

MEMORANDUM  
Mechanics for Implementing New Federal Policy on  
Embryonic Stem Cell Research

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December 30, 2008 (rev.)

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This memorandum recommends mechanics for implementing a new federal policy expanding funding of human embryonic stem cell ('hESC') research. The analysis develops two principal conclusions. The first is that the contemplated expansion may be authorized by legislation but not by executive order. The second is that in order to support the position that eligible research is morally permissible, the conditions for funding eligibility should include those conditions that confer moral permissibility, this as set forth in a bill included herein.

#### **SUMMARY**

According to conventional wisdom, an opinion of counsel has established that funds may be provided for hESC use without violating the Dickey Amendment's prohibition on funding for embryo-exploitative research. It is explained herein that such opinion does not offer the argument ascribed to it, and that neither the argument that the opinion does give, nor any plausible interpretation of the prohibition, sustains the opinion's conclusion. The analysis of the prohibition begins by posing alternative interpretations of its term 'research.' The analysis adduces an articulated legislative intent to preclude complicity in embryo destruction. It is observed that, directly and by invisible hand effects, hESC use induces embryo destruction. It is concluded that, according to the most plausible interpretation of the prohibition, hESC use constitutes embryo-exploitative research by virtue of being part of a research whole consisting of hESC use and embryo destruction induced by demand for hESC. Hence the prohibition bars funding for hESC use. An attempt to maintain a contrary view would verge on self-contradiction by the hESC investigator: it would have the investigator first attest to compliance with norms that demand painstaking scrutiny of embryo procurement and hESC derivation by the investigator's hESC supplier, then would have the investigator claim that embryo destruction is not part of any research whole that should be associated with the investigator in applying the prohibition. Given President-Elect Obama's forthrightness and respect for law, as both scholar and public official, it is urged that he would not wish, by executive order or through agency action, to defy a statute by purporting to authorize what it forbids.

The president may propose to Congress legislation that will override the statutory prohibition to the extent of authorizing a desired scope of research. The crucial provisions of authorizing legislation will be the conditions that render an embryo eligible for use as a subject. Prospects for a stable consensus hinge on whether those conditions ground a moral justification for embryo use within an overlapping consensus of conceptions of justice. Such a justification may be found by moral reasoning that eschews reliance on any premise peculiar to one or another moral or religious view. A bill predicated upon a consensus justification is proposed and explained. Of crucial moral importance is that this bill, unlike legislation twice recently enacted, makes progenitor decisions paramount. The linchpin of the justification is a progenitor decision against intrauterine transfer, this coupled with a

choice to restrict use of a donated embryo to medical research and therapy, each as communicated in written instructions to a donee. The recent legislation has muddled the order of authority between physician and patient and thereby failed to require the conditions of embryo donation that confer moral permissibility. The recent legislation has also inadvertently provided for funding of hESC derivation. Other drafting differences between the recent legislation and proposed bill are noted. The proposed bill should enjoy support even broader than the recent decisive majorities: the scope of authorized research is coextensive with that intended for the recent legislation, while the moral foundation of the proposed bill is stronger and more transparent. The more conspicuous our moral logic, the better the prospects for consensus.

## 1. SCOPE OF AUTHORIZED RESEARCH

Harkening to the expressed views of the President-Elect, and to the concurrence therewith of the biomedical research community, we may take the following to define the scope of funded hESC research sustainable by a present political consensus:

**‘Eligible hESC’ are human embryonic stem cells derived from human embryos that, after creation by *in vitro* fertilization in the practice of assisted reproduction, have been donated to medicine on the condition that no intrauterine embryo transfer shall occur. ‘Eligible hESC Research’ consists in the use of Eligible hESC in medical research and therapy. In the preceding sentence, ‘use’ stands in contradistinction from deriving Eligible hESC from embryos.**

As I have elsewhere argued, a consensus moral justification may be given for the use, in service of humanitarian ends, of embryos donated under instructions forbidding intrauterine transfer.<sup>1</sup>

The task undertaken here is to specify feasible mechanics for authorizing the conduct and support of Eligible hESC Research by the National Institutes of Health (‘NIH’).

## 2. IMPETUS FOR CHOSEN SCOPE

The concept of Eligible hESC Research owes its origin to the scope of research that, during the last two years of the Clinton administration, was declared

<sup>1</sup> *The Morality of Embryo Use* (Cambridge: Cambridge University Press, 2008), pp. 21–50, 53–54, 184–187. The justification devolves from the decisively bounded developmental potential of embryos permissibly barred from the womb. The scope of embryo use encompassed by such justification is broader than Eligible hESC Research. (A comparison is shown schematically in “[A Proposed Stem Cell Research Policy](#),” *Stem Cells* 23: 1023–1027, 1027 (2005). **This font** signifies a hyperlink. Eligible hESC Research is coextensive with the research associated there with the Stem Cell Research Enhancement Act of 2005.) I do not discuss the reasoning for the broader scope here.

fundable by NIH. NIH announced then a policy by which it would fund studies of hESC while purportedly complying with the Dickey Amendment ('DA').

DA reads in pertinent part as follows:

SEC. 509. (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 ['Embryo Creation']; 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 17 CFR 46.204(b) and section 498(b) of the Public 18 Health Service Act (42 U.S.C. 289g(b)) ['Embryo-Exploitative Research'].<sup>2</sup>

The bracketed expressions have been inserted for reference purposes. We shall see shortly how NIH carved its policy relative to DA.

DA is not presently in effect. Congress has not yet enacted the FY 2009 appropriations bill to which DA would be a rider.<sup>3</sup> (DA's verbatim predecessor for FY 2008 restricted only funds appropriated for that year.) The sponsor of the appropriations bill is Senator Harkin, a supporter of hESC research. For those who approve the medical use of donated embryos barred from the womb, and who therefore oppose DA, this might seem a propitious time to eliminate DA subsection (a)(2), a provision hereafter called 'the unavailability of Embryo-Exploitative Research.'<sup>4</sup> If that provision were eliminated, thereafter the president could alone install a new policy: he could issue an executive order rescinding the current policy,<sup>5</sup> then authorize NIH funding of Eligible hESC Research. (It would then even be arguable that the latter authorization is superfluous—if both the current policy and the unavailability of Embryo-Exploitative Research were eliminated, the Director of NIH would possess authority to fund hESC research—but the opportunity to foster

<sup>2</sup> §509, Title V, S. 3230, [Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009](#) (p. 123), and verbatim annual predecessors since 1996. The phrase 'funds made available in this Act' refers to funds appropriated for the Department of Health and Human Services ('HHS'). It has been argued that a nonconscious being cannot be harmed. I have defended a concept of harm to an embryo (*The Morality of Embryo Use*, pp. 34–35; see also Stephen L. Darwall, *Welfare and Rational Care* [Princeton: Princeton University Press, 2002]).

<sup>3</sup> [S. 3230, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009](#).

<sup>4</sup> We may assume that a political consensus has not yet formed to eliminate subsection (a)(1), a provision that bars funding of nonreprocloning (somatic cell nuclear transfer whose product is never transferred to a uterus) and parthenogenesis in research.

<sup>5</sup> The current policy is implemented in "[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) and [Executive Order 13435](#), 72 Fed. Reg. 34589-34593 (June 22, 2007).

consensus would in such case suggest a presidential directive.) But it does not appear that the unavailability of Embryo-Exploitative Research will be eliminated in the near future. The whole of DA is perceived as a cornerstone of the presently achievable political consensus. Hence in the following, we first assume that DA is reenacted. We consider the mechanics of authorizing Eligible hESC Research while DA remains in effect. At the close (in §6.2), we may take note of the ramifications of altering DA at some future time.

### 3. EXECUTIVE AUTHORIZATION PRECLUDED BY STATUTORY PROHIBITION

We return to NIH's previously mentioned policy.

#### 3.1 Opinion of counsel fails to establish conclusion

On January 19, 1999, Dr. Harold Varmus, Director of NIH, announced that NIH had received an opinion of counsel concluding that DA does not prohibit NIH funding of research that utilizes hESC (‘the Rabb opinion’).<sup>6</sup> Immediately it was reported in the press that the Rabb opinion had drawn a distinction between use of hESC and derivation of hESC. It was said that the opinion had concluded that while DA prohibited derivation of hESC, DA did not prohibit use of hESC.<sup>7</sup> NIH then promulgated guidelines according to which NIH would provide funds for research utilizing hESC (the ‘2000 Policy’).<sup>8</sup> NIH declared that it would not provide funds for derivation of hESC.<sup>9</sup> Although NIH expressed the conditions of eligibility by different phrasing, the scope of research was coextensive with what is here defined as Eligible hESC Research. The 2000 Policy narrated that NIH had sought and received the Rabb opinion, then cited the Rabb opinion for the conclusion that “NIH funding for research using pluripotent stem cells derived from human embryos is not legislatively prohibited.”<sup>10</sup> Thereafter, numerous press reports and commentaries

<sup>6</sup> Memorandum dated January 15, 1999 of Harriet S. Rabb, General Counsel of HHS, to Director, NIH ([Appendix](#)). The expression ‘hESC’ previously used as a modifier is also used here to denote cells.

<sup>7</sup> Eliot Marshall, “Ruling May Free NIH to Fund Stem Cell Studies,” *Science* 283: 465–467 (January 22, 1999), and “Ethicists Back Stem Cell Research, White House Treads Cautiously,” *Science* 285: 502 (July 23, 1999).

<sup>8</sup> “[Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells](#),” 64 Fed. Reg. 67576 (December 2, 1999), “[Guidelines for Research Using Human Pluripotent Stem Cells](#),” 65 Fed. Reg. 51976 (August 25, 2000), and “[Guidelines for Research Using Human Pluripotent Stem Cells; Correction](#),” 65 Fed. Reg. 69951 (November 21, 2000).

<sup>9</sup> The 2000 Policy declared that “NIH funds may not be used to derive human pluripotent stem cells from human embryos,” and that “studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds 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).

