

## A Proposed Stem Cell Research Policy

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### ABSTRACT

The aspirations of scientists and patients for human embryonic stem cell (hESC) research in the U.S. motivate attention to the nitty-gritty of law and regulation and its confluence with such moral consensus as lies within our reach. Federal law and regulation form a tangle. Analysis yields several conclusions not widely appreciated. A legislative enactment is the rate-limiting step of federally funded research, the restriction of research imposed by the previous administration's policy as reprised in current proposals fails to achieve its objective of avoiding complicity in embryo sacrifice, the current administration's policy is another failed noncomplicity scheme under which research cannot be expanded without demolishing its putative justification, and the Food and Drug Administration

has already effectively interdicted procreative cloning. While it is not plausible to deny complicity in embryo sacrifice when performing or funding hESC research, one can justify sacrifice of some embryos by an argument whose premises are consistent with a wide range of moral and religious views. This paper proposes a rule of public policy providing for the use of donated embryos barred from the womb. This rule would optimize research while manifesting its moral justification. The rule is suitable for implementation by any government that funds hESC research. The rule's justification provides a cogent argument for such incremental steps toward its implementation as become politically feasible from time to time. *STEM CELLS 2005;23:1023–1027*

All who pin hopes on human embryonic stem cell (hESC) research would cheer if what Jean-Jacques Rousseau called “the general will” would spring forth, recognize the moral case for this research, and remove the shackles that bind it. Instead in the U.S., the vast federally funded biomedical research engine remains on the sidelines, ruled ineligible for action except as to a modicum of cell lines originated before an arbitrary date 4 years past. The first public funds for hESC derivation, so it appears, will flow from state coffers. There has mounted a groundswell of support—from the general public, from state legislators, and within the U.S. Congress—for expanding hESC research.

If ever there were a topic on which a public policy would constitute, in Edmund Burke's phrase, “morality enlarged,” this is one. Yet as drafters of policies that would expand hESC research have respectively invoked one or another moral rationale, they have generally not taken on board the rationale most likely to ground a consensus across competing moral views. I contribute the following so that the case for hESC research may put its best foot forward.

At the outset, it is easy to become confused about the prohibitions and permissions that form the status quo. The situation evokes something of Yogi Berra's puzzlement upon asking, “If people don't want to come to the ballpark, how are you going to stop them?” Apart from the effects of a burgeoning maze of state legislation, the federal regulatory situation is a tangle. By taking pains to sort that out, we shall arrive at conclusions not widely appreciated—that a Congressional enactment, not presidential policy, is the rate-limiting step of hESC research, that such enactment prohibits the research that not only the previous but also the current administration has undertaken to fund, that neither administration's policy achieves any moral gain for the constraints imposed, and that the federal government has already effectively interdicted procreative cloning.

The analysis that I offer will issue in a proposed policy possessed of two desirable features. First, the policy will optimize the scope of research. Second, the policy will manifest a moral justification that can ground a consensus. The first feature will

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avail progress, the second stability. What I shall propose will be a succinct policy suitable for adoption by any government, federal or state, that funds hESC research. One cannot predict when such a policy will gain a preponderance of support. But articulating the proposed policy will map the logical geography. This exercise will allow us to say, at any given policymaking moment, “These are the coordinates of our destination, and this is why it is right to head there.” This exercise will also avail for the short run. It will bring to the fore a moral argument by which proponents of research may broaden support for incremental expansion when, as presently, a legislative opportunity arises.

### CONFLATION AND COMPLICITY

If presidential policy has erected an obstacle to hESC research, the Dickey Amendment (DA) is the elephant in the room. DA is a perennial appropriations rider enjoining that no funds dispensed by the National Institutes of Health (NIH) “may be used for . . . the creation of a human embryo or embryos for research purposes; or . . . research in which a human embryo or embryos are destroyed . . .” [1]. As to NIH-funded research, this provision bars (a) fertilization, cloning, and parthenogenesis; (b) derivation of hESCs by any embryo-destructive means; and (c) studies of hESCs derived by any embryo-destructive means. The prohibition of (a) and (b) is obvious from the text. The conclusion that DA prohibits (c) will be revealed in the following story of two attempts to reach a contrary conclusion.

