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## BIOETHICAL CATCH-22: THE MORATORIUM ON FEDERAL FUNDING OF FETAL TISSUE TRANSPLANTATION RESEARCH AND THE NIH REVITALIZATION AMENDMENTS

In 1988, a moratorium on the use of federal funds for fetal tissue transplantation research (FTTR)<sup>1</sup> halted the promise of a cure for millions of Americans suffering from Parkinson's disease, diabetes, and other debilitating conditions.<sup>2</sup> Since the moratorium began, private and international experimentation continues with mixed success.<sup>3</sup> In the foreground, however, the debate rages over federal funding for fetal tissue transplantation from induced abortions into humans.<sup>4</sup>

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1. Fetal Tissue Transplantation Research (FTTR) refers to the experimentation and research with human fetal tissue for transplantation into humans. See generally John T. Hansen & John R. Sladek, Jr., *Fetal Research*, 246 SCI. 775, 778 (1989) (discussing the characteristics and contributions of fetal research and fetal tissue research). Tissue is removed from the fetus after the removal of the fetus from the mother's womb by spontaneous abortion or induced abortion. *Id.* at 775. After the tissue is extracted, it is injected surgically into the appropriate organ of the recipient patient. *Id.* at 778. Researchers hope that the natural plasticity of the new fetal tissue will allow it to survive, adapt, and replace what the recipient patient lacks, for example, dopamine-producing cells for the patient with Parkinson's or insulin-producing cells for the diabetic patient. *Id.*

2. See *Fetal Tissue Transplantation Research, 1990: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 101st Cong., 2d Sess. 1 (1990) [hereinafter *Fetal Tissue Transplantation Research*] (opening statement of Rep. Henry A. Waxman); see also 138 CONG. REC. S16,232 (daily ed. Oct. 2, 1992); Robert J. Levine, *Fetal Research: The Underlying Issue*, SCI. AM., Aug. 1989, at 112; Patricia M. Ravalgi, *Bush Abandons Victims of Parkinson's Disease*, N.Y. TIMES, Nov. 18, 1989, at 27.

3. See, e.g., William M. Landau, *Artificial Intelligence: The Brain Transplant Cure for Parkinsonism*, 40 NEUROLOGY 733, 739-40 (1990) (The Chairman of Neurology at Washington University in St. Louis surveyed the international reports on fetal tissue transplantation and concluded that the data was worthless and that the science was irresponsible); Olle Lindvall, *Prospects of Transplantation in Human Neurodegenerative Diseases*, 14 TRENDS IN NEUROSCIENCES 376 (1991) (leading researcher reported measured success in the transplant); Jean Marx, *Fetal Nerve Grafts Show Promise in Parkinson's*, 247 SCI. 529, 529 (1990) (stating that fetal tissue transplants produced a clinically significant improvement in a patient's condition); Michael Specter, *Fetal Cells Seem to Aid Parkinson's Patient*, WASH. POST, Feb. 2, 1990, at A3 (reporting that Swedish scientists demonstrate that fetal tissue transplants may be an effective treatment for Parkinson's); R. Weiss, *Fetal-Cell Transplants Show Few Benefits*, 134 SCI. NEWS 324 (1988) (stating that several researchers concede that few Parkinson's patients show definite clinical improvement after transplantation).

4. See *Finding Medical Cures: The Promise of Fetal Tissue Transplantation Research Freedom, 1991: Hearings on S. 1902 Before the Senate Comm. on Labor and Human Re-*

In the House of Representatives and the Senate, the debate culminated with the passage of the National Institutes of Health (NIH) Revitalization Amendments.<sup>5</sup> In addition to authorizing NIH programs, the \$5.4 billion bill included measures designed to overturn the moratorium on federal funding for the transplantation research.<sup>6</sup> Brimming with controversy, the bill was forwarded to the White House where it met President Bush's promised veto.<sup>7</sup> The veto was sustained when the House failed to rally the two-thirds majority vote<sup>8</sup> necessary to override a veto, leaving the moratorium intact and the controversy alive.<sup>9</sup> Modified measures were introduced in both

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sources, 102d Cong., 1st Sess. 1 (1991) [hereinafter *Finding Medical Cures*]; 137 CONG. REC. H5826 (daily ed. July 25, 1991) (House debate on National Institutes of Health Revitalization Amendments of 1991); *NIH Reauthorization, 1991: Hearings on H.R. 1532 Before the Subcomm. on Health and Environ. of the House Comm. on Energy and Commerce*, 102d Cong., 1st Sess. 1, 2 (1991); 138 CONG. REC. S16,228 (daily ed. Oct. 2, 1992) (cloture motion on NIH Revitalization Amendments); 138 CONG. REC. S16,577 (daily ed. Oct. 5, 1992) (NIH Revitalization Amendments put on next session's calendar due to deadlock); Gina Kolata, *Miracle or Menace?*, REDBOOK, Sept. 1990, at 174, 175 (outlining the claims of opponents and proponents); *Fetal Tissue Research: Right or Wrong?*, REDBOOK, Dec. 1990, at 170 (publishing reader survey results); James Mason, *Fetal Transplant Fallacies*, WASH. TIMES, June 16, 1992, at F3 (Dr. James Mason of the U.S. Public Health Service addresses what he considers to be the misrepresentations of the success of and the need for fetal tissue transplants from induced abortions).

5. H.R. 2507, 102d Cong. 2d Sess. (1992). See Marlene Cimon, *House Votes Freer Use of Fetal Tissue; Veto Looms*, COURIER J., May 29, 1992, at A1, A7. Since 1991, the appropriation has increased from \$4.4 billion to \$5.4 billion, although there was an erroneous report of \$7.3 billion. *Id.* at A7. See also Malcolm Gladwell, *Senate Votes to Lift Ban on Fetal Tissue Research*, WASH. POST, Apr. 3, 1992, at A2; *Senate Votes to Lift Ban on U.S. Fetal Tissue Work*, COURIER J., June 5, 1992, at A2.

6. Guy Gugliotta, *House Votes to Drop Ban on Fetal Research Funds*, WASH. POST, July 26, 1991, at A1.

7. Letter from George Bush, President of the United States, to the House of Representatives, 1 (June 23, 1992) (vetoing H.R. 2507, 102d Cong. 2d Sess. (1992)) (on file with the *Journal of Contemporary Health Law and Policy*); *Bush Vetoes Fetal Tissue Bill*, COURIER J., June 24, 1992, at A12; 137 CONG. REC. H5830 (daily ed. July 25, 1991) (statement of Administration Policy: "H.R. 2507 is unacceptable, and if it were presented to the President in its current form, his senior advisors would recommend a veto."). On June 25, 1992, the House of Representatives introduced H.R. 5495 as an altered successor to H.R. 2507. H.R. 5495, 102d Cong., 2d Sess. (1992). The administration renewed its objections to this legislation which, according to HHS, did not substantively alter the legislative intent of H.R. 2507. Letter from Louis W. Sullivan, M.D., Secretary of Health and Human Services, to Rep. Henry Waxman, Chairman of the House Subcommittee on Health and the Environment, (July 28, 1992) [hereinafter *Health and Environment Letter*] (on file with the *Journal of Contemporary Health Law and Policy*).

8. *Fetal-Tissue Veto Stands; New Measure Introduced*, COURIER J., June 25, 1992, at A3 (reporting a vote of 271 to 156 in favor of the bill).

9. *Id.* (reporting that Rep. Waxman immediately introduced a new bill that "would require all researchers to get their material from the fetal tissue bank proposed by the president"); Exec. Order No. 12,806, 57 Fed. Reg. 21,589 (1992); *Fetal Tissue*, USA TODAY, May 20, 1992, at A4 (reporting on the President's proposal for national tissue banks); Letter from

Houses of Congress, but a Senate filibuster in the last hours of the session foreclosed a second veto and placed the bill on the 1993 calendar.<sup>10</sup>

The field of fetal tissue research,<sup>11</sup> currently a fraction of human health research<sup>12</sup> but with the potential for a six billion dollar industry,<sup>13</sup> is the focus of inevitable controversy. FTTR, as a sub-field, presents a volatile combination of the politics of abortion, the international research race, and the cries of millions of Americans suffering from Parkinson's disease and other crippling debilitations. Thus, using fetal tissue as a potential cure commands the interest and the passion of many.

FTTR from induced abortions distinguishes itself from federally approved fetal tissue research because it connects a potentially beneficial health pursuit with a critically divisive moral issue of our day—abortion.<sup>14</sup> By its very nature, FTTR cannot automatically enjoy the approval given to other research pursuits, primarily because at its very core lies an unresolved ethical issue.<sup>15</sup> This issue is found in the connection between the procedures of aborting the fetus, harvesting the tissue, and transplanting it into a needy recipient.<sup>16</sup> Unlike transplantation from ectopic pregnancies<sup>17</sup> or spontane-

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James Mason, Assistant Secretary for Health, to the Louis Sullivan, Secretary of Health and Human Services, (July 28, 1992) (on file with the *Journal of Contemporary Health Law and Policy*) (discussing the New York Times critique by Philip Hilts of the Administration's plan for a fetal tissue bank); see also Michael York, *Fetal-Tissue Research Ban Challenged*, WASH. POST, Oct. 22, 1992, at A29.

10. 138 CONG. REC. S16,578 (daily ed. Oct. 5, 1992) (Senate majority leader George Mitchell committing himself to putting the NIH Revitalization Amendments on the Senate floor the day following the inauguration of President Clinton). President-elect Clinton, however, is committed to nullifying the moratorium immediately. *Another Win for the Zealots*, WASH. POST, Oct. 7, 1992, at A24.

11. Fetal tissue research, as distinguished from fetal research, (the latter dealing with experiments therapeutic to the fetus *in utero*) has been a medical pursuit for decades and is credited with the discovery of the polio vaccine in the 1950s. Dorothy Lehrman, *Summary: Fetal Research and Fetal Tissue Research* ASSOCIATION OF AMERICAN COLLEGES (1988) at v, 9. Fetal tissue cells are used extensively in testing vaccines, virus research, and numerous other NIH-sponsored projects not affected by the ban on federally funded transplantation research. NATIONAL INSTITUTES OF HEALTH HUMAN FETAL TISSUE RESEARCH SUPPORTED IN FISCAL YEAR 1990, 1 (1991) [hereinafter NIH FY 90].

12. NIH FY 90, *supra* note 11, at 1. "Eleven NIH institutes supported 103 projects that utilized human fetal tissue in research for a total of \$7.8 million, or 0.1 percent of the NIH budget." *Id.*

13. See Peggy Finston & Gregory J. Millman, *Alone and Undaunted by the Issues*, OTC REV., Oct. 1989, at 26 (reporting potential market of \$6.5 billion in diabetes and Parkinson's, exclusive of other chronic illnesses).

14. See John C. Fletcher, *Abortion Politics, Science and Research Ethics: Take Down the Wall of Separation*, 8 J. CONTEMP. HEALTH L. & POL'Y 113, 115 (1992) ("In the abortion controversy, the sheer divisiveness of the issues that arise from religious and ethical beliefs seems irreconcilable.").

15. *Id.*

16. REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES

ous abortions,<sup>18</sup> which are permitted by the ban, FTTR directly links decisions and procedures immersed in the moral controversy over induced abortion.<sup>19</sup>

This Comment outlines the debate over the transplantation research affected by the moratorium on the use of federal funds for FTTR. Whether fetal tissue from induced abortions should be procured for transplantation into humans, and if so, how its use can be regulated is a significant contemporary challenge for public policy makers. Part I of this Comment delineates the formation of public policy on the issue. Part II explains the content of the NIH Amendments as a new direction for public policy. Part III discusses the potential benefits and risks of federal funding of FTTR. Finally, part IV addresses whether the executive ban or the legislative measure is a sound, farsighted public policy.

