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ABORTION POLITICS, SCIENCE, AND RESEARCH ETHICS: TAKE DOWN THE WALL OF SEPARATION*

*John C. Fletcher, Ph.D. ***

INTRODUCTION

Reflecting Bush Administration policy, in November 1989 Dr. Louis W. Sullivan, Secretary of the United States Department of Health and Human Services (HHS), rejected an expert panel's report to the Director of the National Institutes of Health (NIH). By a vote of eighteen to three, the panel advised that federal support of fetal tissue transplantation research (FTTR) "was acceptable public policy" provided that twelve guidelines to prevent abuses were adopted to regulate FTTR as part of the existing body of federal regulations to protect human subjects.¹ The Advisory Committee to the Director of NIH had previously approved the panel's report by a unanimous vote.² Dr. Sullivan, however, "indefinitely" continued a moratorium on FTTR that began in March 1988, reasoning primarily that the Administration and Congress opposed any funding of activities by HHS which "encourage or promote abortion."³ Dr. Sullivan also stated: "I, however, note

* I thank the Editor for inviting me to contribute to this volume in honor of my esteemed colleague, Walter J. Wadlington, and his contribution to the study and teaching of health care law and public policy. Walter Wadlington continues to be a pioneer in interdisciplinary work in law, medicine, and ethics. I am also grateful to Robert M. O'Neil and John A. Robertson for their help and comments on First Amendment implications of this subject. In addition, my thanks to Maureen A. Berkner who edited this Article with skill and speed.

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1. 1 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION PANEL 2 (1988) [hereinafter 1 CONSULTANTS TO THE ADVISORY COMM.].

2. ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT ON HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH 7 (1988).

3. Letter from Louis B. Sullivan, M.D., Secretary, U.S. Department of Health and Human Services, to William F. Raub, M.D., Acting Director, National Institutes of Health 1 (Nov. 2, 1989) (on file with author).

that interest exists in the private sector in continuing such research. Thus, whatever biomedical knowledge that may be obtained from such research can be obtained without Federal subsidization."⁴ This action added one more level to a growing "wall of separation"⁵ between federal and private support for any clinical research associated with elective abortion or studies that lead to the loss of human embryos in vitro. The Administration's policy affects several types of clinical research associated with fetal diagnosis and therapy, including the future of human gene therapy in either fetuses or in live-born persons affected by genetic disorders.⁶

This Article examines arguments for and against this policy. A wall of separation between public and private support of religion is sound. A wall of separation between public and private support of embryo and fetal research is misplaced and destructive of clinical research, which ought to be guided by scientific peer review and the ethical tenets that undergird research involving human subjects.

This Article has four parts. The first part has three sections: 1) a description of the links among FTTR, fetal diagnosis, fetal therapy, and human gene therapy; 2) an account of events leading up to and following the moratorium on FTTR; and 3) a description of the divergent ethical perspectives on FTTR with a discussion of their strengths and weaknesses.

The second part places FTTR in the larger historical context of a transition in the federal sector of science from a policy of restriction to a policy of separation of fetal and embryo research from federal support. The third part challenges a position that would permanently separate public and private support for these research activities. It sets out the reasons for a restoration of research freedom to the federal sector of science. The final part enlarges upon the Belmont Report⁷ for guidance in research ethics that apply to these and other controversial activities.

4. *Id.* at 2.

5. The phrase "wall of separation" is attributed to Thomas Jefferson who used the term to describe the intent and the effects of the First Amendment. For a reference to Jefferson's statements about the clause against establishment of religion by law, see *Everson v. Board of Educ.*, 330 U.S. 1, 16 (1946); *Reynolds v. United States*, 98 U.S. 145, 164 (1878).

6. John C. Fletcher, *Controversies in Research Ethics Affecting the Future of Human Gene Therapy*, 1 *HUM. GENE THERAPY* 307, 310 (1990).

7. NATIONAL COMM'N FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH* (1983) [hereinafter *BELMONT REPORT*].

I. USES OF FETAL TISSUE IN EXPERIMENTAL THERAPY

A. *Links to Fetal Diagnosis, Therapy, and Human Gene Therapy*

Investigators have used fetal tissue experimentally to treat some disorders that are caused wholly or in part by genetic factors. For example:

1) The DiGeorge syndrome: A congenital anomaly in the development of derivatives of the third and fourth pharyngeal pouches often involving deformities of the ear, nose, mouth, and aortic arch. Human fetal thymus transplants are known to be effective in the treatment of this syndrome.⁸

2) Diabetes mellitus—Type I: There is a clear genetic factor but an unknown mode of inheritance.⁹ Islet cells from the fetal pancreas have been the source for experimental therapy.¹⁰

3) Investigators have conducted studies on mice, sheep, and rhesus monkeys and learned that fetal stem cells can be given to pre-immune fetuses without use of immunosuppression.¹¹ This procedure amounts to fetal bone marrow transplantation, by which successful intrauterine xenotransplantations (cells from one species to another) of fetal bone marrow have been reported.¹² No recombinant DNA techniques are involved in these procedures. If such studies could be done on humans with diseases that either deprive children of normal hemoglobin (*e.g.*, sickle cell disease) or produce inadequate immune systems (*e.g.*, severe combined immunodeficiency syndrome), then these diseases might be treated in the fetus after prenatal diagnosis by fetal cell transplants.

4) Transplantation of genetically corrected hepatocytes or fetal gene therapy may be a source of treatment for some hereditary disorders, such as some glycogen storage disorders, phenylketonuria, or hemophilia. Recent research on sheep has shown promise for human studies.¹³ Each of these

8. Rebecca H. Buckley, *Fetal Thymus Transplantation for the Correction of Congenital Absence of the Thymus (DiGeorge's Syndrome)*, in 2 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL D50, D53 (1988).

9. VICTOR A. MCKUSICK, *MENDELIAN INHERITANCE IN MAN: CATALOGS OF AUTOSOMAL DOMINANT, AUTOSOMAL RECESSIVE, AND X-LINKED PHENOTYPES*, 927 (7th ed. 1986).

10. Kevin J. Lafferty, *Diabetes Islet Cell Transplant Research: Basic Science*, in 2 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL D142, D143 (1988).

11. R.N. Slotnick et al., *Stable Hematopoietic Chimerism Following In Utero Stem Cell Transplantation*, 43 AM. J. HUM. GENETICS A133 (1988).

12. Maria Michejda et al., *Intrauterine Xenotransplantation of Fetal Bone Marrow: Formation of Hematopoietic Chimerism*, 27 PEDIATRIC RES. 267A (1990).

13. M. Brandt et al., *Targeting the Fetal or Newborn Liver by Hepatocellular Transplantation or Somatic Gene Therapy*, 49 AM. J. HUM. GENETICS 435 (Supp. 1991).

disorders can be diagnosed prenatally.

5) Parkinson's disease: Is there a genetic factor in Parkinsonism? One hypothesis is that idiopathic Parkinsonism, which has a low-level familial association and nonmendelian pattern of inheritance, may be caused by inheritance of mitochondrial genes.¹⁴ More research is needed to prove the theory, but the importance of genetic studies to explain why dopamine cells die in Parkinsonism is crucial. Neurosurgeons in Sweden and the United States, using fetal neural cells known to be rich in dopamine, have attempted dopamine replacement therapy in patients with Parkinson's disease. These clinical results have been mixed.¹⁵

FTTR is closely related to the future of human gene therapy. First, each attempt to treat any genetic disease is a link in the chain of a growing body of knowledge which is the basis for human gene therapy experiments. In FTTR, more understanding of gene expression in fetal cells will be gained, as will the knowledge of how these cells interact with surrounding cells. This knowledge will bear on future attempts at molecular intervention, which may possibly result in a rejection phenomenon from transplant fetal cells.

