

Specially Respecting the Living Human Embryo by Adhering to Standard Human Subject Experimentation Rules

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The being that is now you or me is the same being that was once an adolescent, and before that a toddler, and before that an infant, and before that a fetus, and before that an embryo. To have destroyed the being that is you or me at any of these stages would have been to destroy you or me.¹

The debate about whether to federally fund human embryonic stem cell research is at root a controversy about the legal status that should be accorded the human embryo. The undisputed, scientifically verifiable facts agreed to by even the most liberal proponents of human embryonic stem cell research are that (1) the embryo is living and genetically unique;² (2) the embryo is human and capable of developing into an adult;³ and (3) derivation of human stem cells from embryos terminates them.⁴ Although philosophical and political disagreement subsequently arises about whether the embryo should be deemed a juridical person, quasi-person, or non-person,⁵ we have not adequately addressed the significance of these three undisputed facts for regulating embryonic stem cell research.

On August 9, 2001, President Bush directed the Department of Health and Human Services (HHS) to approve limited federal funding for research on then sixty stem cell lines derived with the “informed consent” of parents who authorized the termination of their embryos.⁶ By informed consent, the Bush Administration meant “informed proxy consent” like the Clinton Administration before it.⁷ Yet, no court has ever found proxy consent adequate to justify ultra-hazardous, non-therapeutic research on

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incompetent living human subjects. Proxy consent to non-therapeutic research thwarts the underlying objectives of the informed consent doctrine applicable to human subject experimentation, including preserving autonomy, self-determination, liberty, and equality. Indeed, the very term “proxy informed consent” is doctrinally oxymoronic and must be recognized as a serious threat to all incompetent human subjects.

Strong legal and policy reasons exist to treat the living human embryo as something more than mere tissue, if not subject to the Federal Policy for the Protection of Human Subjects, including subpart A and subpart B,⁸ or to amended regulations providing greater protection than the fetal tissue research regulations, which the National Institutes of Health (NIH) prefers to invoke.⁹ A living human is more analogous to a “human subject” than human tissue. Categorizing the embryo as mere tissue does not recognize the special status of the human embryo, which a majority of Americans acknowledge,¹⁰ and instead renders the embryos vulnerable to the potential of ever-widening scientific manipulation in the years ahead. The embryo-as-tissue argument also forces the NIH to promulgate legal positions, such as its controversial Rabb Memorandum,¹¹ ignoring Congress’ clear intent to avoid harming living human embryos, and sweeping behind the public’s veil of ignorance the possibility that human embryonic stem cells are totipotent—capable of generating every cell comprising a mature human person. If totipotent, human embryonic stem cells may not be substantially less deserving of protection than the human embryo.

We explore each of these ideas below without imposing our view that the human embryo is indeed a person and without discussing a mother’s moral and legal entitlement to end the life of a living human in her womb.¹² Our point is that, regardless of your view about these important questions, living human embryos merit more protection than those who would gain financially and otherwise from manipulating them or simply donating them are inclined to acknowledge. If as a society we choose now to exclude altogether certain types of living human subjects from standard rules of medical ethics, the utilitarian fog into which medical researchers will travel in the years to come will surely take American medical researchers down the darkened and dead-ended roads previously traveled from Buchenwald¹³ to Tuskegee.¹⁴

I. DEVELOPMENTS IN THE IVF INDUSTRY AND STEM CELL RESEARCH HAVE OUTPACED POLICYMAKING

Today’s controversy concerning federal funding for human embryonic stem cell research represents the confluence of three trends: the

maturation of the in-vitro fertilization (IVF) industry with a protocol resulting in an exploding frozen human embryo population; the isolation of the human embryonic stem cell within the context of promising adult stem cell research; and policymaking that has not kept up with either. The IVF industry sprang into existence in England in 1978.¹⁵ During the last two decades, it has grown in the United States to 371 clinics nationally,¹⁶ with revenues that exceed an estimated \$350 million annually.¹⁷ The typical IVF clinic supervises the creation of many more living human embryos than are implanted because of the physical burden, medical risks, and costs associated with egg recovery.¹⁸

Clinics find it difficult to preserve and, once preserved, successfully fertilize oocytes.¹⁹ Accordingly, within a few hours of surgically removing oocytes, clinics fertilize the eggs and allow them to incubate.²⁰ Successful fertilization usually results in more embryos than women want to implant at one time.²¹ The remainder are cryo-preserved and remain frozen until the parents terminate, donate, or abandon them.²² As a result, one observer estimated in 1999 that 150,000 frozen human embryos were in storage with 19,000 added each year.²³ Anecdotal evidence suggests the number may be higher.

A radical, new purpose for embryo donation was foreshadowed in the early-1980s when mouse embryonic stem cells were derived for the first time from mouse blastocysts.²⁴ Soon thereafter, scientists discovered they were totipotent.²⁵ This finding “revolutionized mouse genetics.”²⁶ Scientists set about trying to duplicate the success with humans. In November 1998, Professor James Thomson at the University of Wisconsin succeeded at isolating human stem cells.²⁷ This prompted President Clinton to ask the National Bioethics Advisory Commission (NBAC) to conduct a thorough review of the medical and ethical issues associated with human stem cell research.²⁸

Pursuant to the NBAC’s recommendation, the NIH published its Draft Guidelines for Research Involving Human Pluripotent Stem Cells,²⁹ and on August 25, 2000, its final Guidelines (NIH Guidelines) allowing funding of research involving human embryonic stem cells if (1) the cells were derived without federal funds from frozen human embryos that were created for the purposes of fertility treatment; (2) the cells were “in excess of the clinical need” of the individuals seeking the treatment; (3) a clear separation existed between the decision to create the embryos for fertility treatment and the decision to donate them for research purposes; (4) no inducements were offered for the donation of the embryos; and (5) the informed consent of “individuals who have sought fertility treatment” was obtained.³⁰

The NIH was unable to award federal money to scientists under the NIH Guidelines because of litigation commenced on March 8, 2001,³¹ leading to entry of a stipulated stay pending the "outcome" of the Bush Administration's review of the NIH Guidelines.³² The legal controversy concerning embryonic stem cell research erupted into a vigorous political debate in the summer of 2001.³³ It was not muted until August 9, 2001, when President Bush decided his Administration's political solution to the debate.³⁴ His closely aligned legal response leading to dismissal of the legal action was announced on November 7, 2001.³⁵ The Administration withdrew portions of the NIH Guidelines inconsistent with the President's decision to condition federally funded embryonic stem cell research on four criteria: (1) stem cells must have been derived from an embryo with the consent of the embryo's donors; (2) they may only have been derived from excess embryos created for reproductive purposes at fertility clinics; (3) the donor embryos must not have been donated in exchange for financial inducements; and (4) all embryonic lines must have been derived on or before August 9, 2001.³⁶

II. THE INFORMED CONSENT MODEL IS INCOMPATIBLE WITH EMBRYONIC RESEARCH

Both the Clinton Administration plan and Bush Administration plan for federally funding embryonic stem cell research require the informed consent of the living human embryo donor.³⁷ In essence, both plans view (1) informed consent as equivalent to proxy consent and (2) proxy consent as sufficient to immunize ultra-hazardous, non-therapeutic research on living humans. As stated earlier, no court has previously approved the latter proposition, and the former one is contradicted by the key medical ethical codes applicable to living human subjects.

A. The Doctrine of Informed Consent Bars Embryonic Stem Cell Research

The doctrine of informed consent applicable to human subject experimentation was essentially birthed by the Holocaust and subsequent Doctor's Trials resulting in the Nuremberg Code.³⁸ According to one commentator, American courts did not even accept the need for medical research on human subjects until 1935.³⁹ The Code prohibited altogether proxy consent for human experimentation.⁴⁰ The Code added that consent cannot immunize human subject experimentation unless the researcher complies with nine other requirements, including that no a priori reason exists to believe that death or disabling injury will occur, that the results of the experimentation are not procurable by other means, and that

adequate preceding animal experimentation has taken place.⁴¹

The first systematic American effort to develop a doctrine of informed consent applicable to federally funded human subject experimentation incorporated the Code.⁴² The impact of the Code has since waned in some respects, yet it endures as the “most complete and authoritative statement of the law of informed consent to human experimentation.”⁴³ The Code’s influence on what some deem a replacement code of ethics,⁴⁴ the Declaration of Helsinki, has actually increased over time as a result of amendments. For example, the Declaration now expressly prohibits proxy consent to research if (1) the research is not necessary to promote the health of the population represented; (2) the research can be performed on legally competent individuals; and (3) the research is not based on sufficient animal studies.⁴⁵

Additionally, the Code remains “part of international common law and may be applied, in both civil and criminal cases, by state, federal and municipal courts in the United States.”⁴⁶ Although federal courts have not found that the Code creates an implied right of action in circumstances where adequate alternative domestic remedies exist,⁴⁷ they have found, contrary to claims of qualified immunity, a “clearly established right” to bodily integrity in § 1983 litigation.⁴⁸ As the District of Massachusetts put it in *Heinrich v. Sweet*, “[A]t the very least, the judgment of the Nuremberg Tribunal regarding fundamental legal principles of human subject experimentation served as an explicit international declaration that the conduct alleged in this case ‘shocked the conscience’....”⁴⁹

Heinrich concerned 140 terminally ill patients under the care of the Massachusetts General Hospital and Brookhaven National Laboratory who were subjected to boron neutron radiation therapy without their knowledge or consent.⁵⁰ The study was deemed essential to evaluate the potential of radioactive medical treatment.⁵¹ *Heinrich* relied on another case where the University of Cincinnati College of Medicine and Cincinnati General Hospital subjected eighty-seven African-American cancer patients, who were terminal, indigent, and poorly educated, to massive doses of radiation to study its effects without their informed consent.⁵² Again, the scientific community considered the study critical to prepare for nuclear war, but the Southern District of Ohio volunteered that the complaint’s allegations made out “an outrageous tale of government perfidy in dealing with some of its most vulnerable citizens.”⁵³

Tragically, this tale has been duplicated with minor variations in the United States in a variety of cases involving non-therapeutic medical research on human subjects performed for valuable reasons.⁵⁴ The objectives of human embryonic stem cell research are also unimpeachable,

but the certain, immediate death that stem cell derivation poses for another living human subject—the human embryo—is in many respects as shocking as in these cases involving not proxy consent, but deception or inadequate informed consent by generally competent adults to non-therapeutic medical procedures with long-term medical consequences.