#### I. THE MORATORIUM ON FEDERALLY FUNDED FETAL TISSUE TRANSPLANTATION RESEARCH AND THE NIH PANEL

In accordance with existing federal regulations, the first request for federal funding of a fetal tissue transplant was made public in 1987.<sup>20</sup> The NIH submitted the proposal to the Assistant Secretary for Health for his ap-

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OF HEALTH, HUMAN FETAL TISSUE TRANSPLANTATION C11 (1988) (statement by James Bopp) ("[T]he essential ethical question before the Panel was whether or not the beneficial prospect of transplantation research is subverted by its association with induced abortion.").

17. An ectopic pregnancy occurs when the fertilized ovum implants outside the endometrial lining of the uterine cavity (usually in a fallopian tube). F. GARY CUNNINGHAM ET AL., *WILLIAMS OBSTETRICS* 511 (18th ed. 1989). The first fetus to fetus transplant was accomplished in the U.S. with tissue from a baby removed as a result of an ectopic pregnancy, not an induced abortion. Letter from National Right to Life Committee to Members of the House of Representatives 2 (July 23, 1991). *But see Finding Medical Cures, supra* note 4, at 20, 23 (oral testimony of Reverend Walden, in support of lifting the ban, did not reveal that this fetal tissue came from an ectopic pregnancy, a transplant unaffected by the moratorium).

18. "The incidence of spontaneous abortion . . . is between 20 percent and 62 percent with an average of 43 percent." F. GARY CUNNINGHAM, *supra* note 17, at 489. The incidence of ectopic pregnancy is greater than 1 percent. *Id.* at 511. The fetal tissue banks set up by Executive Order 12,806, 57 Fed. Reg. 21, 589 (1992), rely on a supply of adequate tissue from such sources; and much of the debate on the modified NIH bills revolved around the issue of adequate quantity and quality of fetal tissue from ectopic pregnancies and spontaneous abortions for the federal fetal tissue bank. 138 CONG. REC. S16,228 (daily ed. Oct. 2, 1992) (statement of Sen. Kennedy suggesting that the federal tissue bank idea is a sham); *but see* letters from leading researchers provided by Sen. Hatch that indicate that five to seven percent of spontaneous abortions would yield acceptable tissue, as compared to the six to nine percent present yield of induced abortions. *Id.* at S16,236.

19. Fletcher, *supra* note 14, at 113, 115.

20. CONSULTANTS TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMANS FETAL TISSUE TRANSPLANTATION RESEARCH PANEL A3 (vol II 1988), [hereinafter FTTR PANEL II].

proval.<sup>21</sup> In March of 1988, the Department of Health and Human Services (HHS) denied the request pending a requirement that the NIH convene a committee to "examine comprehensively the use of human fetal tissue from induced abortions for transplantation."<sup>22</sup> The denial of funding for this research did not ban the use of federal funds for transplantations using fetal tissue from other acceptable sources such as ectopic pregnancies or for otherwise acceptable fetal tissue research, such as maternal-fetal transmission of the AIDS virus research.<sup>23</sup> It did, however, institute a narrow moratorium on the use of federal funds for FTTR.<sup>24</sup> Contrary to the recommendations of the subsequently convened NIH panel,<sup>25</sup> the Secretary of HHS extended the limited moratorium on November 2, 1989 for an indefinite time, stating that "in the specific area of transplantation to humans involving fetal tissue from induced abortions, it is not appropriate that federal support be provided."<sup>26</sup>

#### A. Legal Context of the Moratorium

##### 1. State Law

The Uniform Anatomical Gift Act (UAGA) was adopted by all fifty states between 1969-1973 and serves as the legal guide for the donation of one's body or body parts and for the donation of the body or body parts of another, the decedent.<sup>27</sup> "Decedent" is defined as a deceased individual and includes a stillborn infant or fetus.<sup>28</sup> The UAGA requires written documentation or some record of oral gift to ensure that appropriate consent is obtained, and prioritizes the decision making power of the next of kin to ensure that the interests of the decedent and the family are protected.<sup>29</sup> The state-adopted UAGA is the controlling state law governing the donation and use of the dead fetus. It appears, however, that a significant amount of fetal

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21. *Id.*

22. Memorandum from the Robert E. Windom, M.D., Assistant Secretary for Health to James B. Wyngaarden, M.D., Director of NIH (Mar. 22, 1988) in FTTR PANEL II, *supra* note 20, at B1 [hereinafter Memorandum].

23. NIH FY 90, *supra* note 11, at 3.

24. Memorandum, *supra* note 22, at B3.

25. *Id.* at A3. See generally CONSULTANTS TO THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH (vol. I 1988) [hereinafter FTTR PANEL I].

26. Statement by Louis W. Sullivan, Secretary of Health and Human Services, HHS NEWS (U.S. Dep't of Health and Human Servs., Washington, D.C.), Nov. 2, 1989 [hereinafter *The Sullivan Statement*].

27. UNIF. ANATOMICAL GIFT ACT, 8A U.L.A. 1-47 (West 1983 & Supp. 1992) [hereinafter UAGA] (The UAGA revised in 1987 has not been adopted by all 50 states.).

28. UAGA, *supra* note 27, § 1(b).

29. *Id.* §§ 2, 3, 7.

donation and research is not done in accordance with the UAGA.<sup>30</sup> In addition to the UAGA, a scattering of state laws exist that address the experimentation, disposition, sale, and transport of fetuses and fetal tissue.<sup>31</sup>

While many state laws regarding protection of the fetus were struck down in 1973 following the legalization of abortion,<sup>32</sup> some states enacted legislation to prohibit the experimental use of the aborted fetus.<sup>33</sup> A number of these statutes were held unconstitutional, however, on the grounds that they could interfere with a woman's access to abortion.<sup>34</sup> In a contrasting development, states have enacted laws that affirmatively provide for experimentation on tissue from dead fetuses.<sup>35</sup>

## 2. Federal Law

The Public Health Service Act (the Act),<sup>36</sup> is the federal law that regulates research where federal funds are involved.<sup>37</sup> The Act's chapter entitled "Protection of Human Subjects" provides the main source of guidance regarding federal policy on federally funded human research activities.<sup>38</sup> This chapter was drafted upon the recommendation of the congressionally mandated National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.<sup>39</sup> The intent of the chapter on the protection of human subjects was to ensure that HHS did not fund inhu-

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30. Kolata, *supra* note 4, at 176 ("All too often, the woman is not even told that the tissue will be used for medical research.").

31. Lori B. Andrews, *State Regulation of Human Fetal Tissue Transplantation*, in FTTR PANEL II, *supra* note 20, at D1-D20 (discussing the variety of state laws relating to the regulation of research on, payment for, and disposition and transport of dead fetuses, lives fetuses, and embryos; and noting that the most significant factor in the regulations is the abortion question). Andrews concludes that the regulations are inadequate for the demands of the research. *Id.* at D20.

32. *Roe v. Wade*, 410 U.S. 113 (1973); *Doe v. Bolton*, 410 U.S. 179 (1973).

33. David H. Smith et al., *Using Human Fetal Tissue for Transplantation and Research: Selected Issues in FTTR PANEL II*, *supra* note 20, at F24-27.

34. *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986) (holding that Louisiana abortion statute was unconstitutionally vague as to the term "experimentation" as well as unconstitutional in its requirement that a physician discuss instructions for disposition of fetal remains); *Lifchez v. Hartigan*, 735 F. Supp. 1365 (N.D. Ill. 1990) (holding that statute unconstitutionally restricts a woman's right to make reproductive choices); *cf.* *Planned Parenthood of Minnesota v. Minnesota*, 910 F.2d 479 (8th Cir. 1990) (holding statute did not restrict a woman's abortion decision).

35. Cal. Health & Safety Code § 25,956 (West 1984); *see also* Smith et al., *supra* note 33, at F26 (categorizing state legislation and noting that California gives "explicit protection for the use of tissue for dead fetuses" as compared to other states with varying restrictions and prohibitions).

36. 42 U.S.C. § 201 (1992).

37. 45 C.F.R. § 46.101 (1990).

38. Protection of Human Subjects, 45 C.F.R. § 46.101-124 (1990).

39. NATIONAL COMM. FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL

mane experimentation.<sup>40</sup> As this regulation was being formulated in the mid-1970s, concerns about nonconsensual experimentation on adult subjects weighed heavily in the drafting process.<sup>41</sup> Additionally, allegations of experimentation on live fetuses raised during the drafting process exacerbated these concerns.<sup>42</sup> Thus, HHS is responsible for regulating sponsorship by or affiliation of the government with an activity that subjects a person to more than the minimal standard of risk, whether he or she is a prisoner or a patient, viable or non-viable.<sup>43</sup>

The chapter on protection of human subjects specifically addresses the care required in research using pregnant women and fetuses, both *in* and *ex utero*.<sup>44</sup> As to the dead fetus, however, federal law is deferential to states' powers requiring only that "[a]ctivities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted . . . in accordance with any applicable State or local laws regarding such activities."<sup>45</sup> In effect, no federal law regulates the use of the dead fetus or fetal tissue, unless such use falls under the 1988 ban.

The substance of federal law, summed up in one paragraph of the Code of Federal Regulations suggests that the federal government has no interest in dead fetal tissue.<sup>46</sup> However, HHS, as the agent of the federal government, has been anything but disinterested or deferential in the fetal tissue debate. Perhaps this inconsistency arises because FTTR involves more than access to dead fetal tissue. In order to make the government's position, on behalf of the public, clear, the administration publicly modified the federal policy. Further, NIH and its status as the world's premier biomedical center,<sup>47</sup> the source of the FTTR request that instigated the moratorium, merits public concern. The federal government recognized that disinterested deference ab-

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AND BEHAVIORAL RESEARCH, RESEARCH ON THE FETUS: REPORT AND RECOMMENDATIONS (1975), reprinted in 40 Fed. Reg. 33,530 (1975).

40. *Id.*

41. Barry J. Hoffer & Lars Olson, *Ethical Issues in Brain-Cell Transplantation*, 14 *TRENDS IN NEUROSCIENCES* 384, 385 (1991); Lehrman, *supra* note 11, at 2-3. The Tuskegee study began in the 1930s and was run by the United States Public Health Service to test the long-term effects of syphilis. *Id.* The subjects of the study, 400 black men, were not told if they had the disease and were not treated. *Id.*

42. Lehrman, *supra* note 11, at 3.

43. *Id.* at 2-8, 14; 45 C.F.R. § 46 (1990) (implementing the concern in the chapters on the protection of human subjects).

44. 45 C.F.R. §§ 46.210-211, Subpart B - Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women and Human in Vitro Fertilization.

45. 45 C.F.R. § 46.210 (1990).

46. *Id.*

47. 138 CONG. REC. S16,228, S16,231 (daily ed. Oct. 2, 1992).



dicates its responsibility in safeguarding the public interest in the supervision of cutting-edge health research.

### *B. Ethical Considerations of the Moratorium*

The duty of ethical scientific experimentation is often in conflict with a research race that demands that scientists vigorously compete to find the cures to humanity's ills. Accordingly, the duty to improve health<sup>48</sup> is challenged by the policy informing the Protection of Human Subjects regulation. HHS answers the inevitable ethical questions that arise when these duties conflict, potentially or actually, with three mechanisms: (1) Institutional Review Boards,<sup>49</sup> (2) Ethics Advisory Boards,<sup>50</sup> and (3) funding denials.<sup>51</sup>

For example, HHS prohibited what it determined to be ethically unacceptable research by denying a research grant for FTTR.<sup>52</sup> This ignited the present controversy. Apparently, fetal tissue research had proceeded according to the federal guidelines for decades, unless it fit into the specific exception that disallows the use of federal funds for the transplantation into humans of human fetal tissue from induced abortions.<sup>53</sup>

This exception placed no legal limits on private research, which continues virtually unregulated.<sup>54</sup> Private research, however, is conducted on a smaller scale than some expected, probably as a result of the financial and political effect of the ban.<sup>55</sup> Countering this negative pressure on private research was the evaluative component of the moratorium produced by the NIH Human Fetal Tissue Transplantation Research Panel (the NIH

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48. 138 CONG. REC. S16,228-29, S16,231 (daily ed. Oct. 2, 1992) (statements of Sen. Kennedy and Sen. Wellstone); 137 CONG. REC. H5827 (daily ed. July 25, 1991) (statement of Rep. McEwen).