Furthermore, progenitor cells obtained from the fetus after abortion can now be cultured and proliferated for transplantation.¹⁶ After this step, a potential exists to engineer cells genetically modelled after these original fetal cells and cell lines to be used in treatment.¹⁷

Human gene therapy is a sign of hope in a vast sea of human suffering due to heredity. Gene therapy in the fetus would be a special expression of this hope, since about twenty-two percent of newborn deaths in developed nations are due to congenital malformations or genetic disorders.¹⁸ Approximately one-third of children admitted to pediatric units in Western nations need treatment for the complications of genetic disorders, congenital defects, or mental retardation.¹⁹ In addition, cancer is now best understood as a

14. William D. Parker et al., *Abnormalities of the Electron Transport Chain in Idiopathic Parkinson's Disease*, 26 *ANNALS NEUROLOGY* 719, 719 (1989).

15. Olle Lindvall et al., *Grafts of Fetal Dopamine Neurons Survive and Improve Motor Function in Parkinson's Disease*, 247 *SCI.* 574, 574 (1990).

16. H. Fred Voss, *Statement*, in 2 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL D252, D258-59 (1988).

17. Lars Olson, *Parkinson's Disease Fetal Tissue Transplant Research Basic and Clinical Studies*, in 2 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL D219, D224 (1988).

18. See H. Galjaard, *Early Diagnosis and Prevention of Genetic Disease*, in ASPECTS OF GENETIC DISEASE 1-15 (H. Galjaard ed., 1984).

19. John C. Fletcher, *How Abortion Politics Stifles Science*, WASH. POST, Feb. 5, 1989, at D3; see also Robert L. Brent, *The Magnitude of the Problem of Congenital Malformations*, in

genetic disease.²⁰

Research with the human embryo is also a source of hope to relieve suffering. Because great emotional suffering accompanies infertility, many infertile couples use technology, such as in vitro fertilization (IVF), as a last resort. IVF creates the possibility of diagnosing genetic and chromosomal abnormalities in the pre-implantation embryo. This step would clearly help infertile couples who have experienced a high loss of abnormal human embryos after implantation, and who may expect such losses to increase with maternal age.²¹ As more women seek higher education, enter the work force, and postpone earlier childbearing, a trend toward later pregnancies and their higher chromosomal risks will increase.

The option of selective abortion following positive prenatal diagnosis also carries negative emotional consequences. In fact, there is evidence of serious emotional distress in both parents after a second trimester genetic abortion.²² Although advances in first trimester chorionic villus sampling have reduced the level of such distress, one study shows that couples still suffer emotionally after a first trimester genetic abortion.²³ Clearly, selective abortion is not the best response to genetic disorders in the fetus; if the risks were acceptable, therapy would be a better response. The punishing weight of these burdens of heredity explain why a majority of Americans approve of human gene therapy to treat particular children and to correct a gene "that

PREVENTION OF PHYSICAL AND MENTAL CONGENITAL DEFECTS PART A: THE SCOPE OF THE PROBLEM 55 (Maurice Marois ed., 1985).

20. For recent articles that discuss cancer and genetics, see Jeff M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21*, 250 SCI. 1684 (1990); David Malkin et al., *Germ Line p53 Mutations in a Familial Syndrome of Breast Cancer, Sarcomas, and Other Neoplasms*, 250 SCI. 1233 (1990); Jean Marx, *Genetic Defect Identified in Rare Cancer Syndrome*, 250 SCI. 1209 (1990).

21. S. Harlap et al., *A Life Table of Spontaneous Abortions and the Effects of Age, Parity, and Other Variables*, in HUMAN EMBRYONIC AND FETAL DEATH 145, 149 (Ian H. Porter & Ernest B. Hook eds., 1980); Dorothy Warburton, *Reproductive Loss: How Much is Preventable?*, 316 NEW ENG. J. MED. 158, 159 (1987).

22. For some psychological studies showing the emotional trauma associated with abortions related to the prenatal detection of a genetic defect, see Bruce D. Blumberg et al., *The Psychological Sequelae of Abortion Performed for a Genetic Indication*, 122 AM. J. OBSTETRICS GYNECOLOGY 799 (1975); P. Donnai et al., *Attitudes of Patients After "Genetic" Termination of Pregnancy*, 282 BRIT. MED. J. 621 (1981); O.W. Jones et al., *Parental Response to Mid-Trimester Therapeutic Abortion Following Amniocentesis in 4 PRENATAL DIAGNOSIS 249 (1984); N.J. Leschot et al., Therapeutic Abortion on Genetic Indications: A Detailed Follow-Up Study of 20 Patients*, in ON PRENATAL DIAGNOSIS 96 (Marianne Verjaal & Nicolas J. Leschot eds., 1982); Theresa Marteau et al., *The Impact of Prenatal Screening and Diagnostic Testing Upon the Cognitions, Emotions, and Behavior of Pregnant Women*, 33 J. PSYCHOSOMATIC RES. 7 (1989).

23. Rita B. Black, *A 1 and 6 Month Follow-Up of Prenatal Diagnosis Patients Who Lost Pregnancies*, 9 PRENATAL DIAGNOSIS 795, 795-96 (1989).

would carry the disease to future generations."²⁴ It is reasonable to suppose that if a majority would approve preventive or germline gene therapy, it would also approve FTTR. However, this question has never been studied empirically.

B. Federal Moratorium on FTTR

What were the events that precipitated the moratorium on FTTR in the federal sector of science?

1. In 1986, neurosurgeons at the NIH Clinical Center designed a research project to give patients with Parkinson's disease the choice of an adrenal autotransplant or a fetal neural cell transplant. In keeping with Federal regulations,²⁵ fetal tissue would be legally obtained from a local hospital's obstetrics-gynecology service after consent by the woman and biological father if available.
2. A Clinical Review Subpanel of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) approved the project in September 1987. The Subpanel is an arm of the Clinical Center's human subjects review system. Despite their anticipation of controversy, the highest authorities in NINCDS nonetheless gave their approval to the study. NIH Director Dr. James Wyngaarden decided to seek higher departmental review of FTTR. In October 1987, he asked the Assistant Secretary for Health, Dr. Robert Windom, to review the FTTR project for a single patient who had chosen the fetal transplant approach.
3. In March 1988, Dr. Windom withheld approval of the both proposed experiment and "future experiments" in FTTR under federal auspices using tissue from induced abortions. Since there was no Ethical Advisory Board to which to refer the proposal, as required by federal regulations governing such situations,²⁶ he asked that NIH "convene one or more special outside advisory committees that would examine comprehensively the use of human fetal tissue from induced abortions for transplantation."²⁷ Dr. Windom submitted a list of ten questions concerning the morality and potential abuses of FTTR for the consultant panel to consider.²⁸
4. The NIH panel convened in September 1988, and met three times, vot-

24. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY*, OTA-BP-BA-45, 73-74 (Washington D.C., U.S. Government Printing Office, 1987).

25. 45 C.F.R. § 46.209(d) (1991).

26. *Id.* § 46.204(d).

27. Memorandum from Robert E. Windom, M.D., Assistant Secretary for Health, to James Wyngaarden, M.D., Director, National Institutes of Health 1 (Mar. 22, 1988) (on file with author).

28. *Id.* at 1-2.

ing eighteen to three on December 5, 1988 to approve federal support of FTTR.²⁹ Because it is of moral relevance that fetal tissue is derived from induced abortion, the panel noted that it was acceptable public policy in this pluralistic society to support FTTR. Additionally, the panel outlined principles to safeguard FTTR from abuses and ensure that the decision to abort was well-separated from decisions to donate tissue for research.

5. Dr. Windom left office in December 1988, without acting on the NIH report. The new HHS Secretary, Dr. Louis B. Sullivan, announced on November 2, 1989 that the moratorium on FTTR would be continued "indefinitely."³⁰ His decision remains in effect today.

