The NIH Revitalization Act of 1993 Washed Away Many Legal Problems with Fetal Tissue Transplantation Research but a Stain Remains

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THE NIH REVITALIZATION ACT OF 1993 WASHED AWAY MANY LEGAL PROBLEMS WITH FETAL TISSUE TRANSPLANTATION RESEARCH BUT A STAIN REMAINS

James E. Goddard*

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I. INTRODUCTION

FETAL tissue transplantation (the injection of fetal tissue into persons suffering from certain diseases or disorders) is a relatively new technology. It holds as much controversy as it does promise for curing many diseases. Recent studies have shown that fetal tissue transplants have the potential to restore functioning in persons suffering from severe chronic diseases like Parkinson's disease and juvenile diabetes, and many nervous-system disorders. Scientists and doctors promote and justify experimental research using fetal tissue because it has the potential to cure or greatly improve the quality of life for thousands and possibly millions of suffering patients.

Despite the praises of scientists and doctors, the issue of fetal tissue transplantation research has become a source of heated legal and ethical debate over the past two decades. Although fetal tissue research has been conducted in the United States for over half a century (and played a part in the development of the polio and rubella vaccines), it did not

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1. Experiments have been performed on fetuses for many years in this country, but research involving the use of fetal tissue to cure post-birth illnesses has generally only been attempted since the early 1970s. BONNIE STEINBOCK, LIFE BEFORE BIRTH 172 (1992).

2. See Lee M. Sanders et al., Ethics of Fetal Tissue Transplantation, 159 W.J. MED. 400 (1993).

3. See STEINBOCK, supra note 1, at 171.

4. Rachel B. Gold & Dorothy Lehrman, Fetal Research Under Fire: The Influence of Abortion Politics, FAM. PLAN. PERSP., Jan-Feb. 1989, at 6-7. The polio vaccine was developed with cultures of human fetal kidney cells and fetal tissue was used by the developers of the rubella vaccine to show that the vaccine virus crossed the placenta to infect the fetus. Id. at 7.
Fetal Tissue Transplants capture public attention until the legalization of abortion in 1973. A politically-based debate has since raged over the legality and morality of fetal tissue transplantation research. Many believe fetal tissue transplantation research is morally acceptable because fetuses are not yet human. Many others believe fetuses are human beings and, therefore, experimenting on them is unethical.

Congress attempted to solve the legal and moral problems involved with fetal tissue transplantation research by passing the NIH Revitalization Act of 1993 (“the Act”). This law effectively separates the decision to abort from the decision to donate fetal remains. Additionally, the Act makes it a criminal offense to purchase or to sell any fetal tissue. The specific designation of a person to receive fetal tissue or a promise of such a designation is also made a criminal offense. Although Congress meant for the Act to resolve the existing problems surrounding this issue, it seems that the law may have opened up a new legal can of worms over fetal tissue transplantation research.

The Act on its face is extremely vague. It provides that fetal tissue transplantation research may only be conducted for “therapeutic purposes” but neglects to define that term. Moreover, the Act criminalizes the sale and purchase of fetal tissue for an amount above reasonable processing fees but does not specifically reveal what reasonable processing fees might be. The Act also appears to infringe upon a woman’s fundamental right to have an abortion by making it illegal for the mother to designate the recipient of the fetal tissue.

6. For a discussion on the ethical debate over fetal tissue transplantation research, see infra notes 81-95 and accompanying text.
7. The pertinent part of this Act has been codified at 42 U.S.C. § 289g-1 & g-2 (Supp. V 1993).
10. Id. § 289g-2(b) (Supp. V 1993).
11. See id. § 289g-1(a) (Supp. V 1993).
13. Id. § 289g-2(b) states:
   It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, 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
This Comment discusses these problems. Part II provides a brief description of fetal tissue transplantation research. Part III contains a discussion of the benefits of this type of research. Part IV presents a historical sketch of fetal tissue research in the United States. Part V exposes some aspects of the ethical debate over this research. Part VI reveals the state of current federal law on the topic. With the framework explained in Parts II-VI, Part VII then discusses various problems that remain after the adoption of the NIH Revitalization Act of 1993. Lastly, Part VIII suggests some of the changes that Congress should implement to remedy these problems.

II. DESCRIPTION OF FETAL TISSUE TRANSPLANTATION RESEARCH

Fetal tissue transplantation is a delicate procedure in which cells taken from the brain, pancreas, or other parts of an aborted fetus are processed and injected directly into the faulty organs of persons suffering from particular diseases. As of 1993, experimentation had been performed on "patients with Parkinson's disease, insulin-dependent diabetes, the DiGeorge syndrome, severe combined immunodeficiency, aplastic anemia, acute myelogenous leukemia, thalassemia, Fabry's disease, Hurler's syndrome, and Gaucher's disease." Some researchers and physicians contend that fetal tissue could possibly be used to treat Alzheimer's disease, congenital heart, liver, and kidney failure, and other blood and endocrine problems in humans. Thus far, physicians have met with limited success in treating Parkinson's disease, the DiGeorge syndrome, juvenile (insulin-dependent) diabetes, and certain nerve injuries.