49. 45 C.F.R. §§ 46.102-.113, 46.205 (1990). Institutional Review Boards (IRBs) address compliance with the "protection of human subjects policy" at the local institutional level. *Id.*

50. *Id.* § 46.204.

51. 45 C.F.R. §§ 46.101-.211 (1990).

52. Memorandum, *supra* note 22, at B3.

53. *Id.* at B1-3 (memorandum withholding approval of federal funding for a fetal tissue transplant pending an ethical examination of the issues); *The Sullivan Statement*, *supra* note 26, at 1 (extending the moratorium).

54. Private researchers are outside the scope of the federal ban as is an unregulated market in human fetuses, fetal parts and fetal tissue. Kolata, *supra* note 4, at 175. The natural forces of supply, demand, and private funding fuel an underground operation in what some estimate is a traffic in hundreds of thousands of fetuses. *Id.* American research continues at Yale University and the University of Colorado. George Archibald, *NIH Skirts Ban on Transplants of Fetal Tissue*, WASH. POST, Jan. 6, 1992, at A7.

55. *Abortion Issue Chills Research: Fetal Tissue Fund Ban Sidelines U.S. Experts*, WASH. POST, Mar. 27, 1990, at A1, A8 (concluding that the ban had a chilling effect on American researchers experimenting with fetal tissue transplantation).

panel).<sup>56</sup> Created to examine the ethics of FTTR,<sup>57</sup> the panel produced the most widely cited support for lifting the ban.

### C. *The NIH Human Fetal Tissue Transplantation Research Panel*

The NIH panel was formed in 1988 in accordance with the funding denial for fetal tissue transplants.<sup>58</sup> The NIH director convened the panel to answer ten questions from HHS that hinged on the moral relevance of the source of fetal tissue.<sup>59</sup> These ten questions, and how they were answered (i.e., the respective majority and minority positions) frame the debate as it exists today. The drafting of the NIH Amendments, which is to be discussed in Part II, was explicitly based on the panel's recommendation that the decision to abort should be separated in every way possible from the decision to donate the fetus for research.<sup>60</sup> The panel's recommendation of funding the research and HHS's negative response fueled the congressional abrogation of executive power evidenced in the NIH Amendments.<sup>61</sup> HHS continues to rebut the panel logic of separability and rests its case for extending the moratorium on reasons disposed of by the panel.<sup>62</sup> The debate rages on.

Not surprisingly, the NIH research community welcomed the panel recommendations. Critics of the panel, however, contend that the NIH Director purposefully composed the panel in favor of funding the research.<sup>63</sup> Thus, although the panel's recommendations represent expert opinions, these recommendations must be considered in light of the views of the panel members and of those who testified before the panel.<sup>64</sup> In one analysis of the ethical decision making capacity of the panel, a commentator points out that

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56. Archibald, *supra* note 54, at A7.

57. Memorandum, *supra* note 22, at B1-3 (directing the NIH director "to convene one or more special advisory committees").

58. *Id.* at B1.

59. *Id.* at B1-2.

60. Letter from Arlin M. Adams, Chairman of the Panel, to James B. Wyngaarden, Director of NIH (Dec. 12, 1988) in FTTR PANEL I, *supra* note 25, at i.

61. H.R. 2507, 102d Cong., 1st Sess., at §§ 101, 112, 113 (1991).

62. HHS Legislative Alert, *H.R. 2507: Fact Sheet on Fetal Tissue Research Moratorium*, Apr. 1992 [hereinafter HHS LEGISLATIVE ALERT]; Statement of Administration Policy by the Office of Management and Budget to the Congress (Mar. 31, 1992) (on file with the *Journal of Contemporary Health Law and Policy*); Malcolm Gladwell, *HHS Official Defends Fetal Tissue Policy*, WASH. POST, Apr. 3, 1990, at A3 (quoting Rep. Waxman's critique of the Administration's position).

63. Letter from National Right to Life Committee to Members of the House of Representatives (July 23, 1991) (on file with the *Journal of Contemporary Health Law and Policy*).

64. *Id.*; James Bopp, Jr. & James T. Burtchaell, *Human Fetal Tissue Transplantation Research Panel: Statement of Dissent*, in FTTR PANEL I, *supra* note 25, at 45 ("the scientists selected by the NIH to give testimony were long-term NIH beneficiaries . . .").

the background and bias of the panel members is a key factor in the ethical weight that policy makers should accord the panel recommendations.<sup>65</sup> The fact that the NIH Director selected the panelists knowing that a majority of them supported the NIH and not the HHS position<sup>66</sup> takes on added relevance in light of accusations against the executive branch that it refused the recommendations of its own panel.<sup>67</sup>

Lurking in the shadows behind the issue of the panel's objectivity is another problem: the manner in which the panel hurdled the ethical questions presented to it. The first and fundamental question posed was whether "an induced abortion [is] of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed?"<sup>68</sup> This question demands an evaluation of the pregnant woman, the fetus, and the abortion decision. It exhorts deep thinking about the link between the act and the agent. The remainder of the panel's report is contingent on the ethical resolution of this question. The panel responded to the first question as follows:

It is of moral relevance that human fetal tissue for research has been obtained from induced abortion. However, in light of the fact that abortion is legal and that the research in question is intended to achieve significant medical goals, the panel concludes that the use of such tissue is acceptable public policy.<sup>69</sup>

While the panel ostensibly considered moral relevancy, they rested their decision on the legality of abortion.<sup>70</sup> Eighteen members of the twenty-one member panel approved of the response with three dissenting.<sup>71</sup>

The panel protected this first response with proposed guidelines that would keep the woman's abortion decision distinct from the tissue donation decision and would reduce the possibility of monetary gain for either the woman or the abortion provider.<sup>72</sup> A further caveat was the requirement

65. Dennis G. Smith, *The Moral Dilemma Of Using Fetal Tissue From Induced Abortions As Medical Therapy: Antidote or Atrocity?* (Nov. 29, 1990) (unpublished paper, on file with Congressman Bliley's office and the *Journal of Contemporary Health Law and Policy*).

66. *Id.* at 10 (citing that some panel members had previously given public support to experimentation on nonviable fetuses *ex utero*).

67. Gladwell, *supra* note 62, at A3 (quoting Rep. Waxman's statement " 'that the administration reached its position . . . 'against the recommendation of its own expert panel' "); 138 CONG. REC. S16,231 (daily ed. Oct. 2, 1992) (statement of Sen. Adams: "I just would like to hold [the President] to his word and that of his own blue ribbon panel. His own panel said, 'Lift this ban . . . .'").

68. Memorandum, *supra* note 22, at B1 (listing questions sent by HHS to NIH).

69. FTTR PANEL I, *supra* note 25, at 1.

70. *Id.*; Warren Kearney et al., *Fetal Tissue Research and the Misread Compromise*, HASTINGS CTR. REP., Sept.-Oct. 1991, at 9-10.

71. FTTR PANEL I, *supra* note 25, at 1.

72. *Id.* While some consider "abortionist" or "abortion provider" inflammatory lan-

that abortion providers, as suppliers, and fetal tissue researchers, as receivers, be "ethically isolated."<sup>73</sup> The panel created a matrix of the moral significance of means and ends, grounding their concept of morality on the premise that what is legal is moral. They then ascribed variable moral weights to the decisions of the agents, e.g., the woman, fetus, abortion provider, researcher, and potential tissue recipient, to yield an ethically acceptable end.

The majority concluded that the researcher's desire to use the tissue for the good of the patient is morally acceptable.<sup>74</sup> A woman's equally altruistic goal of helping others, however, does not sustain the moral acceptability of her decision to donate. Such altruism is prohibited as a reason for obtaining an abortion.<sup>75</sup> This ethical puzzle requires that the means be distinct from the end where the source of the tissue is concerned. Consider that although a researcher doing transplants may be compensated with fame and fortune, the woman and the abortion provider should not share in such benefits. They are distinguished from the beneficent purposes of the procedure and regulated accordingly. These paradoxical distinctions permeate the panel recommendations and point to the unanswered moral conundrum: why constrain the moral motives of only certain participants?

The remaining nine questions considered by the panel illustrate how the controversy was further framed and demonstrate the challenge before the panel.<sup>76</sup> The panel convened for three days each in September and October

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guage, the latter is a label which those in the trade use for themselves. *See Information Sheet*, National Coalition of Abortion Providers, Washington, D.C. 1990, at 1.

73. FTTR PANEL I, *supra* note 25, at 2.

74. *Id.* at 1 (distinguishing the morality of the uses of fetal tissue from the morally complex issue of abortion).

75. *Id.* at 2, 3, 8 (discussing the need to insulate a woman's decision to abort from the tissue donation decision and recommending that she be prohibited from designating the recipient and that funds be denied for donations to family, friends, or acquaintances).

76. *Id.* at 3-16.

Question 2: Does the use of fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement?

Question 3: As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research — thus precluding research of this sort, under HHS regulations?

Question 4: Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it?

Question 5: Should there be and could there be a prohibition on the donation of fetal tissue between family member, or friends and acquaintances? Would such a prohibition jeopardize the likelihood of clinical success?

of 1988, and for one day in December of 1988; and, after hearing the testimony of over 50 experts, finalized its report by December 14, 1988.<sup>77</sup> The report has proven to be the popular document in the debate: its recommendations and logic serving as the basis of the legislative attempt to reverse the ban on funding.<sup>78</sup>

The funding denial and concurrent ban instigated the formation of the influential NIH panel whose recommendations were considered but not followed by HHS. Instead, HHS sustained the moratorium and maintained that the ethical problems of the source of tissue cannot be surmounted by procedural controls, which HHS claimed are unlikely to be effective in the clinical setting.<sup>79</sup> This objection is subordinate to HHS' major objection that federal funding of FTTR would provide an "incentive for abortions, and it would create a demand cycle dependent on maintaining the legality of induced abortions."<sup>80</sup>

Because the panel was convened at the direction of HHS, an executive branch agency, many view the refusal of the Reagan and Bush administra-

Question 6: If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely to occur on activities and procedures employed by abortion clinics? In particular, is the optimal or safest way to perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way to ensure that induced abortion are not intentionally delayed in order to have a second trimester fetus for research and transplantation?

Question 7: What actual steps are involved in procuring the tissue from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment?

Question 8: According to HHS regulations, research on dead fetuses must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research application of dead fetal tissue after an induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after an induced abortion? If so, what are the consequences for NIH-funded researchers in those States?

Question 9: For those diseases for which transplantation using fetal tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortion during the first trimester are less risky to the woman, have there been enough animal studies for each of those diseases to justify the reliance on the equivalent of the second trimester human fetus?

Question 10: What is the likelihood that transplantation using fetal cell cultures will be successful? Will this obviate the need for fresh fetal tissue? In what time frame might this occur?

*Id.*

77. Some hold that the panel had insufficient time to comprehensively examine the challenge before them. See Bopp & Burtchaell, *supra* note 64, at 45; Smith, *supra* note 65, at 29.

78. Kearney et al., *supra* note 70, at 7.

79. Letter from Louis W. Sullivan, Secretary of HHS, to William F. Raub, Acting Director of NIH 1, 2 (Nov. 2, 1989) (on file with the *Journal of Contemporary Health Law and Policy*).