6. The term "indefinite" was chosen as a "legal term," according to congressional testimony by Dr. James O. Mason, Assistant Secretary for Health.³¹ The difference between "indefinite" and "permanent" was small, according to Mason, but leaves some room for new information to permit reconsideration.³² In addition, "indefinite" was chosen to lower the risks of legal challenges to the extension of the moratorium.³³ Both Representative Ted Weiss (D-N.Y.) and the press cited a memorandum from HHS Counsel Richard Riseberg, saying that the extension of the moratorium was on a "shaky legal base" since it did not conform with the Administrative Procedures Act.³⁴ Under this Act, such decisions should be published in the *Federal Register* and then made the subject of rule-making.³⁵ Representative Weiss appealed to Dr. Sullivan to reverse his decision. An undisclosed source from the Public Health Service stated that they "have chosen to make the moratorium indefinite rather than permanent [because] a permanent prohibition of this research would require formal rulemaking procedures and thus would require extensive formal public comment and would be rather easily susceptible to litigation which could reverse this action."³⁶

7. Representative Henry Waxman (D-Cal.) introduced the Research Free-

29. See 1 CONSULTANTS TO THE ADVISORY COMM., *supra* note 1.

30. See Letter from Louis B. Sullivan, *supra* note 3, at 3.

31. *Fetal Tissue Transplantation Research: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 101st Cong., 2d Sess. 80 (1990) [hereinafter *Hearings*] (statement of James O. Mason, Assistant Secretary for Health, U.S. Department of Health and Human Services).

32. *Id.*

33. *Id.*

34. Letter from Rep. Ted Weiss (D-N.Y.), Chairman, Human Resources and Intergovernmental Relations Subcommittee of the House Committee on Government Operations, to Louis W. Sullivan, M.D., Secretary, U.S. Dept. Health and Hum. Servs. (Jan. 26, 1990) (on file with author); see also Philip J. Hilts, *U.S. Aides See Shaky Legal Basis For Ban on Fetal Tissue Research*, N.Y. TIMES, Jan. 30, 1990, at C6. The Administrative Procedures Act is located at 5 U.S.C. § 552 (1988 & Supp. 1992)

35. See 5 U.S.C. § 553 (1988).

36. Hilts, *supra* note 34, at C6.

dom Act of 1990 in the 101st Congress.³⁷ The measure would nullify the moratorium and prohibit officials in the executive branch from imposing such a policy on NIH.³⁸ It would authorize support for FTTR by or through NIH once proposals have been reviewed by both local institutional review boards and NIH on scientific and technical levels.³⁹ FTTR can be conducted in accordance with the recommendations of the NIH panel, unless an ethical advisory board convened by the HHS Secretary advises the withholding of funds on ethical grounds.⁴⁰ This measure was approved by the House of Representatives in July 1991, by a margin of 100 votes—16 short of the number needed to override a presidential veto. At this writing the bill is before the Senate.⁴¹

8. The American College of Obstetricians and Gynecologists and the American Fertility Society established a national advisory board to monitor FTTR and embryo research.⁴² This plan, proposed by scientific leaders whose research is most affected by the separation of federal and private support, is similar to the establishment of a voluntary licensing authority to oversee research with the human embryo. The plan was offered after the government failed to take steps to establish standards for research on fetal tissue and new reproductive technologies.⁴³

C. *Ethical Perspectives*

Two ethical perspectives clash on the issue of FTTR. One stresses an imperative to relieve human suffering, the continuity of FTTR with the ethics of organ transplants from cadavers, and the separability of the decision to abort and the decision to donate fetal tissue. The other is based on an imperative to protect fetal life and avoid encouraging abortion without regard to loss of social and individual benefits due to a lack of federal support for FTTR. Those who take the latter position accuse FTTR researchers of moral complicity by benefiting from abortions. Supporters of the former position cannot ethically justify the lost opportunity to relieve suffering in those who will worsen or die without attempted treatment. In this view, many of the 1.5 million legal abortions in the United States each year are “wasted” in

37. H.R. 5456, 101st Cong., 2d Sess. (1990).

38. *See id.* § 203(a).

39. *See id.* § 101.

40. *Id.*

41. 137 CONG. REC. S15,708-10 (daily ed. Oct. 31, 1991).

42. Sally Squires, *Groups Plan Advisory Board to Monitor Embryo, Fetal Tissue Research*, WASH. POST, Jan. 8, 1991, at A3.

43. *Id.* at 3.

the face of the opportunities they present to learn and prevent great human suffering.

Each position begins from premises and analogies that necessarily proceed to different conclusions. Arguments in support of FTTR begin with the premise that either 1) elective abortions are morally acceptable or 2) some abortions are morally justified and some are not, but in either case the decision to donate can be isolated from the decision to abort. Supporters of FTTR stress that a woman's decision about abortion and the act of abortion are distinct from her decision to donate tissue for FTTR and for other fetal tissue research uses. One noted commentator, Dr. Thomas Murray, uses the practice of organ transplantation as an analogy to distinguish between abortion decisions and FTTR that is similar to a distinction made by society between acts leading to deaths of persons who are sources of organs and the use of organs for transplantation.⁴⁴ According to Murray, the use of transplants does not mean that society morally approves of the auto accidents or suicides that result in the availability of organs.⁴⁵ People have no moral difficulty distinguishing the *use* of the organs from the *causes* that lead to their availability. Murray and the majority of the NIH panel argue that a distinction exists between abortion and FTTR, although they say that it is "morally relevant" that the source of most fetal tissue is elective abortion. In fact, another scholar has written a comprehensive response to the moral criticisms of FTTR and the NIH panel's recommendations, which are described below.⁴⁶

On the other side of the issue, advocates begin from a premise that induced abortions are evil almost without exception.⁴⁷ This premise leads them to a conclusion that FTTR is material cooperation with an evil so pervasive that any line-drawing disappears into a chasm of evil. They compare FTTR researchers to bankers who ask no questions but accept large sums for deposit from illegal drug transactions. Also, they link FTTR to Nazi experiments on humans in concentration camps, aiming to evoke images of

44. Thomas H. Murray, *Ethical Issues in Research on Human Fetal Tissue Transplantation*, in 2 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL D197, D199 (1988).

45. *Id.*

46. See generally James F. Childress, *Ethics, Public Policy, and Human Fetal Tissue Transplantation Research*, 1 KENNEDY INST. ETHICS J. 93 (1991) (critically examining charges that if funded by the federal government FTTR would involve complicity in the moral evil of abortion, legitimate abortion practices, and provide incentives for abortions).

47. James Bopp, Jr. & James T. Burtchaell, *Human Fetal Tissue Transplantation Panel: Statement of Dissent*, reprinted in CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, 1 REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL 45-47 (1988).

the epitome of evil. Three formal objections to FTTR are expressed: 1) women motivated to abort their fetuses cannot give an ethically valid informed consent to donate tissue; 2) FTTR creates incentives for more abortions to supply tissue; and 3) FTTR researchers participate in moral complicity with the abortions that are the source of tissue.

In objecting to FTTR and supporting the moratorium on federal funding of FTTR, Drs. Sullivan and Mason adopted the latter two of these three reasons.⁴⁸ Emphasizing the moral complicity with abortion, Mason wrote,

[T]he additional rationalization of directly advancing the cause of human therapeutics cannot help but tilt some already vulnerable women toward a decision to have an abortion.

....