To understand the real impact of embryonic stem cell research on medical ethics, add to the certain, immediate death that derivation of stem cells causes human subjects the following additional violations of the Nuremberg Code and Declaration of Helsinki: (1) At most a handful of animal embryonic stem cell models exist revealing limited success at treating the diseases targeted by human embryonic stem cell research,⁵⁵ and (2) adult human stem cell research has the potential to achieve all of the objectives of embryonic stem cell research.⁵⁶ Thus, embryonic stem cell research is in direct violation of the two primary medical ethical codes governing experimentation on living human subjects.

B. Proxy Consent Has Never Been Held Sufficient to Immunize Ultra-Hazardous, Non-Therapeutic Research on Human Subjects

Proxy consent to ultra-hazardous, non-therapeutic human research, the additional conscious-raising concern not present in the cases explored above, has never been held effective as a matter of law in the United States. Two courts have approved minimally risky non-therapeutic kidney transplants from legally incompetent human subjects to relatives,⁵⁷ where the medical institutions involved obtained judicial consent, in addition to proxy consent, before proceeding, and the court appointed *guardian ad litem*s to represent the incompetent human subjects.⁵⁸ Another court found that it was in the best interest of a forty-three year-old incompetent donor to undergo a bone marrow transplant involving “minimal risk” to the donor to save his brother’s life.⁵⁹ In the last case, a court implied that a proxy could consent to her fifteen year old’s decision to offer a skin graft to his cousin.⁶⁰

The few decisions involving more risky non-therapeutic experimentation on human subjects have disapproved of proxy consent.⁶¹ Two of these concerned studies on inmates,⁶² which if federally funded are now prohibited.⁶³ In one of these cases (not involving federal funding), the New York State Office of Mental Health (OMH) promulgated regulations with the strong support of the medical research community, which would have permitted the administration of experimental antipsychotic and psychotropic drugs, capable of “causing permanent harmful or even fatal side effects.”⁶⁴ A New York appeals court held that the regulations violated the state and federal constitutional rights to due process and a common

law right to personal autonomy of the patients and residents under OMH care.⁶⁵ The Court explained:

The benefits of, and needs for, the medical research at issue are clear and evident; but at what cost in human pain and suffering to those subjects who are not capable of expressing either their consent or objection to participation?... [H]owever laudable the ends which defendants seek to achieve may be, those results must be gained through means within their grant of authority and which properly safeguard the rights of the plaintiffs. It may very well be that for some categories of greater than minimal risk non-therapeutic experiments, devised to achieve a future benefit, there is at present no constitutionally acceptable protocol....⁶⁶

Maryland's highest court agreed in *Grimes v. Kennedy Krieger Inst.*, where researchers associated with Johns Hopkins University subjected otherwise healthy children to the probability of lead poisoning to assess the effect of various levels of lead dust abatement.⁶⁷ The Court found inadequate disclosure of these health risks to the children's parents,⁶⁸ and added: "[I]n our view, parents whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous non-therapeutic research surroundings, than do researchers. In such cases, parental consent, no matter how informed, is insufficient."⁶⁹

The policy underlying the doctrine of informed consent to non-therapeutic research is to preserve the autonomy, self-determination, liberty, and equality of living human subjects, as well as to avoid fraud and abuse.⁷⁰ Proxy consent can never achieve these purposes. The justifying and legally immunizing role of consent depends upon the subject of the research herself agreeing to undergo a non-therapeutic procedure after deliberately weighing the fully disclosed risks. Consent offered by a proxy to non-therapeutic research for his incompetent ward, no matter how well informed, robs the patient of her autonomy and liberty and treats her as having lesser value. Viewed in this light, proxy informed consent is a sham and poor camouflage for mere utilitarianism:

Faced with a subject who presumably cannot consent, the Standard Model looks for someone else's consent. This is a big jump. After all, informed consent supposedly legitimates and justifies experimentation because that consent protects autonomy; but how can it when someone else is providing the consent? 'Proxy consent' is an oxymoron if consent truly aims at protecting self-autonomy and self-determination. Through proxy consent, the subject is labeled a morally impotent agent—less than

autonomous. This is because the unspoken, but persistent, utilitarianism which underlies so much of our thinking about experimentation requires us to find some way to permit needed experiments while still giving lip-service to our values.⁷¹

Historically, informed consent has been deemed the most critical for vulnerable subjects such as the imprisoned, young, and elderly. It is crucial where the imbalance in the power relationship between the researcher and patient is severe,⁷² seriously divergent interests between the researcher and his or her subject may affect the scientist's judgment,⁷³ the researcher has more information about the consequences of the research for the subject,⁷⁴ and the subject places his or her profound trust in the investigator.⁷⁵ Human embryonic research is affected by all of these worst indicia of meaningless consent. The embryo donors seek to avoid the cost of preserving their embryos; researchers and Institutional Review Boards (IRBs) desire federal dollars, corporate sponsorship, and prestige; and the live human embryos themselves are, of course, incompetent and incapable of opposition.⁷⁶

Under these circumstances, we should be seriously concerned about authorizing medical research certain to kill incompetent living human subjects (not merely harm them as in *Grimes*) when the proposed benefits of the research may yet be obtained through harmless means and inadequate animal modeling justifies it. This type of medical research carried to its logical conclusion threatens harm to the elderly, handicapped, and mentally or physically ill.⁷⁷ It has never been vindicated in federal or state court, and it directly violates the Code and Declaration.⁷⁸ The *Grimes* court indicated that certainly no parent may consent to ultra-hazardous, non-therapeutic research affecting her child, no researcher may consent to it because of the fiduciary-like relationship between the researcher and his subject,⁷⁹ and potentially no court may approve it.⁸⁰ Indeed, it is an open question as to whether even a competent person may consent to ultra-hazardous, non-therapeutic research on himself.⁸¹

III. THE LIVING HUMAN EMBRYO DEMANDS SPECIAL RESPECT

Some will vigorously object that *Grimes* is inapplicable to living human embryos, because embryos are not, after all, "children" in a legal sense.⁸² The embryo *in utero* is not a "person" within the meaning of the Fourteenth Amendment,⁸³ rendering any direct analogy to the children in *Grimes* inappropriate. Notwithstanding this, even strong pro-abortion proponents acknowledge that *Roe v. Wade*⁸⁴ has no necessary bearing upon the *ex utero* living human embryo where maternal and fetal rights are not in

opposition.⁸⁵ Professor John Robertson, for example, concedes that efforts to limit the number of cryopreserved embryos,⁸⁶ regulate destruction of human embryos,⁸⁷ require their donation,⁸⁸ and restrict or ban non-therapeutic research on living human embryos⁸⁹ are constitutional.

Robertson adds, “[O]ne may reject the right-to-life position that early embryos are themselves persons...and still agree that early embryos deserve ‘special respect’....”⁹⁰ He acknowledges “wide consensus” favoring this view, which he contends does not hinge on religious convictions, but instead on the essential nature of the embryo as a living, genetically unique human with the potential to develop into a person.⁹¹ Courts echoing this theme include *Kass v. Kass*⁹² and *Davis v. Davis*,⁹³ which expressly rejected the findings of the trial court that the embryo is a person,⁹⁴ and of the appellate court that it was mere property “no different from any other human tissue.”⁹⁵ Instead, the *Davis* court held that living human embryos “occupy an interim category that entitles them to special respect because of their potential for human life.”⁹⁶

The NBAC and the NIH agreed that the embryo deserves special respect, but without influencing the choice of regulatory frameworks they believe applicable to it. In the final analysis, they and Robertson interpret “special respect” for the living human embryo to mean little more than that researchers may not create embryos solely for research purposes.⁹⁷ The “informed consent” rules they believe applicable to living human embryos are the same ones applicable to fetal tissue transplantation research,⁹⁸ as if the doctrine of informed consent ever applied to inanimate tissue. A more intellectually honest description of this form of consent is merely “full disclosure,” since no living human subject is involved. Tissue cannot generate anything beyond itself, whereas the human embryo is totipotent.⁹⁹ Accordingly, the fetal tissue research guidelines appear to have no relevance to living human embryos and, even if applicable, are not truly rules of informed consent.¹⁰⁰

Embryonic stem cells are more like tissue than living human embryos, but still not enough to complete the analogy.¹⁰¹ The NIH concedes that human embryonic stem cells “can form virtually every type of cell found in the human body.”¹⁰² Nevertheless, the NIH has insisted that the cells are merely pluripotent, because embryonic stem cells “are unable to give rise to the placenta and supporting tissues necessary for development in the human uterus.”¹⁰³ The placenta and the supporting tissues come from trophoblast cells.¹⁰⁴ Thus, in scientific terms, the NIH’s claim is that human embryonic stem cells can form all cell types, except trophoblast cells. The scientific record refutes this. In fact, the same scientific study that the NIH cites to demonstrate the alleged potential for human embryonic stem cell

research,¹⁰⁵ states that human embryonic stem cells can form trophoblast cells.¹⁰⁶

In addition, NIH Director Harold Varmus has conceded that the NIH has never performed the necessary experiments to rule-out the possibility that human embryonic stem cells when implanted in a woman may congregate and give rise to a born person.¹⁰⁷ Animal studies using embryonic stem cells suggest this is likely.¹⁰⁸ Accordingly, some stem cell researchers are sharing their misgivings about not admitting this to the public.¹⁰⁹ By contrast, there is no chance tissue can give rise to a born person. Therefore, embryonic stem cells deserve more protection than mere fetal tissue regulations offer.