80. HHS LEGISLATIVE ALERT, *supra* note 62, at 1.

tions to abide by the recommendations as purely political.<sup>81</sup> HHS counters that the panel report is but one factor to weigh in the decision making process along with other factors, such as the Hyde Amendment,<sup>82</sup> and the scientific promises of this and other research.<sup>83</sup> Congress, however, decided to adopt the panel recommendations and implement a legislative solution to the controversial ban.<sup>84</sup>

## II. NIH REVITALIZATION AMENDMENTS

Congress approved the 1991 and 1992 NIH Amendments (the Amendments)<sup>85</sup> in response to both the executive branch's decision to continue the moratorium and the recommendations of the NIH panel. The legislation sought to achieve three purposes: (1) to regulate future HHS decision making on ethical matters;<sup>86</sup> (2) to nullify the ban imposed by HHS on federal funding of FTTR in humans;<sup>87</sup> and 3) to prescribe procedures for donation and procurement of human fetal tissue from induced abortions.<sup>88</sup>

The Amendments represent a legislative attempt to reconcile separation of power interests; the issues of privacy, reproductive freedom, and patient autonomy; the desires of the research community; consent of donor and donee; fears of the increasing commodification of the human body; and the exploitation of women. Can a policy maker incorporate all of these competing interests into a single legal formula? Can the resulting political compromise resolve what many proponents and opponents of FTTR agree is a moral problem?<sup>89</sup>

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81. 138 CONG. REC. S16,229 (daily ed. Oct. 2, 1992) (statement of Sen. Kennedy suggesting that "extreme zealots" of the Republican party were holding up medical progress).

82. *Id.*; The Hyde Amendment prevents the federal government from financing abortions except in cases of medical necessity. Departments of Labor, Health, Education, and Welfare Appropriations Act of 1977, Pub. L. 94-439, § 209, 90 Stat. 1418, 1434; *see also* Harris v. McRae, 448 U.S. 297, 325 (1980) (holding that the Hyde Amendment was constitutional).

83. *Finding Medical Cures*, *supra* note 4, at 4 (statement by James O. Mason, Asst. Sec. for Health and Head of the Public Health Service, explaining the administration's policy, promising research other than FTTR, the scientific evidence disproving the promises of FTTR, the interplay of the Hyde Amendment, and the panel recommendations).

84. Kearney et al., *supra* note 70, at 7.

85. H.R. 2507, 102d Cong., 1st Sess. (1991) (amending Part G of title IV of the Public Health Service Act); *see also* H.R. 5495, 102d Cong., 2d Sess (1992) (amending Part G of title IV of the Public Health Service Act and incorporating the establishment of a federally operated national tissue bank as provided by Exec. Order No. 12,806, (1992)). Otherwise, H.R. 5495 and the equivalent S. 2899 are substantially the same as H.R. 2507, which was vetoed by President Bush on June 23, 1992. *See supra* text accompanying note 7.

86. H.R. 2507 § 101; H.R. 5495 § 101.

87. H.R. 2507 § 113; H.R. 5495 § 113.

88. H.R. 2057 §§ 111, 112; H.R. 5495 §§ 111, 112.

89. *Finding Medical Cures*, *supra* note 4, at 11, 13, 15 (statements of Sen. Coats, Sen. Durenburger and Rep. Waxman); *Fetal Tissue Transplantation Research: Hearing Before the*

### A. *The Amendments As Written*

In the context of protecting human research subjects where research is NIH-supported, the Amendments again prescribe the need for an Institutional Review Board to recommend approval of the research.<sup>90</sup> The Amendments state that if the research comes with a recommendation for approval by the Institutional Review Board, "the Secretary may not withhold funding for the research on ethical grounds . . . ."<sup>91</sup> This restriction was qualified by a directive that the Secretary convene an ethics advisory board of a specific composition<sup>92</sup> whose recommendations he must abide, unless the Secretary "finds . . . that the recommendation is arbitrary or capricious."<sup>93</sup>

Concerning the section on the nullification of the moratorium on FTTR, the amendment states that:

no official of the executive branch may impose a policy that [HHS] is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out . . . without regard to any such policy that may have been in effect prior to the date of the enactment of this Act.<sup>94</sup>

This section of the Amendments further states that the Secretary may not refuse to fund research that complies with the new regulations, and that the report of the NIH FTTR panel of 1988 is retroactively deemed to be an

*Subcomm. on Health and the Environment of the Comm. on Energy and Commerce*, 101st Cong., 2d Sess. Ser. No. 101-135 1 (1990) (statement of Rep. Waxman); 138 CONG. REC. S16,235 (daily ed. Oct. 2, 1992) (statement of Sen. Hatch referring to the "ethical and moral dilemma" deadlocking the Senate during the cloture motion on S. 2899, the Senate NIH Revitalization measure).

90. H.R. 2507 § 101; H.R. 5495 § 101.

91. *Id.*

92. H.R. 2507 § 101(b)(4)(C); H.R. 5495 § 101(b)(4)(C).

An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. Of the members of the board

- (i) no fewer than 1 shall be an attorney;
- (ii) no fewer than 1 shall be an ethicist;
- (iii) no fewer than 1 shall be a practicing physician;
- (iv) no fewer than 1 shall be a theologian; and
- (v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

*Id.*

93. H.R. 2507 § 101(b)(1)(B); H.R. 5495 § 101(b)(1)(B)(ii) (adding a clause that allows the Secretary of HHS to withhold funds for a recommendation that he finds capricious, in an effort by the legislature to placate the executive branch's objections to the separation of powers issue).

94. H.R. 2507 § 113; H.R. 5495 § 113.

ethics advisory board recommendation that he must follow.<sup>95</sup> The revised bill specifically notes that the Panel Report is found to be neither "arbitrary nor capricious."<sup>96</sup>

As to the source of the tissue, the Amendments provide that the donor must give informed consent for the use of the tissue by way of "a statement, made in writing and signed by the woman . . ."<sup>97</sup> The statement testifies to the woman's knowledge that: (1) the tissue is donated for research; (2) the tissue is not designated for a particular recipient; (3) she does not know the identity of the recipients; and (4) that if the abortion is induced, the decision to abort was independent from the decision to donate.<sup>98</sup> The regulation also requires a separate statement by the woman in which she declares that her "decision . . . to undergo the abortion is not made in order to provide fetal tissue for research purposes."<sup>99</sup> These statements must be available for audit by the HHS secretary and other appropriate Federal and state officials.<sup>100</sup>

The NIH Amendments also prohibit the purchase, solicitation, and acceptance of human fetal tissue for valuable consideration.<sup>101</sup> Criminal penalties are assessed if a person knowingly acquires, receives, accepts, or knowingly transfers human fetal tissue "for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce."<sup>102</sup> The revision extends criminal penalties to the solicitation or acceptance of tissue for transplantation in the context of interstate commerce if the tissue:

will be or is obtained pursuant to an induced abortion, and (1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual; (2) the donated tissue will be transplanted into a relative of the donating individual; or (3) the

95. H.R. 2507 § 113; H.R. 5495 § 113.

96. H.R. 5495 § 113(b)(2)(B).

97. H.R. 2507 § 111; H.R. 5495 § 111.

98. H.R. 2507 § 111(b); *see also* H.R. 5495 § 111(b). The new measure modifies the statement required by deleting § 111(b)(1)(D), which mandated that the woman state that the abortion decision and donation decision are independent. *Id.*

99. H.R. 2507 § 111(b)(2); H.R. 5495 § 111(b)(2), the June 25, 1992 version of the bill assigns responsibility for the additional statement to the attending physician. *Id.* The physician must declare in writing that "the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for the tissue to be used in such research" and that he did not alter the abortion method or timing "solely for the purposes of obtaining the tissue." *Id.* The physician's statement also requires that he or she fully disclose his interest and risks to the woman and that he or she attest to this in writing. *Id.*

100. H.R. 2507 § 111(b)(3). H.R. 5495 limits the audit to the Secretary of HHS and adds some confidentiality safeguards absent in the vetoed measure. H.R. 5495 § 111.

101. H.R. 2507 § 112; H.R. 5495 § 112.

102. H.R. 2507 § 112; H.R. 5495 § 112.



person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.<sup>103</sup>

“[R]easonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue” are exempt from criminal prohibition.<sup>104</sup> It is unclear how reasonable payments affect the incentives of the abortion provider or the women contemplating an abortion.

### B. *The Amendments As Applied*

Privacy and reproductive freedom are two of the most important interests at work in this debate, yet they are unresolved in the legislative compromise. Understandably, legislation cannot resolve all of the issues in the FTTR debate. However, the legislature’s handling of the abortion issue in the context of FTTR is at odds with the Supreme Court’s decision in *Roe v. Wade*<sup>105</sup> and *Planned Parenthood v. Casey*,<sup>106</sup> and with the legislative intent of the Freedom of Choice Act.<sup>107</sup> The following two hypotheticals, which apply the proposed regulation to the motives and decisions of two potential donors, will illustrate this conflict.

Z has a father with Parkinson’s disease and would like to donate fetal tissue to him. She knows that she could donate her second kidney to her sibling if the sibling needed one. Z chooses to conceive so that she can produce a fetus for tissue implants for her Parkinsonian father.<sup>108</sup> But Z must testify in writing that she decided to terminate the pregnancy independently from her decision to donate the fetus, and the donation must be an unrestricted donation to a donee whose identity is unknown to Z.<sup>109</sup> In this hypothetical, the Amendments prohibit her from carrying out her decision. The bill’s sponsors demand that “a clear separation is maintained between a woman’s decision to have an abortion and her decision to donate the tissue

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103. H.R. 5495 § 112 (b). The revised amendment continues the prohibitions of H.R. 2507 and adds criminal penalties to those who violate the donation restrictions or finance the abortion in order to obtain the tissue. H.R. 5495 § 112 (b)(1)-(3).

104. *Id.* § 112 (d)(3).

105. 410 U.S. 113 (1973).

106. 112 S. Ct. 2791 (1992).

107. H.R. 25, 102d Cong., 1st Sess. (1992).

108. Larry Thompson, *Fetal Tissue: Should Fetal Tissue from Abortions Be Available for Treatment of Patients with a Range of Diseases?*, WASH. POST, Jan. 26, 1988, (Health), at 11 (reporting on women who come forward wanting to conceive, abort, and use the cells for themselves or relatives).

109. H.R. 2507 § 111. H.R. 5495 deletes the requirement that a woman reveal her decision-making. *Id.*

for research.”<sup>110</sup> Further, the documents testifying to her decision and legally approved motive must be available for inspection.<sup>111</sup>

V, on the other hand, wants to donate the fetus she is carrying. She made the decision to donate the fetus independently from her decision to abort. Knowing that the fetus would help someone, however, did make her feel better about her decision. She refuses to sign any statements about her intent or consent. She does not want there to be a permanent record of this event subject to inspection.<sup>112</sup> V wants this to be a private decision.

A regulation that requires a specific motive for a legal act that is protected by privacy and autonomy interests will not command compliance in the abortion clinic.<sup>113</sup> Requiring that the physician in the clinic disclose certain information to a woman is also constitutionally questionable.<sup>114</sup> In any event, consent is not now routinely obtained in accordance with the UAGA or other state law.<sup>115</sup> The motive for compliance in the clinic setting is not apparent and none was included in the legislation. The financial incentives deemed illegal by the same legislation currently operate against consent and record keeping.<sup>116</sup>

In this political attempt to accommodate opposing interests, the House of

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110. 138 CONG. REC. S16,228 (daily ed. Oct. 2, 1992) (statement of Sen. Kennedy during the cloture motion on the NIH Revitalization Amendments, S. 2899).

111. H.R. 2507 § 111; H.R. 5495 § 111.

112. H.R. 2507 § 111; H.R. 5495 § 111. The new measure still requires that the woman make a written declaration as to the donation decision. H.R. 5495 § 111(b). That statement, the physician's statement, and a statement by the researcher as to his and the recipient patient's informed consent must be available for audit. *Id.*

113. Kolata, *supra* note 4, at 176 (reporting that many clinics refuse to obtain informed consent to donate tissue).

114. *Margaret S. v. Edwards*, 794 F.2d 994, 997 (5th Cir. 1986) (applying *City of Akron v. Akron Ctr. for Reproductive Health, Inc.*, 462 U.S. 416 (1983), and holding that the state cannot intrude into the doctor-patient relationship and specify the information that a physician disclose to a woman-patient in the abortion decision, particularly "less important information about the disposition of fetal remains.").

115. Kolata, *supra* note 4, at 176 (reporting that many clinics refuse to obtain informed consent to donate tissue); Andrews, *supra* note 31, at D18 (citing to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Appendix: Research on the Fetus*, 40 Fed Reg. 33,530 (1975), which reported that "as a matter of medical practice, women's aborted fetuses were being experimented on without the women's knowledge and consent").