<sup>10</sup> 64 Fed. Reg. 67576–67577, 65 Fed. Reg. 51976. Though the 2000 Policy did not identify the passage of DA on which the Rabb opinion was thought to be decisive, it was

glossed the Rabb opinion as having drawn a distinction between prohibited hESC derivation and permissible hESC use.

By virtue of that gloss, which has endured to the present, the Rabb opinion has become an interpretation misinterpreted. The Rabb opinion does not draw a distinction between derivation and use. The opinion instead poses and answers the question whether hESC are embryos.<sup>11</sup> It reasons that because hESC are not organisms, hESC are not embryos according to DA's definition.<sup>12</sup> On the basis of this deduction, the opinion offers the conclusion that "federally funded research that utilizes hPSCs would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such cells are not human embryos." The expression 'utilizes hPSCs' in the preceding sentence is the opinion's only reference to hESC use.<sup>13</sup> The reader will search in vain for a discussion of, or a suggested reason to distinguish, derivation and use.

The Rabb opinion has been claimed to say something that it does not. How could this have occurred? A partial answer may lie in the circumstance that the Rabb opinion has never been published in a generally accessible medium. The opinion may have been invoked by some, including commentators of the present day, who have not read it. Others who have seen it, but not known the legal context, may not have parsed it carefully. From the opinion's truism that hESC are not embryos, it follows that procedures performed on hESC are not procedures on embryos. But that tautology does not sustain the opinion's conclusion.

In respect of the unavailability of Embryo-Exploitative Research, the interesting question is not the definition of 'embryo,' but the construal of 'research.' To show that research utilizing hESC is fundable, one would have to show, as we shall see shortly below, that hESC use should not be considered "research in which a human embryo or embryos are destroyed" by virtue of being part of a whole that includes embryo destruction. That showing will be a tough row to hoe. The opinion never discusses the construal of 'research.' The opinion's argument is therefore the equivalent of

apparent that only Embryo-Exploitative Research was in point. The 2000 Policy did not license Embryo Creation (and by virtue of the fact that derivations were barred, Embryo Creation would not have been authorized even if, in a possibility considered in the Rabb opinion, hESC were embryos).

<sup>11</sup> Referring to hESC as "pluripotent stem cells derived embryos," or "hPSCs."

<sup>12</sup> §509(b), Title V, S. 3230. Whether an early embryo is an organism is a controverted question in the philosophy of biology (see *The Morality of Embryo Use*, pp. 89, 92–96), but for present purposes, we accept the statutory definition.

<sup>13</sup> Rabb opinion, p. 4. A repetition of this conclusion is given in slightly different phrasing employing the gerund "utilizing" ("Summary Answer," p. 1). I related the misinterpretation of the Rabb opinion and its failure to sustain its conclusion in "[Morals and Primordials](#)," *Science* 292: 1659–1660 (2001), and "[A Proposed Stem Cell Research Policy](#)."

Because hearts are not persons, use of public funds for experiments on hearts is permissible even if the experimenters have induced the deaths of the sources.

Nothing so callous as to cordates could have been contemplated by the author. But so runs the logic of asserting that mere failure of hESC to constitute embryos suffices to render studies of hESC eligible for funding.

Thus we have seen that the Rabb opinion failed in its attempt to establish fundability of hESC research. This opinion's reasoning cannot sustain a claim of executive authority to fund Eligible hESC Research.

### 3.2 Interpretations of 'research'

Apart from any prior discussion, or lack of it, we may consider afresh the question at hand. If NIH were to provide funding for use of hESC, but not for derivation, would NIH violate DA? That is, does DA allow funding of Eligible hESC Research?

We know that research harmful to embryos evokes moral concern, and that DA was motivated by such concern. In this context, a common sense reading of 'research' in the exclusionary phrase "research in which a human embryo or embryos are destroyed" would seem to be an inclusive reading. It would read the statute to disallow support for any part of a research whole in which embryos are destroyed. Of course there arises the question of what constitutes a whole, but the following may be said. An artificial division of labor between obtaining and using embryonic derivatives does not prevent recognition of their joinder as a single project. Any division of labor motivated less by scientific reasons than by a wish to dodge DA would seem artificial. Hence a common sense interpretation suggests that DA prohibits funding of hESC use.

Now enter advocates desirous of concluding that DA allows funding of hESC use. They are apt to cite the Rabb opinion for that conclusion, then leave the matter there. Since we now know that the Rabb opinion does not establish its conclusion, they must offer some argument for their desired conclusion. So they assert that there may occur hESC research that is conceptually separable from hESC derivation. They contend that DA should be read to allow funding for some occurrences of the former even as it bars funding for all occurrences of the latter. This notion of conceptual separation requires for its support some notion of the individuation or mereology of events. (Mereology is the logic of parts and wholes.) To sustain such a notion will require some rigor as to the metaphysics of events. So as to give expression to their view in its strongest form, we therefore pose the *disaggregation interpretation* of 'research.' This interpretation asserts that in "research in which a human embryo or embryos are destroyed," the definition of Embryo-Exploitative Research, 'research' signifies an individual event of the kind *research*, and that, in a causal chain of events beginning with donation of an embryo to medicine, one or more elements of the chain may be individuals of the kind *research*. A pertinent causal chain will include occurrences of embryo donation, hESC derivation, and hESC use. The interpretation then stipulates that occurrences of hESC derivation and hESC use are individuals of

the kind *research*. Since an occurrence of hESC use does not itself destroy or harm an embryo, it follows that an occurrence of hESC use constitutes an individual research event that is not Embryo-Exploitative Research. Such an event, it is contended, may be funded without violating DA. Hence DA does not bar funding of hESC use.

As we shall shortly see, DA's proponents sought to preclude complicity in and contribution to putative wrongdoing. Hence a different interpretation inevitably suggests itself. This reading takes account not only of the mereology of events, but of causation. It is first said that events  $e_1$  and  $e_2$  are *related by demand inducement* if demand for materials of the sort used in  $e_2$  has induced, directly or by invisible hand effects, supply of such materials by occurrence of  $e_1$ . The *fusion* of  $e_1$  and  $e_2$ , written ' $e_1 + e_2$ ,' is their mereological sum. This is defined as that thing that overlaps all and only things that overlap  $e_1$  or  $e_2$ . (The fusion of two things may also be described as the smallest thing of which both are parts. We may recognize the fusion of any two things; what significance we assign to a fusion is a matter of choice.) Each of  $e_1$  and  $e_2$  is a part of  $e_1 + e_2$ . The *fusion interpretation* now asserts that in the definition of Embryo-Exploitative Research, 'research' signifies an individual event of the kind *research*, and that for any causal chain of events beginning with donation of an embryo to medicine, if two elements of the chain are individuals of the kind *research* and are related by demand inducement, the fusion of such elements is also an individual of the kind *research*, and is called an *induced fusion*. It is then said that if a research event  $e$  is a part of an induced fusion that constitutes Embryo-Exploitative Research,  $e$  constitutes Embryo-Exploitative Research. Thus is the fusion interpretation stated. It is observed that any occurrence of hESC use is an event of a causal chain that includes some occurrence of hESC derivation to which such occurrence of hESC use is related by demand inducement.<sup>14</sup> The induced fusion of such occurrences of hESC use and hESC derivation constitutes Embryo-Exploitative Research, and of this induced fusion, the occurrence of hESC use is a part. Hence DA bars funding of hESC use.

### 3.3 Fusion interpretation the more plausible

Regardless whether one supports DA, its legal effect depends upon its plain meaning and the legislative intent. The following considerations show the fusion interpretation of 'research' to be the more plausible, and the disaggregation interpretation untenable.

#### 3.3(a) Congressional admonition to heed breadth of prohibition

In a letter to Secretary of Health and Human Services Donna E. Shalala,

<sup>14</sup> Inducement of hESC derivation by demand for hESC qua research materials "may occur one-to-one, as when an investigator induces a collaborator to supply cells, or may occur by an invisible hand effect, as when aggregate demand of consumers acting independently induces aggregate supply by suppliers acting independently" ("[A Proposed Stem Cell Research Policy](#)," p. 1024). Of this more shortly below.



seventy members of Congress led by Rep. Dickey attacked the Rabb opinion and the NIH decision to rely upon it.<sup>15</sup> They argued that when DA's drafters wished to refer to events of kinds narrower than *research*, they knew how to do it. In DA subsection (a)(1), they referred "narrowly" to "the creation of" an embryo. In subsection (a)(2), they could have referred only to "the destruction or discarding of human embryos," but instead they referred more broadly to "research in which" events of such kinds occur. To buttress this argument that the breadth of subsection (a)(2) may be shown to have been deliberate by observing the narrower scope of subsection (a)(1), Dickey *et al.* drew on a Supreme Court decision in which an attempt to deny the breadth of one subsection was held to be "refuted by the language of" a narrower adjoining subsection.<sup>16</sup> Dickey *et al.* urged that HHS "put a stop to a proceeding which so clearly does violence to the meaning and intent of Federal law."

### 3.3(b) *Concern for complicity through inducement*

For proponents of DA, a compelling motivation obtained for inserting "research in which." The motivation of DA was not fiscal discipline. Nor was the motivation efficiency, nor vindication of a view about which diseases pose greater threats. The motivation was moral. DA's sponsors harkened to the contention that the government should not render taxpayers complicit in the putative wrongdoing of embryo sacrifice. Hence the complaint by Dickey *et al.* that "it would be a travesty for this Administration to attempt to unravel" what it called an "accepted ethical standard."

The following explains that government support for hESC research brings complicity in its train. Later subsections explain why legislative intent to prevent complicity compels the fusion interpretation.

Complicity is said to obtain when a moral agent becomes blameworthy by dint of some nexus to a wrongdoer.<sup>17</sup> Contributing to or inducing harm is one type of complicity-generating nexus. As I have elsewhere explained,

If  $s_j$ , who derives and studies embryonic stem cells without use of public money, sacrifices an embryo in order to meet a request for embryonic stem cells from some public scientist  $t_i$ ,  $s_j$  and  $t_i$  are effectively collaborators (and will probably call themselves such). Another  $s_j$ 's sacrifice of an embryo may not correspond to any particular public scientist's request. It may be that  $s_j$  sacrifices embryos so as to develop cell lines for  $s_j$ 's own work, and, in fulfilling requests from other scientists,  $s_j$  may split

<sup>15</sup> Letter dated February 11, 1999 of Representative Dickey *et al.* to Secretary Shalala.