[I]f just one additional fetus were lost because of the allure of directly benefiting another life by the donation of fetal tissue, our department would still be against federal funding.⁴⁹

Until hearings convened before the Subcommittee on Health and the Environment on April 2, 1990, the only HHS statements available on the subject were those by Drs. Sullivan and Mason.⁵⁰ Dr. Mason, speaking at the hearings, reviewed the reasoning for the moratorium: 1) The Administration and Congress are opposed to funding activities that encourage or promote abortion;⁵¹ 2) It is a fact—and of moral relevance—that human fetal tissue is obtained from abortions;⁵² and 3) One “must accept the likelihood” that permitting FTTR will increase the incidence of induced abortions across the country⁵³ because providing the additional “rationalization” of advancing the cause of human therapeutics cannot help but tilt some already vulnerable women toward a decision to have an abortion.⁵⁴

During his testimony, Dr. Mason was asked to explain the sources from which he derived the evidence that FTTR would encourage abortions:

Mr. Waxman: The Federal Government has supported other forms of fetal tissue research in cancer vaccines, developmental and childhood medicine for over 30 years. Do you have any evidence at all or any data that this has resulted in increased abortion?

Dr. Mason: No. That is what I have been trying to explain, Mr.

48. James O. Mason, *Fetal Tissue Transplantation Research*, 5 AM. SOC'Y MICROBIOLOGY 304, 304 (1990); James O. Mason, *Should the Fetal Tissue Research Ban be Lifted?*, 2 J. NIH RES. 17, 17 (1990) [hereinafter Mason, *Should the Ban be Lifted?*].

49. Mason, *Should the Ban be Lifted?*, *supra* note 48, at 17-18.

50. *See Hearings*, *supra* note 31.

51. *Id.* at 72 (statement of Dr. Mason).

52. *See id.* at 71-72 (statement of Dr. Mason).

53. *Id.* at 72 (statement of Dr. Mason).

54. *Id.* at 74 (prepared statement of Dr. Mason).

Chairman, that we have been doing fetal tissue research for 30 years, but this powerful inducement called fetal tissue transplantation with potential beneficial therapeutic effects is a new ball game. We have no experience in that particular area, it is too new. Can you imagine if fetal tissue transplantation proves to be successful, that it is hyped in the media, the powerful inducement this becomes to a woman who is caught in that dilemma as to whether or not to have an abortion and she knows that it may have a beneficial effect for some other person?⁵⁵

Some flaws mar the reasoning of advocates who would prohibit FTTR, and one in particular affects the reasoning of the NIH panel. First, this reasoning suffers from the logical fallacy of *petitio principii* or "begging the question." In this instance, the premise that FTTR will *causally* increase abortions by motivating women in doubt about abortion to have one is assumed to be true. Based on this unsupported premise, the public is asked to accept as a significant conclusion, *i.e.*, "one must accept the likelihood," that the potential for benefit in FTTR will persuade hesitant women toward abortions.

No study exists on the cause and effect relationship between abortion and FTTR. In fact, any study would have been anecdotal and retrospective given the few cases to date. If a study could be done involving women in the context of abortion counseling in which the hypothetical question "Would you be more inclined to consider abortion if you knew that you could donate tissue from the abortion that might even help someone in a desperate physical condition?" is asked, such a study would still be speculative, since the subjects would not be in a real life situation.

In response to this assertion, the NIH panel stated, "[R]esearch using fetal tissue has been conducted and publicized for over 30 years. There is no evidence that this use of fetal tissue for research has had a material effect on the reasons for seeking an abortion in the past."⁵⁶ The evidence available to the panel when making this statement was the historical record, the literature, and the experience to date in Sweden's use of FTTR. Directed donations occur when donors select recipients in advance. The panel noted that although Sweden now prohibits this practice with fetal tissue, there is no reported evidence that their prior experience with donations of fetal tissue for basic research, such as growing cell cultures to test vaccines, was an inducement to abortion by resolving ambivalence. Nonetheless, the important point remains that the question of the psychological effects of donating

55. *Id.* at 77.

56. 1 CONSULTANTS TO THE ADVISORY COMM., *supra* note 1, at 3.

fetal tissue has not been studied, even in the context of donating it for basic research or FTTR.

To reduce chances that abortion would be induced or pressured by the prospect of donation, the panel recommended obtaining consent for FTTR only *after* a woman decides to abort. The panel also recommended prohibiting directed donations. There are no studies investigating whether the decision to abort and the decision to donate are, in fact, separable or kept separate by researchers and subjects in the decision-making process. Secretary Sullivan stated that he doubted whether a line could be successfully maintained between the decision to abort and the decision to donate.⁵⁷ He argued that women would need to be consulted about the use of fetal tissue *before* “the abortion is actually performed” because of the need to use the tissue promptly.⁵⁸ He claimed that need would “influence the decision[-]making process.”⁵⁹ Thus, the question becomes whether current requests to use fetal tissue for research after abortion influence the decision-making process to have an abortion. The need for data creates an important opportunity for creative social science and psychological research to provide valuable contributions to research ethics.

A second flaw in the reasoning of Mason and other defenders of the moratorium is an omission to condemn *all* research with fetal tissue obtained from induced abortion. If moral complicity with abortion is so evil as to halt federal support of possible lifesaving therapy to prevent the loss of one additional fetus by abortion, then why does the condemnation not apply to *all* uses of fetal tissue after induced abortion, including all research with fetal tissue funded by HHS through the NIH?

Dr. Mason addresses this question less in the context of the argument of cooperation with the evil of abortion than in consequential terms that construe FTTR as a “powerful inducement” to abortion and a technique that, if effective, will require a large supply of fetal tissue. As he testified:

Mr. Waxman: We do have these other fetal research activities going on which we have had for 30 years. Your ban does not address any of these other areas of fetal tissue research. Why is that? How do you justify banning transplant research alone. What do you say to the Parkinson’s patients who think you are treating cancer patients more fairly?

Dr. Mason: Mr. Chairman, a number of people have favored extending the moratorium to include all fetal research. We rejected that for a number of reasons. First of all, in the context of quantifi-

57. See Letter from Louis B. Sullivan, *supra* note 3, at 1.

58. *Id.* at 2.

59. *Id.*

cation of inducement for abortion, the direct benefits another human might receive from fetal tissue transplantation . . . would tip the scale to a decision already the result of deep soul searching. The inducement here is high. It is like an organ transplant inducement is much higher than donating a cadaver to a medical school for dissection. General research is not as dramatic as direct therapeutic effect upon another human being.

. . . .

The second [reason] . . . is the concept of tissue requirements. For polio, for example, all of the . . . research and therapeutics were carried out on stable cell lines derived from three fetuses. In other words, whether the fetus was derived from a spontaneous abortion or however you started with the first fetus, you didn't have to go back and derive further fetal tissue because it was a stable cell line, while with human fetal tissue transplantation from induced abortions, right now, with regard to Parkinson's disease, they had to use the tissue from—what is it?—two to four fetuses for one patient, and each time you have to go back to a fresh supply of fetal tissue.

. . . So inducement and the quantification of the supply were both powerful reasons in our deciding that we should not continue to support fetal tissue research⁶⁰

This argument invalidates the premise that abortion is so evil that *even one* abortion induced by research would be wrong. What about all the past and future abortions that serve basic research involving fetal tissue? Dr. Mason invokes the polio example alone, but basic fetal tissue research continues to be done with fetal material from new abortions. To be consistent with his premise, there should be *no* abortion-derived research.

Dr. Sullivan's observation that FTTR can be done with private funding gives rise to a third flaw in reasoning, *i.e.*, he bases morality on the source of funds rather than on principles, beliefs of what is right or wrong, and consequences. According to his reasoning, unless there are different moralities for the public and private sector, FTTR deserves blame however supported. The comment that FTTR can be done with private funds undermines the moral position that Dr. Sullivan tries to take.

There is a clear need for a social and psychological study conducted with a hypothesis that FTTR either does or does not have the effects presumed by the HHS Secretary or the NIH panel. The study could be prospective and accomplished through interviews of a large sample of women in the context of abortion counseling. It is a fact that a moratorium on FTTR—in the face

60. See *Hearings*, *supra* note 31, at 79.

of great human suffering—is being extended on the basis of an unproven, speculative premise. Without data to resolve the question of undue inducement, the moral burden on those opposed to FTTR is very great.