The first attempt occurred in 2000 when NIH announced that it would fund studies of pluripotent stem cells not derived using federal funds, or what I shall call “other-derived” lines [2]. NIH evidently predicated this policy on an imagined responsibility firewall between a given investigator’s downstream experiments on hESC lines and some other scientist’s blastocyst immunosurgery by which the lines were derived. For the purported legality of this policy, NIH relied on an opinion of counsel that DA “would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo . . .” [3]. It is of course a truism that using or destroying pluripotent stem cells does not in itself constitute using or destroying an embryo. Or as NIH chose to put it (by a distinction not developed in the opinion), using stem cells is not deriving stem cells. But neither the opinion nor NIH discussed the key question, namely, what does DA’s phrase “research in which” encompass? One interpretation would be that the phrase encompasses only directly funded acts. That interpretation would appear to thwart legislative intent. For this we have the word of DA’s proponents, who vociferously condemned NIH’s announcement as an attempt to subvert their intent. The proponents’ concern for what they saw as complicity in wrongdoing—they did not want the federal government to come within a country mile of embryo killing—suggests a different interpretation. It suggests that “research in which” must be read to capture any research project of which embryo destruction is a self-performed or induced stage. Investigators’ presentations themselves suggest this reading. Embryo donation and hESC deri-

vation, even if they will originate with clinicians and other scientists remote from the investigator’s laboratory, will appear in a protocol for an hESC study as stages of the study—this because NIH and institutional review boards require those performing such studies to provide assurances about how hESCs were obtained. Thus the interpretation of “research in which” most faithful to legislative intent conflates derivations and the downstream studies that induce derivations. For this reason, Congressional supporters of DA held a compelling case as they threatened suit for a restraining order against NIH. A new administration withdrew NIH’s plan [4].

That studies by one scientist may induce others to sacrifice embryos also explains why the use of other- rather than self-derived cells provides no moral gain. A distinction between deriving and using derivatives, when expressed by reference to the embryo rather than the investigator, is a distinction between killing and using remains. Moral agents may use remains from a killing without complicity in the killing only if, as typically occurs in an organ transplant, they played no role in inducing the death. The moral verdict is otherwise when demand induces supply. Inducement 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. Stem cell investigators and their funding sources collectively induce derivation of cell lines. Through any channel of inducement, complicity transmits. We may give a cogent moral defense of the hESC investigator’s work. This I shall try emphatically to show. But it is no part of that defense to deny complicity in embryo sacrifice. A distinction between other- and self-derived cell lines gains no moral traction.

The second attempt to eschew DA—or, it might better be said, to ignore it—is the current executive policy. Cast in its most favorable light, this policy might be understood as predicated upon surprise. At time  $t_0$  (in fact, on August 9, 2001), the government announces that thereafter it will fund the study of all and only derivatives of embryos sacrificed prior to  $t_0$ . To defend this move, a proponent distinguishes between killing embryos and using remains. The proponent contends that prior to  $t_0$ , the government had barred grantee use of embryonic derivatives, and hence that the government never induced any rational agent to destroy an embryo. But this gambit avoids neither DA nor moral complicity in embryo sacrifice. Taking the moral concern first, the historical facts belie the premise of noninducement. As we have seen, NIH announced in 2000 that it would fund hESC research. Hence it cannot be said that the government’s actions before August 9, 2001, were such that no rational investigator could have been induced to initiate a cell line. Try as the current administration might to repudiate its predecessor’s actions, a government is a continuing entity. Distinctions about who previously controlled the government do not absolve a present government from responsibility. The government rides in the same boat of moral responsibility with

grantees who induce derivations and others who perform them. In respect of DA, insofar as “research in which” captures any project of which embryo destruction is an induced stage, DA bars even the present trickle of funded research. Insofar as an investigator has contributed to aggregate demand that induced supply, embryo destruction may be said to be an induced stage of hESC research, including that using presidential lines. Interest groups that oppose hESC research have so protested, although the point has otherwise gotten little attention. Congressional supporters of DA have turned a blind eye toward DA’s preclusion of present policy, this doubtless because the policymaker is an administration of their party. But the elephant remains in the room.

The surprise announcement scheme also cannot satisfy demand for more and newer cell lines unless some later  $t_1$  replaces  $t_0$  as origination date of the oldest eligible cell line. But after any such replacement, the need would arise to replace  $t_1$  with some later  $t_2$ , and so on. Once there began a practice of advancing the cutoff date, no one would believe that any date is permanent. The likelihood of government-supported demand would induce ongoing derivations of cell lines in anticipation of the next date change. To widen this scheme’s supply channel is to explode its purported defense.