<sup>16</sup> *Russello v. U. S.*, 464 U. S. 16, 23 (1983), quoting with approval a holding in *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5<sup>th</sup> Cir. 1972), that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."

<sup>17</sup> *The Morality of Embryo Use*, p. 175. Readers of this work will know that I hold hESC research to be virtuous. The motivation of the present discussion is respect for law, not endorsement of it.

off and ship cells from already created, indefinitely propagating lines. Still another  $s_k$  might be a nonprofit institution that regularly sacrifices embryos as  $s_k$  develops and stockpiles embryonic stem cell lines in anticipation of demand from public stem cell scientists. Public scientists who receive cells from  $s_i$ ,  $s_j$ , or  $s_k$  must provide assurances to their institutional review boards concerning their sources of embryonic derivatives. Hence in their research protocols, public scientists will identify these intermediaries as their sources.

In each of the foregoing cases, public scientists have induced supply. Demand for embryonic derivatives induces supply not only directly, but as an invisible hand effect of the independent actions of prospective investigators. . . . We have seen this illustrated in another controversy in which complicity is pivotal. A furrier acquires coats from wholesalers at the end of a distribution chain composed of multiple intermediaries. The furrier never lays a hand on an animal, but the furrier's demand for coats, and that of other retailers acting independently, produces a retail demand function for coats. This supply-inducing effect renders the retailers complicit in animal killing. Antivivisectionists would add that consumers who buy fur coats are also complicitous in animal killing, this by an invisible hand effect creating the consumer demand that engenders retail demand.

Complicity transmits through the channels of inducement. When a chain of induced supply runs from investigators who sacrifice embryos to investigators who experiment with the sacrificed embryo's derivatives, the downstream investigators are complicit in embryo sacrifice. From a moral point of view, the source and the recipient ride in the same boat.

. . . [T]he circumstances of research are such that there is no practical scheme for supplying embryonic derivatives to funded projects that will immunize the projects' investigators or funding grantors from complicity in embryo sacrifice. Embryo-based research without complicity in embryo use is infeasible.<sup>18</sup>

Someone who worries about complicity worries about cooperating with evil, condoning wrongdoing, or effecting scandal. Concern attaches to indirect as well as direct effects of conduct. Concern attaches to appearances. By definition, complicity concerns conduct removed from an agent's immediate actions. Someone concerned about complicity will look straight through a purported responsibility firewall, self-serving characterization, or any other artificial arrangement designed to mask responsibility or to let someone off the hook for conduct that they appear to foster, aid, or induce.

A taxpayer who loathes complicity in embryo destruction two steps removed, as when performed by government-funded investigators, will also abhor embryo destruction three steps removed, as when performed by investigators induced by demand generated by government-funded investigators. Such a taxpayer will maintain that a government that funds hESC use will render taxpayers complicit in embryo sacrifice induced by funded demand for hESC.

<sup>18</sup> *Ibid.*, pp. 215–216. 'Public scientist' is used here for a scientist for whose research in regard to embryos the state directly or indirectly provides funds.

### 3.3(c) *Contribution to embryo destruction*

The 2000 Policy effectively compelled an investigator not only to be complicit in, but to be involved in, embryo-destructive hESC derivation, this to the following extent. The policy provided that consent to donate an embryo must not be sought until after an embryo is “determined to be in excess of clinical need,” that detailed requirements be met concerning disclosures to a prospective embryo donor and the informed consent process, that a person performing a derivation not be the attending physician to the embryo donor, and that no inducement be offered for a donation. The policy provided that an investigator seeking a grant must file with NIH the following: an assurance that all the foregoing requirements have been satisfied, a copy of the form of informed consent, a description of how consent was obtained, an abstract of the derivation protocol, and documentation of an institutional review board’s approval of the protocol.<sup>19</sup>

Thus NIH insisted that a funded investigator using hESC must enter deeply into dictating and scrutinizing the circumstances in which progenitors donate an embryo to the scientist who performs derivation of hESC. This seemingly draws the funded investigator into so contributing to, not merely inducing, hESC derivation that it scarcely seems plausible to deny that derivation is a stage of an individual of the kind *research* of which the investigator’s work is a part. On the other hand, in order to assert compliance with DA, the investigator and NIH would have to maintain, here adopting the disaggregation interpretation, that the funded hESC research is not “research in which a human embryo or embryos are destroyed,” and that nothing more need be said. To support that conclusion, NIH would have to suggest that, by forbidding use of federal money to pay for hESC derivation, NIH policy erects a firewall shielding the funded investigator, and taxpayers, from complicity in embryo destruction. So, in the first instance, the investigator must contend that derivation is procured, prescribed, scrutinized, and accounted for by the investigator in the course of an endeavor that the investigator presents to an institutional review board and NIH for approval, and, in the second case, the investigator must contend that hESC derivation is not part of any individual of the kind *research* that is associable with the investigator’s use of federal funds. This line of defense verges on the self-contradictory. The firewall would no sooner be built than the interactions of funded investigator and hESC supplier would demolish it.

Someone might try to avert contradiction by asserting that derivation is “procurement of materials,” not research. But that claim would be belied by the fact that derivation consists in immunosurgery followed by cell culture techniques performed by specialists in stem cell research.

Nor could NIH scrap the above-mentioned mandates. Only by imposing a set of conditions that provide for morally permissible research may NIH assure the moral permissibility of what it funds. Because the morality of donated embryo use

<sup>19</sup> 65 Fed. Reg. 51979-51980.

depends on decisions of progenitors, insistence upon and verification of morally permissible embryo use unavoidably involves mandates about structuring and scrutinizing interactions among progenitors, their physicians, and embryo donees who perform derivations. A careful investigator would impose conditions of such sort anyway in order to assure the morality of the investigator's work. One must take a sceptical view of any claim that an investigator conducting morally permissible hESC research is free of involvement in hESC derivation.

### 3.3(d) *Fusion interpretation as precluding inducement and contribution*

The disaggregation interpretation purports to allow one to separate hESC derivation, for purposes of testing for Embryo-Exploitative Research, from everything else. By that interpretation, an investigator could receive federal funding for hESC experiments using cells derived by the investigator with private funds. Precisely that practice is envisioned under a policy providing for Eligible hESC Research. But it is not plausible to read DA as allowing that practice. Supposing that the disaggregation interpretation were adopted, and that funded investigators were permitted to procure hESC by means as ready at hand as performing the derivations themselves—or as complicitous as instructing and scrutinizing others who perform the derivation—an NIH-funded investigator could conduct hESC studies merely by garnering modest private support for performing derivations or buying cells. Whereupon DA would be a hollow accomplishment. DA would have allowed large-scale funding of research whose demand for materials induces embryo destruction. Congress would not have bounded the quantity of embryos killed in research at an amount that, so it would seem, would be much less than what the amount would be were the government to pay for the derivations. From that quantitative point of view, any suggestion that DA had protected embryos would be empty rhetoric. Congress would also have allowed so much investigator involvement in derivations that it would become plain that taxpayer complicity had arisen for conduct contributed to as well as conduct induced. Hence the disaggregation interpretation collides with a common sense understanding of what those who voted for DA, motivated by the moral concerns that animated them, expected to accomplish.

DA prevents involvement in embryo destruction by others and complicity in induced destruction only if the fusion interpretation of 'research' in the definition of Embryo-Exploitative Research is given effect. Only on that interpretation does Embryo-Exploitative Research capture the acts and practices effecting such involvement and giving rise to such complicity.

### 3.3(e) *Congressional objection to funding inducement*

It does not appear that the sponsors of DA anticipated the disaggregation interpretation. It also seems clear that had they thought of it, they would have rejected it. Dickey *et al.* argued as follows:

We prohibited the funding of . . . projects where the material used in the experiments is obtained by destruction of an embryo that would not otherwise be done (or not otherwise done in the same way).<sup>20</sup>

This reference to embryo destruction that would not otherwise occur may be understood to describe induced embryo destruction. Thus did the principal sponsor of DA, with conferees, declare that they had prohibited funding for experiments that would induce destruction of embryos in order to obtain research materials.

Secretary Shalala replied to Dickey *et al.*, but neglected to discuss the foregoing objection.<sup>21</sup> Instead she challenged remarks by Dickey *et al.* that DA bars funding of research that “follows or depends upon” embryo destruction or harm, or for which embryo destruction or harm is a “necessary prerequisite.” The Secretary urged the contrary, asserting that the provision on Embryo-Exploitative Research does not apply to research “preceding or following embryo destruction,” but she gave no argument for her contrary assertion. She could have argued convincingly that a rule intended to prevent moral complicity in wrongdoing of a given kind would sweep too broadly were it to condemn every act consequent on wrongdoing of that kind. (We do not wish to prohibit receipt of organs for transplantation where a source’s death was consequent on wrongful conduct but the prospective transplant recipient had no involvement in the death.) But parrying the foregoing remarks by Dickey *et al.* was beside the point. Their stance against funding of hESC use was sustained by their complaint of inducement.

Incentives created by funding research on embryonic derivatives were also the principal ground of objection by seven prominent DA proponents in the Senate. They complained 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.<sup>22</sup>

The seven senators described the stance taken by NIH as “a unilateral attempt on your part to effectively undermine congressional intent” by “circumventing” DA.

The disaggregation interpretation would allow federally-supported hESC use generating incentives for nonfunded scientists to perform embryo-destructive hESC derivations. The fusion interpretation would not allow that.

### 3.3(f) *Disaggregation interpretation allows studies of clone derivatives*

Another strike against the disaggregation interpretation is that under such interpretation, DA would allow NIH to fund studies of hESC derived from clones. DA subsection (a)(1) bars Embryo Creation, but the work of denying support for studying derivatives of created embryos falls to the unavailability of Embryo-

<sup>20</sup> Letter of Dickey *et al.*, p. 2.