Another option in obviating the moral concern of FTTR opponents is to secure fetal tissue from spontaneous abortions, as proposed by Thorne and Michejda.⁶¹ They argue that the number (possibly 750,000) of such events occurring in U.S. hospitals justifies organized preparedness to use these tissues rather than those from elective abortions. They do not address the problem of the large number of such pregnancy losses due to chromosomal malformations or intrauterine infections. Either of these conditions is reason for not using these tissues. However, tissues from some spontaneous abortions would be useable and this option is not prohibited by the moratorium.

II. FTTR IN HISTORICAL CONTEXT: FETAL AND EMBRYO RESEARCH

Current federal policy on FTTR cannot be understood apart from the history of federal policy on fetal and human embryo research in the period from 1974 to the present. The history of this policy reveals a radical change from a policy of restriction requiring national review for due process purposes to prevent exploitation of the fetus and embryo in research to a policy separating private from federal support and withdrawing the latter due to association with abortion or embryo loss.⁶² Public consideration of these issues arose in the 1970s when federal policy was that the public/private partnership in science was intact and that a national forum in which to debate important ethical issues in biomedical science was a priority for the well-being of the nation and the public interest. In this period, “bridges” rather than “walls” were built between the public and private sector to increase communication and resolve conflicts.

Fetal research in the abortion context was originally debated in 1974 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research following the appointment of the Commission by a Congress concerned that, in the wake of *Roe v. Wade*,⁶³ fetuses would be exploited for research after abortions.⁶⁴ Subsequent federal regulation⁶⁵

61. See Emanuel D. Thorne & Maria Michejda, *Fetal Tissue From Spontaneous Abortions: A New Alternative For Transplantation Research?*, 4 *FETAL THERAPY* 37 (1989).

62. John C. Fletcher, *Restriction and Suppression: Fetal and Embryo Research: 1974-1990*, Proceedings of Symposium on the Beginnings of Human Life, University of Iowa, (Nov. 1990) (forthcoming 1992).

63. 410 U.S. 113 (1973).

64. NATIONAL COMM'N FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH. REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS 61-88 (Washington, D.C., U.S. Government Printing Office, DHEW Publication No (OS) 76-127 (1975)).

adopted the Commission's recommendations to restrict fetal research in the context of abortion and especially to limit investigative fetal research with federal funds to a "minimal risk" level, which "means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."⁶⁶

The regulations also provided that if valuable knowledge was impossible by means other than fetal research, minimal risk could be exceeded if an Ethical Advisory Board (EAB) advised the Secretary of HHS to use a secretarial "waiver" of the risk standard.⁶⁷ No EAB has existed to advise the Secretary since 1979. No research proposals for fetal research in the context of abortion have been submitted to the NIH since 1979, when a trial of fetoscopy to diagnose sickle cell disease was recommended to Secretary Califano by an EAB.⁶⁸ Historically, federal funds have supported few fetal studies of any type, including fetal therapy.⁶⁹

Ethical understanding of fetal research in the context of abortion has seriously shifted among public officials since the 1970s. Albert Jonsen, a member of the National Commission, wrote that the majority of commissioners in 1974 who favored fetal research in the context of abortion likened the activity to phase I cancer studies, *i.e.*, both fetal research and phase I cancer research are morally problematic.⁷⁰ The cancer patient is going to die. Society permits phase I cancer trials largely to study drug toxicity. Lipsett argued that if phase I trials are to be ethical, a probability of benefit based on animal research is required.⁷¹ In reality, the probability of benefit from phase I trials is very small. However, some phase I studies involving children are financed under federal auspices, and these trials are conducted on living children when no data is available from experience with adults.⁷² Children cannot consent because of their minority, and their parents must

65. 45 C.F.R. § 46.205-.211 (1991).

66. 45 C.F.R. § 46.102(i) (1991).

67. 45 C.F.R. § 46.211 (1991).

68. Ezra C. Davidson, Jr., *Statement, in 2 CONSULTANTS TO THE ADVISORY COMM. TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL D82, D84, D87* (1988).

69. John C. Fletcher & Joseph D. Schulman, *Fetal Research: The State of The Question*, HASTINGS CENTER REP., Apr. 1985, at 6, 6.

70. Albert R. Jonsen, *Transplantation of Fetal Tissue: An Ethicist's Viewpoint*, 36 CLINICAL RES. 215, 218 (1988).

71. Mortimer B. Lipsett, *On The Nature And Ethics of Phase I Trials*, 248 JAMA 941, 941 (1982).

72. Richard S. Ungerleider & Susan S. Ellenberg, *Cancer Clinical Trials: Design, Conduct, Analysis, and Reporting*, in PRINCIPLES AND PRAC. OF PEDIATRIC ONCOLOGY 275, 277 (Philip A. Pizzo & David G. Poplack eds., 1989).

give permission for such research after it has been approved by an Institutional Review Board (IRB) under rules for research exceeding minimal risk.⁷³ Jonsen stated that the commissioners reasoned along these lines to justify fetal research.

Jonsen used another analogy to describe the views of opponents, namely that fetal research in the context of abortion was like research on prisoners condemned to die. This ethical understanding apparently predominates today among public officials. Under present federal policy, reinforced by a congressional ban on investigative fetal research, the secretarial waiver cannot be used. The thrust of current research policy is that fetuses in the context of abortion have a higher priority for social protection than living children. Should society permit research⁷⁴ with greater than minimal risks with living children⁷⁵ and deny research with the first trimester fetus in the context of abortion? Present federal policy encourages this moral contradiction.

The moral contradictions involved in withholding federal support for embryo research are even sharper. The study of cells and genes in human embryos may add discoveries that will directly affect treatment of genetic disorders and cancer. Yet, under federal regulations in effect since 1975, no federal funds may be spent on embryo research until a chartered EAB advises the Secretary that it would be ethical to do so.⁷⁶ An EAB so advised Secretary Califano in 1979,⁷⁷ but its term was then allowed to lapse, never to be rechartered. No subsequent HHS Secretary has ever approved the EAB report. The losses to diagnosis and treatment of infertility and genetic and other diseases are significant because no studies involving in vitro fertilization (IVF) can proceed to scientific and technical review at the NIH without EAB approval.⁷⁸

Among these losses are advances in cancer research. Scientists now have the tools to understand the origins of many cancers and to apply this knowledge to cancer treatment. As long ago as 1983, Dr. G. Barry Pierce reviewed embryonic regulation of some types of cancer and the role of this

73. John C. Fletcher et al., *Ethical Considerations in Pediatric Oncology*, in *PRINCIPLES AND PRAC. OF PEDIATRIC ONCOLOGY* 309, 312 (Philip A. Pizzo & David G. Poplack eds., 1989)

74. 45 C.F.R. § 46.306 (1991).

75. 45 C.F.R. § 46.406 (1991).

76. 45 C.F.R. § 46.204(d) (1991).

77. See *ETHICS ADVISORY BOARD: REPORT AND CONCLUSIONS: HEW SUPPORT OF RESEARCH INVOLVING HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER* (May 4, 1979).

78. See *supra* note 69 and accompanying text.

understanding for therapy.⁷⁹ Pierce began with the knowledge that embryonic fields determine the changes from benign to malignant cells as in testicular carcinoma. He proposed that it is possible that "an embryonic field capable of regulating every carcinoma" exists.⁸⁰ Studies of embryos might lead to purposeful induction of changes in cells from malignant to benign. Finally, physicians might substitute ways to induce malignant cells to change as a replacement for cytotoxic agents in cancer treatment.