IV. EXISTING FEDERAL AND STATE LAWS WOULD PROHIBIT FEDERALLY FUNDING ULTRA-HAZARDOUS, NON-THERAPEUTIC RESEARCH ON LIVING HUMAN EMBRYOS

Existing federal and state law potentially or actually applicable to living human embryos provide additional reason to believe that specially respecting them requires more protection than the NIH and others acknowledge. Subparts A and B of the Federal Human Subjects Policy may be interpreted to ban embryonic stem cell research altogether, and the Dickey Amendment may be interpreted to ban research on living human embryos. State laws affecting living human embryos establish tort liability for damages to the unborn and restrict or ban research on embryos and authorize their adoption. We explore these rules below.

A. *If Applicable, Federal Human Subjects Policy, Subparts A and B, Prohibit Federally Funding Human Embryonic Stem Cell Research*

The springboard for *Grimes'* finding that researchers owe quasi-fiduciary obligations to human subjects was, in addition to the Nuremberg Code, the Federal Policy for the Protection of Human Subjects, including Subpart A and Subpart B (Human Subjects Policy).¹¹⁰ Subpart A states it is applicable "to all research involving *human subjects* conducted, supported, or otherwise subject to regulation by any federal department...."¹¹¹ Human subjects are defined as "*living individual[s]* about whom an investigator...conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."¹¹² This definition does not reference a legal juridical person.

Under Subpart A, the informed consent requirement states: "[N]o investigator may involve a *human being* as a subject in research covered by this policy unless the investigator has obtained the *legally effective* informed

consent of the subject or the subject's legally authorized representative."¹¹³ The rule does not make clear whether, by "human being," someone or something other than a "human subject" was intended; however, it defines as an element of necessary consent, "a statement that the particular treatment or procedure may involve risks to the subject (or to the *embryo* or fetus, if the subject is or may become pregnant) which are currently unforeseeable."¹¹⁴

Accordingly, Subpart A does not state that its application is limited to living human persons and leaves open the possibility that a living human embryo is a "human being," which may be equivalent to a "human subject" and, therefore, regulated. A leading definition of human subject experimentation outside of the federal regulatory framework supports this view: Human subject experimentation is "any manipulation, observation, or other study of a human being—or of anything related to that human being—that might subsequently result in manipulation of that human being—done with the intent of developing new knowledge and which differs in any form from customary medical (or other professional practice)."¹¹⁵ The counterargument is that an "individual" frequently is a natural person, and the "human being" referenced in Subpart A's rules of informed consent may not be more expansive than its definition of "human subject." In rebuttal, the NIH itself has implied that human embryos are individuals.¹¹⁶

The informed consent rule of Subpart A implies that some proxy consent may not be legally effective, a fact the *Grimes* court emphasized in calling for prior judicial (not mere IRB) review before implementing non-therapeutic research on a human subject.¹¹⁷ The court opined, "[s]cience cannot be permitted to be the sole judge of the appropriateness of such research methods on human subjects...."¹¹⁸ Likewise, in the single other reported instance of non-therapeutic experimentation posing a greater than minimal risk to the living human subject, a New York appeals court found that proxy consent would be ineffective under state law.¹¹⁹

Subpart B of the Human Subjects Policy, considered by some more relevant to human embryonic research than Subpart A,¹²⁰ "applies to all research involving pregnant women or human fetuses, and to *all research involving the in vitro fertilization of human ova*, conducted or supported by" HHS.¹²¹ The definition of IVF is "any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means."¹²² Subpart B incorporates all of Subpart A's obligations and calls for additional IRB duties.¹²³ The NIH and others resist an interpretation of IVF within the meaning of Subpart B incorporating extra-corporeal embryo research.¹²⁴ The NIH believes the embryo is only protected under the Human Subjects Policy if it

is *in utero*.¹²⁵ Regardless, it is clear that the human embryo, which is the subject of the Clinton and Bush plans for stem cell research, may only come from IVF, and that Subpart B applies to “all research involving...in vitro fertilization.”¹²⁶

If the Human Subjects Policy is thus applicable to human embryos, we must decide whether proxies can provide legally effective consent to ultra-hazardous, non-therapeutic derivation of stem cells from living human embryos. In addition, we must evaluate whether this derivation is necessarily related to research utilizing those stem cells. Subpart A (which is incorporated in Subpart B) requires that IRBs ensure that risks to human subjects are minimized and reasonable in relation to anticipated benefits.¹²⁷

“Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research may not be “greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”¹²⁸ In addition, IRBs must incorporate additional safeguards for subjects vulnerable to coercion.¹²⁹ Thus, to the extent derivation of stem cells is inherently related to their use, Subpart A would prevent federally funding embryonic stem cell research.

B. The Dickey Amendment Protects the Living Human Embryo From Any Federally Funded Procedure Posing More Than Minimal Risk to It

Concededly, it may be argued that the Human Subjects Policy does not regulate research on living human embryos. The so-called Dickey Amendment defines “human embryo” as “any organism, *not protected as a human subject* under the Human Subjects Policy 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.”¹³⁰ Accordingly, the NIH believes that we must derive our hermeneutic of special respect for the human embryo from a memorandum issued on January 15, 1999, by HHS General Counsel Harriet S. Rabb, interpreting the Dickey Amendment (Rabb memorandum).¹³¹

The Dickey Amendment, included in every HHS appropriations bill since 1995,¹³² states: “None of the funds made available by this Act may be used for...research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero*....”¹³³ Interpreting this language, the Rabb memorandum claimed that the Dickey Amendment bans federal funding of the derivation of embryonic stem cells—a

euphemism for the procedure that kills the living human embryo—but not research utilizing the derived embryonic stem cells.¹³⁴

This interpretation flatly contradicted legislative history through 2001, and the original purpose for passing the Dickey Amendment—to prevent embryonic research.¹³⁵ Until 1994, a *de facto* federal ban on human embryo research existed.¹³⁶ The Clinton Administration took steps to reverse this ban pursuant to the recommendation of an *ad hoc* advisory committee, the Human Embryo Research Panel (HERP),¹³⁷ while still prohibiting the creation of embryos for research purposes.¹³⁸ In testimony before the House Appropriations Committee, NIH Director Varmus stated that he “firmly agree[d]” with several portions of the HERP report, and told the Committee that the NIH was currently deciding whether to go forward with funding.¹³⁹

Before the NIH could approve any grants, Congress passed the Dickey Amendment for the first time.¹⁴⁰ Opponents of the amendment objected to it on the grounds that it would foreclose action on the HERP report and “segregate [human embryo] research into private laboratories, which are not subject to any set scientific or ethical guidelines.”¹⁴¹ Senator Boxer agreed that the Dickey Amendment amounted to “a *total prohibition* of Federal funding for human embryo research.”¹⁴² That first year, the House Appropriations Committee rejected an alternative rider offered by Representative John Porter, which would have codified President Clinton’s directive by prohibiting only the funding of the *creation* of embryos for research purposes.¹⁴³

During the 1997 reauthorization cycle, the full House roundly rejected an amendment offered by Representative Lowey and identical to the Porter Amendment.¹⁴⁴ Again, the proponents and opponents of embryo research operated on the same premise (i.e., that the Dickey Amendment banned federal funding of *all* research dependent upon the destruction of an embryo).¹⁴⁵ Porter argued, for example, that repeal of the Dickey Amendment was necessary because federal funding of research “could also lead to breakthroughs *in the use of embryonic stem cells*.”¹⁴⁶ No further attempts were made to modify the Dickey Amendment until the 2001 reauthorization cycle. Therefore, the conclusion is inescapable that the Rabb memorandum, NIH Guidelines, and even the proposed Bush plan proposing funding on sixty stem cell lines necessarily derived through the termination of human embryos were inconsistent with the Dickey Amendment as passed from 1995 to 2000.¹⁴⁷

In 2001, the Senate was widely expected to modify the Dickey Amendment; however, the national tragedy of September 11 changed the political landscape. The House reauthorized the Amendment without

change, but interpreted its action as consistent with the proposed Bush plan.¹⁴⁸ Representative McDermott and Senator Arlen Specter proposed amendments permitting liberal embryonic stem cell research.¹⁴⁹ Both failed. The resulting Amendment is not a vindication of the Rabb memorandum's derivation-versus-use dichotomy.¹⁵⁰ Nor is it a vindication of the limited protection that President Clinton; Representatives Lowey, Porter, and McDermott; and Senator Specter offered (i.e., prohibiting the funding merely of the *creation* of embryos for research purposes).

Rather, the resulting Amendment is a vindication of the principles permitting research on already dead fetuses. President Bush refused to justify research on living human embryos based on the derivation-versus-use dichotomy; he authorized research only on embryos terminated before August 9, 2001, without creating federal incentives to kill more.¹⁵¹ Accordingly, the "special respect" Congress and the President wish to accord living human embryos is best understood as security from any procedure that would pose more than minimal risk to them, including use-inspired derivation of stem cells.