<sup>21</sup> Letter dated February 23, 1999 of Secretary Shalala to Rep. Dickey.

<sup>22</sup> Letter dated February 12, 1999 of Senators Brownback, Nickels, Kyl, Helms, Ashcroft, Smith, and Enzi to Secretary Shalala.

Exploitative Research in subsection (a)(2), and only on the fusion interpretation is that work accomplished.

3.3(g) *Disaggregation interpretation under siege*

In the foregoing chorus of protest against the 2000 Policy, various interest groups joined. As had DA's proponents in Congress, these advocates announced plans to sue for an injunction, an injunction enforcing DA by ordering NIH to refrain from funding hESC research.

Upon imagining arguments of these congressional and other advocates in court, we hear the untenability of the disaggregation interpretation. Their counsel would have had a field day with the government's case. Addressing a witness for the Secretary, counsel might have begun by saying, "Please identify the passage in the Rabb opinion that draws a distinction between derivation and use." Counsel for members of Congress might have gone on to argue, "Your Honor, my clients are nothing if not categorical. They favor simple rules, most of which fit on bumper stickers. They meant to prevent taxpayer complicity in embryo destruction, completely and unexceptionably. They never imagined that an agency, departing from what even its own counsel advises it, might claim that embryo killings are not part of a research project if the investigators induce other people to do the killings. The drafters of the statutory prohibition, motivated as they were, would have blocked any move so devious had they anticipated it. They were motivated to condemn embryo destruction, as were their constituents, not by financial or prudential considerations. They sought to prevent moral complicity in embryo sacrifice. It is inherent in the concept of complicity that connections between acts matter. One looks through artifices to detect contribution, inducement, or indirect involvement. No responsibility firewall stands between those who induce and those who perform embryo killings. In view of the manifest legislative intent, there is no colorable reason to withhold 'research' from research of a kind whose demand for materials induces embryo killings." By all indications, the plaintiffs would have won hands down.

As events transpired, the NIH never dispensed any funds pursuant to the 2000 Policy. The arrival of a new administration brought a suspension of the policy, then its revocation.<sup>23</sup> The policy was replaced by what I have called the "surprise announcement scheme" of August 9, 2001. That scheme was itself a violation of DA, this by dint of induced embryo destruction.<sup>24</sup> Few voices were heard to complain of

<sup>23</sup> Formal revocation was effected in National Institutes of Health, "[Notice; Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells Derived from Human Embryos](#)," 66 Fed. Reg. 57107 (November 14, 2001).

<sup>24</sup> I have explained this as follows:

[T]he historical facts cut the legs from under the surprise announcement scheme. After well-publicized deliberations, the National Institutes of Health (NIH) published notice on August 25, 2000, a year before the surprise announcement, that it would fund

that violation. Members of Congress who objected to the Clinton policy fell silent. Perhaps they did not wish to attack an administration of their own party, which was then thwarting efforts of political liberals to fund a wider scope of embryo-destructive research. They may also have reflected that the new policy authorized only a trickle of hESC research and purportedly would not induce any future embryo destruction,<sup>25</sup> or that an injunction against the presidential policy might spur liberal opponents to introduce legislation authorizing a broader scope. For its part, the White House did not tarry over the basis of presidential authority. It did not discuss DA, did not invoke the Rabb opinion. By its standards, the surprise announcement scheme was a modest step. One has only to recall the leaps that it routinely took while emboldened by its claims about “the unitary executive.”

Were a Democratic president today to reprise the Clinton administration gambit, and attempt to authorize funding of hESC research by executive action (executive order, agency policy, or rulemaking), no obvious consideration would motivate DA’s proponents in Congress, or like-minded advocates, to forbear from suit.

### 3.3(h) *Agency failure to consider fusion interpretation*

The history of NIH’s failure to engage the aforementioned criticisms of its interpretation of DA may furnish guidance for the future. When NIH published its draft guidelines on December 2, 1999, HHS had had nearly a year to consider the argument, raised by members of Congress (if not by others), that the breadth of the term ‘research’ was such that hESC use would constitute Embryo-Exploitative Research. But the draft guidelines, after narrating that the Rabb opinion had been obtained and reciting its conclusion, did not acknowledge any question raised about the opinion. Later in announcing the final 2000 Policy, NIH responded to comments on many matters of detail in the draft guidelines. But again on the fundamental

embryonic stem cell research . . . . Thereupon, so we must assume, the prospect of federally funded support boosted the invisible hand effect in which demand of independently acting investigators for embryonic stem cells induces supply. . . . The NIH’s stipulation that it would not fund derivations increased the incentive for scientists not funded by NIH to develop cell lines. . . . NIH’s announcement may even be said to have established the complicity nexus of rendering embryo destruction “more eligible in an experimenter’s mind.”

. . . . [G]overnment is a continuously existing entity. The entity does not escape moral responsibility for a direct or induced wrong because its stewards change (“[A Failed Noncomplicity Scheme](#),” *Stem Cells and Development* 13: 456–459 [2004]).

<sup>25</sup> The latter surmise would have neglected the circumstance that

If it is known or anticipated that the government will periodically advance the cutoff date, then demand by NIH-funded scientists will continuously induce creation of cell lines in the expectation of the next advance. As the scheme responds to scientific need, it will torpedo the noninducement premise on which its justification depends (*ibid.*, p. 458).

question whether the policy was itself legally permissible, the agency offered no discussion. It did not mention the issue of how to construe ‘research’ in DA’s definition of Embryo-Exploitative Research. Rather it reiterated the Rabb opinion’s conclusion. Then it added this remarkable statement: “Comments questioning this conclusion did not present information or arguments that justify reconsideration of the conclusion.”<sup>26</sup> Why this short shrift? It may be that, as occurred in the Rabb opinion, the authors of the 2000 Policy missed the significance of induced embryo destruction—and thus the importance of construing ‘research’—even though congressional submissions had been emphatic. Or perhaps they discounted the congressional objections because of unsophisticated phrasing, or perhaps they supposed that insights would not issue from the known political biases of their critics. If indulged, such reasoning would have misled them, because as we have seen, the congressional objections can be given a rigorous formulation, and it refutes NIH’s conclusion about the statute. Viewing the history charitably to NIH, we should recognize that the well-intentioned administration of HHS acted in the hope of fostering research that holds great promise for the relief of suffering. They acted with noble intentions, and with ample support in moral reasoning. But in regard to the law, HHS went out on a limb. It clung to its perch, but its proffered defense was untenable. So that defense remains today.

### 3.3(i) *Rider reenactments*

Since NIH’s gambit in 1999–2000, Congress has annually reenacted DA as a rider, not changing a word. A proponent of the disaggregation interpretation might venture that failure to change the language of the rider indicates congressional acquiescence in the disaggregation interpretation. Two facts would refute this suggestion. First, there has been no implementation of the disaggregation interpretation in which to acquiesce. No funds were dispensed pursuant to the 2000 Policy. The disaggregation interpretation has never been formally expressed as such. Nothing resembling it has been officially asserted since the 2000 Policy. Second, the authorizing language of the Castle-DeGette Bill (hereafter ‘C–DeG’), begins with “Notwithstanding any other provision of *law*” (emphasis added).<sup>27</sup> Public attention has long been trained on the current presidential policy, which C–DeG’s ensuing phrase “including any regulation or guidance” also overrides. But the reference to “law” evinces recognition that in order to authorize funding of hESC research, Congress must override DA, as C–DeG thereby does. This recognition presupposes the fusion interpretation of ‘research.’ It presupposes that DA bars funding for hESC use because such use induces embryo destruction. To which DA’s proponents might

<sup>26</sup> [65 Fed. Reg. 51976](#). One notable comment was a letter signed by a multitude of Nobel laureates praising the 2000 Policy as “laudable and forward-thinking” (Letter to the editor, *Science* 283: 1849 [March 19, 1999]). But the letter did not discuss the question whether, given DA, NIH possessed the authority to fund the research.

<sup>27</sup> [H. R. 7141, The Stem Cell Research Enhancement Act of 2008](#), the current version of a bill twice enacted and vetoed.



add, if immodestly, that the disaggregation interpretation is so implausible that they never saw need to revise DA.

### **3.4 Conclusion concerning executive power, need for legislation**

We have taken account of the derivation–use distinction mistakenly attributed to the Rabb opinion. We have seen that the disaggregation interpretation would not fulfill, but instead would frustrate fulfillment of, evident legislative intent. The disaggregation interpretation would require gymnastics of statutory interpretation that are untenable even to the point of verging on self-contradiction. The notion that DA allows funds to be used for hESC research is an untenable interpretation of DA. Principled opposition has already espied that. Fidelity to legislative intent requires the fusion interpretation. Once this is recognized, the situation is clear. So long as DA is in effect and has not been overridden by other legislation, DA prohibits NIH funding of hESC research. Both use and derivation collide with DA. All along, the rate-limiting step has been DA, not executive policy.

While an executive order is a prized vehicle for presidential action where no statute constrains, here there is no vacuum. A statutory prohibition obtrudes. President-Elect Obama’s respect for the law, both as a scholar thereof and as a public official, counsels in this instance against any action that would fairly be described as an attempt to defy the pertinent statute.

Two remarks make this more vivid. First, we have recently witnessed the rampant abuse of presidential power under claim of right. From this regime, we shall shortly be delivered. It would be disappointing if, in consequence of a mistaken legal analysis, the new administration were to regress by taking some action exceeding executive authority—especially if a good cause would then be ill-begotten. Second, congressional opponents of hESC research have been quoted as saying that when legislation authorizing hESC research again comes to a vote, they expect to lose. If instead of bringing forward legislation, an attempt were made to fund Eligible hESC Research by executive order, that would play into the hands of those opponents, and of the interest groups who have joined them in threatening suit. It would hand them a cause of action for violation of DA. Upon asserting such, they could obtain an injunction barring expenditure of funds for hESC research. If an injunction issued, after conclusion of the litigation and appeals, the recourse for proponents of such research would be legislation. This would have transpired in a setting in which delay is measured in death and suffering. It would better avail progress to acknowledge presently that implementing the contemplated new policy requires legislation, then to propose same and urge its prompt enactment.

