefit has come not from embryonic stem cells, but from the

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<sup>7</sup> Executive Order 13505 of March 9, 2009, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," 74 *Fed. Reg.* 10667 (March 11, 2009) at 10668, revoking Executive Order 13435 of June 20, 2007, "Expanding Approved Stem Cell Lines in Ethically Responsible Ways," 72 *Fed. Reg.* 34591-3 (June 22, 2007).

<sup>8</sup> National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* (Sept. 1999), Volume I, at 53.

<sup>9</sup> See Remarks of President Barack Obama, "Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum," Office of the press Secretary, The White House, March 9, 2009, at [www.whitehouse.gov/the\\_press\\_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/](http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/).

adult and cord blood stem cells that this organization and others have said should receive priority attention.<sup>10</sup>

Therefore we agree with the President's statement on March 9 that the government must ensure "that scientific data is never distorted or concealed to serve a political agenda – and that we make scientific decisions based on facts, not ideology." But it is ideology, not fact, that continues to insist that millions of taxpayers with moral objections to the killing of embryonic human beings must subsidize research that involves such killing. This Administration should not adopt the misguided belief that such a policy is demanded by "science." As the President noted, we must not make "a false choice between sound science and moral values." In fact, these sources of guidance both point in the same direction, *away from* destructive embryonic stem cell research. His executive order and these Guidelines nonetheless insist on a course of action that is both morally objectionable and, increasingly, scientifically obsolete.<sup>11</sup>

## The Scope of the Guidelines

### 1. Creating Embryos for Research

The President's executive order of March 9 gave the NIH broad authority to pursue "responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law."<sup>12</sup> This authority was potentially broad enough to authorize federally funded stem cell research involving mass-production of embryos in laboratories solely for research purposes, using *in vitro* fertilization, cloning or other techniques. The President underscored the scope of his order by stating in his accompanying remarks that he would not allow "the use of cloning for human reproduction," generally understood to mean the transfer of cloned embryos to women's bodies in an attempt to produce a live-born child. The prospect was left open that cloning human embryos for use in stem cell research may be acceptable, as long as no embryo is placed in a woman's body to attempt a live birth.

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<sup>10</sup> See: Do No Harm, "Peer-Reviewed References Showing Applications of Adult Stem Cells that Produce Therapeutic Benefit for Human Patients" (April 11, 2007), at [www.stemcellresearch.org/facts/asc-refs.pdf](http://www.stemcellresearch.org/facts/asc-refs.pdf); M. Levesque et al., "Therapeutic Microinjection of Autologous Adult Human Neural Stem Cells and Differentiated Neurons for Parkinson's Disease: Five-Year Post-Operative Outcome," 1 *The Open Stem Cell Journal* 20-29 (2009), at [www.neurogeneration.com/pdf/Levesque-MS.pdf](http://www.neurogeneration.com/pdf/Levesque-MS.pdf).

<sup>11</sup> "The world has changed... Over time, these [iPS] cells will be used in more and more labs. And human embryo stem cell research will be abandoned by more and more labs." Dr. James Thomson, quoted in C. Nickerson, "Breakthrough on stem cells," *The Boston Globe*, November 21, 2007, at [www.boston.com/news/nation/articles/2007/11/21/breakthrough\\_on\\_stem\\_cells/?page=full](http://www.boston.com/news/nation/articles/2007/11/21/breakthrough_on_stem_cells/?page=full). Also see Bernadine Healy, M.D. (former director of the NIH), "Why Embryonic Stem Cells are Obsolete," *U.S. News & World Report*, March 4, 2009, at <http://health.usnews.com/blogs/heart-to-heart/2009/03/04/why-embryonic-stem-cells-are-obsolete.html>.

<sup>12</sup> Executive Order 13505, note 7 *supra*, Sec. 2, at 10667.

Such creation of human life in the laboratory, solely for use as an “object” of research, is especially abhorrent to Americans on all sides of the stem cell debate.<sup>13</sup> Therefore we are relieved that the Guidelines do not, at this time, contemplate funding stem cell research that involves creating human embryos for research purposes. However, this prospect still looms on the horizon, as the President’s order instructs the NIH to “review and update” the Guidelines periodically.<sup>14</sup> This Administration should make a clear and authoritative statement, as the Clinton Administration did, that it will *never* fund research that relies on the creation of human embryos for research purposes.<sup>15</sup>

## 2. Comparison with Past Guidelines

While the Guidelines do not encourage researchers to create human embryos solely for stem cell research, in key respects the Guidelines are nonetheless broader or more permissive than any policy approved in the past by any branch of the federal government. Therefore the President’s March 9 statement that the government would “develop strict guidelines, which we will rigorously enforce,” is not reflected in the text of the Guidelines.