C. State Regulations Affecting Living Human Embryos Limit or Ban Embryonic Research, Permit Adoption, and Create Tort Liability

Likewise, the special respect that state law affords living human embryos resembles more closely human subjects than dead fetuses or human tissue. Thirty-seven states and the District of Columbia have recognized expressly or implicitly by statute, resolution, and/or court decision that "fertilization" and "conception" initiates the life of a human being.¹⁵² In many of these states, courts impose tort liability for damages to the unborn without regard (for purposes of standing) to the viability of the child at the time of injury.¹⁵³ Ten states expressly regulate human embryonic research; seven of these states permit only therapeutic human embryonic research.¹⁵⁴ Three additional states tried to regulate human embryonic research, but their regulations were overbroad.¹⁵⁵ Two states have enacted a rudimentary legal framework for human embryo adoption,¹⁵⁶ a concept ordinarily not applied to mere tissue or dead human subjects.

V. A PERMANENT LEGAL COMPROMISE NO WEAKER THAN THE BUSH PROPOSAL IS URGENTLY NEEDED

In the final analysis, the nascent federal and state legal regime applicable to human embryos reflects the objective reality that they are living members of the human species, not merely inanimate tissue.

Although not yet judicially recognized as persons within the meaning of the Fourteenth Amendment, the legal regime treats them as juridical quasi-persons with some of the rights of incompetent living persons. A permanent legal compromise is necessary to protect these quasi-persons against ever-widening scientific manipulation threatened by proponents of broader federal funding for embryonic stem cell research and to prevent further erosion of the standard human subject experimentation rules.¹⁵⁷

We would have preferred to prevent any embryonic stem cell research.¹⁵⁸ The policies informing the case law and legislative intent explored above, that we believe strongly militate in favor of rendering standard human subject experimentation rules applicable to embryos, include (1) all other living humans—even the least desirable criminals—are specially protected; (2) treating any living human as expendable impacts all by lowering the ethical bar; (3) derivation of stem cells is immediately terminal for the embryo and unlikely to have any therapeutic impact on embryos as a class in the near future; (4) proxy consent can never achieve the objects of informed consent, including autonomy, self-determination, liberty, and equality; (5) those urging, monitoring, and even offering proxy consent for derivation of stem cells have much to gain from it; and (6) scientists have not satisfied their burden of proving that (a) embryonic stem cell research is likely to prove successful; (b) its speculative objectives cannot be secured through other means; and (c) embryonic stem cells are merely pluripotent.

If embryonic stem cells are merely pluripotent, stem cell lines extracted without the legally effective informed consent of their donors would still be illegal.¹⁵⁹ If totipotent, embryonic stem cells may also be subject to the Dickey Amendment, because they qualify as “human embryos” within the meaning of the Amendment as interpreted by the NIH. That is, the Dickey Amendment defines “human embryo” as “any *organism*...that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”¹⁶⁰ Although the Amendment does not define “organism,” the NIH contends that it means “an individual constituted to carry out all life functions.”¹⁶¹ By definition, a totipotent cell is capable of developing into a mature individual if nurtured in the right environment and, thus, able to carry out all life functions.¹⁶² Under these circumstances, the Dickey Amendment would prohibit research posing more than minimal risk to embryonic stem cells—a fact Congress has so far not considered probably because the NIH has swept under the rug the potential totipotency of human embryonic stem cells.

Nevertheless, the advantage of permanently legislating the proposed

Bush plan over the Clinton plan is that the former offers a meaningful interim category between the embryo-as-tissue and embryo-as-person regulatory framework. The idea of federally funding research on a limited number of already terminated human embryos while permitting states to ban it altogether, puts some flesh on the special respect most Americans believe is due the living human embryo. Space prevents us from expounding on a proposed Subpart E (Additional Protections for Human Embryos), and the additional legislation we believe necessary to accord meaningful special respect to the living human embryo. Suffice it to say that we believe the Human Subjects Policy must carefully distinguish the various forms of consent and disclosure, removing any possibility that proxies may give their consent to ultra-hazardous, non-therapeutic research on living humans, except as permitted in our proposed revised permanent Dickey Amendment.¹⁶³ Furthermore, Subpart E should generally permit research posing no more than a minimal risk to living human embryos. Finally, federal or state laws should ban creation of human embryos for research purposes,¹⁶⁴ ban cloning,¹⁶⁵ limit the number of human embryos that may be cryopreserved in the IVF treatment process,¹⁶⁶ regulate the disposition of living and frozen human embryos,¹⁶⁷ and encourage embryo adoption over donation.¹⁶⁸ In this manner, we can ensure special respect for the living human embryo.

References

1. Robert George, *Stem Cell Research: A Debate; Don't Destroy Human Life*, WALL ST. J., July 30, 2001, at A18. Robert P. George, J.D., D. Phil. is the McCormick Professor of Jurisprudence, Princeton University, and Director of the James Madison Program in American Ideals and Institutions. On January 18, 2002, President Bush appointed Dr. George to be one of eighteen members of the President's Council on Bioethics charged with keeping the President apprised of new developments in the bioethics arena and providing a forum for discussion and evaluation of those issues.

2. John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 974-75 (1986) [hereinafter Robertson I]; John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 437, 444 & n.24, 445, 515 (1990) [hereinafter Robertson II].

3. *Id.*

4. See, e.g., Gabriel S. Gross, Comment, *Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis*, WIS. L. REV. 2000, at 855, 856.

5. See *Davis v. Davis*, No. E-14496, 1989 WL 140495, at *1 (Tenn. Cir. Ct. Sept. 21, 1989) (embryos are children in vitro), *rev'd*, No. 180, 1990 WL 130807 (Tenn. Ct. App. Sept. 13, 1990) (embryos are property), *aff'd*, 842 S.W.2d 588 (Tenn. 1992) (embryos deserve "special respect" as neither property nor person), *cert. denied*, 507 U.S. 911 (1993).

6. Press Release, Office of the Press Secretary, White House, President's Embryonic Stem Cell Research Policy (Aug.

9, 2001) [hereinafter Bush Press Release] (on file with author), available at www.whitehouse.gov/news/releases/2001.

7. Compare George W. Bush, *Stem Cell Science and the Preservation of Life*, N.Y. TIMES, Aug. 12, 2001, at 13, with National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,980 (Aug. 25, 2000) [hereinafter NIH Guidelines].

8. See 45 C.F.R. § 46 (2000).

9. See NIH Guidelines, *supra* note 7 (citing 42 U.S.C. § 289g-1).

10. Robertson II, *supra* note 2, at 515.

11. See *infra* note 131 and accompanying text.

12. See Robertson II, *supra* note 2, at 499 ("The constitutionality of state laws that seek to prevent the discard or destruction of IVF embryos does not depend on whether *Roe v. Wade* is reversed."); Christine L. Feiler, Note, *Human Embryo Experimentation: Regulation and Relative Rights*, 66 FORDHAM L. REV. 2435, 2446 (1998) ("Experimentation involving deliberately fertilized embryos...is fundamentally different from both the abortion and IVF scenarios because individual reproductive autonomy is not implicated."); Sharon M. Parker, Note, *Bringing the "Gospel of Life" to American Jurisprudence: A Religious, Ethical and Philosophical Critique of Federal Funding for Embryonic Stem Cell Research*, 17 J. CONTEMP. HEALTH L. & POL'Y 771, 772 (2001) ("[T]he Supreme Court's abortion jurisprudence has not been dispositive of the issues surrounding early human life.").

13. German scientists deliberately infected patients with typhus to study the rapidity of the disease at Buchenwald concentration camp during World War II.

14. So that researchers could study the

terminal stages of syphilis, African Americans suffering from the disease were not told about or given potential remedies. See William J. Curran, *The Tuskegee Syphilis Study*, 289 NEW ENG. J. MED. 730 (1973).

15. Victor Cohn, *First U.S. Test-Tube Baby is Born; Norfolk Test-Tube Baby First in United States*, WASH. POST, Dec. 29, 1981, at A1.

16. The Centers for Disease Control and Prevention (CDC) reported that the number of IVF clinics in 1998 was 360. CTR. FOR DISEASE CONTROL & PREVENTION, 1998 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 4 (2000) [hereinafter CDC REPORT]. However, the Society for Assisted Reproductive Technology reports that the number of IVF clinics in 2001 is 371 (on file with author).

17. Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger*, 34 HOUS. L. REV. 609, 613-14 (1997).

18. J.B. v. M.B., 783 A.2d 707 (N.J. 2001).

19. *Id.*

20. *Id.*; Warren A. Kaplan, Note, *Fetal Research Statutes, Procreative Rights, and the 'New Biology': Living in the Interstices of the Law*, 21 SUFFOLK U. L. REV. 723, 727-28 (1987).

21. J.B., 783 A.2d at 707; *Opportunities and Advancements in Stem Cell Research: Hearing Before the Gov't Reform Subcomm. on Criminal Justice, Drug Pol'y, & Human Res.*, 107th Cong. n.16 (2001) [hereinafter *Opportunities and Advancements Hearing*] (statement of JoAnn L. Davidson, Director, Snowflakes Embryo Adoption Program). IVF clinics implant only about three embryos per IVF cycle. J.B., 783 A.2d at 707; Kaplan, *supra* note 20, at 730. According to calculations based on CDC data, the average cycles of IVF treatment necessary for a live birth for women under

thirty-five is 3.1; 3.8 for women between 35-37; 5.6 for women between 38-40; and 12.2 for women over forty (on file with author).