What we have just seen is that while policymakers of different stripes have imagined a moral separation between embryo destruction and studies of cell lines, the facts reveal inducement of the former by the latter. Such are the circumstances of research that it appears that we cannot construct any practical scheme for supplying funded projects with cell lines obtained through embryo sacrifice while immunizing the project investigators and their grantors from complicity in the embryo sacrifice. If we are going to perform hESC research, we shall not achieve any moral gain from a futile quest for noncomplicity. We shall not achieve a moral gain by reprising, as has recently proposed legislation [5, 6], the NIH policy precluding derivation of hESCs. Nor shall we gain morally by constraining the number, availability, or genetic diversity of cell lines, or by settling for lines that are contaminated. Such artificial and constringent arrangements impose an appreciable scientific cost [7].

Political hay has lately been made of a claim that there exist sources of pluripotent stem cells whose use would be morally superior to the use of embryos. Elsewhere I have challenged that claim of moral superiority [8]. To the extent that the purported alternative sources happen to use or produce embryos, lean on a defense whose generality justifies the use of embryos, or fail to produce pluripotent cells, a choice to explore only the peculiar products of those techniques and to renounce use of donated embryos would not be a moral improvement.

#### **VIRTUOUS USE OF EMBRYOS BARRED FROM THE WOMB**

As against a history of steering for a spurious legal loophole and an illusory moral harbor, we shall better fulfill our hopes for social harmony and scientific progress by insisting on open and

direct policymaking. As public opinion changes, there will be no dearth of commentary about what political compromises might be struck. But we should first get clear about what a morally justified policy would say.

The principal objections to use of embryos solely as means are, first, that to every embryo there corresponds a possible person, and, second, that we should classify every embryo as an actual person for purposes of the duty not to kill. If embryo use were always wrong on either ground, it would be wrong for government to support research of which embryo use forms an induced part. But, so I have argued [9, 10], there exists a set of embryos whose use and consumption in medicine is permissible and virtuous. That set consists of embryos donated to medicine under instructions forbidding intrauterine transfer. The kernel of the argument for this conclusion is as follows. A woman from whose oocyte an embryo is formed in vitro is, with the coprogenitor, the only person in the world privileged to decide whether the embryo will be transferred to a uterus. No moral view of which I know holds that a woman lies under a duty to undergo such a transfer, or that she or the coprogenitor lie under a duty to surrender for adoption an embryo formed from her oocyte. A decision to decline intrauterine transfer is a morally permissible exercise of discretion. When there occurs such a declination, the consequent lack of uterine enablement so bounds the activated oocyte’s developmental potential that it cannot mature. Hence no possible person corresponds to an embryo barred from the womb. Nor could we gain anything, for that embryo or for any other being in the universe, by classifying the embryo as an actual person for purposes of the duty not to kill; we could only bring about that the embryo will die in vain. Embryos barred from the womb and donated to medicine present us with a means by which we might relieve suffering in actual lives at no cost in potential lives. The duty of mutual aid commands us to come to the rescue of our neighbors in peril when we can do so without unreasonable cost. Whereupon it is not only virtuous but obligatory to use donated embryos in the relief of human suffering.

The foregoing argument uses no premise peculiar to any particular religious or moral view. It does not, for instance, assert that before day 40, a conceptus lacks a soul (as in Thomistic Catholicism) or is “mere water” (as in Judaism). The duty of mutual aid, the absence of a duty of intrauterine embryo transfer—these are common to all leading moral and religious views. The foregoing argument occupies a place in an overlapping consensus, albeit a place not yet widely recognized.

On the basis of this argument, I propose the following rule of public policy applicable in any polity:

The government shall support biomedical research using human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine transfer.

The donor action referenced here is more than informed consent. In respect of donor action, voluntary informed consent without inducement (save for expense reimbursement) is necessary but is not, as assumed in recent proposals [2, 5], sufficient. Embryo use is justified when there occurs a morally permissible exercise of discretion, by a woman and coprogenitor from whose cells the embryo has been or will be formed, to refuse intrauterine transfer and give the embryo to medicine. Such donors do not merely acquiesce, they choose. This accords with common sense. We do not say that Sue acquired a bicycle on her birthday because her parents provided informed consent that it be transferred to Sue. We say that they *gave* it to Sue.