There have been three major proposals for a federal policy on funding embryonic stem cell research:

(1) The Clinton guidelines of 2000 were similar to the new Guidelines in encouraging the destructive harvesting of stem cells from so-called “spare” embryos originally created for reproductive purposes in fertility clinics. However, the 2000 policy was limited to embryos that had previously been frozen, so parents in these clinics could exhaust other options and have significant time to consider whether to donate their embryonic son or daughter for destructive research.<sup>16</sup>

(2) The Bush guidelines of 2001, now rescinded by President Obama, did not allow the use of federal funds to encourage researchers to destroy human embryos for their stem cells. Only previously existing stem cell lines (from embryos destroyed before President Bush issued his policy) were eligible for federally funded research. Under this

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<sup>13</sup> “The creation of human embryos specifically for research that will destroy them is unconscionable... [I]t is not necessary to be against abortion rights, or to believe human life literally begins at conception, to be deeply alarmed by the notion of scientists’ purposely causing conceptions in a context entirely divorced from even the potential of reproduction.” Editorial, “Embryos: Drawing the Line,” *The Washington Post*, October 2, 1994, at C6. Also see remarks by Rep. Nancy Pelosi during House floor debate on the Dickey/Wicker amendment in 1996: “Let me say that I agree with our colleagues who say that we should not be involved in the creation of embryos for research. I completely agree with my colleagues on that score.” *Congressional Record*, July 11, 1996, at H7343.

<sup>14</sup> Executive Order 13505, note 7 *supra*, Sec. 3, at 10667.

<sup>15</sup> President William J. Clinton, Statement, 30 *Weekly Comp. Pres. Doc.* 2459 (Dec. 2, 1994).

<sup>16</sup> See “National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells,” 65 *Fed. Reg.* 51976-81 (August 25, 2000) at 51980.

policy, the Bush administration argued, federal funds could be used to explore the potential of embryonic stem cell research, but providing these funds for stem cell research grants would not encourage researchers to destroy more embryos for such research; any cell lines thus obtained would be ineligible for use in a federally funded project.<sup>17</sup>

(3) Legislation passed by Congress in 2006 and 2007 was vetoed by President Bush as violating the ethical limits he had tried to place on federally funded embryonic stem cell research. However, even under this legislation, embryonic stem cells could only be used for federally funded research if, “[p]rior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded.”<sup>18</sup> This two-step consent process – parents must first be sure they would never allow the embryos to survive, and only then would be approached about the possibility of donating them for stem cell research – had been recommended by the National Bioethics Advisory Commission to ensure that federal funds would not be used to encourage the destruction of embryos whose parents otherwise may have allowed them to survive.<sup>19</sup>

The new Guidelines are broader than any of these proposals. Unlike the Bush policy, the new policy will encourage researchers who want to receive federal stem cell research grants to destroy new embryos for their stem cells – embryonic human beings who are alive now, and others not yet conceived as of this writing. Unlike the Clinton guidelines, it will encourage the destruction of recently conceived or “fresh” embryos as well as those which have been frozen. And unlike past bills approved by Congress that were vetoed by President Bush, it will ensure that parents are invited to consider donating their embryonic children for destructive stem cell harvesting at the same time that they consider all other options –including the options that would have allowed these children to survive and ultimately be born alive. In short, the Guidelines do not present this option only to parents who had already decided not to let these embryos survive. The embryos destroyed under this policy will not only be embryos that “would be discarded anyway.”<sup>20</sup>

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<sup>17</sup> See National Institutes of Health, “NIH Funding of Research Using Specified Existing Human Embryonic Stem Cells,” Notice NOT-OD-01-059 (August 27, 2001), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-059.html>.

<sup>18</sup> See: Stem Cell Research Enhancement Act of 2007, 110<sup>th</sup> Congress, S. 5; Stem Cell Research Enhancement Act of 2005, 109<sup>th</sup> Congress, H.R. 810.

<sup>19</sup> See National Bioethics Advisory Commission, note 8 supra, at vi.