116. Kolata, *supra* note 4, at 176. In an interview with James S. Bardsley, president of the International Institute for the Advancement of Medicine, the nation's largest supplier of fetal tissue, Bardsley revealed that "[a]ll too often, the woman is not even told that the tissue will be used for medical research." *Id.* Bardsley admitted, "[s]ome major hospitals and major research institutions do not obtain a woman's informed consent. This goes on all the time." *Id.* "Bardsley tried to make sure that his suppliers informed the patients of their intentions" by insisting on a formal signed consent only to find that "about half of the clinics simply stopped supplying the tissue." *Id.*

Representatives legislated morally acceptable motives and thereby set the stage for public policy confusion.<sup>117</sup> As some experts noted, “[t]his extension of the separation guidelines of the NIH panel recommendation by the authors of [the legislation] is harmful to both the interests of women and the goal of encouraging research into fetal tissue transplantation.”<sup>118</sup> Not only will abortion providers be wary of the regulation, but researchers will be very reluctant to maintain private records for inspection, knowing that a “breach of confidentiality” could be disastrous.<sup>119</sup>

Will the NIH Amendments protect the interests of women, abortion providers, or researchers? Women want uncompromisable privacy and the freedom to control their bodies and what their bodies create.<sup>120</sup> Women also value giving and may view the donation of fetal tissue as a gift to a loved one or someone who needs that tissue.<sup>121</sup> Both of these qualities however, make women particularly vulnerable to the abortion provider and the researcher. The abortion provider makes greater profit with less restriction. The researcher wants the freedom to search for the cure with financial support and minimal interference.<sup>122</sup> An Amendment subtitled Research Freedom<sup>123</sup> with incongruous restrictions on these parties will command lip service, but will it serve a purpose beyond that?<sup>124</sup> Women are the means to an end in this scenario and the procedural controls of the NIH Amendments facilitate that reality under the guise of preventing it.<sup>125</sup>

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117. H.R. 2507; H.R. 5495; Kearney et al., *supra* note 70, at 7 (pointing out that the provisions of H.R. 2507 that require certification of motive by women were not recommended by the panel but were a misinterpretation of the ambiguity of the panel report). The authors warn of a new direction of public policy that presents “important problems.” *Id.*

118. Kearney et al., *supra* note 70, at 11.

119. *Id.* H.R. 5495, the bill put on the House floor following President Bush’s veto of its predecessor, H.R. 2507, modifies the inspectability of the records, but does not eliminate the problems of privacy and motive. H.R. 5495 § 111.

120. Kearney et al., *supra* note 70, at 8-9 (questioning the “new and inventive incursion on the privacy of women seeking abortion” and on the “fiduciary relationship between doctor and patient”).

121. Judith C. Areen, *Legal Regulation of Fetal Tissue Transplantation*, in FTTR PANEL II, *supra* note 20, at D25.

122. George Archibald, *Embryonic Enterprises, Researchers Reap Harvest in Abortions*, WASH. POST, Jan. 6, 1992, at A1, A7. “The researchers want peace and quiet in their labs. They do not want to make it public what kind of research they are engaged in and that they use this sort of tissue because they also fear disruption of their work”, (quoting a co-director of the project at the University of Minnesota Center for Biomedical Ethics to survey the fetal tissue business). *Id.* at A7.; see also Fletcher, *supra* note 14, at 112 (discussing the wall of separation between funding abortion and embryo research).

123. H.R. 5495 §§ 111, 112.

124. Kearney et al., *supra* note 70, at 9.

125. H.R. 2507; H.R. 5495. Statements of ethical intent on the part of women do not sanitize the moral question in theory or prevent abuse in practice. See generally Bopp & Burt-

Moreover, "any federal law that would require written declarations of ethical intent on the part of women donating aborted fetal tissue, and that would transfer these declarations to the public sphere, is peculiar enough to merit significant concern."<sup>126</sup> Instead of resolving this conflict, as the NIH panel attempted to do, the legislature merely transplanted the panel solution and put it in the form of law.<sup>127</sup> Motive, then, sits on the ethical seesaw, rendering FTTR legally and hence morally sanctioned in procedurally correct cases.

Yet the concern about motive does not obstruct research ventures in the private sector or other federally funded fetal tissue research such as animal transplantation research, viruses, vaccines, pharmacology, and cell line formation.<sup>128</sup> Although they depend on the same sources, these uses attract little debate. Even controversial experiments have been hidden behind the research doors.<sup>129</sup> Nonetheless, federal funding for FTTR, and the conflicting attempts to defuse the debate (e.g., the ban, the NIH panel, and NIH Amendments) have yet to resolve the ethical challenge that lies between the abortion decision and the transplantation therapy. And, because the funding denial was publicly cast in terms of denying help to millions in need of a cure, the controversy took on a political life. The legislative response to that problem created new ones. The result is particularly unfortunate where the lives and health of millions of patients, women, and the unborn—none of whom are served by the politicization of the ban or the NIH Amendments—are caught in the balance.

### III. BENEFITS AND COSTS OF THE MORATORIUM AND ITS NULLIFICATION

Any risk analysis of the scientific merit of FTTR pits the promises of a cure against the alternative therapies that proceed while the ban is in effect. Meanwhile, an ethical benefit/hazard analysis must consider the demands of

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chaell, *supra* note 64, at 47-71 (addressing the various arguments and issues in a statement of dissent from the FTTR Panel recommendations).

126. Kearney et al., *supra* note 70, at 11.

127. *Id.* (asserting that this is based on a mistaken presumption that women would abort to donate).

128. 45 C.F.R. § 46; H.R. 2507; H.R. 5495. The federal regulation and the Amendments do not address the motive issue in any context other than in that of federally funded fetal tissue transplantation from induced abortions. *Id.*

129. Smith, *supra* note 65, at 21 (describing Case Western Reserve University experiment on live aborted fetuses that involved decapitation); see also Gina Kolata, *U.S. Rule on Fetal Studies Hampers Research on AZT*, N.Y. TIMES, Aug. 25, 1991, at 20 (reporting on a researcher who "had taken live aborted fetuses . . . and submerged them in a tank of salt water to see if they could obtain oxygen through their skin and 'kept the fetuses alive swimming in the fish tank for 24 to 48 hours'").

the research race, the issue of consent, and the potential exploitation of women. Thus we are faced with a bioethical catch-22. The promises and problems are interdependent as the success of the scientific research depends in part on the resolution of the ethical debate, and the ethical debate's resolution is affected by the corresponding success of the research.<sup>130</sup>

#### A. *Research Promises: Success and Failure*

Clearly, the costs of the ban and the nullification are more than financial. Although fetal tissue transplantation may have the potential to be a six billion dollar industry, it presently represents a fraction of national and international public and private health research.<sup>131</sup> There are not any cures yet, and while there is hope, there are contraindications that point to the likelihood of success through alternative areas of cell research.<sup>132</sup> Fetal tissue transplantation is held out by proponents as the miracle treatment for a host of debilitating diseases and injuries.<sup>133</sup> Some researchers say that 20% of the population, or any number who suffer from some form of tissue damage, could benefit from transplants.<sup>134</sup> In contrast, other researchers say that the promises are false and border on irresponsible science given the lack of control groups and the questionable success of a few operations.<sup>135</sup> Decisions about where to channel limited resources also enter the ethical debate because all promising research cannot be adequately financed.

##### 1. *Promises of Fetal Tissue Transplantation*

"Fetal tissue is a tremendous natural resource . . ." <sup>136</sup> Human fetal tissue has remarkably unique capacities that nature designed for the growth of

130. FTTR PANEL I, *supra* note 25, at 1.

131. NIH FY 90, *supra* note 11, at 1; *supra* text accompanying note 12; *Background Material on Human Fetal Tissue Bank* HHS (U.S. Dep't of Health and Hum. Servs., Washington, D.C.) July 31, 1992 [hereinafter *Background Material*] (reporting that in FY 91, NIH funded \$9,767,718 of human fetal tissue research); see *supra* text accompanying note 5 (proposed NIH reauthorization of \$5.4 billion).

132. Letter from Bernadine Healy, M.D., Director of NIH, to Sen. Orrin Hatch (1992), (*reprinted in* 138 CONG. REC. S16,235-36 daily ed. Oct 2, 1992). In letter supporting the proposed fetal tissue banks, Dr. Healy stated that NIH hopes to "accelerate research to establish human fetal cell lines in laboratory cultures where they can be properly characterized, assured of being pathogen free, and in some cases genetically engineered to be of more therapeutic value." *Id.*; see also Landau, *supra* note 3, at 733-39.

133. *Finding Medical Cures*, *supra* note 4, at 2 (statement of Sen. Adams criticizing the Bush administration for "depriving millions of Americans of their only hope of a cure").

134. Dave Andrusko, *Spare Parts from Babies - Are We Going too Far?*, FOCUS ON THE FAM., June 1988, at 10, 11.

135. Landau, *supra* note 3, at 738-39.

136. Peggy Orenstein, *Health*, VOGUE, Oct. 1989, at 298, 302 (quoting Robin Duke of the Population Crisis Committee of New York City).

newly created human life.<sup>137</sup> Fetal cells are very plastic—able to change in shape, to move to assume correct location, and to integrate functionally with a new environment.<sup>138</sup> The cells are amenable to storage and they proliferate rapidly.<sup>139</sup> They are also immunologically compatible in that they do not express antigens until later in the gestational period, thus diminishing the need for immune suppression therapy.<sup>140</sup> They can sprout a vascular system that allows for the transfer and reception of blood and nutrients.<sup>141</sup> All of these properties diminish with development and therefore make fetal tissue very attractive for transplantation.<sup>142</sup>

In the United States there are more than 14 million people affected by diabetes, 4 million with Alzheimer's, 1.5 million with Parkinson's, and some 250,000 people with spinal injuries, who could potentially benefit from successful research.<sup>143</sup> Fetal tissue may also be beneficial to the treatment of stroke victims, epileptics, hemophiliacs, victims of multiple sclerosis, persons with certain learning disabilities, Huntington's chorea, and some blood-related diseases.<sup>144</sup> Scientists use the tissue for cancer research and for a variety of other diseases.<sup>145</sup> There is also discussion of using fetal cells to combat the AIDS virus.<sup>146</sup>

The incredible promise of the properties of the tissue and the needs of so many patients prompted researchers to start experimenting with transplantation of both human and animal fetal tissue into animals.<sup>147</sup> These trials indicated the clinical usefulness of the therapy.<sup>148</sup> In an attempt to test the basic principles learned from the Parkinsonian animal model, the transplantation therapy is being tested on humans; but the scientists doing the research warn that these experiments "cannot be viewed as clinical trials . . . ."<sup>149</sup> As to transplantation for other neurodegenerative disorders, fur-

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137. Curt Harris, *Do We Need Fetal Tissue Research?*, *PHYSICIAN*, Sept.-Oct. 1990, at 1, 3.

138. Robert Auerbach, *Qualities of Fetal Cells and Tissues*, in FTTR PANEL II, *supra* note 20, at D28.

139. *Id.* at D31.

140. *Id.*

141. *Id.*

142. *Id.* at D30.

143. *Finding Medical Cures*, *supra* note 4, at 1 (statement of Sen. Adams referring to statistical data compiled by the staff of the Sen. Committee on Labor and Human Resources).

144. Lehrman, *supra* note 11, at 11.

145. *Id.*

146. Laurie Garrett, *Fetal Tissue Backed for AIDS Research?*, *N.Y. NEWSDAY*, Nov. 3, 1989, at 8, 15 (reporting the speculative comments of the director of the National Institute of Allergy and Infectious Diseases); Hansen & Sladek, *supra* note 1, at 777 (citing AIDS tests on fetal cells).