In our national debate, discussants have overlooked the justificatory importance of donor decisions. For their part, policy-makers have become preoccupied with producing the longest possible lists of “strict ethical standards.” Most of the entries on the lists either reiterate requirements that are already law (e.g., informed consent) or set forth procedures that most proponents of hESC research immediately find congenial. But for presumptive opponents, and those on the fence, the issue is not how, but whether. A convincing argument that research meets “ethical standards” must confront the main bone of contention, which remains embryo sacrifice. Therefore it behooves proponents to emphasize the event that justifies embryo sacrifice, a donor decision against intrauterine transfer conveyed by instructions to the donee. In recent legislation, neither this decision nor these instructions are mentioned.

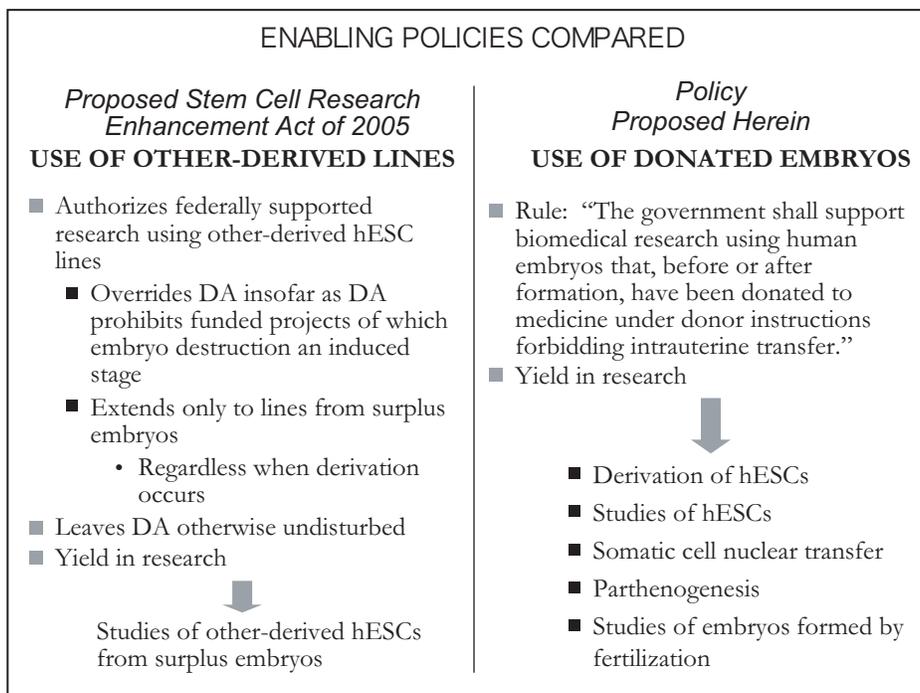
To excuse that oversight, it might be said that a parental decision against intrauterine transfer is inferable if we assume that parents know that some rule applicable to investigators prohibits intrauterine transfer. Instead of hoping for an inference, we can be explicit. The above proposed rule authorizes the use of a donated embryo if and only if the donor has decided and instructed against intrauterine transfer. This rule wears its justification on its sleeve. In public debate, this will show to its advantage. We need ancillary norms too, but the proposed rule is primary.

The proposed rule authorizes not only stem cell but other humanitarian research. This includes studies by fertility clinicians who, challenged to produce one healthy baby without producing multiple births, seek to study embryogenesis. The rule does not allow procreative cloning. I have elsewhere related a story that has been neglected by legislators welcoming an opportunity to vote. Since 1998, the Food and Drug Administration (FDA) has effectively interdicted procreative cloning, this because the practice would be manifestly unsafe. I have also related in detail, against anticipated objections, that the FDA possesses the authority to do what it has accomplished, and that the agency solidified its exercise of authority by a regulation effective January 21, 2004 [11]. In consequence of FDA vigilance, there has not occurred a single reported attempt at procreative cloning in the U.S. On pain of criminal penalties for any attempt, the likely incidence is

nil. As for procreative cloning when safe, we have heard speculations about the lives of clones, speculations betraying a heavy dose of genetic determinism. We have not reached a consensus that there obtains a compelling nonsafety ground for government intervention curtailing reproductive privacy. That will be a topic for another decade. For the indefinite future, the need for legislative action is a figment of legislative imagination. Legislation against cloning is at best redundant, at worst a platform for banning nuclear transfer in research.

