

Federal Funding and the Regulation of Embryonic Stem Cell Research: The Pontius Pilate Maneuver

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So when Pilate saw that he could do nothing, but rather that a riot was beginning, he took some water and washed his hands before the crowd, saying, "I am innocent of this man's blood; see to it yourselves."¹

In this volume, my colleagues have presented a comprehensive account of the pros and cons of stem cell research and cloning; I will not repeat this discussion, nor will I focus on my own views regarding the moral acceptability of these activities.² Instead, I plan to focus on the typical response of the federal government to issues of the type that are presented by embryonic stem cell research and cloning and to evaluate the consequences of this typical response.

The issues to which I refer are, in general, features of much research in the field of reproductive biology. The issues arise when a particular project or a field of research or practice entails either the creation by any means other than

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1. *Matthew* 27:24.

2. My position on the moral acceptability of various types of stem cell research is, in general terms, as follows: Any statement on the moral acceptability of human stem cell research presupposes that particular research proposals conform to all relevant standards for the ethical justification of research involving humans as subjects. I believe that it is morally acceptable to perform any and all types of stem cell research when there is no plan to create or use cells having the potential to become a human person. Plans to use or create cells having the potential to become a human person are ethically more problematic. I do not regard as decisive the distinction between human embryos created for research purposes and human embryos created for procreative or other non-research purposes (e.g., "leftover" embryos created *in vitro* with the aim of achieving pregnancy). In deference to those who regard this distinction as important, however, I would support a requirement that creation of such cells for research purposes be limited to those cases in which the research objective cannot be realized using cells created for non-research purposes. Finally, I would favor the specification of a maximum permissible stage of development for embryos that are destined to be used for research purposes; precedents in the US favor the identification of fourteen days as the maximum permissible stage of development. I would be willing to consider allowing further development in some cases. The details of my positions and arguments supporting them are beyond the scope of this discussion.

“natural procreation” of an entity that could develop into a human person, or the destruction of such an entity, whether the entity was created “naturally” or *in vitro*. Embryonic stem cell research includes both problematic procedures: the creation of embryos via *in vitro* fertilization (IVF) or cloning, and the derivation of cell lines (necessitating the destruction of the potential for an embryo to develop into a person). Cell lines created from so-called “adult” stem cells do not fall under this category because an “adult” stem cell cannot develop into a human person.³ Federal officials would strongly prefer not to alienate those who believe destruction of embryos that could develop into human persons is murder (notably, but not exclusively, the religious right) or that the creation of human life by artificial means is morally wrong. They similarly do not want to appear to oppose the efforts of scientists to pursue cures for deadly or disabling diseases, particularly when the means to pursue such cures are advocated aggressively by popular public figures.

The federal official who must produce a policy to govern such fields of research or practice appears to be ensnared in a true dilemma. To choose either side is fraught with grave political risk. In such circumstances, the official can, and often does, make a “safe” decision, choosing neither side in this controversy. The safe decision is to *permit* the conduct of the activity in the private sector while withholding the support of public funding for the field of study or practice. The official, like Pontius Pilate, washes his or her hands of the matter.

On the occasion of announcing such a decision, the official takes note of the great benefits that could be developed through the proposed research. The official also observes that there are citizens who reject the proposal on moral grounds. On the one hand, the decision allows the development of the new technology in the private sector. Those who wish to develop it are thus free to do so, and those who wish to benefit from it after development are free to purchase it. On the other hand, those who oppose the development on moral grounds are also treated with respect. They are not forced to contribute through taxes to a development they find immoral. Some of those in the latter group may protest that the government should go further—for example, that it should act affirmatively to rule out the destruction of human embryos, equated with the murder of unborn children. The standard response to these protests is that the U.S. Supreme Court removed this decision from the executive or legislative branches in *Roe v. Wade*.⁴ It is commonly said that the Supreme Court has ruled that the

3. The President’s Council on Bioethics discusses research on the possibility that adult cells could be dedifferentiated or reprogrammed back to a totipotent state and thus, if implanted, capable of developing into an entire organism. See PRESIDENT’S COUNCIL ON BIOETHICS, ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS 51 (2005), available at http://www.bioethics.gov/reports/white_paper/alternative_sources_white_paper.pdf.