Other cancer experts also see the value of embryo studies. Adamson's review of the role of oncogenes in development stressed the need to study cells in the entire period of gestation, e.g., embryonic, fetal, and placental.⁸¹ Reviewing molecular and cellular biology in pediatric cancer, Israel writes, "With great success, it has become possible to identify the chemical and biological agents that can transform normal cells to malignant ones . . . [and that] dramatic advances in cellular biology and recombinant DNA technology . . . [have] combined to focus attention on cancer as a genetic disorder"⁸²

If cancer is a genetic disorder, then hope for diagnosis and treatment is realistic given the tools of modern molecular biology. In this vein, the first true experiment involving rDNA in humans was a diagnostic study in cancer patients that teamed oncologists at NIH with a group studying experimental human gene therapy.⁸³ This experiment has created great hope for cancer treatment using genetic techniques. Physicians must, however, learn how to use these techniques, especially in the human embryo in which many cancers begin. It is starkly contradictory that federal policy encourages cancer drug studies in children, including phase I trials that can cause harm and even death from toxicity to a child with cancer,⁸⁴ and yet prohibits support of embryo studies to discover how such cancers might begin.

The same contradictions are found in the withholding of support from basic research using embryonic cells for genetic research. Such research may reveal the origins of classical mendelian genetic disorders. Caskey, a geneticist long interested in genetic diagnosis and treatment, states that the natural history of genetic disorders will be vastly improved "if we study em-

79. See G. Barry Pierce, *The Cancer Cell and its Control by the Embryo*, 113 AM. J. PATHOLOGY 117, 117 (1983).

80. *Id.* at 123.

81. Eileen D. Adamson, *Oncogenes in Development*, 99 DEV. 449, 449 (1987).

82. Mark A. Israel, *Molecular and Cellular Biology of Pediatric Malignancies*, in PRINCIPLES AND PRACTICE OF PEDIATRIC ONCOLOGY 39, 39 (Philip A. Pizzo & David G. Poplack eds., 1989).

83. See Leslie Roberts, *Human Gene Transfer Test Approved*, 243 SCI. 473, 473 (1989).

84. Wayne L. Furman et al., *Mortality in Pediatric Phase I Clinical Trials*, 81 J. NAT'L CANCER INST. 1193, 1193-94 (1989).

bryonic cells in early development to learn how genetic disease occurs at all. We must learn how and when genes that cause diseases 'turn on and off' as the embryo develops."⁸⁵ In human genetics this discovery is comparable in significance to Pasteur's discovery of the bacteriological origins of many common diseases. However, approaches to prevention and treatment on the molecular level are infinitely more complex than pasteurization or vaccination. Braude and others in the United Kingdom have learned that human gene expression first occurs between the four- and eight-cell stages of pre-embryo development.⁸⁶ Do any harmful genes begin to express *before* implantation? Can these expressions be detected by new techniques like polymerase chain reaction, from which the smallest amounts of DNA can be amplified many times for testing purposes? If so, then genetic diseases as well as chromosomal disorders could be diagnosed in the preimplantation embryo, thus enabling the avoidance of implantation of an affected embryo by selection.

Finally, another contradiction arises with respect to federal support of the Human Genome Project, which proposes to map the location of genes on human chromosomes by the year 2005.⁸⁷ This mapping project is on a collision course with federal policy not to support fetal and embryo research. Congress and the public have embraced the Human Genome Project largely on the basis of the *clinical* benefits it will bring. How can these benefits come without support of the research required? Until obstacles to clinical research are removed, these benefits will be long delayed or impossible to attain.

III. A WALL OF SEPARATION: PERMANENT OR TEMPORARY?

A growing wall of separation prevents federal research or review activities in public health and science linked to abortion or embryo research. The wall began in 1977-78, not in research but in medical services, when Congress separated the federal share of the costs of elective abortions for Medicaid-eligible women from other forms of state, local, and private funding.⁸⁸ The Hyde Amendment,⁸⁹ named for its sponsor, Representative Henry Hyde (R-

85. Fletcher, *supra* note 19, at D3.

86. See Peter Braude et al., *Human Gene Expression First Occurs Between the Four- and Eight-Cell Stages of Preimplantation Development*, 332 NATURE 459, 459-61 (1988).

87. NATIONAL INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUM. SERVS., THE HUMAN GENOME PROJECT: NEW TOOLS FOR TOMORROW'S HEALTH RESEARCH 4 (1991).

88. ALAN GUTTMACHER INST., ABORTIONS AND THE POOR: PRIVATE MORALITY, PUBLIC RESPONSIBILITY 6 (1979).

89. 122 CONG. REC. H20,410 (daily ed. June 24, 1976) (statement of Rep. Hyde). The Hyde Amendment became law in 1976. Departments of Labor and Health, Education, and

Ill.), limits federal funding only to cases of reported rape and incest and when two physicians attest that continuation of the pregnancy will result in severe and long-lasting damage to the woman's physical health. New increments to the wall have been added. Separating federal and private support for activities that bear directly on fetal diagnosis and therapy affect: 1) research involving the human embryo and fetus *in utero* from implantation to delivery or the human fetus *ex utero* after induced abortion; 2) the pre-implantation human embryo after IVF; and 3) in FTTR, as this Article has shown. Table 1 summarizes the scope of research activities that are blocked—the latter three activities—or hampered—the first.

The wall also prevents any federal funding of clinical research and development of the drug RU-486, which acts as an abortifacient. This drug is a possible treatment of Cushing syndrome, breast cancer, and other disorders. While NIH is able to do therapeutic research with RU-486, an FDA alert prevents the importation of RU-486 for use as an abortifacient. Although trials in other nations demonstrate its efficacy for this purpose, abortion opponents in Congress influenced the FDA to prohibit its use in the United States.⁹⁰ One does not have to be an opponent of abortion and embryo loss to desire a wall of separation between public and private funding. This desire may stem from hope for social harmony, similar to reasons that led to separation of private support of religion from the government's establishment and support of it. As noted above, Thomas Jefferson first used the phrase "wall of separation" to describe the effect on religions of the first clause of the First Amendment.⁹¹ In that context, the state is benignly neutral toward religion, not giving privilege or support to the activities of religious groups, nor making any law to prohibit the free exercise of religion by citizens. Just as the purpose of the First Amendment is ameliorative, *i.e.*, to prevent social conflict and special privilege stemming from state partiality in religious matters, so might a wall preventing federal involvement in fetal and embryo research be seen as peacemaking in the long run. In this vein, John Courtney Murray, a preeminent twentieth century Catholic scholar on church and state, stated that commitment to the First Amendment was a moral commitment, the equivalent to "articles of peace in a pluralist society."⁹² In the abortion controversy, the sheer divisiveness of the issues that

Welfare Appropriations Act of 1977, Pub. L. 94-439, § 209, 90 Stat. 1418, 1434. The Amendment went into effect in 1980, after the Supreme Court declared its constitutionality. *Harris v. McRae*, 448 U.S. 297, 326 (1980).

90. See Joyce Price, *Fear of Pro-Lifers Kept Abortion-Pill Tests From U.S.*, WASH. TIMES, Dec. 6, 1991, at A3.

91. See *supra* note 5.

92. JOHN C. MURRAY, *WE HOLD THESE TRUTHS: CATHOLIC REFLECTIONS ON THE AMERICAN PROPOSITION 85* (Image Books 1964) (1960).