## **4. CONTENTS OF AUTHORIZING LEGISLATION**

The Appendix includes a text of draft legislation providing for conduct and support of Eligible hESC Research (hereafter the ‘Bill’). The Bill would authorize Eligible hESC Research by partially overriding DA. The following comments reveal how the Bill differs in crucial respects from C–DeG. The scope of Eligible hESC Research is coextensive with the research provided for in the 2000 Policy and with that intended for C–DeG. Because the scope of the Bill is no larger than that

intended for the twice-enacted C–DeG, while the moral foundation of the Bill is stronger and more transparent, prospects for passage would appear excellent.

#### 4.1 Grounds within an overlapping consensus

Even if legislation were not the only available path to funding hESC research, it would be the better path. We as a society are not likely to reach a harmonious and stable resolution concerning medical use of donated embryos until the people’s representatives, in open discussion, have come to a position lying within an overlapping consensus of conceptions of justice. The “wide view” of “public reason,” as developed by John Rawls,<sup>28</sup> bids us seek a stable resolution both by according respect to verdicts rendered by comprehensive moral and religious views, and by demanding of all discussants that they support their verdicts with reasons that lie within an overlapping consensus of conceptions of justice. Social harmony and scientific progress require not merely a majoritarian result, but a stable consensus.

At the outset, policy should be laid atop such consensus foundation as can be constructed. The ingredients of the moral justification on which the Bill rests compel assent across the gamut of leading moral and religious views.<sup>29</sup> These grounds include the autonomous discretion of progenitors whether to elect intrauterine transfer of embryos, and the duty of beneficence. The developmental potential of an embryo donated under progenitor instructions permissibly barring intrauterine transfer is permissibly bounded. From this follows that use of the embryo in experiment cannot inflict discomfort nor prevent any experience that would otherwise occur. Nor can any gain be achieved for any being by classifying the embryo thus barred as a person for purposes of the duty not to harm. The foregoing joins with the duty of beneficence in yielding a justification for using donated embryos for humanitarian purposes. This justification finds a place in an overlapping consensus because it does not invoke any premise peculiar to one or another moral or religious view.

#### 4.2 Conditions that confer moral permissibility

The surest way to confine authorized research to morally permissible research is to define funding-eligible research by conditions that confer moral permissibility. Defining eligible research by conditions that confer moral permissibility will also render transparent the moral justification for funding. Transparency will avail in public debate when presenting policies to fellow citizens who do not yet believe that medical use of donated embryos is justified. The more conspicuous the moral logic, the better the prospects for consensus.<sup>30</sup>

<sup>28</sup> John Rawls, *Political Liberalism* (New York: Columbia University Press, 1996), pp. 212–254, and “The Idea of Public Reason Revisited,” 64 *University of Chicago Law Review* 765–807 (1997).

<sup>29</sup> See *The Morality of Embryo Use*, Chapter 5.

<sup>30</sup> *Ibid.*, p. 234.

Moral permissibility is not a matter of fact. It is a matter often in dispute between competing moral views. But in this case, it has above been mentioned that we may proceed on an understanding of what is permissible deriving from consensus arguments that do not rely on premises peculiar to any particular moral or religious view.

#### 4.2(a) *Primacy of progenitor decisions*

To clarify the conditions of moral permissibility that may ground legislation, we may begin by asking, may a fertility physician decide that an embryo will be donated to medicine? Clearly not. We reserve such a decision for an embryo's progenitors. But many legislative proposals rest on the premise that progenitor informed consent alone establishes the permissibility of using a donated embryo as a means. These proposals rest on the supposition that an embryo belongs to the progenitors. Such reasoning fails.

The fact of informed consent avails when the consenting person and the research subject are the same individual. It also avails in the circumstance in which a guardian (e.g., a parent) acts in the best interests of a subject (e.g., a minor child). In the case of embryo use, neither of these circumstances obtains. The embryo is a subject distinct from its parents. The embryo cannot consent. The contemplated research will not benefit or avoid serious harm to the embryo, but instead will sacrifice it. Embryo use does not fit the mold of 'human subjects research' as institutions have heretofore conceived it. For embryo use, the consent of the mother and coprogenitor is necessary—she is a subject insofar as oocyte retrieval is performed—but not sufficient.<sup>31</sup>

There is one type of decision, one that a progenitor and only a progenitor can make, that will so bound the developmental potential of an embryo as to ground a justification for use of the embryo by a donee.

A progenitor possesses singular authority. The progenitor is the only person in the world, save for the coprogenitor, privileged to decide what will happen to embryos formed from the progenitor's cells. It is in virtue of a progenitor decision against transfer of an embryo into a uterus that it becomes permissible for a donee to use the embryo in experiment. The key premise for a government in endorsing or funding experiments that involve embryo use, as for investigators in conducting experiments, is that investigators act in consequence of permissible donor decisions barring intrauterine transfer.

. . . The first pertinent action is a progenitor decision, communicated in a written instruction, forbidding intrauterine transfer. That decision constitutes the linchpin of a recipient institution's moral justification, within public reason . . . , for using an embryo in experiment.

Why do progenitors possess singular authority concerning the disposition of embryos? Because even though progenitors do not own embryos, we deny that anyone else is privileged to meddle in decisionmaking about embryos. The

<sup>31</sup> This and the other quotations in this subsection are taken from *ibid.*, pp. 232–234.

progenitor privilege is exclusive in default of anyone else possessing the privilege. The consequence of a progenitor decision against intrauterine transfer is that the developmental potential of the embryo is bounded such that the embryo cannot even complete gastrulation.

4.2(b) *In recent legislation, order of authority muddled*

The crucial conditions for expression in public policy are the conditions (each an ‘eligibility condition’) that render it morally permissible to use an embryo solely as a means, in this case as a source of hESC. The following compares the eligibility conditions set forth in the Bill with their counterparts in C–DeG.

[1] *Decision against intrauterine transfer*

C–DeG states the eligibility condition that “. . . 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” (l. 22–24, emphasis added). This condition is stated from the vantage point of the physician. The language suggests that the physician has some role in the referenced determination, if not a decisive one. The 2000 Policy, imitated here and elsewhere by C–DeG, required only the mere receipt by prospective embryo donors of a “statement that embryos donated will not be transferred to a woman’s uterus.”<sup>32</sup>

C–DeG’s “consultation with” eligibility condition could be read to place the order of authority backwards. At the very least, the condition muddles the order of authority. To justify use of an embryo in research, it does not suffice merely that there occur a prohibition against intrauterine transfer of an embryo; there must occur a *permissible* prohibition. It is progenitors who alone may appropriately decide that an embryo will be kept or donated. Only a progenitor may permissibly bar an embryo from the womb. If progenitors decide to donate an embryo, the physician’s role is to follow their instructions in transmitting the embryo, accompanied by their instructions against intrauterine transfer, to a donee.

The Bill treats the pivotal decision to bar intrauterine transfer as progenitors’ alone. The Bill states as an eligibility condition that progenitors have prohibited intrauterine transfer by written instructions. The Bill defines “Eligible hESC” as hESC derived from embryos donated under written progenitor instructions, accepted by the respective recipients, according to which the embryos may be used only in medical research and therapy and may never be transferred to a uterus. As the Bill thus defines the kind of embryos that may serve as sources, it adheres to and displays its moral justification. It assures that authorized research is morally permissible research, the latter having taken its definition from an overlapping consensus.

[2] *Progenitor motivation*

C–DeG sets forth an eligibility condition that the embryos “were in excess of

<sup>32</sup> 65 Fed. Reg. 51980.

the clinical need of the individuals seeking . . . treatment” (l. 18–19). The 2000 Policy speaks of donations “after the embryos are *determined to be* ‘in excess of clinical need’” (emphasis added).<sup>33</sup> “Clinical need” sounds like something that a physician determines. Prospective parents do not speak in that idiom. Of course a reproductive endocrinologist will advise on the quality of embryos created, and will recommend, in light of probabilities of pregnancy, how many to transfer. But beyond that, the decision whether to transfer an embryo rests on considerations that only a patient can resolve. Many sorts of considerations move patients to direct destruction of embryos (e.g., having as many children as desired, the morphology of an embryo, or not wishing anyone else to bear their offspring). If the foregoing eligibility condition is read to refer to what a patient has “determined” (as the 2000 Policy would put it), the condition is either an excessive formality for what a donation implies, or a demand that the patient act on one specified reason. As to the former, the donative instruments will make clear that the patient has declined transfer into herself. As to the latter, we should be loathe to specify what a patient’s motivation may be, or to require that she recite a motivation. Hence the Bill includes no condition such as the foregoing.

It might be worried that absence of a definition of ‘surplus embryo’ would allow funding of hESC derived from embryos created “for research purposes.” The case may be posed of a woman who undergoes fertility care intending to donate one or more embryos to research. The answer must be that as we rightly retain our liberty to decide about medical procedures and to keep our own counsel about family planning, we cannot prevent such an occurrence. In fact most fertility patients do not intend procreation as to every embryo created.<sup>34</sup> If one sought to verify a patient’s determination that embryos “were [or are] in excess of clinical need” or like conclusion, the patient could always conceal her reason for declining intrauterine transfer. But there does come to bear the Bill’s requirement that an eligible embryo must have been created “in the practice of assisted reproduction.” In compliance with professional norms, reproductive endocrinologists screen patients for suitability. We may expect such screenings to minimize the incidence of fertility care without procreative intent.

### [3] *Limited effect of informed consent*

C–DeG states the condition that “the individuals seeking fertility treatment donated the embryos with written informed consent” (l. 25–26). Informed consent is requisite, hence the Bill also requires it. But as we have seen, consent is not sufficient.