4. The Supreme Court in *Roe v. Wade* made it clear that under the laws of the United States, a “person,” with all the rights attaching to that status, is a live-born human capable of life apart from

government may not unduly burden a woman seeking an abortion, even if she gives no reason to justify it.⁵ It seems even more difficult to intervene when embryonic cells are destroyed for a health-promoting reason such as research on therapies. With the passage of the Dickey-Wicker Amendment in the mid-1990s,⁶ and bolstered by presidential actions in the Bush Administration,⁷ federal action regarding embryonic stem cell research has become a classic example of hand-washing. Although the policy landscape has changed somewhat under the Obama Administration,⁸ it remains to be seen whether new federal funds and regulation will actually be devoted to stem cell research involving human embryos.

In this Article, I will investigate the implications of this federal habit of evading policy decisions that either support or prevent advances in the field of reproductive biology. Part I will examine the history of federal fund withholding, outlining the statutory and executive interventions that contributed to this system. Part II will explore the ways that embryonic stem cell researchers and many of their colleagues interact with federal regulations on research, particularly regulation by the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS). Finally, Part III will outline some of the recent consequences of past withholding of federal funds.

I. A BRIEF HISTORY OF WITHHOLDING OF FEDERAL FUNDS FROM EMBRYONIC STEM CELL RESEARCH

Since 1973, the year of the *Roe v. Wade* decision, the federal government has decided to withhold federal funding for the support of many research or

the body of his or her mother. *Roe v. Wade*, 410 U.S. 113, 163 (1973) (“With respect to the State’s important and legitimate interest in potential life, the ‘compelling’ point is at viability.”). Since that decision, executive or legislative attempts to declare frozen stem cells to be “persons” in circumstances where they will never be positioned to become live-born humans seem in direct conflict with the jurisprudence of *Roe*. Additionally, since the pregnant woman has the right to make decisions about her fetus, she would certainly seem to have the right to make decisions about the cells that would make up that fetus. As a recent article demonstrates, most couples who have stored frozen embryos opt for their use in research over any other method of disposal. Anne Drapkin Lyerly & Ruth R. Faden, *Embryonic Stem Cells: Willingness To Donate Frozen Embryos for Stem Cell Research*, 317 *SCIENCE* 46, 47 (2007).

5. *Roe v. Wade*, 410 U.S. 113 (1973); see also *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992).

6. *Balanced Budget Downpayment Act of 1996*, Pub. L. No. 104-99, §128, 110 Stat. 26, 34 (1996).

7. Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 22, 2007); Press Release, Office of the Press Sec’y, White House, President Discusses Stem Cell Research (Aug. 9, 2001), available at <http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>.

8. See Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

service activities in the field of reproductive biology. It has been particularly restrictive of those activities that are designed either to create an entity that could develop into a human person by any means other than “natural procreation” or to destroy such an entity whether it was created “naturally” or *in vitro*. Among the activities that have had their federal support terminated, forbidden, or suspended by federal legislation or executive order are *in vitro* fertilization, fetal research, therapeutic transplantation of tissues derived from human fetal tissue, and cloning of humans.⁹ The most recent example was President George Bush’s first use of his veto power in July of 2006 to block the enactment of H.R. 810, the Stem Cell Research Enhancement Act of 2005.¹⁰

Within a year of the *Roe v. Wade* decision, Congress passed the National Research Act,¹¹ Title II of which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission).¹² This legislation was enacted in response to public concern over multiple reports of abuses in research involving human subjects. One of the exposés of abuse in this field concerned research on “newly delivered live fetuses . . . before they died.”¹³

Two provisions in the Congressional mandate to the Commission signaled the high priority assigned by Congress to addressing the ethical problems presented by proposals to perform research on fetuses.¹⁴ Firstly, in an act that allotted two years to a comprehensive investigation of all research involving human subjects, Congress directed the Commission to report on research on the fetus within four months.¹⁵ Secondly, pending receipt of this report, Congress imposed its only moratorium on the conduct or support by the Department of Health, Education, and Welfare of all “research . . . on a living human fetus, before or after the induced abortion of such fetus, unless such research is done

9. See, e.g., John Garvish, *The Clone Wars: The Growing Debate over Federal Cloning Legislation*, 2001 DUKE L. & TECH. REV. 0022, <http://www.law.duke.edu/journals/dltr/articles/2001dltr0022.html> (discussing proposed regulation of research involving human cloning).