147. Hansen & Sladek, *supra* note 1, at 777-79.

148. Lindvall, *supra* note 3, at 376, 382.

149. *Id.* at 376.

ther animal studies are required before the leading researchers will advocate experimenting on humans.<sup>150</sup>

Recent Swedish experiments found that fetal cells can stay alive, but their survivability and the long-term success of the transplant is unproven.<sup>151</sup> Similarly, although the first experiments in Mexico were claimed a success by the experimenting doctors, their results have been questioned.<sup>152</sup> In one review, a leading scientist concluded that "[a]lthough about one hundred operations with fetal [neural] implants have now been completed, there is little evidence of implant survival . . . . The technical difficulties of the procedure suggest that neural implantation is unlikely to benefit many patients with Parkinson's disease."<sup>153</sup> In the United States, fetal pancreatic tissue transplants in the United States have also shown mixed results.<sup>154</sup> Other researchers continue to maintain that the transplants are promising.<sup>155</sup>

Because FTTR is experimental, the effect of imperfections in the fetal tissue are not completely known.<sup>156</sup> "Only limited testing for infectious agents before transplantation is possible for fresh or recently aborted fetal tissue."<sup>157</sup> "It is not known, for example, whether fetal transplants might cause cancer, AIDS or other diseases months or years after foreign fetal tissue has been transplanted into the heads of adult recipients."<sup>158</sup> Tissue freshness, which is discussed further in the next section, is another factor of success in transplantation.<sup>159</sup> These unknown disadvantages and the dubi-

150. *Id.*

151. *Id.* at 383; Marx, *supra* note 3, at 529; cf. G.C. Clough, *Parkinson's Disease: Management*, 337 LANCET 1324, 1326-27 (1991) (indicating that promising laboratory animal work has not been successfully verified in human subjects).

152. Weiss, *supra* note 3, at 324.

153. Clough, *supra* note 151, at 1327.

154. Leslie Bond, *Fetal Pancreatic Tissues Used In Diabetes "Treatment"*, NAT'L RT. TO LIFE NEWS, Jan. 22, 1989, at 11.

155. FTTR PANEL I, *supra* note 25, at 14-15, 19-20.

156. FTTR PANEL II, *supra* note 20, at A6 (discussing the status of FTTR and various speculations relating to fetal cell properties).

157. George Archibald, *Personal Needs, Fears Blur Old Abortion Lines*, WASH. TIMES, Jan. 6, 1992, at A7 (citing the University of Minnesota's Center for Biomedical Ethics study which questions whether experiments on humans should be done given the known and unknown risks).

158. Archibald, *supra* note 122, at A7.

159. Kolata, *supra* note 4, at 176. James Bardsley, leading tissue supplier, explains the importance of technique and tissue freshness:

that his group advertises for doctors who use certain suction methods in early abortions to obtain particular fetal parts intact—for example, the Parkinson's disease treatment requires fetal brains. In second-trimester abortions, he advertises for doctors who use a technique called dilation and evacuation (D&E), in which the fetus is essentially pulled out of the anesthetized woman. Because the fetus is alive when the abortion begins, 'some doctors are squeamish about D&E's,' Bardsley says. But he

ous success of the human experiments to date have prompted experts in the field of neurology<sup>160</sup> to point out that there may well be serious risks for the patient.<sup>161</sup> Some reports show that "it is likely that more Parkinsonian [patients] have died as a result of adrenal transplants than have been helped. The same is likely to be true of fetal transplants. . .,"<sup>162</sup> leading skeptics to conclude that the lack of knowledge about controlling fetal tissue makes it far too experimental for human use at this stage.<sup>163</sup> This danger is enhanced by the lack of cell purity,<sup>164</sup> which is why the alternative of developing cell lines in the lab is advocated by opponents of the therapy.<sup>165</sup>

In a recent analysis of the international and national stories of fetal tissue transplant success, one neurologist has noted that although there is positive publicity, it comes without the benefit of evidence that either clinical or experimental Parkinson's is cured by the transplantation of fetal tissue into the brain of humans or primates.<sup>166</sup> Additionally, the successful animal trials conducted to date reportedly did not adequately recreate the human experience with Parkinson's.<sup>167</sup> Similarly, experiments on humans are not conducted in the context of control groups to test the human therapy,<sup>168</sup> and there are indications that "at 1 year most patients had returned to their pre-

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cannot use fetuses aborted by the more common second-trimester method, saline infusion. In this method, doctors infuse salt water into the uterine cavity, killing the fetus before initiating labor. The problem with the saline method, Bardsley says, is that 'we need tissue that is fairly fresh. We have to process the tissue within minutes of the time of death.' Fetuses from saline abortions have been dead too long to be usable.

*Id.*

160. *Fetal Tissue Transplantation Research*, *supra* note 2, at 105-07 (testimony of Keith A. Crutcher, Ph.D. and statement signed by 41 physicians and scientists who object on ethical grounds to the use of fetal tissue derived from elective abortions). *But cf. Finding Medical Cures*, *supra* note 4, at 101 (statement by American Academy of Neurology supporting the bill that would overturn the moratorium).

161. *Fetal Tissue Transplantation Research*, *supra* note 2, at 101, 103, 105 (statements of Jonathan H. Pincus, M.D.).

162. *Id.* at 103.

163. *Id.* at 102 (oral statement of Jonathan Pincus, M.D., concluding that "[i]f [FTTR] were a drug, it would not be approved.").

164. Edwin Kiester, *Helping the Brain Heal Itself*, SCI. ILLUSTRATED, Feb.-Mar. 1988, at 17.

165. Leslie Bond, *Promising Alternatives to Fetal Tissue Use Offer Hope to Patients*, NAT'L RT. TO LIFE NEWS, Jan. 22, 1989, at 9; *see also* David Lore, *New Tools in Medical Technology: Replicated Cells from Fetuses*, DISPATCH, Oct. 9, 1988 (Capitol Magazine), at 8-9 (reporting on fetal tissue transplants as well as the hope of "immortal lines of purified and genetically engineered cells").

166. Landau, *supra* note 3, at 739.

167. Keith A. Crutcher, *Fetal Tissue Transplantation: Part.1 Experimental Use of Tissue Grafts to Treat Parkinson's Disease*, SCIENCE FOR LIFE, June 1991, at 1, 3.

168. Clough, *supra* note 151, at 1327; Landau, *supra* note 3, at 738.



operative state."<sup>169</sup> Further, the treatment of the patient is not isolated to distinguish the brain's regenerative capacity from the effects of the transplant and the ensuing drug therapy.<sup>170</sup> "In patients with advanced Parkinson's disease, who are the most suitable candidates for an experimental therapeutic procedure such as transplantation, L-DOPA [drug] treatment cannot be withdrawn. It is still an unresolved issue whether the continuous antiparkinsonian drug therapy interferes with survival and growth of grafted dopaminergic neurons."<sup>171</sup> Thus, what may be honestly reported as a successful neural graft in the research community is hailed as the cure-all by the media and politicians.<sup>172</sup>

## 2. *Alternative Therapies*

Fetal tissue transplantation from induced abortions is a relatively minor field yielding skeptical results, but extensive publicity, compared to the other projects and discoveries in the research community. NIH annually spends at least \$9 million on other areas of fetal tissue cell research.<sup>173</sup> Moreover, in specific disease research, at least \$60 million was allocated to Parkinson's research for fiscal year 1992.<sup>174</sup> Of critical note, then, are the other contenders for funds in the research race.

Numerous projects that attempt to mimic the properties of fetal cells in a pure laboratory setting, including research on cultured cell lines, compete for federal funding.<sup>175</sup> The benefit of this effort is that it may overcome the unknown risks of using fetal tissue cells obtained from induced abortions, spontaneous abortions, and ectopic pregnancies.<sup>176</sup> Cell lines developed in the laboratory make purification possible, proliferation controllable, and,

169. Clough, *supra* note 151, at 1327.

170. *Fetal Tissue Transplantation Research*, *supra* note 2, at 101 (statements of Jonathan Pincus); *see also* Kiester, *supra* note 164, at 15-18.

171. Lindvall, *supra* note 3, at 380.

172. *Fetal Tissue Transplantation Research*, *supra* note 2, at 1-2 (opening statement of Rep. Henry A. Waxman); 138 CONG. REC. S16,228 (daily ed. Oct. 2, 1992) (statement of Sen. Kennedy that the NIH Revitalization Amendment will give "the victims . . . the new hope that they deserve.").

173. *Background Material*, *supra* note 131 and accompanying text.

174. FACT SHEET, *Fetal Tissue Transplant Research*, (Feb. 1992), NATIONAL COMMITTEE FOR A HUMAN LIFE AMENDMENT 1 (citing Dr. Mason of HHS). Fiscal year 1993 spending by NIH on Parkinson's, Alzheimer's and diabetes' researcher is estimated at \$600 million. HHS LEGISLATIVE ALERT, *supra* note 62.

175. *Finding Medical Cures*, *supra* note 4, at 4 (statement of Dr. Mason); *see also* Letter from the George Bush, President of the United States, to the House of Representatives (June 23, 1992), at 1 (objecting to the total cost of the NIH Revitalization Amendments as fiscally irresponsible) (on file with the *Journal of Contemporary Health Law and Policy*).

176. Kiester, *supra* note 164, at 17 ("Transplanted cells could even develop on their own and form a kind of brain within a brain.").

with improvements in genetic engineering, may allow the insertion of messengers in the cultured cells to meet the patient's specific needs.<sup>177</sup> The NIH panel considered this alternative and estimated that development would take ten years.<sup>178</sup> In May 1990, researchers announced that a culture of human brain cells had been successfully grown and divided for three years in a lab.<sup>179</sup>

Auto-transplants, cells extracted and transplanted in the same patient, are another option under investigation by NIH at a more sophisticated level than the failed adrenal transplants.<sup>180</sup> In this new development of auto-transplantation, a patient's non-neural cells are genetically modified to perform a particular function that was deficient in the patient, such as dopamine production in the patient with Parkinson's disease.<sup>181</sup> Ideally, the patient's immune system would accept the altered cells.<sup>182</sup>

The work of scientists studying the fundamental properties of cells offers additional hope to those seeking a cure. In October 1991, the Nobel Prize in Physiology or Medicine was awarded to two German scientists for research in the basic functions of the cell, which is predicted to "pav[e] the way to tailor-made drugs."<sup>183</sup>

The brain's own chemical repair system coupled with pharmacological treatment for stimulating activity is the subject of still another branch of research.<sup>184</sup> In contrast to scientists who declare that fetal cell transplant fixes the brain, these researchers assert that "the most promising news in brain repair is yet to come."<sup>185</sup> They note further that the claimed success in some celebrated FTTR cases came before the grafts could have "taken."<sup>186</sup> Similar experiments with laboratory animals showed that the brain itself, not the transplanted cells, grew the vital cells to generate the dopamine, thus explaining the premature improvement in patient activity.<sup>187</sup> These new discoveries in brain repair may assist those with Parkinson's,

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177. FTTR PANEL I, *supra* note 25, at 16; *see also* 138 CONG. REC. S16,235-6 (letter from the Bernardine Healy, Director of NIH Director, endorsing this possibility).

178. FTTR PANEL I, *supra* note 25, at 16.

179. Jonathan Bor, *Hopkins Breakthrough Raises Hope for New Treatment of Brain Disease*, BALT. SUN, May 4, 1990, at 1A.

180. FAMILY RESEARCH COUNCIL, FACT SHEET: ALTERNATIVES TO USING FETAL TISSUE FROM INDUCED ABORTIONS 1, 2 (1991).

181. *Id.*

182. *Id.* at 2.

183. Lawrence K. Altman, *Cell Channel Finding Earns Nobel Prize*, N.Y. TIMES, Oct. 8, 1991, at C1.

184. Kiester, *supra* note 164, at 17-18.

185. *Id.* at 15.

186. *Id.*

187. *Id.*

Alzheimer's, traumatic brain injuries, and other ailments.<sup>188</sup> The debate in this promising discovery consists of discerning and managing the properties of the neurotrophic growth factor (brain healing powers).<sup>189</sup>

### 3. *Ethics in the Research Race*

Quantifying and qualifying the needs of the researcher bring to light the risks that the researcher assumes in pursuing FTTR. The researcher's work acknowledges the human identity of the fetus as a scientific matter. Must he do so as an ethical matter? The unique properties of human fetal cells derive from their human source and the dynamism of developing life in the pre-natal stage.<sup>190</sup> Human adult cells do not possess the characteristics required by the researcher. Thus, the pressure to find the cure in the human fetus is escalated,<sup>191</sup> but does this pressure or clinical procedures morally insulate the researcher's role?