22. The typical contract between an IVF clinic and its patients provides that the clinic will store patients' frozen embryos for a fixed period of time, usually not more than five years. Then, the clinic offers genetic parents the option of extending storage for a fee varying between \$100 and \$500 annually, implanting the embryos, terminating them, or donating them for some purpose. *Opportunities and Advancement Hearing, supra* note 21, at n.12 and accompanying text.

23. Lori B. Andrews, *Embryonic Confusion; When You Think Conception, You Don't Think Product Liability; Think Again*, WASH. POST, May 2, 1999, at B1. No law requires that genetic parents be informed about all their options, and many genetic parents report they were never advised, for example, that they could place their unwanted human embryos for adoption and implantation by adoptive parents.

24. David Solter, *Cloning and Embryonic Stem Cells: A New Era in Human Biology and Medicine*, 40 CROAT. MED. J. 3 (1999).

25. *Id.*

26. *Id.*

27. Gross, *supra* note 4, at 866-67. At roughly the same time, an independent investigation team lead by John Gearhart at Johns Hopkins University derived stem cells from cadaveric fetal tissue. *Id.* at 866 n.70.

28. *Id.* at 866-67 (referencing the NBAC's report, *Ethical Issues in Human Stem Cell Research*).

29. See Draft National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576 (Dec. 2, 1999).

30. NIH Guidelines, *supra* note 7.

31. *Nightlight Christian Adoptions v. Thompson*, Civil Action No. 1.01CV00502-RCL (D.D.C. Mar. 8, 2001).

32. *Nightlight Christian Adoptions v. Tommy G. Thompson*, Civil Action No. 1.01CV00502-RCL (D.D.C. May 7, 2001) (order granting stipulated stay), *available at* <http://www.nihsuit.com>. During the pending of the Bush Administration review and for thirty days thereafter, HHS was ordered to continue its “present policy of not funding any research involving use of pluripotent stem cells derived from human embryos.” *Id.*

33. *See, e.g., Opportunities and Advancements Hearing*, *supra* note 21; *Stem Cell Research: Hearing Before the Subcomm. on Labor, Health & Human Servs., & Educ.*, 107th Cong. (2001) [hereinafter *Stem Cell Hearing*].

34. Bush Press Release, *supra* note 6.

35. Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells (Nov. 7, 2001), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-003.html>; Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry (Nov. 7, 2001), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>; Memorandum from Alex M. Azar, General Counsel, Dep’t Health & Human Serv., to Ruth Kirchstein, Acting Dir., Nat’l Inst. Health (Jan. 11, 2002) (on file with author) [hereinafter Azar memorandum].

36. *See* Bush, *supra* note 7; Bush Press Release, *supra* note 6.

37. The NIH Guidelines require that the informed consent include “a statement that the embryos will be used to derive human pluripotent stem cells for research”

from the “individuals who have sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes.” NIH Guidelines, *supra* note 7. Likewise, the Bush plan requires a statement that each cell line was derived from an embryo with the consent of the embryo’s donor. *See supra* note 36 and accompanying text.

38. *See United States v. Carl Brandt, II TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10*, at 181-82 (1946-49).

39. Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 169 (1998) (citing *Fortner v. Koch*, 261 N.W.2d 762 (1935) (“We recognize the fact that if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him and must not vary too radically from the accepted method of procedure.”)). Only one case preceding the Nuremberg Code dealt with non-therapeutic human subject experimentation and held that a fifteen-year-old minor, together with his parent, could consent to a non-therapeutic skin graft benefiting the minor’s cousin. *George J. Annas, Mengele’s Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL’Y 17 (1991) (citing *Bonner v. Moran*, 126 F.2d 121, 121 (D.C. Cir. 1941)).

40. The Nuremberg Code states, “[t]he voluntary consent of the human subject is absolutely essential,” and the human subject “should have legal capacity to give consent; should be so situated as to be able

to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." *United States v. Carl Brandt, II TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10*, at 181-82 (1946-49).

41. *Id.* See also Annas, *supra* note 39, at 21.

42. The original guidelines applicable to human subject medical experimentation adopted by the NIH and the Department of Defense incorporated the Nuremberg Code. NAT'L INST. HEALTH, HANDBOOK ON THE UTILIZATION OF NORMAL VOLUNTEERS IN THE CLINICAL CENTER § 3.06 (1961); Memorandum for the Secretary of the Army, Navy, Air Force (Feb. 26, 1953) (cited in *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995)). See also Morin, *supra* note 39, at 169 ("By 1952, the Armed Forces Medical Policy Council adopted a resolution whereby principles found in the Nuremberg Code were to become the guidelines of research related to atomic, biologic, and chemical warfare.").

43. GEORGE J. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 21 (1977).

44. *Id.* at 24 (stating that the medical community adopted the Declaration out of a sense that the Code was a context-bound relic of Nazi Germany too inflexible and rooted in natural law for modern medicine); Richard Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455

(1996).

45. Initially, the Declaration of Helsinki expressly allowed proxy consent "in accordance with national legislation" for therapeutic human experimentation, but not necessarily non-therapeutic experimentation. Declaration of Helsinki (1964), <http://www.cirp.org/library/ethics/helsinki>. The Declaration otherwise preserved the Code's emphasis on uncoerced, informed, and competent consent and, regardless of consent, left the responsibility for the human subject on the researcher. The Declaration also firmly stated, "Concern for the interests of the subject must always prevail over the interests of science and society." *Id.* The Declaration has been amended five times since, including as recently as October 2000, so that now proxy consent for legally incompetent persons is expressly prohibited unless "the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons." Declaration of Helsinki (2000), http://www.wma.net/e/policy/17-c_e.html. The amended Declaration adds that vulnerable research populations merit special protection and that human experimentation should not proceed until there is "adequate laboratory and, where appropriate, animal experimentation." *Id.*

46. ANNAS ET AL., *supra* note 43, at 21. *Accord* *Heinrich v. Sweet*, 49 F. Supp. 2d 27, 42 (D. Mass. 1999) (citing *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995)).

47. *Heinrich*, 49 F. Supp. 2d at 42 (citing *White v. Paulsen*, 997 F. Supp. 1380, 1383-84 (E.D. Wash. 1998)).

48. *Heinrich v. Sweet*, 62 F. Supp. 2d 282, 319-21 (D. Mass. 1999) (referencing 42 U.S.C. § 1983 (2001) and citing *In re*

Cincinnati Radiation Litig., 874 F. Supp. at 821). These courts also considered tort law relating to informed consent and the progeny of *Griswold v. Connecticut*, 381 U.S. 479 (1965) and *Eisenstadt v. Baird*, 405 U.S. 438 (1972). See *Heinrich*, 62 F. Supp. 2d at 320; *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 816-19.

49. *Heinrich*, 62 F. Supp. 2d at 321.

50. *Id.* at 290.

51. *Id.* at 294.

52. *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 800-01, 803. Researchers hoped to develop a baseline for determining how much radiation exposure was too much and how shielding could decrease its deleterious effects.

53. *Id.* at 800.

54. See *United States v. Stanley*, 483 U.S. 669 (1987) (discussing the secret administration of LSD to soldiers by the CIA and the Army in the 1950s and 1960s); *CIA v. Sims*, 471 U.S. 159 (1985); *Jaffee v. United States*, 663 F.2d 1226 (3d Cir. 1981), *cert. denied*, 456 U.S. 972 (1982) (discussing the intentional exposure of soldiers to radiation in the 1950s); *Whitlock v. Duke Univ.*, 637 F. Supp. 1463 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987) (discussing a diver who suffered organic brain damage from decompression experiments after defective informed consent); *Begay v. United States*, 591 F. Supp. 991 (1984), *aff'd*, 768 F.2d 1059 (9th Cir. 1985) (discussing tests involving the exposure of Navajo miners to radiation); *Zeleznik v. Jewish Chronic Disease Hosp.*, 366 N.Y.S.2d 163 (1975) (discussing chronically ill and debilitated patients who were injected with cancer cells without their consent); *Application of Hyman*, 248 N.Y.S.2d 245 (1964), *rev'd*, *Hyman v. Jewish Chronic Disease Hospital*, 251 N.Y.S.2d 818 (1964), *rev'd*, 258 N.Y.S.2d 397 (1965)

(discussing chronically ill, incompetent non-cancer patients injected with foreign cancer cells without their informed consent because "the doctors did not wish to stir up any unnecessary anxieties in the patients," *Hyman*, 251 N.Y.S.2d at 820); W.J. Curran, *The Tuskegee Syphilis Study*, 289 NEW ENG. J. MED. 730 (1973) (discussing that African Americans infected with syphilis were not informed of the availability of penicillin for treatment of the illness, so that scientists could examine the effects of their illness); Franz J. Ingelfinger, *Ethics of Experiments on Children*, 288 NEW ENG. J. MED. 791 (1973) (discussing the Willowbrook studies, where mentally ill children were deliberately infected with hepatitis); Jeffrey H. Barker, *Human Experimentation and the Double Facelessness of a Merciless Epoch*, 25 N.Y.U. REV. L. & SOC. CHANGE 603 (1999) (discussing a patient with ornithine transcarbamylase deficiency disease subjected to non-therapeutic genetic experimentation with defective informed consent).