10. Press Release, Office of the Press Sec’y, White House, Message to the House of Representatives (July 19, 2006), available at <http://georgewbush-whitehouse.archives.gov/news/releases/2006/07/20060719-5.html>; see also Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2005).

11. National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974) (codified at 42 U.S.C. § 2891-1) (repealed).

12. *Id.*; see also ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 297 (2d ed. 1988).

13. See ALBERT R. JONSEN, THE BIRTH OF BIOETHICS 94 (1998).

14. See John C. Fletcher & Joseph D. Shulman, *Fetal Research: The State of the Question*, HASTINGS CENTER REP., Apr. 1985, at 6, 6 (1985); Robert J. Levine, *Symposium on Definitions of Fetal Life*, 23 CLINICAL RES. 103, 103 (1975).

15. National Research Act, Pub. L. No. 93-348, § 202(3)(B), 88 Stat. 342, 350 (1974).

for purposes of assuring the survival of such fetus.”¹⁶

Very similar language was chosen fourteen years later by the Assistant Secretary for Health when he imposed a ban on the conduct of another category of research on the human fetus: “The Assistant Secretary for Health, Department of Health and Human Services, is instituting a moratorium, effective immediately, on research funded by the Public Health Service (PHS) utilizing human fetal tissue, obtained from induced abortions, for therapeutic transplantations.”¹⁷ It is worth noting that the language chosen by Congress and by the Assistant Secretary contains an implicit acknowledgement of the limits of the federal government’s constitutional authority to regulate. In the field of research involving human subjects, the authority to regulate activities for which the federal government provides funding in the form of grants or contracts is established by the “conditional spending power” provisions of the Constitution.¹⁸ Similarly, the regulatory power of the FDA is established by the constitutional authority to regulate interstate commerce. According to the Tenth Amendment, “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”¹⁹

There is one apparent substantive difference between the targets of the two moratoria. In its charge to the National Commission, by specifying that its moratorium applies only to the living human fetus, Congress suggested that its primary concern was for the well-being of the individual fetus. This was also reflected in its exclusion from the moratorium of “research . . . done for purpose of assuring the survival of such fetus.”²⁰ The Assistant Secretary, by specifying that the moratorium applied only to “induced abortion,” as distinguished from spontaneous abortions (or miscarriages), seemed primarily concerned with the moral legitimacy of induced abortions.²¹

These apparent differences notwithstanding, the arguments presented by those who opposed fetal research in both cases focused on the morality of abortion, which was discussed as indistinguishable from the destruction of human embryos. Abortion was portrayed as murder of an innocent child. The conduct of research on fetuses or on their tissues was characterized as lending legitimacy to the “abortion industry,” as providing incentives to women to have abortions, and as a revealing conspiracy of physicians and researchers to increase the supply of “research material.” The conduct of research on the fetus was

16. *Id.* § 213, 88 Stat. at 353.

17. NAT’L INSTS. OF HEALTH, NIH GUIDE FOR GRANTS AND CONTRACTS (1988), available at http://grants.nih.gov/grants/guide/historical/1988_05_09_Vol_17_Special_Notice.pdf.

18. U.S. CONST. art I, § 8, cl.1.

19. U.S. CONST. amend. X.

20. National Research Act, Pub. L. No. 93-348, § 213, 88 Stat. 342, 353 (1974).

21. *Id.*

portrayed as material cooperation in an evil act. The proponents of fetal research, in addition to presenting the benefits that could be realized through the conduct of such research, directed much of their energy toward refuting their opponents' claims. They concentrated particularly on rejecting their opponents' claims about the moral status of the fetus at various stages of its development.²²

Research and any derived therapies that utilize stem cell lines created from embryos, whether cloned or created by *in vitro* fertilization, evoke similar concerns. That is, those who oppose the *in vitro* creation or use of embryos for research purposes characterize this research as legitimizing these practices. Under current regulations, however, given Congressional restrictions still in force,²³ the creation of new embryos for research is not permissible with federal funding. While there is no explicit "ban" on embryo research, and while federal funds can now support research on existing lines or lines derived without federal funding,²⁴ the use of federal funding to create new cell lines remains prohibited through the Dickey-Wicker Amendment of 1995 since its passage.²⁵ This amendment has been carried over through NIH appropriations acts every year since. This amendment indicates that, in research supported by federal funds, embryos cannot be created for research purposes or "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero*" in other federally funded research.²⁶ That is,