Someone might query whether a consent suffices in a case in which the protocol describes itself as governed by a rule against intrauterine transfer of received embryos. We first observe the oddity of this imagined arrangement, since

<sup>33</sup> 65 Fed. Reg. 51978.

<sup>34</sup> *The Morality of Embryo Use*, pp. 50–51.

only a progenitor can permissibly forbid intrauterine transfer. But, the inquirer asks, could not a progenitor prohibition be inferred from execution of a consent form? The process of obtaining execution of a consent form places a patient in a passive role—sometimes even to the extent of raising a question of inducement. The requisite event is not merely that an embryo donor consent to someone else’s promised conduct, it is that a donor first initiate a decision against intrauterine transfer, then prohibit intrauterine transfer by issuing instructions conditioning a gift. A progenitor decision should be taken and observed, not merely inferred. It is a progenitor decision that will ground the donee’s moral justification for sacrificing the embryo. Hence the wording of the Bill that makes such ground transparent.

#### *4.2(c) Unfundability of derivations requires expression*

C–DeG has been reported and debated as a bill that would allow funded studies of hESC lines derived without HHS funds, but would not allow funding for hESC derivation. That is to say that C–DeG is described as providing for a scope of research activity that is coextensive with Eligible hESC Research—even though the eligibility conditions of embryo sources differ.

But the text of C–DeG does not exclude hESC derivation from the scope of funded research. The coupling of C–DeG’s opening expression, “notwithstanding any other provision of law,” followed by authorization of support for hESC use unaccompanied by any provision that would bar use of funds for hESC derivation, has the effect of overriding DA so as to allow hESC derivation. It may fairly be inferred that hESC investigators knowledgeable enough about the circumstances of embryo donation so as to comply with the pertinent eligibility conditions in C–DeG must be performing derivations themselves.

When funding for Eligible hESC Research is provided, good reason obtains to allow funding for hESC derivations (of which more in §6.1). But judging by their public statements on behalf of C–DeG, it does not appear that C–DeG’s proponents intended to allow funding for derivations. Perhaps C–DeG’s drafters imagined that they were referring to derivations by persons other than a funded investigator when they used the past tense in the eligibility condition, “the stem cells were derived from human embryos that . . . .” But that tense could just as plausibly be read as indicating that the funded investigator had derived cells before studying them. Or they may have imbibed the gloss on the Rabb opinion so as to believe that a reference to ‘use’ obviously excluded derivation, and hence did not perceive that if a scientist is described as using something whose procurement by scientific methods is immediately thereafter described, the impression is conveyed that the scientist may accomplish the procurement. Since the 2000 Policy explicitly declared derivation unfundable, and since C–DeG evidently was drafted with the intent of authorizing the same scope, it does not appear that C–DeG’s proponents were trying to smuggle in funding for derivations while publicly saying that funding for derivations was

barred. The overbreadth of their text appears inadvertent.<sup>35</sup> C-DeG appears to be a document that, as in the case of the Rabb opinion, has been glossed as saying something that it does not.

The Bill adheres to the scope publicly advocated in the past, and said to be accepted by a political consensus at present. It authorizes only hESC use, stipulating that ‘use’ stands in contradistinction from derivation.

#### 4.2(d) *Embryo use only in service of humanitarian ends*

While a permissible prohibition of intrauterine transfer is the linchpin of moral justification for using donated embryos, that justification also depends on the premise that the embryos will be used for humanitarian purposes in partial fulfillment of the collective duty of beneficence. Humanitarian use stands in contrast with, say, use of embryos for testing industrial chemicals. C-DeG does not include any eligibility condition about the purpose for which a donated embryo may be used. The Bill requires that the progenitor instructions restrict use to medical research or therapy. Donors will often specify that their embryos may be used for therapy as well as research. An envisioned example of therapeutic use consists in transplantation of specialized cells differentiated from a banked hESC line whose major histocompatibility complex is histocompatible with a patient. (It is not known whether such practice will become common.) The moral justification in the case of therapy is the same as in the case of research.

### 4.3 Other topics

#### [1] *Provision for guidelines and regulations*

The appropriate procedures for respecting a fertility patient’s discretion to decide for or against intrauterine transfer of an embryo, and to decide for or against a donation to medicine, are not contingent on stem cell biology and will not likely vary as research progresses. Rules concerning clinical trials are another matter, but responsibility therefor falls to the Food and Drug Administration. Hence the C-DeG mandate for “updates” to NIH guidelines seems misplaced, while its specification of intervals between updates seems artificial. Nor does any need appear to require that the Director consult guidelines published by others. Insofar as recommended norms are predicated on laws and mores of other countries, or offered at a level of generality so as to be cognizable within many countries, they might be inapt for emulation by NIH. The Director may be presumed to know appropriate sources of guidance. It seems sufficient to authorize the Director of NIH, as does the Bill, to promulgate regulations and guidelines.

<sup>35</sup> This overbreadth cannot be explained as the consequence of the drafters assuming the disaggregation or fusion interpretations. Those interpretations pertain to the individuation of the kind *research*. They do not call into doubt that DA prohibits use of funds for hESC derivation, nor that the coupling of “notwithstanding any other provision of law” and what follows overrides that prohibition.

[2] *Effective dates of ethical norms*

C-DeG directs the Director of NIH to “determine the extent to which the guidelines under this section shall apply to research . . . that uses human stem cells derived before the effective date of such guidelines.”<sup>36</sup> If NIH promulgates eligibility criteria that bear on moral permissibility—as many criteria, such as those concerning requisite informed consent, presumably would—then lines that do not meet such criteria should be ineligible. We should be sceptical of any rule that would “grandfather” past events that do not satisfy what is presented as a moral norm. It seems ill-advised for a statute, especially one that says nothing about the contents of norms, to invite the general practice of grandfathering exceptions. Some rules may lack moral significance, and for these rules, perhaps NIH will establish effective dates. But no statutory provision is needed to establish NIH’s authority to do that.

The motivation for this provision may also wane. At present, fundable research is constrained by an arbitrarily chosen latest origination date of an eligible hESC line. In the future, an investigator may procure (or, with private funds, derive) a new line if some extant line fails to satisfy either the statutory definition of Eligible hESC or NIH guidelines.

[3] *Time of derivation moot*

The phrase in C-DeG, “(regardless of the date on which the stem cells were derived from a human embryo),” holds significance only relative to current executive policy, soon to be revoked, and hence has no counterpart in the Bill.

[4] *Whether to codify rider*

There arises the question whether reenactment of DA, subsequently to enactment of the Bill, may be interpreted as overriding the latter, this according to a rule of construction that in the event of conflict, a later legislative act dominates an earlier. Concern for this might motivate moving DA into the Bill. A disadvantage of doing so would be that, when the day comes that the political resolve has formed to eliminate DA, it will be easier to omit a rider than to repeal a statutory subsection. Two other considerations suggest that one may forgo codification of DA. First, a committee report and the record of the floor debate could make clear that the Bill’s proponents had argued for the preservation of DA in making their case for the Bill, thus implying that the two enactments are consistent. Second, one could argue that the introductory phrase “Notwithstanding any other provision of law” insulates the Bill from any subsequent enactment that does not specifically refer to the Bill.

## 5. EXECUTIVE AND AGENCY ACTIONS

Prior to the effective date of legislation overriding DA, an order rescinding the current policy could accomplish only the unavailability of research on the presidential hESC lines. But after the president signs authorizing legislation,

<sup>36</sup> C-DeG, pp. 4, l. 24, to 5, l. 5.



implementing policies may be instituted by executive order and by agency action. Agency action in adopting the 2000 Policy was preceded by publication of draft guidelines for comment.<sup>37</sup> The wisdom of that choice was vindicated by the volume of comments received (said to approximate 50,000) and the subtlety of some issues.<sup>38</sup> It may be that release of proposed orders or agency guidelines would best await enactment of legislation. Announcement of subsidiary rules prior to enactment of legislation might convey the impression that congressional action is not needed, an impression that might weaken the incentive for Congress to act. But such planning lies outside the scope of this discussion.

## 6. PROVISIONS FOR RECONSIDERATION IN FUTURE

### 6.1 Exclusion of funding for derivations

One component of the envisioned new policy suffers from an infirmity that should be known even as it is presently retained for the role that it is perceived to play in underwriting a political consensus. This component is the exclusion, discussed in §4.2[c], of hESC derivation from Eligible hESC Research (hereafter ‘the Derivation Exclusion’). The infirmity to be described constitutes a reason, should a future legislative opportunity arise, for deleting the Derivation Exclusion from the then effective statute.

To see this, we first clarify how the Bill interrelates with DA. The Bill effectively carves an exception to the unavailability of Embryo-Exploitative Research. Assuming the fusion interpretation, the effect of the Bill is (i) to allow funding of such Embryo-Exploitative Research as constitutes Eligible hESC Research, as the latter is defined giving effect to the Derivation Exclusion, and (ii) to bar funding of all other Embryo-Exploitative Research. For purposes of the following, we suppose that NIH, duly authorized, now funds Eligible hESC Research.

Consider that a taxpayer either approves the practice of sacrificing donated embryos in medical research, or does not. Those who do not approve of embryo sacrifice, or who find themselves on the fence about it, have no reason to put any store in the Derivation Exclusion. We earlier saw that complicity transmits through any channel of inducement. We have also seen how involved in derivations responsible investigators may become as they comply with appropriate norms (e.g., the 2000 Policy). Given that use of hESC induces and even contributes to embryo destruction, a government and its taxpayers cannot fund one practice without complicity in the other. As earlier noted, there is no practical scheme for supplying embryonic derivatives to projects while immunizing those who perform or fund the

<sup>37</sup> 65 Fed. Reg. 51976.

<sup>38</sup> The Bill’s definition of an “embryo donated to medicine under instructions forbidding intrauterine transfer” provides “a justificatory cornerstone upon which other norms may be placed” (*The Morality of Embryo Use*, pp. 232–234). I have suggested other norms, including protections governing embryo donation. These do not, as did the 2000 Policy, provide that only frozen embryos may be donated.

projects from complicity in embryo sacrifice. Any purported responsibility firewall is an illusion. Noncomplicity is an illusion.