A. PARKINSON'S DISEASE

Parkinson's disease is caused by the degeneration of brain cells located in the substantia nigra. The death of these cells results in a decrease in the brain's production of dopamine, a neurochemical necessary for...
proper motor coordination. The result of this lack of dopamine is violent trembling and muscular rigidity.

Since 1987, researchers have transplanted dopamine-producing fetal cells into the brains of patients with Parkinson's disease. Results have varied, but the research consistently shows that transplantation improves "self-assessed quality of life; it decreases the frequency and intensity of 'freezing spells'—a characteristically disabling feature of the disease—and decreases the required dosage of levodopa." These results indicate that fetal tissue transplantation may be the source of a cure for Parkinson's disease. There are, however, at least three alternate explanations for these benefits.

First, poking around in the brain during surgery may stimulate diseased cells to start production of repair chemicals, including growth factors that could trigger dopamine release. Second, perhaps the developing fetal cells themselves make the growth factors but not dopamine. Or third, the success stories may have nothing at all to do with the transplants but are just part of the mysterious remission-and-relapse cycle characteristic of Parkinson's.

In any case, the National Institutes of Health recently awarded a $4.5 million grant to test the benefits of dopamine-producing fetal tissue transplants in the brains of Parkinson's patients. Dr. Curt Freed of the University of Colorado received the grant and will use the money to experiment on forty patients suffering from the disease. The patients will have small holes drilled into their skulls through which injections can be made directly into their brains. Half of the patients will have fetal cells injected into these holes and the other half will act as a control group and will be injected with only a saline solution. This study should

19. McAuliffe, supra note 14, at 69.
20. See id.; see also Jaroff, supra note 18, at 56. Another aspect of the disease is that even though Parkinson's patients eventually lose the ability to talk, walk, and move, their mental facilities remain untouched. Traci Watson, A Tissue of Promises, U.S. News & World Rep., Aug. 8, 1994, at 50.
21. Sanders, supra note 2, at 401.
23. Sanders, supra note 2, at 401. Levodopa, or L-dopa, is a drug that has been given to Parkinson's patients since the 1960s to boost the amount of dopamine in their brains to a normal level. The Encyclopedia of Common Diseases 1063 (Charles Gerris et al. eds., 1976); see Jeff Goldberg, Fetal Attraction: Fetal Tissue Transplant Treatment for Parkinson's Disease, Discover, July 1995, at 86.
26. Id.
28. Id.
provide definitive results as to the efficacy of fetal tissue transplants for Parkinson's patients.

B. **DiGeorge Syndrome**

The DiGeorge syndrome is "an immunodeficiency resulting from the absence of thymus and parathyroid tissue at birth." It is extremely rare but very deadly. Among the symptoms of the disease are heart defects, mental retardation, and severe immune system deficiencies. For over twenty-five years patients with the DiGeorge syndrome have responded well to transplants of fetal thymus cells. Fetal thymus transplantation remains the only treatment option for this disease if a tissue-compatible sibling is not available.

C. **Juvenile Diabetes**

Juvenile (insulin-dependent) diabetes occurs when the pancreatic cells that produce insulin gradually die. The lack of insulin allows blood-sugar levels to rise dangerously and can cause the rupture of eye capillaries (resulting in blindness) and heart and kidney failure. Daily injections of insulin are necessary to slow the effects of the disease, but they cannot prevent the disease from progressing.

By implanting specially cultured insulin-producing fetal tissue, some researchers have been successful in treating insulin-dependent diabetes. Of thirty-nine diabetics treated with fetal tissue transplants at Shanghai People's Hospital since 1982, three were no longer insulin dependent and the others reduced their insulin requirements from thirty percent to almost one hundred percent. Results in the United States have not been as impressive.