22. There are several collections of references on this topic. For an early overview, see LEVINE, *supra* note 12, at 299. Collections of papers may also be found in DEP'T OF HEALTH, EDUC., & WELFARE, APPENDIX: RESEARCH ON THE FETUS (1976) and *Human Fetal Tissue Transplantation Research Panel: National Institutes of Health*, in SOURCE BOOK IN BIOETHICS: A DOCUMENTARY HISTORY 103 (Albert R. Jonsen, Robert M. Veatch & LeRoy Walters eds., 1998).

23. See Sheryl Gay Stolberg, *New Stem Cell Policy To Leave Thorniest Issue to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1.

24. *Id.*; see also Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

25. Balanced Budget Downpayment Act of 1996, Pub. L. No. 104-99, §128, 110 Stat. 26, 34 (1996).

26. See, e.g., OFFICE OF MGMT. & BUDGET, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2005, Appendix § 510, at 735-36, available at <http://georgewbush-whitehouse.archives.gov/omb/budget/fy2005/pdf/appendix/lab.pdf>. Such language has appeared in the appropriations bills each year since FY 2002. In his State of the Union Address in January 2008, President Bush reasserted his determination to ban the use of federal funds to do research on embryonic stem cells:

On matters of life and science, we must trust in the innovative spirit of medical researchers and empower them to discover new treatments while respecting moral boundaries. In November, we witnessed a landmark achievement when scientists discovered a way to reprogram adult skin cells to act like embryonic stem cells. This breakthrough has the potential to move us beyond the divisive debates of the past by extending the frontiers of medicine without the destruction of human life.

Press Release, Office of the Press Sec'y, White House, President Bush Delivers State of the Union Address (Jan. 28, 2008), available at <http://georgewbush-whitehouse.archives.gov/news/>

research must either promote or at least avoid shortening the life of the embryo. Accordingly, creating embryos for research purposes and deriving embryonic stem cell lines from embryos are not permitted.

After his August 9, 2001 announcement,²⁷ which limited the permissibility of embryonic stem cell research, President Bush decided to retain the language of the Dickey Wicker Amendment. Further, Bush chose to add language governing funds for research on stem cell lines already created.²⁸ The “bad deeds” of creating embryos through IVF and then destroying embryos were already done in the private sector, but the public sector could reap the benefits of stem cell research. Any cloning technology used to create stem cells of course would have to be in the private sector, if it was not explicitly banned by state laws. President Bush reaffirmed these restrictions in July of 2006 when he vetoed the Stem Cell Research Enhancement Act of 2005.²⁹ Without further Congressional action to overturn the Dickey-Wicker Amendment, this funding structure will persist to some extent despite President Obama’s recent executive order;³⁰ although federal funds may now support research on all existing stem lines and those yet to be derived with non-federal funding, researchers may not use federal money to create new lines.

II. FEDERAL REGULATION OF RESEARCH INVOLVING HUMAN SUBJECTS

Research designed to develop novel therapeutic, diagnostic, or preventive agents (hereafter called “therapies”) is generally regulated by the federal Food

releases/2008/01/20080128-13.html.

27. Press Release, Office of the Press Sec’y, White House, President Discusses Stem Cell Research (Aug. 9, 2001), *available at* <http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html>.

28. For one example of Bush’s support, see Office of Management & Budget, S. 1536 – Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Bill, FY 2002, Oct. 30, 2001, <http://georgewbush-whitehouse.archives.gov/omb/legislative/sap/107-1/S1536-s.html>:

The President strongly believes that the Dickey-Wicker Amendment, which for years has ensured that the federal government observes important ethical boundaries at the same time that it provides support for scientific research, should not be altered. The Administration therefore strongly opposes the Senate version of the bill, which modifies the existing language and would signal a weakening of the Federal Government’s commitment to protecting human embryos. The Administration strongly supports the House version of the bill, which retains the current language, and includes clarifying report language that is consistent with the President’s August 9, 2001 announcement. The President’s senior advisors would recommend that he veto the bill if it contains the Senate’s language.

29. Message to the House of Representatives Returning Without Approval the “Stem Cell Research Enhancement Act of 2005,” 42 WEEKLY COMP. PRES. DOC. 1365 (July 19, 2006).

30. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

and Drug Administration.³¹ Research designed to evaluate the safety and efficacy of the novel product must be carried out according to an orderly set of protocols as specified in the regulations and guidelines of the agency (phases I, II, and III). Each of the specific protocols must be reviewed and approved by an Institutional Review Board (IRB) before the research may be initiated. There are detailed regulations specifying protections of the rights and welfare of the research subjects including provisions for negotiating and documenting informed consent. The IRB must determine that the burdens and benefits of research are distributed equitably. The sites of the research are subject to monitoring by agents of the FDA to ensure compliance with the regulations. Other regulations of the FDA authorize inspections of the laboratories in which some aspects of the research are carried out along with quality control activities directed at the manufacture and distribution of the product. Finally, the FDA has the authority to determine if and when regulated “test articles” (novel therapies) may be licensed for commercial distribution. The approval of a “New Drug Application” or a “marketing permit” occurs only after the FDA determines that the product is safe and that its efficacy has been established by trials recognized as adequate and well-controlled.

The FDA does not have jurisdiction over all research designed to develop novel therapies. As noted earlier, the scope of its authority is limited to interstate commerce. Some novel therapies are not products that will be entered into interstate commerce. Notable among these are surgery and “talking psychiatry.”

The development and use of some drugs and “biologicals” has taken place entirely within the borders of a single state, and recent state initiatives to fund stem cell research suggests this may become more common.³² An interesting and highly publicized case in point was the Biotherapeutics Corporation developed in the state of Tennessee by Dr. Robert Oldham and his colleagues.³³ The novel therapies it developed for its patients were not subject to FDA regulation because they were not shipped across state lines. Many of the patients traveled across state lines to get to Tennessee where individualized therapy was made available for them. This was entirely a fee-for-service program and it was not covered by insurance. Criticism was primarily directed at the fact that none but the relatively wealthy could afford this individualized therapy; some commentators also expressed concern that the products employed by Biotherapeutics had not been shown to be safe and effective.

Therapies derived from embryonic cell lines, including those derived from

31. For an overview of FDA regulations, see LEVINE, *supra* note 12; and ISLAT Working Group, *ART into Science: Regulation of Fertility Techniques*, 281 SCIENCE 651 (1998).

32. See James W. Fossett, *Beyond the Low-Hanging Fruit: Stem Cell Research Policy in an Obama Administration*, 9 YALE J. HEALTH POL'Y L. & ETHICS 523 (2009).

33. See Paul Cotton, *Treatments of Last Resort?*, 17 HARV. HEALTH LETTER 9 (1991); Steven Flax, *Leading-Edge Cancer Treatments for Sale*, FORTUNE, Feb. 17, 1986, at 77.

cell lines available for federally-funded research, would fall under the FDA regulations insofar as they were intended for use in humans.³⁴ However, it is conceivable that for therapies derived from cloning, interstate commerce need not necessarily take place. Just as in the Oldham case, all the necessary materials could be developed and utilized within the confines of a single state. Other therapies developed from existing embryonic stem cell lines, or from a “universal” cell line if and when it is created, could have interstate uses and, if so, would be regulated by the FDA.

The federal government also has the authority and responsibility to regulate research and health care practices that are funded at least partially by the federal government. In the field of health care research, most of the funding is in the form of grants and contracts from HHS. The federal regulations for the protection of human subjects for almost all federally-funded research are called the Common Rule;³⁵ its provisions for IRB review and informed consent are substantially similar to those in the FDA regulations. In addition, all applications for federal funds to support research must be reviewed and approved by committees of experts to determine that they are scientifically meritorious and that the researchers have the requisite skills and facilities to perform the research successfully; at the NIH, for example, these committees are called Initial Review Groups (IRG) or Study Sections. After review by the IRG, the applications must also be reviewed by advisory bodies to determine, among other things, whether they match the priorities of the funding institute.

All institutions that receive federal funding to support the conduct of research involving human subjects are required to file an “assurance” with the federal Office for Human Research Protection (OHRP) that they will comply with the federal regulations for the protection of human research subjects.³⁶ Although the authority of the federal government to regulate research is limited by the Constitution to those activities for which it provides funding or that will produce products for interstate commerce, OHRP requests that institutions receiving such funding promise “voluntarily” to apply the requirements of these regulations to all research carried out within the institution. This is accomplished by adding a commitment to do so to their statements of assurance. Most, but not all, institutions do this.