If using an embryo in research is not permissible, then whether a scientist sacrifices embryos, or instead induces someone else to do so, will make no moral difference.<sup>39</sup>

Realizing this, there can be little solace in the knowledge that taxpayer money does not pay for embryo sacrifice by some scientists while taxpayer money does pay for research that induces embryo sacrifice by other scientists.<sup>40</sup> That this is widely understood became evident from substantial opposition to the 2000 Policy notwithstanding its explicit exclusion of derivations.

Taxpayers who approve the practice of sacrificing donated embryos in medical research also will put no store in the Derivation Exclusion. The Derivation Exclusion bars funding of something that they approve. It is no part of the defense of hESC research to deny complicity in embryo sacrifice.

If one is going to perform research using embryonic derivatives, one must justify embryo sacrifice. . . . [R]esearch is moral not because obtaining derivatives and studying them are separable, but because both are permissible.<sup>41</sup>

Hence when Eligible hESC Research is funded, the Derivation Exclusion gains nothing for anyone reluctant to countenance embryo sacrifice, nor for anyone willing to countenance it. The infirmity of the Derivation Exclusion is that it achieves no moral gain for anybody. The Derivation Exception was not conceived, we may recall, by moral reasoning. The Derivation Exclusion was a bureaucratic invention introduced by NIH as a purported safe harbor from DA.

Within legislation that overrides DA, there is no legal reason to steer toward that harbor. That the Derivation Exclusion achieves no moral gain renders it futile. If the Derivation Exception exacts a cost by hampering scientific progress at no moral gain, so much the worse.

If one decides to authorize embryo use that induces derivation, there is no compelling reason not to authorize derivations. The Derivation Exception may be sent by the board at no loss to the moral position of any discussant in respect of hESC research. If the definition of Eligible hESC Research is thus revised, one will then have carved a wider exception to the unavailability of Embryo-Exploitative Research.

But by virtue of confusion about the moral logic here—in this regulatory

<sup>39</sup> *Ibid.*, p. 216.

<sup>40</sup> *Ibid.*, pp. 214–217; “A Proposed Stem Cell Research Policy,” pp. 1024–1025; “Morals and Primordials.” The symbolic offense given by the Derivation Exclusion ostensibly consists in paying some deference to the belief that use of donated embryos in medicine is wrong, but only very little deference, since the policy enclosing the Derivation Exclusion tramples on that belief by inducing the purported wrong.

<sup>41</sup> *The Morality of Embryo Use*, p. 217.

tangle, who would not get confused?—the Derivation Exception is perceived as a touchstone of present political consensus. Although ardent opponents of hESC can see through it, some policymakers or citizens evidently put stock in the Derivation Exclusion. This raises a concern about stability.

Some people might be taken in for the moment by the illusion of a complicity firewall, but in the long run, one cannot construct a stable consensus on an illusion.<sup>42</sup>

When it comes to be more widely understood that moral justification for hESC use follows from the bounded developmental potential of embryos permissibly barred from the womb, it will be seen that the same justification encompasses hESC origination. There will then remain no motivation to posit noncomplicity in embryo sacrifice. That understanding will help to solidify the foundation of a stable consensus. But that lies in the future.

## 6.2 Prohibition on funding exploitative research

At such time as omitting the Derivation Exclusion is considered, a stronger proposal will also become pertinent. This proposal would have Congress eliminate the unavailability of Embryo-Exploitative Research. Thereupon DA would provide only for the unavailability of Embryo Creation. NIH could then provide funds to study derivatives of surplus embryos whose donation may or may not satisfy the eligibility conditions set forth in the Bill. The studies could occur within any field of biomedicine. This move would also render hESC derivation from surplus embryos fundable if the Derivation Exclusion had not yet been deleted from the definition of Eligible hESC Research. In theory, NIH could also fund studies of derivatives of clones, parthenotes,<sup>43</sup> and embryos formed by fertilization for research purposes.

Plausible reasons obtain for supporting studies that use surplus embryos in fields other than stem cell biology, the locus of present political consensus. For example, reproductive endocrinologists would like to study embryos so as to perfect techniques of assisted reproduction. But the Bill's conditions of eligibility are morally crucial as to all embryos. Funding those of studies that do not use derivatives of surplus embryos would, directly or by invisible hand effects, induce creation of embryos in research.<sup>44</sup> For these reasons, the political will does not yet obtain to eliminate unavailability of Embryo-Exploitative Research *tout court*.

## 7. THE PRESENT TASK AS CARVING AN EXCEPTION TO A GENERAL RULE

Viewed in light of what has just been said, DA's provisions for the unavailability of Embryo-Exploitative Research and unavailability of Embryo

<sup>42</sup> *Id.*

<sup>43</sup> Which are defined as embryos in DA subsection (b).

<sup>44</sup> As an additional reason to oppose funding of such studies, it might be argued that they would *effect* Embryo Creation for which funding is proscribed by subsection DA (a)(1)—except that DA's congressional proponents were content to describe that provision as narrow, this because it does not refer to 'research in which' an embryo is created.

Creation may be seen as tenable if taken as general rules from which exceptions may be carved. Imposition of the general rules forces anyone who proposes embryo use to adduce a compelling moral justification for the envisioned use. This the Bill is designed to do. To which it may be added that the regrettable history of DA is the absence *ab initio* of any exceptions to the unavailability of Embryo-Exploitative Research. By the time that the first exception will become law, thirteen years will have passed during which the unavailability of Embryo-Exploitative Research has barred federal funding of highly meritorious research (save for a trickle dispensed during a recent uncontested violation). During that time, research could have been conducted using embryos permissibly barred from the womb, embryos of decisively bounded developmental potential. Although nothing in the appropriate eligibility conditions for embryo use refers to stem cell biology, it has taken hESC research, and the hopes attached to it, to motivate the political will that will now carve an exception.

The mechanics of establishing this exception present an opportunity for presidential leadership. The president may propose or endorse legislation that gathers wide support as it locates authorized research transparently within morally permissible research—this as best public reason allows us to see the conditions that confer permissibility.

## **APPENDIX**

### **1. PROPOSED LEGISLATION**

Bill authorizing NIH conduct and support of Eligible hESC Research

### **2. RABB OPINION**

Memorandum dated January 15, 1999 of Harriet S. Rabb, General Counsel of the Department of Health and Human Services, to the Director, National Institutes of Health

111TH CONGRESS  
2nd SESSION

S. \_\_\_\_

To provide for embryonic stem cell research

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IN THE SENATE OF THE UNITED STATES

SEPTEMBER , 2010

M. \_\_\_\_\_ introduced the following bill, which was read  
twice and referred to the Committee on \_\_\_\_\_

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## A BILL

To provide for human embryonic stem cell research.

1           *Be it enacted by the Senate and House of Representatives of the United States of*  
2 *America in Congress assembled,*

3 SECTION 1. SHORT TITLE

4           This Act may be cited as the “Stem Cell Research Act of 2010.”

5 SECTION 2. RATIONALE AND PURPOSE

6           The purpose of this Act is to foster embryonic stem cell research and other  
7 research in regenerative medicine for the purpose of contributing to the alleviation of  
8 human suffering. This Act is adopted in recognition that

9           (1) it lies within a woman’s discretion whether to elect a transfer into her, and  
10 lies within her and her coprogenitor’s discretion whether to elect a transfer into any  
11 other woman, of an extracorporeal embryo formed from her oocyte,

12           (2) after an exercise of discretion to decline intrauterine transfer of an  
13 extracorporeal embryo, the developmental potential of the embryo outside a uterus is

14 so bounded that the embryo cannot develop even to the completion of gastrulation,  
15 and

16 (3) from the foregoing and our collective duty of beneficence, there follows a  
17 moral justification for using, in service of humanitarian ends, embryos that have been  
18 donated to medicine under progenitor instructions forbidding intrauterine transfer.

19 SECTION 3. AMENDMENT OF PUBLIC HEALTH SERVICE ACT

20 The Public Health Service Act is amended by inserting after section 498C (42  
21 U.S.C. 289g-3) the following:

22 ‘§498D. HUMAN EMBRYONIC STEM CELL RESEARCH.

23 “(a) SCOPE OF RESEARCH. Notwithstanding any other provision of  
24 law, the Secretary shall conduct and support, and may expend appropriated  
25 funds for, Eligible hESC Research.

26 “(b) DEFINITIONS. “(1) As used herein, ‘embryo’ denotes a human  
27 embryo.

28 “(2) ‘Eligible hESC Research’ consists in the use of Eligible hESC in  
29 the course of biomedical research. ‘Use of Eligible hESC’ stands in  
30 contradistinction from deriving Eligible hESC from embryos.

31 “(3) ‘Eligible hESC’ are embryonic stem cells derived from embryos  
32 donated to medicine under instructions forbidding intrauterine transfer.

33 “(4) An embryo is ‘donated to medicine under instructions forbidding  
34 intrauterine transfer’ if and only if

35 (i) the embryo was created by *in vitro* fertilization or other sexual  
36 means of oocyte activation in the practice of assisted reproduction,

37 (ii) the progenitors of the embryo have donated the embryo on the  
38 conditions, set forth in written instructions accepted by the recipient, that

39 (A) the recipient shall use the embryo solely in medical  
40 research or therapy, and

41 (B) never may the embryo or any totipotent cell taken from  
42 the embryo be transferred into a woman or into an artificial  
43 uterus,

44 provided that, as to a donation prior to the effective date of this Act, this  
45 requirement shall be deemed satisfied if imposition of such conditions may  
46 reasonably be inferred from a document executed by the progenitors even if  
47 such conditions are not explicitly set forth therein,

48 (iii) applicable requirements for informed consent by the  
49 progenitors have been satisfied, and

50 (iv) the progenitors have not received any financial or other  
51 consideration in exchange for donation of the embryo.