A researcher needs brain cells from four first-trimester fetuses to treat one Parkinsonian patient or pancreatic cells from twenty-five second-trimester fetuses to treat one diabetic.<sup>192</sup> Qualitative success is measured in terms of freshness, as shown in recent Swedish experiments.<sup>193</sup> The following narrative by a collector of pancreatic tissue illustrates how fresh and close to the human source the demands of research extend:

"Two mornings a week, instead of going to her campus lab, Norris drives to a private women's clinic in Denver, where she spends several hours in a small harvesting room, removing tiny pancreases from the remains of 16 to 24 week fetuses brought to her in sterile pans from the operating room where the abortions are being performed."<sup>194</sup>

This scene invites the "potential for obtaining tissue from live fetuses. Fetal tissue degenerates as soon as it is without oxygen. Therefore, fetal research

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188. *Id.* at 17-18.

189. *Id.* at 18.

190. Irwin L. Slesnik & Jal S. Parakh, *Difficult Decisions: Fetal Cell Transplants*, *SCI. TCHR.*, May 1990, at 39.

191. Lehrman, *supra* note 11, at 10.

192. Bond, *supra* note 154, at 11.

193. Olle Lindvall et al., *Human Fetal Dopamine Neurons Grafted Into the Striatum in Two Patients With Severe Parkinson's Disease: A Detailed Account of Methodology and a 6-Month Follow-up*, 46 *ARCH. NEUROLOGY*, 615-31 (1989); see *supra* text accompanying note 160 (quoting president of the largest tissue supplier in the United States); see also *Finding Medical Cures*, *supra* note 4, at 50 (statement of Mt. Bopp where he explains that transplantation requirements of fresh, intact, and sterile tissue are met by preferred collection techniques now in employ where the brains of the human fetus are suctioned out while the fetus "lies yet alive within the uterus of the mother.").

194. Lore, *supra* note 165, at 10.

using animal tissue has involved removing tissues directly from living animal fetuses . . . ." <sup>195</sup> Thus, current harvesting methods are inadequate. Proponents of FTTR (leaders in the field) themselves warn that an "alternative source of donor tissue must be found," <sup>196</sup> while other scientists suggest that we redefine life and death for such purposes. <sup>197</sup>

A network of powerful interests operate in the context of the fetal tissue transplantation debate. A cure can mean billions of dollars to those competing to solve the mysteries of many diseases. It can also mean changing abortion techniques to obtain the freshest tissue at the optimal gestational age in the best condition possible, <sup>198</sup> potentially, putting women at greater risk. <sup>199</sup> From a different perspective, those fearful of the research and the commodification of human beings call this transplant technology "neo-cannibalism." <sup>200</sup> If we add legal sanctions, which in our community can assume moral encouragement, fetal farming is not far off. <sup>201</sup> Surrounding the medical procedures are the physical dilemmas of protecting women and their wombs. An assessment of the risks must take into account the human costs of the transplant, as well as the potential benefits of the cure. The "natural resource" we may be wasting may well be more than fetal tissue. <sup>202</sup>

Purified and engineered cells developed in the laboratory may provide an alternative to FTTR without the ethical dilemma. <sup>203</sup> As with the delay in testing of FTTR, complete testing will also delay the use of these therapies. In addition, none of the research projects have delivered a cure, and the many questions about experimenting on humans without adequate animal or

195. FTTR PANEL I, *supra* note 25, at 61.

196. Lindvall, *supra* note 3, at 383.

197. FTTR PANEL I, *supra* note 25, at 61-62 (citing researchers and ethicists that propose utilitarian definitions of life and death).

198. Leslie Bond, *NRL News Special Report: Fetal Tissue Transplants*, NAT'L RT. TO LIFE NEWS, Jan. 22, 1989, at 7 (reporting that newer methods of induced abortion developed in Sweden yield an intact fetus whose organs are readily harvestable before death). Dr. Linda Gourash, University of Pittsburgh School of Medicine, states that "fetal tissue involves taking living tissue from a living fetus." 137 CONG. REC. H5826 (daily ed. July 25, 1991).

199. Stuart A. Newman, *Proposed Uses of Human Fetal Tissue*, in FTTR PANEL II, *supra* note 20, at D205, D206 ("[W]omen would certainly experience pressure to undergo abortion procedures that are more invasive and dangerous to them, but more sparing to the fetus. Such pressure might be sweetened by a *quid pro quo* in the form of relief from medical costs."). Kolata, *supra* note 4, at 176.

200. Leslie Bond, *Fetal Tissue Transplants: The Horrible Harvest*, LIGUORIAN, July 1988, at 34, 35 (quoting Jeremy Rifkin, President of the Foundation on Economic Trends, who "warns of a society in which 'one generation literally consumes its offspring - harvesting the next generation for spare parts.'").

201. Don Feder, *The Shadow of Auschwitz*, NAT'L RT. TO LIFE NEWS, Jan. 22, 1989, at 8.

202. Kolata, *supra* note 4, at 175-76 (discussing potential risks to women's health).

203. Lore, *supra* note 165, at 8; Kiester, *supra* note 164, at 17.

human trials remain.<sup>204</sup> Nonetheless, many projects compete in the race for funding. Each contender costs millions of dollars and promises to support multi-million dollar industries. The allocation of limited health research and health care funds presents challenges measured in lives saved. The threshold question of clinical efficacy, however, persists. Congress and HHS must consider the promises of the alternatives to FTTR from induced abortion as compared to its limited success as they evaluate the risks and benefits in forming public policy.

### *B. Ethical Challenges in Fetal Tissue Transplantation Research*

If 50 million people could benefit from fetal tissue transplantation, it would present a serious demand for the human fetal tissue industry. Such a demand should be considered in resolving this public policy issue.<sup>205</sup> A \$6 billion health industry<sup>206</sup> would undoubtedly have political clout.

The impact of FTTR on women is most relevant. Public policy and the demand for tissue will shape women's view of themselves and the community's view of their maternity. Women's share or stake in the harvest of the womb, an issue of scant attention in the controversy,<sup>207</sup> cannot be obfuscated by procedure. Simple fairness demands that policy-makers exercise greater care to avoid exploitation of those impacted by their policies.

The goal of alleviating the physical suffering of 50 million people in America is a worthy one. Yet not even 10% of the 1.6 million fetuses aborted annually are usable for transplantation.<sup>208</sup> Will fetal tissue be allocated according to other organ donation models or will the pressure to create adequate supply be too great?<sup>209</sup> Funding determines research priorities and thereby can manipulate the supply.<sup>210</sup> These challenges suggest that the

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204. Landau, *supra* note 3, at 734-39.

205. Lore, *supra* note 165, at 10 (reporting on the shortage of fetal tissue for a kidney transplant in Denver where shortages of fetal islet cells are common).

206. See Finston & Millman, *supra* note 13, at 26 (forecasting a potential human fetal tissue market of \$6.5 billion).

207. See Kolata, *supra* note 4, at 176, 216 (discussing whether and how women and their health will be exploited by the abortion providers' profit motive and the researchers' tissue requirements).

208. *Id.* at 176, 216 (quoting calculations of Janice Raymond, Professor of Women's Studies and Medical Ethics at the University of Massachusetts, and Associate Director of the MIT Institute on Women and Technology). Despite Ms. Raymond's support for legal abortion, she opposes the fetal tissue research because it will exploit women by creating an "international trafficking in fetal parts." *Id.* at 216.

209. Newman, *supra* note 199, at D206. This embryologist, who supports legal abortion, warns that "as various interest groups become accustomed to and dependent on supplies of fetal tissue, they will inevitably seek to enforce their rights to this material." *Id.* at 205-06.

210. Hoffer & Olson, *supra* note 41, at 385 (discussing allocation of funding for research).

ethics underlying the ban and the NIH Amendments will not sustain public policy in the year 2000.

### 1. *The Consent Controversy*

The consent issue emerges as one of the most complex in the ethical debate over whether and how to regulate the donation of fetal tissue. What may sound purely hypothetical in biologic terms to most people is the dream of many researchers. Because of the altruistic motives vested in the researcher's efforts, we tolerate the rationalization, that it "is going to die anyway,"<sup>211</sup> and legally provide for post-mortem donation. Absent lofty motives and legal constraints, respect for the dead does not permit organ harvesting.

We further respect the wishes of the decedent by disallowing the anatomical gift when it appears that the decedent would not or did not choose to be "harvested."<sup>212</sup> Consent becomes the focal point, the moral value on which our legal and ethical system is based. In the context of FTTR, the consent issue impacts upon the woman carrying the fetus, the fetus, and the patient who will receive the tissue.

Our current regard for the moral and legal value embodied in voluntary and informed consent has its roots in the history of World War II.<sup>213</sup> "Obtaining voluntary, informed consent is the first principle of the Nuremberg Code, which was designed to prevent recurrences of the Nazi atrocities."<sup>214</sup> In fact, the world's condemnation of those crimes is the foundation of the current ethical model of obtaining patient consent before treatment or experimentation.<sup>215</sup> Although Nazi pathologists did not themselves kill the people whose brains they examined, that fact did not exculpate them from criminal classification.<sup>216</sup> So complete is the world's denunciation of the Nazi crimes that the *New England Journal of Medicine* consistently refuses to publish the results of any Nazi experiments.<sup>217</sup> Accordingly, the morally wrong act cannot be divorced from its potentially beneficent results.<sup>218</sup>

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211. Andrusko, *supra* note 134, at 11 (discussing the flaw in the argument that impending death is a license for organ harvesting).

212. UAGA, *supra* note 27, § 3(b)(2).

213. Harris, *supra* note 137, at 2.

214. Michael Specter, *When Research, Treatment Overlap*, WASH. POST, Dec. 14, 1989, at A33.

215. *Id.*

216. Harris, *supra* note 137, at 2 ("When the Nazis on trial at Nuremberg said they only meant to use Jewish tissue for the good of humanity, the world was not impressed.")

217. *Id.*

218. Specter, *supra* note 214, at A39 (quoting Marcia Angell, executive editor of the *New England Journal of Medicine*, stating that "[a] study does not become ethical if it succeeds" and that "[t]he importance of results has no place in judging ethics").

*a. The Fetus*

It is obvious that the decedent in FTTR, the fetus, cannot give consent to transplantation or experimentation, leaving open the question of whether anyone can give authentic consent.<sup>219</sup>

*b. The Woman*

In our own time, the issue of the mother's consent to donate the fetus is most cumbersome.<sup>220</sup> If the fetus is considered an anatomical gift which the woman is having surgically removed, then her consent is sufficient.<sup>221</sup> Note, however, that she is not permitted to designate a recipient, indicating that some value is distinguished in the fetus, or indicating that the fetus cannot be classified as an organ.<sup>222</sup> Ideally, an organ is removed and transplanted while it is still alive, but when the donor dead.<sup>223</sup> For this reason, the UAGA prohibits the physician who certifies death from participating in the removal or transplantation of the organ.<sup>224</sup> In an abortion, however, the abortion provider both removes the fetus and declares its death, incident to his role in causing the death. This dual role not only conflicts with the UAGA, it also makes for a questionable determination of death in abortions that produce whole fetuses.<sup>225</sup> Also, procuring organs from the living fetus or experimenting on it make the abortion process less analogous to situations covered by the UAGA. Nevertheless, the UAGA recognizes that the organ-donating fetus is a decedent itself and not an organ.<sup>226</sup> Therefore it is entitled to the same regard as other decedents. Curiously, though, in abortion, the donor is the mother and the decedent is the fetus.

"[D]onations are [to be] agreed to by the appropriate proxy . . . ."<sup>227</sup> According to the UAGA, either the mother or father is the most eligible person

219. Harris, *supra* note 137, at 2.

220. *Id.*; FTTR PANEL I, *supra* note 25, at 3-7, 47-50; *see also supra* text accompanying note 114; *see generally* FTTR PANEL II, *supra* note 20 (most of the statements made to the panel touch or focus on the consent issue).