The voluntary agreement by most research institutions to extend the

34. OFFICE FOR HUMAN RESEARCH PROT., DEP’T HEALTH & HUMAN SERVS., GUIDANCE FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS REGARDING RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS AND STEM CELL-DERIVED TEST ARTICLES 2 (2002), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf> (noting that “cells or test articles regulated as drugs, devices, and biological products” are “subject to FDA regulations”).

35. 45 C.F.R. § 46 (2008). For an overview of DHHS regulations and the Common Rule, see Levine, *supra* note 12.

36. 45 C.F.R. § 46.103 (2008).

applicability of the Common Rule to all research conducted within the institution has the good effect of ensuring, for example, that all research conducted within the institution will be reviewed by an IRB and that informed consent will meet the federally mandated standards. However, the effects of such voluntary compliance in the field of assisted reproductive technology (ART) are difficult to assess. Lack of federal (or other external) funding serves as a disincentive to some university hospitals or other research institutions to allow such research and development activities within the institution; particularly in the early stages of development, the institutions may lack confidence that they will recover the costs of the development without subsidy. Moreover, many researchers (and not just those who are unethical or unscrupulous) would likely prefer to carry out their research and practice activities in clinics that receive no federal research funds and other settings that are beyond the reach of increasingly burdensome human subject protection bureaucracies.³⁷

III. CONSEQUENCES OF WITHHOLDING OF FEDERAL FUNDING

When the federal government withholds or withdraws funding from a field of research, there are often consequences that adversely affect the rights and welfare of the people. This is particularly problematic when the research is designed to develop a therapeutic intervention that is not covered by FDA regulations. In short, all of the checks and balances mentioned earlier in this paper are likely to be absent.

ART is a field of research and practice that serves as a good case study for evaluating the adverse consequences of withholding federal funding for a field of research designed to develop therapeutic interventions. In her excellent brief overview of the regulation (or lack thereof) of ART, Rebecca Dresser begins by noting that “[r]eferences to the ‘Wild West’ of infertility treatment are common.”³⁸ Dresser summarizes the main features of the problem as follows:

Because novel ART procedures are not covered by the FDA approval process that governs drugs and other medical products, ART procedures need not meet FDA safety and efficacy standards before entering the clinical arena. The National Institutes of Health and other federal agencies rarely support research relevant to ART; thus, innovative approaches may be tried in the clinical setting without prior research ethics review. Because insurance coverage for ART is quite limited, reimbursement requirements fail to promote quality care. Moreover, because ART interventions may be performed outside hospital

37. Norman Fost & Robert J. Levine, *The Dysregulation of Human Subjects Research*, 298 JAMA 2196 (2007); Robert J. Levine, *Institutional Review Boards: A Crisis in Confidence*, 134 ANNALS INTERNAL MED. 161 (2001).

38. Rebecca Dresser, *Regulating Assisted Reproduction*, HASTINGS CENTER REP., Nov.-Dec. 2000, at 26, 26.

settings, hospitals are not able to screen out unqualified practitioners. Last, the malpractice system's ability to stimulate quality care is weakened by difficulties in proving negligence, causation, and harm on behalf of patients who fail to have children or have children with health problems.³⁹

Lack of IRB review in the field can have many additional consequences. For example, the research may proceed without "independent" assessment of the risks and benefits of participation. Procedures for obtaining and documenting informed consent may fall short of standards federally mandated under the Common Rule and corresponding FDA guidelines. Research may also proceed without assurance that there is equitable distribution of its burdens and benefits, undermining established duties of justice, beneficence, and nonmaleficence. With regard to the latter, owing to the lack of external funding, even during the "investigational" stage, the interventions are most likely to be tested on patients who can pay for them. Subsequently, owing to the lack of insurance coverage, the use of such procedures is generally limited to the relatively wealthy who can finance these therapeutic interventions out-of-pocket.⁴⁰

Lack of FDA involvement means that there is no monitoring for compliance with FDA standards for, among other things, high-quality laboratory services. Moreover, unsupervised research lacks an enforceable standard for determining whether and when it is appropriate to move out of the investigational stage to make a technology available as part of the routine and accepted practice of medicine.⁴¹ Lack of federal funding also removes the various review policies and procedures designed to ensure both high quality in research methodologies and facilities and the competence of the investigators.