52 “(c) IMPLEMENTATION. The Director of the National Institutes of  
53 Health shall the authority to promulgate regulations and guidelines to effect  
54 the implementation of this Act. Nothing herein implies the neglect of  
55 research concerning nonembryonic stem cells. Funds shall be allocated by  
56 the Director for research in stem cell biology according to scientific merit.”





January 15, 1999

TO: Harold Varmus, M.D.  
Director, NIHFROM: Harriet S. Rabb *Harriet S. Rabb*

SUBJECT: Federal Funding for Research Involving Human Pluripotent Stem Cells

The Office of the General Counsel of the U.S. Department of Health and Human Services (HHS) has prepared the following in response to your request for a legal opinion on whether federal funds may be used for research conducted with human pluripotent stem cells derived from embryos created by *in vitro* fertilization or from primordial germ cells isolated from the tissue of non-living fetuses. This inquiry arises from the recently reported research of: (1) Dr. James A. Thomson of the University of Wisconsin-Madison, who isolated pluripotent stem cells from embryos donated for research by persons undergoing fertility treatment<sup>1</sup>; and (2) Dr. Michael Shablott of the Johns Hopkins University School of Medicine, who derived pluripotent stem cells from primordial germ cells from non-living fetuses.<sup>2</sup> The research described in these two published reports was not funded by HHS.

#### Summary Answer

The statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition. To the extent human pluripotent stem cells are considered human fetal tissue by law, they are subject to the statutory prohibition on sale for valuable consideration, the restrictions on fetal tissue transplantation research that is conducted or funded by HHS, as well as to the federal criminal prohibition on the directed donation of fetal

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<sup>1</sup> James A. Thomson et al., Embryonic Stem Cell Lines Derived from Human Blastocysts, Science, vol. 282, November 6, 1998, pp. 1145-1147.

<sup>2</sup> Michael J. Shablott et al., Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells, 95 Proc. Nat'l. Acad. Sci. USA 13726 (Nov. 1998).

tissue. Research involving human pluripotent stem cells excised from a non-living fetus may be conducted only in accordance with any applicable state or local law. Finally, the Presidential Directive banning federal funding of human cloning would apply to pluripotent stem cells, only if they were to be used for that purpose.

### Analysis

#### I. Prohibition on Federal Funding for Human Embryo Research

In the appropriations provision for the Departments of Labor, Health and Human Services, and Education, and Related Agencies in the Omnibus Consolidated and Emergency Supplemental Appropriations Act, Fiscal Year 1999, Public Law 105-277, section 511 provides that none of the funds made available in that appropriation 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)).

The term "human embryo or embryos" is defined in the statute to include "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."

Pluripotent stem cells are not a human "organism" as that term is used in the definition of human embryo provided by statute. The term "organism" is not itself defined by law, and the question of what is an organism calls for a science-based answer. According to the McGraw-Hill Dictionary of Scientific and Technical Terms (hereinafter McGraw-Hill), an organism is "[a]n individual constituted to carry out all life functions."<sup>3</sup> Pluripotent stem cells are not organisms

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<sup>3</sup> McGraw-Hill Dictionary of Scientific and Technical Terms 1408 (5<sup>th</sup> edition 1994). See also N. Campbell, Biology, (4<sup>th</sup> edition 1996) pp. 8-9, which defines organism as follows:

While cells are the units of organisms, it is organisms that are the units of life. It's an important distinction. Except for unicellular life, 'cell' does not equal 'organism.' A single-celled organism such as an amoeba is analogous not to one of your cells, but to your whole body. What the amoeba accomplishes with a single cell -- the uptake and processing of nutrients, excretion of wastes, response to environmental stimuli, reproduction, and other functions -- a human or other multicellular organism accomplishes with a division of labor among specialized tissues, organs, and organ systems. Unlike the amoeba, none of your cells could live for long on its own. The organism we recognize as an animal or plant is not a

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.<sup>4</sup> They are, rather, human cells that have the potential to evolve into different types of cells such as blood cells or insulin producing cells.

Moreover, a human embryo, as that term is virtually universally understood, has the potential to develop in the normal course of events into a living human being. The scientific definition of embryo, as described in McGraw-Hill, is "[t]he product of conception up to the third month of human pregnancy."<sup>5</sup> Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus.<sup>6</sup> Therefore, in addition to falling outside of the legal definition provided by statute, pluripotent stem cells cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term. Thus, based on

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collection of unicells, but a multicellular cooperative with the emergent properties of 'whole organism.'

<sup>4</sup> At a December 2, 1998, stem cell research hearing before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee, Senator Tom Harkin asked five scientists, two bioethicists, and a theologian testifying before the committee if, in their view, stem cells were organisms. All of the experts who responded concluded that human pluripotent stem cells are not organisms. Use of Fetal Tissue in Brain Stem Cell Research: Hearing Before the Subcomm. on Labor, Health and Human Services, and Education of the Senate Appropriations Comm., 105th Cong. (December 2, 1998) available in LEGI-SLATE, Transcript No. 983360015 [hereinafter Stem Cell Hearing] (statement of Dr. Harold Varmus, Director, National Institutes of Health; Dr. John Gearhart, Johns Hopkins University School of Medicine; Dr. James Thomson, Wisconsin Primate Research Center, University of Wisconsin; Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System; and Mr. Richard Doerflinger, Associate Director for Policy Development, Secretariat of Pro-Life Activities, National Conference of Catholic Bishops). One expert, Dr. Eric Meslin, Executive Director of the National Bioethics Advisory Commission, stated that he could not speak on behalf of the Commission because it had not considered the question. Stem Cell Hearing, supra, (statement of Dr. Eric Meslin).

<sup>5</sup> McGraw-Hill Dictionary, supra note 3, at 673.

<sup>6</sup> See Letter from the Chair of the National Bioethics Advisory Commission, to the President of the United States, response to question no. 2, November 20, 1998; National Institutes of Health, Report of the Human Embryo Research Panel, Sept. 1994, p. 26. See also Stem Cell Hearing, supra note 4, (statements of Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; and Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System).

an analysis of the relevant law and scientific facts, federally funded research that utilizes human pluripotent stem cells would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such stem cells are not human embryos.

## II. Restrictions on the Use of Human Fetal Tissue

There are a number of potential sources of human pluripotent stem cells; some of these stem cells may fall within the legal definition of human fetal tissue and would, therefore, be subject to federal regulations. Section 498A of the Public Health Service Act specifies that fetal tissue “means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.” 42 U.S.C. 289g-1(g). Some stem cells, for example those derived from the primordial germ cells of non-living fetuses, would be considered human fetal tissue for purposes of Section 498A.

The Public Health Service Act (hereinafter “The Act”) contains three relevant provisions governing the use and transfer of human fetal tissue: (1) a criminal prohibition against the sale of human fetal tissue for valuable consideration; (2) restrictions on fetal tissue transplantation research supported by federal funds; and (3) a prohibition on the directed donation of fetal tissue for transplantation. We explore each of these restrictions in turn.

Section 498B(a) of the Act states that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration,<sup>7</sup> if the transfer affects interstate commerce.<sup>8</sup> 42 U.S.C. 289g-2(a). It is common practice for scientists throughout the United States to share research materials through transactions that result in such materials crossing state boundaries. Such exchanges, as well as transactions within the District of Columbia, or exchanges within a state that “affect interstate commerce” would meet the statutory criterion of affecting interstate commerce, but would not fall within the scope of the criminal

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<sup>7</sup> The term “valuable consideration” encompasses both monetary and non-monetary payments. Section 498B (d)(3) provides that the term does not include “reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.”

<sup>8</sup> The statute adopts the definition of interstate commerce in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b): “. . . commerce between any State or Territory and any place outside thereof, and . . . commerce within the District of Columbia or within any other Territory not organized with a legislative body.” The statute does not define what “affects” interstate commerce, but, in interpreting similar language in another criminal statute the Supreme Court found that “affecting interstate commerce” is an expression of Congress’ intent to broadly exercise its Commerce Clause power under the Constitution. Scarborough v. United States, 431 U.S. 563, 571-72 (1977).

prohibition unless the scientist providing the materials sought payment in excess of the expenses included in the statutory definition of "valuable consideration."

In addition, the law places some restrictions on federal support for research on the transplantation of fetal tissue. Section 498A of the Act provides that the Secretary may conduct or support research on the "transplantation of fetal tissue for therapeutic purposes," only if certain statutory requirements are met. 42 U.S.C. 289g-1. These requirements include obtaining: (1) the informed consent of the woman donating the tissue; (2) a statement by the attending physician regarding the woman's consent and the method of obtaining the tissue; (3) a statement by the researcher regarding his or her understanding of the source of the tissue, that such information has been conveyed to the donee, and that the researcher has not participated in any decision regarding termination of the pregnancy.

Finally, section 498B(b) of the Act provides that it shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation into another person if the tissue will be or is obtained pursuant to an induced abortion, and there is a promise to the donor: (1) to transplant the tissue into a person specified by the donor; (2) the tissue will be transplanted into a relative of the donor; or (3) the donee of the tissue has provided valuable consideration for the costs associated with the abortion. 42 U.S.C. 289g-2(b). The Act provides criminal penalties for violation of the prohibition on directed donations.

### III. Federal Restrictions on Fetal Research

Federal regulation provides that activities involving cells, tissues, or organs excised from a non-living fetus shall be conducted only in accordance with any applicable state or local law. 45 CFR 46.210, Subpart B. This regulation would apply to certain human pluripotent stem cells, including those derived from the primordial germ cells of non-living fetuses.

### IV. Prohibition on Federal Funding for Cloning of Human Beings

In a March 4, 1997, memorandum to the heads of executive departments and agencies, the President directed that no federal funds will be used for the cloning of human beings and that federal funds shall not be allocated for that purpose.<sup>9</sup> There are myriad uses for human pluripotent stem cells that are completely unrelated to cloning. However, to the extent such stem cells were to be used for human cloning, the prohibition on the use of federal funds for that purpose would apply.

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<sup>9</sup> Memorandum from the President of the United States to Heads of Executive Departments and Agencies (March 4, 1997).