<sup>20</sup> Once embryos are identified as “no longer needed” for reproductive purposes, a decision which parents may make at any time, the Guidelines require that “all options” including donation for destructive stem cell research be presented. 74 *Fed. Reg.* at 18579. Generally fertility clinics offer options such as: discarding the embryos; freezing them for possible later reproductive use in case the couple later decides they want another child; donating them to another couple for their reproductive attempts; and donating for research.

To be sure, the argument that the federal government may provide financial incentives for researchers to destroy developing human beings at any stage, simply because those human beings may soon be abandoned or destroyed by their parents, is logically flawed and morally invalid in our view. The fact that someone else may plan to do harm to another human being gives researchers and the government no right to destroy that fellow human being for their own purposes – still less a right to force conscientiously opposed taxpayers to subsidize such a project. Our society does not condone such behavior in the case of terminally ill patients expected to die soon, or in the case of convicted prisoners expected to be executed soon. We do not authorize one human being to kill another simply because a third person has already decided to accomplish the same end. Thus, even if the Guidelines did allow destruction of human embryos only in those cases, they would still be morally flawed. But in fact they allow much more.

### 3. Consistency with Current Law

The President's order authorized the NIH to pursue embryonic stem cell research "to the extent permitted by law."<sup>21</sup> The most directly applicable federal law on this subject is the Dickey/Wicker amendment to the annual Labor/HHS appropriations bills, approved by Congress every year since 1995. This provision forbids the use of federal funds to (1) create human embryos for research, or (2) support "any research in which" human embryos are harmed, destroyed or subjected to risks not permitted for unborn children in the womb.<sup>22</sup>

The claim that these Guidelines are consistent with existing law is based on the assumption that paragraph (2) of the Dickey/Wicker provision, forbidding federal funding of "research in which" embryos are destroyed, forbids only the direct use of federal funds for the act of destroying embryos -- thus all subsequent steps in the research project, making use of stem cells obtained through this act of destruction, may receive federal funds. This assumption is flawed. If Congress had intended to forbid only the use of federal funds for the act of destruction, it would have said so in language mirroring the immediately preceding paragraph (1), which prohibits the use of federal funds for the creation of human embryos: "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..." But Congress did not do that. Instead it barred the use of federal funds for "research in which" a human embryo is destroyed, discarded or harmed, which goes beyond merely barring the use of federal funds for destroying a human embryo.<sup>23</sup>

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<sup>21</sup> Executive Order 13505, note 7 *supra*, sec. 2, at 10667.

<sup>22</sup> Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, Div. F, tit. V, § 509(a).

<sup>23</sup> Interpreting paragraph (2) to cover only the act of destruction itself would violate two principles of statutory construction. First, a statute must be construed to avoid rendering any of its words superfluous. *Walters v. Metropolitan Educational Enterprises*, 519 U.S. 202, 209-10 (1997); *United States v. Menasche*, 348 U.S. 528, 538-39 (1955). The NIH's interpretation renders the words "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.*

In 2002, HHS's then-General Counsel opined that the Dickey-Wicker amendment would not be violated by an executive branch policy that permits federal funding of research on a discrete set of stem cells derived from human embryos "with respect to which the life and death decision had been made" prior to the policy's announcement, and which provided "no incentives for the destruction of additional embryos."<sup>24</sup> However, even if this interpretation is valid, it has no application to the new Guidelines, which give researchers a financial incentive to destroy new living human embryos as an integral and necessary part of the research project that NIH intends to fund. The Guidelines' detailed protocol for how to regulate the consent process and obtain human embryos for destruction is best described as the initial phase of a larger research project which will receive funds from the federal government. Thus, in our view, the Guidelines violate the intent of federal statutory law.

### Comments on Specific Provisions

These additional specific comments are to be understood within the larger context of our general comments above, to the effect that the Guidelines overall are morally unacceptable, medically unnecessary, and legally flawed. Those basic flaws will not be resolved by addressing the specific questions below.

1. The Guidelines require "a clear separation" between the parents' decision to create embryos for reproduction and their decision to donate some embryos for destructive research. Guidelines, II.B.4, 74 *Fed. Reg.* at 18579. The nature of this "separation" is left undefined. Arguably it could mean nothing more than a separate consent form regarding the future disposition of any embryos that later turn out to be "spare," a form provided immediately after the decision to create embryos for reproduction. This interpretation is supported by the Guidelines' statement that parents should again be asked about their decision later, when the time to donate the embryos has actually arrived. *Id.*, II.B.5, 74 *Fed. Reg.* at 18579. No waiting period is established between the decision to create the embryos, and the initial decision that some embryos will ultimately be donated for stem cell research, as would have been the case if the Guidelines required that parents be approached with this option only after the embryos were frozen.