221. FTTR PANEL I, *supra* note 25, at 6.

222. Alan Meisel, Testimony before the Consultants to NIH Advisory Panel, in FTTR PANEL II, *supra* note 20, at D174, D183-84, D186 (identifying a societal interest in according some legal protection to the fetus).

223. UAGA, *supra* note 27, § 8(a).

224. UAGA, *supra* note 27, § 8(b).

225. Mary B. Mahowald et al., *The Ethical Options in Transplanting Fetal Tissue*, HASTINGS CTR. REP., Feb. 1987 (noting that even a nonviable fetus may survive for a short time after an abortion, that the tissue is still alive, and that the fetal brain may also be alive). New abortion technology will allow access to an intact fetus as is currently done in a hysterotomy. Bond, *supra* note 200, at 6-7.

226. UAGA, *supra* note 27, § 1.

227. Hoffer & Olson, *supra* note 41, at 386.

to make the donation decision.<sup>228</sup> This presumes, however, that the person making a decision for another is acting in the interests of or with the authority of the decedent (i.e., a proxy).<sup>229</sup> The clause also allows the mother or father to disqualify the donation decision of the other parent.<sup>230</sup> Recognizing that the person aborting apparently does not want the child, applying the UAGA model to the abortion decision seems theoretically problematic. The interests in continuing the life and bodily integrity of the fetus are not the concern of either the aborting woman or the abortion provider. In fact, cessation of the life and bodily integrity of the fetus is their shared goal. Arguably, then, the woman forfeits her authority to give maternal consent.<sup>231</sup>

The consent issue for women is further compromised by the psychological pressures involved in the abortion decision.<sup>232</sup> This is where the rationale of the ban on funding rests.<sup>233</sup> Whether women will have more abortions as a result of lifting the ban is impossible to prove at this stage in the research. If there are financial incentives as well, such as the "reasonable expenses" proposed by the American Medical Association,<sup>234</sup> a woman is not free from pressure.<sup>235</sup>

In addition to the financial incentives, it can be argued that there will be the pressure of altruism or even charity to give to those in need.<sup>236</sup> The knowledge that the decision could benefit someone could be an inducement to abortion.<sup>237</sup> Women have in fact come forward expressing a desire to

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228. UAGA, *supra* note 27, § 3; *see also* 46 C.F.R. §§ 46.207-209.

229. UAGA, *supra* note 27, § 3; *see also* *Finding Medical Cures*, *supra* note 4, at 4 (statement of Dr. Mason) (asserting that maternal consent in the abortion decision "belies any notion of a genuine consent safeguard").

230. UAGA, *supra* note 27, § 3(b)(3); *see also* FTTR PANEL I, *supra* note 25, at 7 (addressing the need for additional consent).

231. Harris, *supra* note 137, at 2; *see also* Kolata, *supra* note 4, at 176 (noting that "major hospitals and some major research institutions" do not respect informed maternal consent requirements in practice).

232. FTTR PANEL I, *supra* note 25, at 52-60 (discussing the ambivalence of women contemplating abortion and the following pressures that federally funded FTTR could impose upon them: concern for self and others, abortion provider and clinic self-interest, financial incentives, transplant success, and corresponding social pressure).

233. *Finding Medical Cures*, *supra* note 4, at 4 (statement of Dr. Mason, Assistant Secretary for Health).

234. Teri Randall, *AMA Endorses Using Aborted Fetal Tissue*, CHI. TRIB., June 25, 1989, at C16.

235. Newman, *supra* note 199, at D206; Bopp & Burtchaell, *supra* note 64, at 60 (calculating that one abortion could yield \$100 worth of fetal organs thereby increasing demand and financial incentives).

236. Bopp & Burtchaell, *supra* note 64, at 54-57 (pointing out that the decision to donate could become a "noble and selfless act of 'doing good for humanity'").

237. James O. Mason, *Should the Fetal Tissue Research Ban Be Lifted?*, J. NIH RES., Jan.-Feb. 1988, at 17.



conceive and to abort to provide fetal tissue for a loved one or for themselves.<sup>238</sup> It is not hard to imagine that women could feel family pressure to conceive in order to abort and thus suffer exploitation of unknown consequences.<sup>239</sup> As opposed to being the beneficiaries of the abortion, women may very well be psychologically and financially subjected to the reproductive demands of tissue suppliers, researchers, and society. The therapeutic value of what their womb can provide will institutionalize abortion for the health needs of others and nullify the issue of consent for women.

### c. *The Patient*

As to the recipient patient, his informed consent may be compromised as "[it] is unclear at present whether investigators know enough about the potential efficacy of [fetal tissue] transplants to provide an accurate and impartial assessment for the patients."<sup>240</sup> Some patients may not be competent to consent and their family members may be coerced into consent.<sup>241</sup> The movie, *Awakenings*, based on the true story of the experimental use of the drug, L-DOPA, illustrates this risk.<sup>242</sup> In consultation with the patient, Leonard, and his mother, the ambitious doctor tested L-DOPA on Leonard.<sup>243</sup> Leonard was awakened from a thirty year Parkinsonian "sleep" brought on by an anencephalic condition as a child.<sup>244</sup> Within a month of his return to normal behavior, or his "awakening", Leonard started a violent regression that lasted many months.<sup>245</sup> This true story reveals the risk of raising the hopes of patients and their loved ones in an atmosphere of the unknown. As the doctor in *Awakenings* confessed, "our models . . . were insufficient to

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238. Thompson, *supra* note 108, at 11 (recounting the following situations: 1) a woman with diabetes who wanted to get pregnant, abort, and have the islet cells of the fetus transplanted into her as a cure for diabetes; 2) a woman who was searching for a doctor to put fetal cells into her husband from the brains of fetuses that their daughters would conceive; and 3) a woman who wanted to conceive from the sperm of her father with Alzheimer's disease and then abort to provide cells for transplantation into his brain.); *see also* Andrusko, *supra* note 134, at 10.

239. Andrusko, *supra* note 134, at 10. *Contra* H.R. 5495, § 111 (prohibiting donation to a designated recipient); *see also* FTTR PANEL I, *supra* note 25, at 8 (recommending that federal funding be denied for intrafamilial use of fetal tissue, subject to further developments in scientific knowledge).

240. Hoffer & Olson, *supra* note 41, at 385; *see also* Specter, *supra* note 214, at A39 (quoting Jay Katz, Yale Law Professor and leading researcher in the ethics of human experimentation) ("[w]e might as well dispense with informed consent. . . . It is now practiced as a bit of a charade.").

241. *Id.*

242. OLIVER SACKS, *AWAKENINGS* (5th ed. 1983).

243. *Id.* at 192.

244. *Id.* at 188-189, 192.

245. *Id.* at 194-200.

allow comprehension, let alone control, of the peculiar and universal difficulties now encountered."<sup>246</sup>

In a desperate situation like that portrayed in *Awakenings*, there is no doubt that many patients and their families will try anything that may lead to a cure. Unfortunately, some researchers will also try anything or "take [consent] as a license to do whatever they want."<sup>247</sup> The rationale underlying much experimental therapy and fetal harvesting centers on the opinion that "people are going to die anyway."<sup>248</sup> This position arguably disregards the protection that authentic consent intended to provide to the participants in the fetal tissue research maze.

#### IV. UNSATISFACTORY STATUS QUO AND THE LEGISLATIVE RESPONSE

Although many people, including the experts, attempt to divorce the fetal tissue issue from abortion, they fail.<sup>249</sup> The connection of the morality of abortion and the subsequent experimental or transplantation use of the fetus, however, does not necessarily condemn the research. The connection merely challenges those formulating public policy to do so with that recognition.

Consideration must be given to the value ascribed by the community to the fetus, as well as the community's responsibility to protect it, the woman carrying it,<sup>250</sup> and the patient in need of a cure. The ban at issue prohibits only federally funded transplants that would purposefully connect the three parties.<sup>251</sup> The ban does not protect the fetus from other uses, such as transplantation into animals or use in cosmetics, for example.<sup>252</sup> Nor does it limit a woman's choice in terminating a pregnancy for any reason.<sup>253</sup> Nor does it

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246. *Id.* at 32.

247. Specter, *supra* note 214, at A33 (quoting Arthur Caplan, Director of the Biomedical Ethics Center at the University of Minnesota who also stated that " 'the fact consent was obtained is least likely to mean the patient is being treated ethically.' ").

248. *Id.* at A33 (quoting George Annas, Professor of Health Law at Boston University Medical School, in his critique of experimental therapy).

249. Fletcher, *supra* note 14, at 102 (discussing the two clashing ethical perspectives on the separability of abortion from FTTR); *see also* FTTR PANEL I, *supra* note 25, at 50-52 (discussing whether the research is "dissociable from abortion").

250. Archibald, *supra* note 157, at A7 (quoting Janice Raymond, a feminist who favors legal abortion, yet sounds the lone warning that women will " 'become the resources whose bodies are mined for scientific gold, whose body becomes raw material. We are also concerned that women do not become handmaidens to medical procedure transplants.' "). Archibald also reports on the consent procedure used by the medical school surgeon for the Nathan Walden fetus-to-fetus transplant: "[H]e ran alongside the hospital stretcher carrying a woman with a tubal pregnancy to convince her to give him the fetal remains after her emergency abortion." *Id.*

251. *The Sullivan Statement*, *supra* note 26, at 1.

252. *Id.*

253. *Id.*

protect a person in need of a cure from undergoing other experimental therapies. If the government has a legitimate interest in any of the three parties, the ban does not make that concern clear. The ban is, rather, the proverbial finger in the dike with regard to FTTR.

The legislative response set forth in the NIH Amendments does not clarify public policy in this matter either. Although they recognize that society is charged with protecting something of human dignity, the Amendments' compromising and confusing regulatory procedures undermine this idea.<sup>254</sup> Furthermore, the Amendments commodify women and the unborn, and deceive those in need of help when then they give so much attention to an unproven promise.<sup>255</sup>

Finally, the Amendments' limited condemnation of abortion makes for confusing public policy. Congress laid out morally weighted procedures to divorce the means and ends and limited these to federally funded activities.<sup>256</sup> Rather than recognize the incongruity of such a legal enterprise, Congress sought to pass federal law incommensurate with any other regulation regarding abortion or research.

## V. CONCLUSION

FTTR is expensive in human terms for women, the unborn, patients, and society at large. Federal funding will not lessen these human costs, but it will further confuse the entangled ethical issues. Procedurally correct federal funding will also not lessen the real risks, if in substance, the research is not in the community's interest.

The purpose of law is to order the common good.<sup>257</sup> A law that reinforces our respect for women, their maternal gift, and the fruit of their womb would serve the common good. When each human being, regardless of his or her status as a legal entity, can be regarded with dignity, the human community is better off. When that respect is diminished, disregard is contagious and will lead to horrific results. The idea of a marketplace of human parts procured from those without a voice is so barbaric that we deny its possibility. Today, however, it is not far-fetched. Having a healthy stock of human fetuses in the research freezer may be the ordinary.<sup>258</sup> Vivisection on

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254. See *infra* part II.B.

255. Landau, *supra* note 3, at 739 ("The irreversible tragedy is the death and damage to many patients and their families produced by the extravagance of the transplantation fad.")

256. See generally H.R. 2507 §§ 112, 113 and H.R. 5495 §§ 112, 113 (delineating procedures to separate women, abortion providers, researchers, and their respective responsibilities and interests).

257. THOMAS AQUINAS, *SUMMA THEOLOGICAE*, I-II, q. 90, a.2.

258. See Bond, *supra* note 200, at 35.

live non-consenting humans (non-viable, pre-viable, viable, anencephalic) will continue behind the protected doors of the researcher,<sup>259</sup> unless we are willing to unbolt the doors, turn on the lights, and honestly assess the human values at stake. Farsighted, sound public policy depends on laws made in the interest of the common good, a good that celebrates humanity and creation, not one that consumes it.

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259. *See supra* text accompanying note 130.