TABLE 1. FEDERAL RESEARCH ACTIVITIES BLOCKED OR HAMPERED

- 1) Experimental somatic cell gene therapy in diagnosed and affected fetuses to be delivered.*
- 2) Fetal tissue transplant research with tissue or cells from early induced or spontaneous abortions** for treatment of diseases with genetic causes in liveborn affected individuals (Parkinson's disease, diabetes mellitus — Type I, diGeorge syndrome, and diseases that destroy normal hemoglobin or produce inadequate immune systems). Treatment in fetuses with these or similar conditions is also possible.***
- 3) Basic DNA research involving fetal tissues or embryonic cells after early induced abortion to understand gene expression and understand the natural history of genetic diseases including some familial cancers; such research could facilitate development of gene therapy by rDNA or by drugs.
- 4) Research on diagnosis of genetic disease in the human preimplantation embryo to learn if embryo selection can prevent genetic disease, avoid selective abortion, and perhaps open a way to germ-line gene therapy.****

* This activity is seen as "hampered" and the remaining three as "blocked." It is uncertain whether fetal gene therapy experiments can be approved by the Human Gene Therapy Subcommittee and the Recombinant Advisory Committee alone. Will a recommendation also be necessary from an Ethics Advisory Board (EAB) required by Federal regulation but unchartered since 1980? There is precedent for review of Federally supported fetal research by an EAB. Technically, a fetal gene therapy project would not require any use of the "secretarial waiver" of minimal risk so problematic in investigative fetal research in the context of elective abortion. Fetal gene therapy is therapeutic in intent, designed to "meet the health needs of . . . the particular fetus 45 C.F.R. § 46.206 (1991). However, the Secretary of HHS, can request advice from an EAB about ethical issues raised by individual applications or proposals. *Id.* § 46.204(b). Reinstating an EAB is controversial due to links with fetal research.

** Federally funded therapeutic research with fetal cells after spontaneous abortion would not be precluded by the present moratorium. However, there have been no proposals submitted to the NIH. Why? The answer may lie in the rate of infection and chromosomal abnormalities in spontaneous abortions. Another reason may be due to the absence of an Ethics Advisory Board to which to refer proposals. We must presume that there is a strong perception of an obstacle in the minds of investigators even though no obstacle exists.

*** For relevant discussions to these points, see *supra* notes 8-14 and Table 2.

**** John C. Fletcher & W.H. Anderson, *Human Gene Therapy: A New Stage of Debate*, L. MED. & HEALTH CARE (forthcoming 1992).

arise from religious and ethical beliefs seems irreconcilable. In this light, some might view a permanent wall of separation as fitting.

Another reason to desire separation between public and private support of research is recognition of the failure of government, under the pressures of abortion politics, to be a fair and impartial source of conflict resolution in research ethics.⁹³ Rather than be a wise patron of debate in this area, the government has become more than an active participant in the debate since it has used political authority to bring closure. The government has been unwilling or unable to provide a forum to study, debate, and resolve these issues. For example, Congress created a Congressional Biomedical Ethics Board in 1985 with a mandate to examine the power given to the Secretary of HHS to waive the minimal risk requirement in fetal research.⁹⁴ This Board was given the mandate to examine issues related to research in human genetics.⁹⁵ However, the Board collapsed in 1989, unable to function due to conflicts about the abortion issue.⁹⁶ Due to abortion politics, there is now no official national forum within which to consider these questions. However, neither peacemaking nor loss of confidence in government are reasons that outweigh four ethical and public policy arguments to dismantle this wall.⁹⁷

One of the primary ends of medicine—the relief of human suffering—gives rise to the first of the reasons to dismantle the wall. This obligation, also grounded in social ethics, must not be set aside in the research arena unless the *means* or *ends* of research violate ethical principles or rights cherished by a wide majority in society. A minority opposes embryo and fetal research on ethical grounds. However, if the cause is ethically justified, the will of a minority ought to be overruled. The obligation to relieve human suffering continues to be violated by vast deprivation in resources, knowledge, and personnel caused by federal disengagement from research and therapy in these areas. As the population ages and as the value of each healthy child continues to increase, these benefits will be more difficult to deny. The modern state's dependence on science, especially in human reproduction, is too deep and beneficial to reverse permanently. These benefits are being stunted

93. Myron Genel & Sarah Carr, *The Politics of Abortion are Stifling Promising Areas of Research*, CHRON. HIGHER EDUC., Nov. 15, 1989, at 56.

94. See Philip J. Hill, *Abortion Debate Clouds Research on Fetal Tissue*, N.Y. TIMES, Oct. 16, 1989, at A19.

95. *Id.*

96. *Id.*

97. See generally Kenneth J. Ryan, *Fetal Tissue Transplantation Research: Against The Moratorium*, 56 ASM NEWS 304 (1990) (maintaining that the moratorium on federal funding of transplantation research impedes progress in relieving human suffering, discourages the scientific community, creates a moral vacuum on the issue it is supposed to address, and cedes progress in medicine and science to other countries).

in the United States. However, if experience in the United States is comparable to that in the United Kingdom, clinical success will create a better climate to restore a federal/private sector partnership in the whole domain of science. As mentioned above, the project to map the human genome will create more pressure for support of clinical research to apply the knowledge gained. The Research Freedom Act is the first step in that process.

The second reason arises from a need to redress serious violations of academic and scientific freedom in the federal sector of science. Federal regulations that require one or more Ethical Advisory Boards have been flaunted openly by the last two Administrations. Due to this evasion of the law, no applications are being received at the NIH for support of embryo or fetal research. This forum must be restored to enable scientists to apply for funding under federal law and to have ethical disputes about their proposals properly discussed and negotiated. It is this author's opinion that the scientific and academic freedom of neurosurgeons at the NIH's Clinical Center to do FTTR has been violated by HHS officials. Many other scientists have been blocked from applying to the NIH for support of fetal or embryo research. Moreover, an opportunity for scientists to petition for redress of these grievances, guaranteed by the Administrative Procedure Act, was evaded when HHS officials chose not to conduct legally required hearings and rule-making for extending a moratorium on FTTR. If the argument to this point in this Article has been persuasive, it should lead to the conclusion that one of the greatest harms done to science in the federal sector has been not only lack of support but also the manipulation and elimination of the due processes created in the 1970s for resolving ethical and scientific disputes in proposed clinical research. Those persuaded by the argument must work to reverse the situation and to restore these national bridges of communication and negotiation, lest other legitimate areas of science be separated and functionally suppressed. If the United States is to support a federal sector of science, it should include every legitimate scientific area including research activities with the fetus and embryo.

A third reason to dismantle the wall is that the ban on FTTR and other restrictions on fetal and embryo research clearly violate the imperatives of distributive justice in clinical research. The ethics of research require that its benefits be shared equitably with those who can clinically benefit the most from the knowledge to be gained. Neither embryo research, clinical trials of FTTR, randomized trials of fetal diagnosis, nor fetal therapy⁹⁸ have yet occurred with federal support; therefore, the populations most affected by

98. The National Institute of Child Health and Human Development has recently decided to fund a clinical trial of fetal surgery for diaphragmatic hernia.

blockage of this research have been unjustly treated. Since tax proceeds are used to support federal research, Americans and their descendants who are most adversely affected by the withdrawal of federal support for fetal and embryo research are unfairly taxed. As a result of these practices, the burdens of research are unfairly distributed to the private sector and other nations.

A final reason was given by the physician-investigators who have created a new national body⁹⁹ to monitor FTTR and embryo research. Dr. Kenneth Ryan, one of their leaders, noted a "moral vacuum" for the oversight of FTTR and embryo research which, if unfilled, will lead to premature and untested standards for clinical practice. This has already occurred with in vitro fertilization and other methods of assisted reproduction. Scientists and their colleagues in ethics, law, and other disciplines need to support this new group in its formative period and activities. However, they also must not lose sight of a goal to dismantle, by legal means, a wall in the federal sector that impedes the goal of medicine and the progress of science and that unjustly deprives millions of Americans and their children of knowledge that will lead to better health.

IV. RESOURCES IN RESEARCH ETHICS: ADEQUACY OF THE BELMONT REPORT

There is no legal or constitutional question about the authority of the Administration or Congress to deny funds or NIH scientific peer review to these activities.¹⁰⁰ No constitutional right for research funding exists. The U.S. Supreme Court has ruled that government may select to promote one or more interests above a constitutionally protected activity, such as, in this case, the protection of the interests of fetuses and embryos above the unimpeded freedom of research understood as free speech.¹⁰¹ The major goal of this Article is to question the ethical and public policy wisdom of a wall of separation. Is a separation similar to that which exists between organized religion and the state necessary between public and private support of fetal and embryo research? The answer is that while religion and government need to be vigorously separated, biomedical research and government do

99. See *supra* note 42 and accompanying text.

100. This Article does, however, raise two legal questions for examination: 1) Have HHS officials duly observed the requirements of the Administrative Procedure Act in continuing the moratorium on FTTR "indefinitely" with no public notice or hearings?; and 2) Have HHS officials violated Federal regulations by avoiding to recharter an EAB? See 45 C.F.R. § 46.204(b) (1990).