2. Given that parents may make their initial decision to donate for research any embryos that ultimately turn out to be "spare," even before any embryos are actually created for

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*United States*, 464 U.S. 16, 23 (1983), and cases cited therein. Thus, NIH is correct when it says that the Dickey-Wicker amendment prohibits "NIH funding of the derivation of stem cells from human embryos." Guidelines, IV.A, 74 *Fed. Reg.* at 18580. It goes wrong by failing to realize that it prohibits *more* than that.

<sup>24</sup> See Memorandum of January 11, 2002, from HHS General Counsel Alex M. Azar II to Dr. Ruth Kirchstein, Acting Director of NIH. An earlier analysis of 1999, by then-General Counsel Harriet Rabb, failed to address this issue at all, but found the Clinton guidelines on stem cell research to be consistent with the Dickey/Wicker amendment based largely on the claim that an embryonic stem cell is not, in and of itself, an embryo. Memorandum of January 15, 1999, from HHS General Counsel Harriet S. Rabb to NIH Director Harold Varmus, M.D. This analysis misses the point, which is not that a stem cell is an embryo but that the NIH would encourage researchers to destroy embryos as part of the project for conducting research on the stem cells thus obtained.



reproduction, nothing in the Guidelines prevents fertility clinics from deliberately overproducing embryos (ostensibly for reproduction) for parents choosing that option, to ensure that a number of embryos will later be available for federally funded research. In practice, then, the Guidelines could invite exactly the abuse they claim to prohibit, that of encouraging the creation of embryos solely so they can be used for stem cell research. The Guidelines do state that decisions about creating embryos for reproductive purposes should be made “free from the influence of researchers” who want embryonic stem cells. *Id.*, II.B.6, 74 *Fed. Reg.* at 18579. However, this seems to be wishful thinking, backed up by no actual safeguards.

3. The Guidelines state that “whenever it was practicable,” the physician responsible for the couple’s reproductive care and “the researcher deriving and/or proposing to utilize” embryonic stem cells “should not have been the same person.” *Id.* The qualifying phrase “whenever it was practicable” creates an obvious and needless loophole, as it is always “practicable” to have these tasks done by different people if that is what the Guidelines require for eligibility for federal funding. More importantly, this provision ignores a much greater abuse, as it contemplates that the researcher “deriving” the stem cells (that is, killing the embryo), and the person making subsequent use of the stem cells in federally funded research, can and often will be the same person. That is the obvious implication of the use of “and/or” in the quoted phrase. The intent of the Dickey/Wicker amendment is once again being violated in this provision. It is difficult to see how one might maintain even the façade that the research project using embryonic stem cells is totally independent of the act of destroying embryos for those cells, when the stem cell researcher is the same person who destroyed the embryos, precisely so he could obtain this grant.

4. The informed consent protocol requires that parents will be told “what would happen to the embryos” when stem cells are “derived” from them. *Id.*, II.B.7.d, 74 *Fed. Reg.* at 18579. This is, to say the least, euphemistic. An informed consent process inviting parents to make a life-and-death decision about their nascent offspring is no place to be coy or evasive. The informed consent guidelines of the American Society for Reproductive Medicine on such donation of embryos for stem cell research state that parents should be told that the process of deriving the stem cells “leads to the embryo’s destruction.”<sup>25</sup> Anything less candid would be a form of malpractice.

5. Listed as “ineligible for federal funding” is research in which human embryonic stem cells or induced pluripotent stem cells “are introduced into non-human primate blastocysts.” *Id.*, III.A, 74 *Fed. Reg.* at 18580. The limitations to this statement are puzzling. Why only “non-human” primate blastocysts? Clearly, any research in which *human* embryos are manipulated in the laboratory (whether injected with stem cells or not) is ineligible for funding under the Dickey/Wicker amendment, because such embryos would be exposed to risks much greater than those generally encountered by embryos in their mothers’ wombs. Moreover, why forbid only the use of primate

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<sup>25</sup> Ethics Committee of the American Society for Reproductive Medicine, “Donating spare embryos for stem cell research,” 91 *Fertility and Sterility* 667-70 (March 2009) at 668.