There are some federal regulations concerned with ART.⁴² For example, federal law requires IVF programs to report their treatment success rates to the Centers for Disease Control and Prevention (CDC), which publishes these data annually. The Federal Trade Commission has issued "cease and desist" orders to several IVF clinics whose advertisements misrepresented their success rates. The FDA is developing rules to screen sperm, egg, and embryo donors for communicable diseases. The CDC has developed standards for labs and professionals performing ART services and some states are considering incorporating them into law. In general, however, these regulatory activities stop far short of providing the level of protection for subjects and patients that is customary for those therapeutic interventions that are either regulated by the

39. *Id.* at 27.

40. *See, e.g.,* Neil Davis, *The Constitutionality of Fetal Experimentation Statutes: The Case of Lifchez v. Hartigan*, 25 J. HEALTH & HOSP. L. 37 (1992); Dresser, *supra* note 38, at 27.

41. *See* Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 0012.

42. *See* Dresser, *supra* note 38.

FDA or funded by the federal government.⁴³

CONCLUSION

When a field of research or a particular project entails either the creation by any means other than “natural procreation” of an entity that could develop into a human person or the destruction of such an entity, whether the entity was created “naturally” or *in vitro*, it usually incites strong controversies. These controversies are particularly strident when the purpose of the research is to develop products or procedures intended to cure, prevent or relieve lethal or disabling diseases. Those who make policy are presented with a choice between two politically undesirable alternatives. They may side with those who oppose the research, a stance which will be attacked as callous disregard for the well-being of afflicted persons. Or, they may side with those who advocate for the research and be branded as evil in that they condone the murder of innocent babies.

Politicians often evade such criticism by making a safe decision in which they do not take a side. I refer to such a decision as the Pontius Pilate Maneuver: the decision-maker figuratively washes his or her hands of a difficult problem so as to avoid alienation of either of the disputing constituencies. The safe decision is to permit the conduct of the activity in the private sector while withholding the support of public funding for the field of study or practice. The decision has the effect of allowing the development of the new technology in the private sector. Those who wish to develop it are thus free to do so and those who wish to benefit from it once it is developed are free to purchase it. On the other hand, those who oppose the development on moral grounds are also treated with respect. They are not forced to contribute (through their taxes) to a development they find immoral.

Such a decision may have serious consequences that impact both the rights and welfare interests of research subjects and the patients who might be treated with the new product or procedure once it is developed. The withholding of federal funding limits the authority of the federal government to engage in many of its activities that are designed to protect the rights and interests of research subjects and patients. If, as in the case of embryonic stem cell research, the technology that is not a new drug or other therapeutic product that will be introduced in interstate commerce, the FDA has no authority to regulate its development and subsequent introduction into the practice of medicine. Thus, the research and therapeutic use of the technology will proceed without any of the federal checks and balances we rely on to assure that medical research and practice are carried out with due regard for the safety and other interests of subjects and patients; such checks and balances include IRB review and approval, monitoring by the FDA of the sponsor and laboratories, and other

43. See Robert L. Stenger, *The Law and Assisted Reproduction in the United Kingdom and United States*, 9 J.L. & HEALTH 135 (1994-1995); see also Dresser, *supra* note 38.

practices common to most clinical trials.

President Obama's executive order of March 9, 2009,⁴⁴ "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," has taken a small step towards changing this balance. This order lifted the restrictions previously imposed by President Bush's 2007 order,⁴⁵ which had limited federally funded stem cell research to a set of lines created before August 2001. At the time of this writing, the NIH has drafted guidelines to implement President Obama's new policy,⁴⁶ setting forth "the conditions and informed consent procedures that would have been required during the derivation of human embryonic stem cells for research using these cells to be funded by the NIH."⁴⁷ These steps may be signs of increased federal involvement in stem cell research for both funding and regulatory purposes. However, the extent of this new federal involvement remains unclear. Given the continuing force of the Dickey-Wicker Amendment and the history of federal Pontius Pilate maneuvering regarding reproductive biology, a break from the past is by no means assured.

44. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

45. Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 22, 2007).

46. Draft National Institute of Health Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18,578 (proposed Apr. 23, 2009).

47. *Id.* at 18,578.