55. Three mice studies examining the impact of embryonic stem cells on diabetes exist, none of which produced results nearly as good as adult stem cell models. See *Opportunities and Advancements Hearing*, *supra* note 21 (supplemental statement of David Prentice, Professor of Life Sciences, Indiana State University). The authors are aware of no other published reports of successful treatment of animal models of disease. Proponents of embryonic stem cell research were repeatedly asked to provide additional examples of successful animal studies in Congressional hearings. Dr. Gerald Fischbach responded by implying that the dopaminergic neurons generated from mouse embryonic stem cells in a study performed by Dr. Ronald McKay at the NIH led to improvements in the condition

of rats. *Id.* (statement of Dr. Gerald Fischbach, Director, National Institute of Neurological Diseases and Stroke). However, Fischbach misstated the extent of McKay's study, which did not involve actually implanting the embryonic stem cells in Parkinson's rats. Rather, McKay called for additional "studies in Parkinsonian rodents...to further assess the function and safety of [embryonic stem] cell-derived DA neurons *in vivo*." *Id.* (supplemental statement of David Prentice). If in the future a few additional authentic animal studies predating President Bush's decision to federally fund embryonic stem cell research are uncovered, the extent of animal modeling using embryonic stem cells will still have been totally inadequate to satisfy the Code and Declaration.

56. Opponents have been forced to concede that adult stem cell research, although new, is proving remarkably successful. For example, adult stem cell research has been used to treat various forms of cancer, autoimmune diseases, immunodeficiencies and anemias, stroke, cartilage and bone diseases, blood and liver disease, cornea failure, and cardiac damage. *See Opportunities and Advancements Hearing, supra* note 21, at nn.49-66 and accompanying text (statement of David Prentice); *Id.* at nn. 5-6 and accompanying text (supplemental statement of David Prentice). Nevertheless, opponents assert that embryonic stem cell research remains critical, because adult stem cells allegedly are hard to isolate, have not been isolated from all tissues of the body, may be difficult to grow, are not pluripotent, and may contain more genetic abnormalities than embryonic stem cells. DEP'T HEALTH & HUMAN SERVS., HUMAN PLURIPOTENT STEM CELL RESEARCH GUIDELINES (2001); NAT'L

INST. HEALTH, STEM CELLS: A PRIMER (2000) [hereinafter PRIMER]. Substantial evidence contradicts each of these claims. *See, e.g., Opportunities and Advancements Hearing, supra* note 21. (statement and supplemental statement of David Prentice) (summarizing the literature).

57. *See Hart v. Brown*, 289 A.2d 386 (1972) (approving the transplant of a kidney from one seven-year-old twin to another where the donor was expected to live a normal and productive life afterwards and the recipient twin had only a 50% chance of surviving for five years without the kidney); *Strunk v. Strunk*, 445 S.W.2d 145 (Ky. 1969) (approving the donation by a mentally incompetent adult of her kidney to her twenty-eight-year-old brother).

58. *Hart*, 289 A.2d at 374. Notably, most state statutory schemes permitting surrogate decision-making in various health care treatment situations contain provisions for notice to the individual patient and/or exhaustive administrative and judicial review procedures. *See, e.g., T.D. v. New York State Office of Mental Health*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996) (making this point with regard to New York state surrogacy regulations).

59. *Matter of Doe*, 481 N.Y.S.2d 932 (N.Y. App. Div. 1984) (*per curiam*).

60. *Bonner v. Moran*, 126 F.2d 121 (App. D.C. 1941) (finding that guardian (aunt) consent was necessary for a fifteen-year-old to give a skin graft to a badly burned cousin; appellate court did not state that parental consent was sufficient for non-therapeutic research).

61. *See Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807 (Md. 2001); *T.D. v. New York State Office of Mental Health*, 626 N.Y.S.2d 1015 (N.Y. Sup. Ct. 1995), *aff'd*, 650 N.Y.S.2d 173 (N.Y. App. Div. 1996) (finding that a state agency could not authorize

non-therapeutic experiments on mental patients including both adult and minor subjects).

62. *T.D.*, 650 N.Y.S.2d at 176; *Kaimowitz v. Michigan Dep't of Mental Health*, Civil No. 73-19434-AW (Cir. Ct. Wayne County, Mich. July 10, 1973).

63. *See* Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, Subpart C.

64. *T.D.*, 626 N.Y.S.2d at 177-78, 184 (noting that the medical community supports research guidelines and that research is not federally funded).

65. *Id.* at 176.

66. *Id.* at 177.

67. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807 (Md. 2001).

68. *Id.*

69. *Id.*

70. *See* Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 U.C.L.A. L. REV. 67, 78, 124-25 (1986); Garnett, *supra* note 44, at 457; Morin, *supra* note 39, at 165, 177, 210 (citing Robert Levine, *The Nature and Definition of Informed Consent in Various Research Settings*, in NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter BELMONT REPORT]).

71. Garnett, *supra* note 44, at 486.

72. *Id.* at 477-81 (citing 45 C.F.R. §§ 46.304-305; 306(a)(2)(i-iii) (1994) (limiting the scope of prisoner research eligible for federal funding, notwithstanding that prisons are ideal places for behavioral research); *Kaimowitz v. Michigan Dep't of Mental Health*, Civil

No. 73-19434-AW (Cir. Ct. Wayne County, Mich. July 10, 1973) (holding that psychosurgery could not be undertaken even on a consenting prisoner)); *Grimes*, 782 A.2d.

73. *Id.*

74. *Id.*

75. *Id.*

76. *See* Delgado & Leskovic, *supra* note 70, at 91-107 (noting that the interests of the patient and scientists are sharply opposed in the experimental setting); Feiler, *supra* note 12, at 2452 (noting that research embryos are more vulnerable than minor children and, therefore, should be protected after the potential harm to them is weighed against public detriment and researcher's interests); Carl Elliott, *Pharma Buys a Conscience*, 12 AM. PROSPECT, Sept. 24, 2001 (concerning the remarkable extent to which bioethicists and the medical community have permitted private corporate dollars to influence their research and judgment).

77. Feiler, *supra* note 12, at 2453.

78. Ultra-hazardous, non-therapeutic research on incompetent living humans also violates the Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Apr. 4, 1997, Council on Europe, art. 6(1), 17(2), ETS No. 164 [hereinafter Convention on Human Rights and Biomedicine].

79. *Id.* at 85.

80. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807 (Md. 2001) (citing 626 N.Y.S.2d 1015 (N.Y. Sup. Ct. 1995) (finding that a state agency could not authorize non-therapeutic experiments on mental patients including both adult and minor subjects)).

81. *Id.* At some point, a risky non-therapeutic procedure could be deemed suicide.

82. Embryos are children only in the genetic sense that they are a result of fertilization of the parents' gametes and pragmatic sense that they are their parents' wards. The born human embryo is presumed the child of the birth mother. See *Opportunities and Advancements Hearing*, *supra* note 21, at n.16 and accompanying text (statement of JoAnn L. Davidson); see also *In re O.G.M.*, 988 S.W.2d 473 (Tex. Ct. App. 1999) (finding that a male gametes provider was entitled to a grant of paternity in relation to a child born through IVF from a frozen pre-embryo conceived during marriage, but implanted in his former wife after divorce).

83. *Roe v. Wade*, 410 U.S. 413 (1973).

84. *Roe*, 410 U.S. at 413.

85. Robertson II, *supra* note 2, at 499 ("The constitutionality of state laws that seek to prevent the discard or destruction of IVF embryos does not depend on whether *Roe v. Wade* is reversed."); Parker, *supra* note 12, at 786-87. *But see Doe v. Shalala*, 862 F. Supp. 1421 (D. Md. 1994) ("The Court sees no distinction between fetuses *in utero* or *ex utero*.")

86. Robertson II, *supra* note 2.

87. *Id.* at 487.

88. *Id.* at 499.

89. *Id.* at 504-06.

90. Robertson II, *supra* note 2, at 446-47; see also Robertson I, *supra* note 2, at 972-75.

91. Robertson II, *supra* note 2, at 515.

92. 1995 WL 110368, at *4 (N.Y. Sup. Jan. 18, 1995) (unpublished), *rev'd on other grounds*, 663 N.Y.S.2d 581 (App. Div. 1997) (failing to reconsider trial court's endorsement of the view that embryos are more than property but less than persons).

93. 842 S.W.2d 588 (Tenn. 1992), *cert. denied sub nom.*, *Stowe v. Davis*, 507 U.S. 911 (1993) (citing The American Fertility Society approving this position).

94. *Davis v. Davis*, No. E-14496, 1989 WL 140495, at *1 (Tenn. Ct. App. 1989), *rev'd*, 1990 WL 130807 (Tenn. Ct. App. 1990) (unpublished), *aff'd*, 842 S.W.2d 588 (Tenn. 1992), *cert. denied sub nom.*, *Stowe v. Davis*, 507 U.S. 911 (1993).

95. *Davis*, 1990 WL 130807.

96. *Davis*, 842 S.W.2d at 597. *But see York v. Jones*, 717 F. Supp. 421 (E.D. Va. 1989) (treating the embryo as property).

97. Robertson I, *supra* note 2, at 782-83.

98. NIH Guidelines, *supra* note 7 (referencing 42 U.S.C. § 289g-1); Parker, *supra* note 12, at 781 (citing NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 50 (1999)).

99. Robertson II, *supra* note 2, at 510. It should be added that 21 C.F.R. § 1270.3 defines "banked human tissue" as "any tissue derived from a human body, which (1) is intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease; (2) is recovered, processed, stored, or distributed by methods that do not change tissue function or characteristics; (3) is not currently regulated as a human drug, biological product, or medical device; (4) excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and (5) excludes semen or other reproductive tissue, human milk, and bone marrow."

100. See also *Davis*, 842 S.W.2d at 596 (finding that the Uniform Anatomical Gift Act, which governs fetal tissue, was "not precisely controlling" in relation to the human embryo).

101. See also *Simkins v. Nevadacare*, 229

F.3d 729, 735 (9th Cir. 2000) (“We believe the average person would not...understand stem cells to be ‘tissue.’”).