101. See John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1209 (1978).

not. Does the moral issue of research arise from its source of funding? If the answer to this question is obvious, then political and scientific leaders need to turn to the task of dismantling a wall which has been erected in the wrong place. In the meantime, many health benefits have already been lost, as documented by the Institute of Medicine.¹⁰² There have already been extremely serious consequences to the limited quality and quantity of U.S. biomedical research in treatment of infertility, fetal diagnosis, maternal-fetal medicine, reproductive genetics, and cancer.

The foremost reason to dismantle the wall is a moral obligation to learn if paths of research will lead to therapies for fetuses and live-born persons which would relieve great suffering and prevent premature death. This obligation falls equally on the public and private sector. Therapy, the end of these research activities, is virtually nonobjectionable. As mentioned above, the *means* of such research should also be ethically acceptable to the majority. The issue of means can only be worked out in a public forum with full debate about the moral significance of disputed means. The most objectionable actions of public officials, in terms of this requirement, are to dismantle or abandon all duly authorized public forums for such bioethical and scientific debate—except the Congressional forum. No national bioethics forum exists in the United States today to address the agenda in research ethics.

The United States must begin anew in the 1990s to restore the progress in research ethics made in the 1970s. To reinvigorate this arrested process, we should enlarge our vision of goals for research, the ethical principles that structure and pattern research activities, and the tasks that must be done in prior group review of specific projects.

What are the major ethical resources for the particular tasks of learning through biomedical and behavioral research? The Belmont Report¹⁰³ was an early consensus document on the ethics of biomedical research in the United States. It set forth three major ethical principles to guide research with human subjects, including fetuses. The principles include respect for persons, beneficence, and justice.¹⁰⁴ An argument can be made however that a more complex set of five ethical principles, outlined in Table 2, is required to guide the scope and practices of biomedical research.

The Belmont Report interpreted the principle of beneficence to contain within it the imperatives to avoid and prevent harm.¹⁰⁵ Would it not serve ethical analysis better to use the principle of beneficence only as the frame-

102. See SUZANNE WYMELENERG, *SCIENCE AND BABIES: PRIVATE DECISIONS, PUBLIC DILEMMAS* 147-49 (1990).

103. BELMONT REPORT, *supra* note 7, at 4-10.

104. *Id.*

105. *Id.* at 6.

TABLE 2. ETHICAL PRINCIPLES FOR PRACTICE AND RESEARCH

RESPECT FOR PERSONS: The duty to respect the self-determination and choices of autonomous persons, as well as to protect persons with diminished autonomy (e.g., young children, mentally retarded persons, and those with other mental impairments).

BENEFICENCE: The obligation to secure the well-being of persons by acting positively on their behalf and, moreover, to maximize the benefits that can be attained.

NONMALEFICENCE: The obligation to minimize harm to persons and, wherever possible, to remove the causes of harm altogether.

PROPORTIONALITY: The duty, when taking actions involving risks of harm, to so balance risks and benefits that actions have the greatest chance to result in the least harm and the most benefit to persons directly involved.

JUSTICE: The obligation to distribute benefits and burdens fairly, to treat equals equally, and to give reasons for differential treatment based on widely accepted criteria for just ways to distribute benefits and burdens.

Material adapted from: 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* (1983); TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 121 (3d ed. 1989).

work for maximizing the benefits of research? It would make sense to turn to a clearer principle, nonmaleficence, to guide the imperative to avoid and prevent harm. The principle of nonmaleficence, prominent in the history of biomedical ethics,¹⁰⁶ is relevant to ethical issues caused by the necessity of taking risks and doing harm by research.

According to Belmont, beneficence was the primary source by which assessments of risks and benefits to human subjects and society were to be made.¹⁰⁷ The principle of proportionality, however, provides more direct and cogent guidance for riskbenefit assessments, one of the most difficult tasks in research ethics especially when the fetus is involved. When on the brink of research justified by a goal of seeking a remedy for great suffering and yet unattainable except by doing some harm, researchers need guidance on the question of *how much* harm is proportionate to the goal sought. Do the expected benefits outweigh the risks that can be reasonably expected? The proportionality principle is a major source of guidance in this task. An-

106. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 121 (3d ed. 1989).

107. BELMONT REPORT, *supra* note 7, at 7.

other way to understand the function of the proportionality principle is to see it working on second-order questions in research review. In prior review of any research with human subjects, there is a first-order obligation to ask: "Should this research be done at all?" To examine this question fully requires attention to four of the five ethical principles that are shown in Table 2. Once good reasons for a "yes" appear, the risk-benefit issues can be more fully treated in the context of proportionality. Turning to proportionality issues too soon is a sign of avoidance of first-order questions.

Belmont also needs to re-examine its discussion of the tasks entailed in the protection of human subjects. The Report discussed three tasks: informed consent, risk-benefit assessment, and selection of subjects.¹⁰⁸ These are clearly indispensable tasks, but are there not two more? The Belmont Report focused primarily on protection of human *subjects*. Who will be concerned with the discussion of appropriate *goals* for research and protection of the *freedom of the pursuit* of important biomedical knowledge by researchers? The authors of the Belmont Report probably assumed that freedom of research was not a major issue in the research review process. The EAB was designed to respond to long-range social and ethical issues embedded in specific research projects; Institutional Review Boards (IRBs) were seen as inappropriate to deal with these long-range issues. But who shall address these tasks in view of the "moral vacuum" that exists at the national level? When a controversial research protocol in fetal or embryo research comes before an IRB, it also raises long-term social and ethical issues. In fact, federal regulations permit the hiring of consultants or other experts to consider special issues confronting an IRB.¹⁰⁹ NIH's Office of Protection from Research Risks (OPRR) has recognized that the absence of an EAB creates a serious problem for controversial protocols that should be referred to this national forum. In lieu of an EAB, the OPRR recommends augmenting the IRB with experts who can broaden the scope of discussion beyond the immediate riskbenefit analysis of the project.¹¹⁰ As long as the nation and its scientists are deprived of an EAB, the IRBs are the only publicly accountable bodies for such discussions.

The prohibitions on the federal side of the wall should not be permitted to freeze out research on the private side. To ensure the fullest scope of research freedom on the private side—until the wall is removed—two tasks can be added to IRBs: discussion of goals for research and protection of the freedom to pursue important biomedical knowledge.

108. *Id.* at 10-20.

109. 45 C.F.R. § 46.107(f) (1991).

110. John C. Fletcher, *How Abortion Politics Stifles Science*, WASH. POST, Feb. 5, 1989, at D3.

In conclusion, the reader is referred to the four activities in Table 1. These activities are ranked in the order of their clinical relevance to fetuses, to live-born persons suffering from genetic or other diseases, and to future development of human gene therapy. These are the research activities most negatively affected by the wall of separation. When the wall is dismantled, each activity will need to be ranked in a hierarchy of social priorities for biomedical research.¹¹¹

111. For a thorough discussion of the ethical, scientific, and political aspects of these issues, see John C. Fletcher, *Controversies in Research Ethics Affecting the Future of Human Gene Therapy*, 1 *HUM. GENETIC THERAPY* 307 (1990); John C. Fletcher, *Fetal Tissue Transplantation Research and Federal Policy: A Growing Wall of Separation*, 5 *FETAL DIAG. THERAPY* 211 (1990).