What does require legislative attention is DA. For Congress without self-contradiction to authorize NIH-funded use of hESCs, it must override, let lapse, or repeal DA. The proposed Stem Cell Research Enhancement Act of 2005, popularly known as “the Castle-DeGette bill,” would override DA. Its provisions would govern “notwithstanding any other provision of law” [6]. But it would override DA only to the extent of authorizing use of other-derived lines from surplus embryos (Fig. 1). In hitching itself to the use-derivation distinction originated by NIH, this legislation produces an effect presumably not intended by its sponsors, namely, it reinforces the belief that to derive stem cells from donated embryos is wrong. Consider then discussants who start from that belief. These discussants find reason to oppose the legislation inasmuch as a government that induces embryo destruction is complicit in the destruction. Although some people might be taken in by the illusion of a responsibility firewall between embryo destruction and the government, that illusion has not yet influenced enough people to boost support for the legislation to a veto-proof majority in the U.S. Congress. And for the long run, we cannot construct a stable consensus on an illusion. The opportunity remains to populate a broader and stable consensus. To those who hesitate to approve embryo use, we may offer an earlier mentioned twofold argument. First, no possible persons correspond to donated embryos barred from the womb. Second, no one can gain anything for such embryos, or for any other beings, by declining research. Research on hESCs is moral not because derivation and use are distinguishable, but because both are permissible in consequence of permissible donor decisions. This reasoning—not recitals of biological facts about embryos—meets head on any posit of actual or corresponding potential persons. It furnishes a cogent case for the Castle-DeGette bill and for other incremental steps toward the proposed rule.

To any legislator prepared to support use of other-derived hESCs, three further reasons may be given for overriding DA to the extent of the proposed rule. First, a legislator will want to get in step with the voters. Consider that a voter either approves of sacrificing donated embryos, or does not. A voter who approves of donated embryo sacrifice will assume that funded investigators sacrifice embryos. That voter has no reason to distinguish between self- and other-derived lines. That distinction, like that between deriving and using lines, is not heard in moral discourse. Nor does it appear in such state policies as California proposition 71. The



**Figure 1.** Authorizing publicly supported research involving human embryos. Abbreviations: DA, Dickey Amendment; hESC, human embryonic stem cell.

distinction is wholly a bureaucratic invention, one that may be sent by the board with the DA prohibition that prompted it. DA itself, a mere appropriations rider, is unknown to most of the public. Meanwhile for a voter who disapproves of any embryo sacrifice, there is no solace in prohibiting only the use of self-derived hESC lines. To that voter, it will be apparent—either immediately, or as soon as the voter discovers that the imagined firewall is illusory—that inducing others to derive hESC lines brings in its train complicity in embryo destruction. Second, leaving in place a ban on embryo destruction while authorizing use of embryonic derivatives will hamper research. The third reason pertains to DA’s ban on creating embryos. As scientists use surplus embryos to derive cell lines, create embryos by nonprocreative cloning, and use clones to study reprogramming, to model diseases, and to perform autologous transplantation, the moral justification does not vary with the procedure. The argument given above for the proposed rule justifies all medical use of donated embryos, whether surplus embryos or embryos formed in research, on one and the same ground—donor exercise of discretion to decline intrauterine transfer [10].

Nowhere does intent to initiate a pregnancy play a role in that argument. Hence the use of surplus embryos does not rest on morally higher ground than the creation of embryos in research.

On the foregoing grounds it may be said that each of DA’s prohibitions frustrates fulfillment of our collective moral responsibilities as above conceived. This constitutes a compelling reason to retire both prohibitions. So long as they remain, it may be pertinent to adduce one institutional observation. The National Science Foundation and Department of Energy are funding sources to which DA has never applied.

Under the proposed rule, not only will the publicly supported and the morally permissible coincide, the rule itself will manifest this. The rule defines eligible research by conditions that confer moral permissibility. As the rule optimizes the scope of research, it displays its justification. This avails for purposes of presenting the rule to our fellow citizens who do not yet approve of the humanitarian use of embryos barred from the womb. The more conspicuous we make our moral logic, the stronger the moral consensus that we may foster.

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