102. PRIMER, *supra* note 56.

103. *Id.*

104. *Id.*

105. See Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576 (1999) (citing James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145 (1998)).

106. Thomson, *supra* note 105, at 1145 (“After undifferentiated proliferation in vitro for 4 to 5 months, these cells still maintained the developmental potential to form trophoblast and derivatives of all three embryonic germ layers....”).

107. Ironically, Varmus insists that the investigation itself would be unethical. *Stem Cell Hearing*, *supra* note 33. (“It is true that sometimes these cells can aggregate and may appear like one of the early phases in the development of a normal embryo. But to my mind nothing would be less ethical than to attempt to ascertain whether or not this was indeed a precursor to an organism, a viable embryo....”).

108. Mice studies prove that mice embryonic stem cells when implanted in the female give rise to a born mouse with the genetic make-up of the embryonic stem cells. See Andr s Nagy et al., *Derivation of Completely Cell Culture-Derived Mice from Early-Passage Embryonic Stem Cells*, 90 PROC. NAT’L ACAD. SCI. 8424 (1993). Experiments with cattle indicate that these results are not limited to mice. See Shizue Iwasaki et al., *Production of Live Calves Derived from Embryonic Stem-Like Cells Aggregated with Tetraploid Embryos*, 62 BIOLOGY REP. 470 (2000) (finding that the implantation of cattle embryonic stem cells into a host

leads to the birth of live cattle).

109. Nelle S. Paegel, Note, *Use of Stem Cells in Biotechnological Research*, 22 WHITTIER L. REV. 1183, 1188, 1190, 1203 (2001). Dr. Lee Silver, a mouse geneticist at Princeton University, has stated that, whereas he favors human embryonic stem cell research, “he is offended by the winking and nodding of scientists who do not want to admit the potential of the cells to become babies.” *Id.* at 1203. Nagy, who created born mice from stem cells, added: “I don’t think there’s a theoretical or practical impossibility of creating a completely stem-cell derived human being, if one wanted to do that.” *Id.* See also DIANE T. DUFFY, BACKGROUND AND LEGAL ISSUES RELATED TO STEM CELL RESEARCH 2 (Oct. 9, 2001) (CRS Report No. RS21044) (on file with authors) (“The earliest embryonic stem cells are called totipotent cells.”).

110. *Id.*

111. 45 C.F.R. § 46.101(a) (2001) (emphasis added).

112. 45 C.F.R. § 46.102(f) (2001) (emphasis added).

113. 45 C.F.R. § 46.116 (2001) (emphasis added).

114. 45 C.F.R. § 46.116(b)(1) (2001) (emphasis added).

115. Robert Levine, *The Boundaries Between Biomedical or Behavioral Research and Accepted and Routine Practice of Medicine*, in 1 THE BELMONT REPORT, 1-6 (Nat’l Comm’n for the Protection of Human Subjects of Biomedical and Behavioral Research ed., 1979).

116. Cf. 45 C.F.R. § 46.402(a) (2001) (“‘Children’ are persons....”). According to the Rabb memorandum, human stem cells do not qualify as “organisms” within the meaning of the term “embryo,” as defined by the Dickey Amendment, because they are not “individual[s] constituted to carry

out all life functions." Rabb memorandum, *infra* note 131, at 2. The necessary implication is that, by contrast, living human embryos are individuals able to carry out all life functions.

117. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807 (Md. 2001).

118. *Id.*

119. *T.D. v. N.Y. State Office of Mental Health*, 650 N.Y.S.2d 173, 185, 192 (N.Y. App. Div. 1996). The New York Court of Appeals did not pass on the question of whether proxy consent of a child committed to a mental institution would have satisfied 28 C.F.R. Subpart D. *Id.* at 192.

120. Gross, *supra* note 4, at 862 (Subpart B is more on point, but "still fails to adequately address the complex issues raised by embryonic stem cell research.").

121. 45 C.F.R. § 46.201(a) (2001) (emphasis added).

122. 45 C.F.R. § 46.202(c) (2001).

123. 45 C.F.R. § 46.203 (2001).

124. Nat'l Inst. Health, Notice of Meeting of Panel, 59 Fed. Reg. 45,293, 45,293 (1994) [hereinafter Meeting of Panel] ("The Panel's charge encompasses only research involving the extracorporeal human embryo produced by in vitro fertilization, *i.e.*, in the test tube, or parthenogenesis.... Research involving in utero human embryos or fetuses is not part of the Panel's mandate. Guidelines for such research are embodied in...45 C.F.R. Part 46...."); Gross, *supra* note 4, at 862 ("Research on isolated stem cell lines, involving neither human sperm nor egg cells, does not meet the definition of IVF research.").

125. Meeting of Panel, *supra* note 124, at 45,293.

126. 45 C.F.R. § 46.201(a) (2001) (emphasis added). Notably, if the rest of

Aldous Huxley's prophecy becomes reality in the future, the totipotent living human embryo at an IVF clinic could be deemed an *ex utero* "fetus" subject to Subpart B. 45 C.F.R. § 46.209. Section 46.209 expressly addressed "activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects." Yet the definition of "fetus" in Section 46.202 is "the product of conception *from implantation* until a determination is made after delivery that it is viable" (emphasis added). The embryo which is the subject of human stem cell research has not been and will not be implanted and, thus, cannot currently qualify as a fetus. On the other hand, fetuses *ex utero* (more advanced than embryos) may theoretically exist in the future without implantation, rendering the definition of fetus in Section 46.202 unhelpful.

127. 45 C.F.R. § 46.111(a) (2001).

128. 45 C.F.R. § 46.102(i) (2001).

129. 45 C.F.R. § 46.111(b) (2001). For children, Subpart D of the Human Subjects Policy makes clear that federal funds can be expended on non-therapeutic research involving no more than "a minor increase over minimal risk." 45 C.F.R. § 46.406(a)(b) (2001). Additionally, 45 C.F.R. § 46.408 (2001) requires that IRBs solicit the assent of children to the research, unless the children are simply too young to give it and the intervention holds out a prospect of direct benefit to the children.

130. Consolidated Appropriations Act, Pub. L. No. 106-554, § 510(b) (emphasis added).

131. Memorandum from Harriet S. Rabb, General Counsel, U.S. Department of Health and Human Services, to Harold Varmus, Director, National Institutes of Health (Jan. 15, 1999) (on file with

author).

132. *See* Balanced Budget Downpayment Act, Pub. L. No. 104-99, 110 Stat. 26, 34, Title I, § 128 (Jan. 26, 1996); Omnibus Bill, Pub. L. No. 104-208 § 512 (Sept. 30, 1996); Labor/HHS/Education Appropriations Act, Pub. L. No. 105-78 § 513 (Nov. 13, 1997); Omnibus Bill, Pub. L. No. 105-277 § 511 (Oct. 21, 1998); Omnibus Bill, Pub. L. No. 106-113 § 510 (Nov. 29, 1999); Omnibus Consolidated Appropriations Act of 2001, Pub. L. No. 106-554 § 510 (Dec. 21, 2000).

133. *Citing* 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. § 289g(b) (the risk standard for fetuses intended to be aborted and fetuses intended to be carried to term)).

134. *See* 65 Fed. Reg. 51976. The Rabb memorandum and, thus, the NIH Guidelines also stated that human embryonic stem cells are not “human embryos,” as defined by the Dickey Amendment, on the grounds that they “are not organisms and do not have the capacity to develop into an organism that could perform all the life functions of a human being—in this sense they are not even precursors to human organisms.” *Id.*

135. The authors wish to acknowledge the contribution of Gibson, Dunn & Crutcher LLP to this analysis of legislative history, which is partially reflected in the complaint that Human Life Advocates and Gibson, Dunn & Crutcher crafted in *Nightlight Christian Adoptions v. Thompson*, Civil Action No. 1:01CV00502-RCL, U.S. District Court, District of Columbia (March 8, 2001).

136. Although federal funding for IVF research projects was permissible, it required the approval of an Ethical Advisory Board (EAB). 45 C.F.R. § 46.204(d), nullified by section 121(c) of

the NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (June 10, 1993). HHS declined to direct an EAB to perform any funding review of a proposed IVF research project until September 1978. That board concluded that certain funding was theoretically ethical, but the NIH declined to take any action on this conclusion. In early 1993, the Clinton Administration proposed, and Congress subsequently passed, legislation intended to eliminate the EAB approval prerequisite, as well as the executive moratorium on fetal tissue research. *Id.*

137. NAT'L INST. HEALTH, I REPORT OF THE HUMAN EMBRYO RESEARCH PANEL 49 (1994); *see also id.* at xvii, 2, 8, 26-27, 47, 49, 50, 76 (recommending federal funding for human embryonic stem cell research using “spare” embryos from IVF clinics).

138. 30 Weekly Comp. Pres. Doc. 2459 (Dec. 2, 1994) (on file with author).

139. *Dep't of Labor, Health & Human Servs., Educ., and Related Agencies Appropriations for 1996: Hearings Before a Subcomm. of the House Comm. on Appropriations*, 104th Cong., 1st Sess. 139, 144 (1995); *see also* NAT'L INST. HEALTH, BACKGROUND INFORMATION ON THE IMPACT OF THE HUMAN EMBRYO RESEARCH AMENDMENT 2 (1996) (The NIH would have funded six out of nine applications for grants involving embryo-related research “if the NIH had been able to proceed according to the [Human Embryo Research Panel's] recommendations and the President's directive.”).

140. H.R. REP. NO. 104-209, at 384 (1996) (emphasis added).

141. *Id.* at 385.

142. 142 CONG. REC. S429, S433 (1996) (emphasis added).