embryos, as though efforts to make human/cow or human/mouse hybrids by introducing human embryonic stem cells into embryos of other species poses no ethical problem? Here as well, the Guidelines are less strict than those issued by the Clinton administration, which listed as ineligible for federal funding any research in which human embryonic stem cells are “utilized to create or contribute to a human embryo” or are “combined with an animal embryo.”<sup>26</sup>

6. The Guidelines are silent on the neuralgic question whether previously existing stem cell lines – those created before August 9, 2001, that were eligible for federally funded research under the Bush policy, as well as those hundreds of lines created by researchers using private funds since then – will be eligible for federally funded research, even if they were obtained in ways that do not conform in every respect to the new Guidelines. The question presents a moral dilemma that has no morally acceptable solution. If these cell lines are “grandfathered in” to maintain continuity in this field of research, any claim that the Guidelines insist on strict consent protocols and other “ethical” requirements will be rendered largely meaningless. However, if they are not made eligible, the Guidelines will demand that researchers discard their current projects, destroy many more human embryos using the new protocols, and begin again with entirely new cell lines in order to be eligible for federal funds. There is, of course, a solution that transcends this dilemma. Now that researchers in a very short time have produced hundreds of pluripotent stem cell lines using iPS cells, and are finding these cells to be more useful for many applications than embryonic stem cells themselves, the NIH can focus on aggressive pursuit of this and other morally unproblematic avenues, to determine whether embryonic stem cells are simply unnecessary for medical progress.

## Conclusion

In these Guidelines, the NIH is missing an enormous opportunity to show how sound science and responsible ethics can not only co-exist but support and enrich each other. More than a decade after human embryonic stem cells were first isolated, we have seen incredible advances in the use of stem cells to treat dozens of ailments and disabling conditions – but these advances have come from the adult and cord blood stem cells that the NIH has prematurely dismissed as being of secondary interest and limited benefit. The new advance in producing iPS cells without using or harming human embryos has prompted leading stem cell researchers to declare that this is “the beginning of the end” of embryonic stem cell research and its attendant moral controversy.<sup>27</sup>

Here is a new common ground for Americans of many different moral views, a path to cures we can all live with. Yet this Administration seems to be stuck in the ideological battles of the past, as if embryonic stem cell research must receive priority attention and funding precisely *because* so many Americans have raised moral objections.

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<sup>26</sup> See Guidelines of August 25, 2000, note 16 *supra*, Secs. III.B and III.F, at 51981.

<sup>27</sup> See Dr. Thomson in *The Boston Globe*, note 11 *supra*.

Among those declaring “the beginning of the end” of the embryonic stem cell debate is the researcher seen as prompting that debate in the first place, Dr. James Thomson of the University of Wisconsin. Dr. Thomson was the first scientist to isolate and culture human embryonic stem cells in 1998. He is now one of the first scientists to produce the iPS cells that are rapidly replacing embryonic stem cells among researchers. “Isn’t it great to start a field and then to end it,” he says.<sup>28</sup>

Dr. Thomson has said this outcome is a source of no small relief to him personally, as he will no longer have to struggle with his conscience over destroying human embryos for their stem cells in the name of medical progress. Now that other avenues seem equally or more promising for the future of regenerative medicine, he and other researchers have begun to express their own misgivings about the real moral problem of embryonic stem cell research. This is not merely a political or ideological problem, or a problem of religious dogma, but a deeply human problem: We are testing the limits of our obligation to treat all fellow human beings, of every age and condition, with basic respect.

“If human embryonic stem cell research does not make you at least a little bit uncomfortable,” says Dr. Thomson, “you have not thought about it enough.”<sup>29</sup> With all due respect, we hope the President and this Administration will do some more thinking about this issue.

Sincerely yours,



Msgr. David J. Malloy  
General Secretary

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<sup>28</sup> Quoted in G. Kolata, “Man Who Helped Start Stem Cell War May End It,” *The New York Times*, November 22, 2007, at [www.nytimes.com/2007/11/22/science/22stem.html](http://www.nytimes.com/2007/11/22/science/22stem.html). Also quoted in R. Weiss, “Advance May End Stem Cell Debate,” *The Washington Post*, November 21, 2007, A1, at [www.washingtonpost.com/wp-dyn/content/article/2007/11/20/AR2007112000546\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2007/11/20/AR2007112000546_pf.html) (“What a great bookend.... Ten years of turmoil and now this nice ending. I can relax now.”)

<sup>29</sup> Dr. Thomson in *The New York Times*, note 28 supra.