143. H.R. REP. NO. 104-209, at 213-14 (1995).

144. *Id.* at H7364; 142 CONG. REC. H7339 (July 11, 1996).

145. *Id.* at H7339-43.

146. *Id.* at H7340 (emphasis added).

147. In a letter dated February 11, 1999, approximately seventy-five members of Congress requested that then-Secretary Shalala correct the HHS General Counsel's misinterpretation of the Dickey Amendment (on file with author). Paul Recer, *Work Using Fetal Cells Draws Fire*, BOSTON GLOBE, Feb. 18, 1999, at A10 (seventy Congressmen). On February 12, 1999, seven U.S. Senators added their disapproval (letter on file with author). The authors' review of the administrative record shows that the NIH received approximately 50,000 comments on the Draft Guidelines from members of Congress, patient advocacy groups, scientific societies, religious organizations, and private citizens, the majority of which were opposed.

148. The House report language states, "The committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President." H.R. REP. NO. 107-229, § 510 (2001). See also Azar memorandum, *supra* note 35.

149. H.R. 2059, 107th Cong. (2001) (killed in committee); S. 723, 107th Cong. (2001) (killed in committee); S. 1536, 107th Cong. § 510 (2001) (adding to the Dickey Amendment part (c): "Federal dollars are permitted, at the discretion of the President, solely for the purpose of stem cell research, on embryos that have been created in excess of clinical need and

will be discarded, and donated with the written consent of the progenitors.")

150. Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act, 2002, Pub. L. No. 107-116 (Jan. 10, 2002).

151. Azar memorandum, *supra* note 35.

152. See *Opportunities and Advancements Hearing*, *supra* note 21, at n.19 (statement of JoAnn L. Davidson).

153. Parker, *supra* note 12, at 789.

154. FLA. STAT. ANN. § 390.0111(6) (West 2001) (prohibiting all research except that which preserves the life or health of the fetus); LA. REV. STAT. ANN. § 9:122 (West 2001) (banning all research on embryos and prohibiting the cultivation of embryos for the same); ME. REV. STAT. ANN. tit. 22, § 1593 (West 2001) (prohibiting all use of the product of conception in scientific research); MASS. ANN. LAWS ch. 112, § 12J (Law. Co-op. 2001) (regulating the use of a live conceptus and banning non-therapeutic experimentation thereupon); MICH. COMP. LAWS ANN. § 333.2685 (West 2001) (banning non-therapeutic research on embryos, if that research substantially jeopardizes the embryo's life or health or if the embryo is the subject of a planned abortion); MINN. STAT. ANN. § 145.422 (West 2000) (banning all use of a conceptus in scientific research except where it is "harmless" to the conceptus); N.H. REV. STAT. ANN. § 168-B:15 (2000) (limiting the maintenance of non-frozen pre-embryos *ex utero* to fourteen days and prohibiting the transfer of a research pre-embryo to a uterine cavity); N.D. CENT. CODE § 14-02.2-01 (2001) (criminalizing the use of a fetus in experimentation except where the purpose is to determine/preserve the life or health of the fetus or mother); 18 PA. CONS. STAT.

ANN. § 3216 (West 2001) (criminalizing all non-therapeutic research on the conceptus); R.I. GEN. LAWS § 11-54-1 (2001) (prohibiting experimentation on all living embryos except as necessary for the life or health of the mother).

155. *Forbes v. Napolitano*, 236 F.3d 1009 (9th Cir. 2000), *amended*, 247 F.3d 903 (9th Cir. 2000) (Ariz. Rev. Stat. § 36-2302); *Jane L. v. Bangerter*, 61 F.3d 1493 (10th Cir. 1995), *rev'd on other grounds sub nom*, *Leavitt v. Jane L.*, 518 U.S. 137 (1996) (overturning UTAH CODE ANN. § 76-7-310 ("Live unborn children may not be used for experimentation....")); *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill. 1990) (overturning 720 Ill. Comp. Stat. § 510/6(7)); *See also* *Robertson II*, *supra* note 2, at 503 (noting that at least twenty states have laws restricting fetal research and that, "[i]n many instances the statutes are drawn so broadly that they would apply to embryo research as well."). *See, e.g.*, MO. REV. STAT. § 188.037 (2000); N.M. STAT. ANN. § 24-9A-1 to 7 (Michie 2001); S.D. CODIFIED LAWS §§ 34-14-16, 34-14-17 (Michie 2001); UTAH CODE ANN. § 76-7-31 (2001) ("Selling, buying, offering to sell and offering to buy unborn children is prohibited.").

156. FLA. STAT. ANN. §§ 63.212(i)(2) (West 2001) provides that individuals may enter into a pre-planned adoption agreement wherein the mother agrees to become pregnant through "fertility techniques" including embryo adoption. The agreement must be reviewed and approved by a court of law to effect a final adoption. *Id.* LA. REV. STAT. ANN. § 9:126 (West 2001) requires "adoptive implantation" of embryos when the creators of the embryos are unidentifiable or no longer want the embryos. Embryo adoption is fulfilled when the couple "executes the notarial act of adoption of

the ovum and birth occurs." LA. REV. STAT. ANN. § 9:130 (West 2000). *See also* OKL. STAT. tit. 10 § 556 (2001) (written consent of husband and wife desiring to receive and donate an embryo is necessary; the former statute also requires consent from a physician and any judge of a court having adoption jurisdiction in the state); TEX. FAM. CODE ANN. § 151.103 (West 2001) (written consent necessary of husband and wife desiring to receive embryo and of husband and wife desiring to donate embryo).

157. The compromise should not be merely administrative, because of the NIH's inherent conflict of interest as the regulatory agency enforcing the Human Subjects Policy. "On one hand, it will be overseeing oversight to ensure the fund recipients are following the guidelines. On the other hand, it's own scientists will be among those receiving the federal funds and competing in the marketplace with their results." Paegel, *supra* note 109, at 1198-99.

158. It makes little sense to us philosophically and theologically to treat any developmental stage of the human as less valuable than another or to distinguish the respect accorded the living human depending on its location within, partially outside, or completely outside the womb.

159. Some have argued that stem cells taken from living human embryos without the legally effective consent of their donors is to eat fruit of the poisonous tree. Of course, fruit of the poisonous tree doctrine stems from the Fourth Amendment and is applicable to embryonic stem cell research only by analogy. *See Fourth Amendment Rights; Fruit of Poisonous Tree Doctrine*, 29A AM. JUR. 2D *Evidence* § 752 (1994).

160. Consolidated Appropriations Act, Pub. L. No. 106-554, § 510(b) (emphasis

added).

161. Rabb memorandum, *supra* note 131, at 2.

162. *Accord* DUFFY, *supra* note 109, at 2 (“The earliest embryonic stem cells...can develop into an entire organism, producing both the embryo and tissues required to support it in the uterus.”).

163. Proposed revised permanent Dickey Amendment incorporating Bush Proposal: (a) None of the funds made available by this Act may be used for—(1) the creation of a human embryo or embryos for research purposes; (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. §289g(b)); or (3) research that directly or indirectly involves or relates to [any cell or combination of cells derived directly or indirectly from] any cell line derived or obtained in any manner in which a human embryo or embryos were destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 C.F.R. § 46.208(a)(2) and section 489(b) of the Public Health Service Act (42 U.S.C. §289g(b)); or that necessitates, entails, or creates the potential for the destruction of or injury to a human embryo [including without limitation any research involving or relating to any cell or tissue directly or indirectly obtained from or produced by any such cell line] except to the extent that such cell line was derived entirely (A) on or before August 9, 2001, (B) with the consent of the embryo’s donors after full disclosure of the consequences of cell derivation, (C) from an embryo that was created solely for

reproductive purposes at a fertility clinic but subsequently deemed by the embryo’s donors to be in excess of need, and (D) from an embryo that was donated for research purposes without the payment of any financial or other consideration to or on behalf of any donor or fertility clinic. (b) “Human embryo” is any organism that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

164. *See* European Council, Convention on Human Rights and Biomedicine Art. 18(2); Feiler, *supra* note 12, at 2466.

165. *See* Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. § 302 (2001); European Council, Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings Art. 1 (1998).

166. Concerning the embryo cryopreservation practice, see *Opportunities and Advancements Hearing*, *supra* note 21, at n.9 and accompanying text (statement of JoAnn L. Davidson). Robertson has argued, “IVF and freezing create and protect embryos; they do not destroy them.” Robertson II, *supra* note 2, at 493. But the evidence suggests otherwise. Conservatively, 50% of the frozen human embryos perish in the cryopreservation and thawing process when one or more of their cells suffer cyroinjury. *See Opportunities and Advancements Hearing*, *supra* note 21, at n.17 and accompanying text (statement of JoAnn L. Davidson).

167. *See* LA. REV. STAT. ANN. § 9:130 (West 1991) (no embryo may be intentionally destroyed, and if IVF patients renounce their parental rights, the embryo shall be available for adoptive implantation); KY. REV. STAT. ANN. §

311.715 (Michie 1995) (public medical facility's intentional destruction of embryos shall be illegal). Robertson admits that IVF clinics are discarding embryos. See Robertson I, *supra* note 2, at 977 ("To avoid controversy with right-to-life groups and gain hospital approval, most American IVF programs claim to transfer all fertilized eggs to a uterus. However, many occasions will arise in which the gamete providers or others with decision-making authority over embryos will want to discard embryos.").

168. See *Opportunities and Advancements Hearing*, *supra* note 21 (testimony of J. Davis); Paul C. Redman II & Lauren F. Redman, *Seeking a Better Solution for the Disposition of Frozen Embryos: Is Embryo Adoption the Answer?* 35 TULSA L.J. 583 (2000).