29. Sanders, supra note 2, at 401.
30. Thompson, supra note 24, at 53. If the absence of the thymus gland is not corrected, the child is apt to die of infection within the first year of its life. Kenneth J. Ryan, Tissue Transplantation from Aborted Fetuses, Organ Transplantation from Anencephalic Infants and Keeping Brain-Dead Pregnant Women Alive Until Fetal Viability, 65 S. CAL. L. REV. 683, 684 (1991). The absence of the thymus results in the person falling victim to many viral and fungal infections that the person is unable to fight off due to weak production of lymphocytes. Rebecca H. Buckley, Immunodeficiency Diseases, 268 JAMA 2797, 2800-01 (1992).
33. Ryan, supra note 30, at 685.
34. McAuliffe, supra note 14, at 68.
35. Id.
36. See Levine, supra note 17, at 62; McAuliffe, supra note 14, at 68.
37. Levine, supra note 17, at 62.
38. Id.
39. Id. The reduction in insulin requirements for diabetics after transplantation in the United States appears to be transient. Medical Applications of Fetal Tissue Transplantation, 263 JAMA 563 (1990). The greatest reduction of insulin requirements recorded is 30%,
D. Nerve Injuries

Injuries that cause damage to the spinal cord are currently incurable because the damaged nerve cells cannot repair themselves. Doctors, however, have attempted fetal nerve cell transplantations on cats with some success. In one experiment, partially paralyzed cats were injected with fetal nerve cells and some began to walk again—one cat could even climb stairs. The researchers believe the growing fetal cells branched out and connected with the cats' undamaged nerve tissue, raising hopes that the same potential exists for humans.

E. The Necessity for Electively Aborted Tissue

Most researchers contend that the success of fetal tissue transplantation depends on tissue obtained through elective abortions. Fetuses obtained from spontaneous abortions and ectopic pregnancies often contain genetic abnormalities that make the tissue unusable in transplantation research. Thus, it seems essential that research be conducted with electively-aborted tissue to lessen the risk of infecting a recipient with genetically-defective tissue and to increase the likelihood of the transplantation's success.

III. Benefits of Fetal Tissue Transplantation

Fetal tissue holds great promise for helping to cure many diseases because it has several unique properties that make the transplantations effective. Unlike transplants involving adult human tissue, fetal tissue transplants are generally not rejected by the recipient's body. This is because fetal tissue has a greater growth ability, special immune properties, and is more adaptable than adult tissue.

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however, many times it is closer to 0%. See Levine, supra note 17, at 62; McAuliffe, supra note 14, at 69; Thompson, supra note 24, at 53.

40. Watson, supra note 20, at 50.

41. Id.

42. Id.

43. Id.

44. See Jaroff, supra note 18, at 57; Levine, supra note 17, at 62; Sanders, supra note 2, at 404; Thompson, supra note 24, at 53.

45. Jaroff, supra note 18, at 57. It has been contended that only 3.8% of spontaneous abortions will provide tissue eligible for transplantation, but this figure includes fetuses which died much earlier in pregnancies and, thus, were not developed enough for transplantation. Sanders, supra note 2, at 404. Of ectopic pregnancies, only 1% are unassociated with tubal hemorrhage that causes early organ death in fetuses. Daniel J. Garry et al., Are There Really Alternatives to the Use of Fetal Tissue from Elective Abortions in Transplantation Research? 327 NEW ENG. J. MED. 1592, 1595 (1992).

46. See S. REP. NO. 2, supra note 8, at 21.

47. Ryan, supra note 30, at 684.

48. See infra notes 49-58 and accompanying text.
A. GROWTH ABILITY

One of the greatest advantages of fetal tissue is that it has a greater ability to divide and grow than adult tissue.\textsuperscript{49} Cell division occurs very rapidly in a fetus and then slows with age.\textsuperscript{50} "Similarly, the percentage of cells capable of division decreases with age."\textsuperscript{51} Fetal tissue thus has a greater potential to grow inside a transplant recipient and to possibly repair damaged cells than does adult tissue.

B. SPECIAL IMMUNE PROPERTIES

Another advantage of fetal tissue is that these cells have special immune properties.\textsuperscript{52} Fetal cells have not yet developed all the antigens that cause the recipient's immune system to locate and subsequently reject them.\textsuperscript{53} Moreover, the cells can be purified to reduce the possibility of rejection.\textsuperscript{54} Thus, there is little need for tissue matching or immunosuppression treatment with fetal tissue transplants.\textsuperscript{55}

C. ADAPTABILITY

Another unique advantage of fetal tissue is its adaptability or "plasticity."\textsuperscript{56} Fetal cells have the ability to functionally adapt to their environment.\textsuperscript{57} They "change shape, migrate, and become functionally integrated into their surroundings better than cells from an older organism."\textsuperscript{58} This means that fetal tissue has the potential to replace, if not entirely repair, damaged cells in a patient.

D. ABILITY TO BE FROZEN

Another characteristic that makes fetal tissue more attractive to researchers than other tissue is, as some researchers contend, its ability to be frozen and still remain viable.\textsuperscript{59} It is not yet known with certainty, however, if frozen fetal tissue can be used for all purposes because fetal tissue transplantation research is still in its infancy stage.\textsuperscript{60} Fetal tissue appeals to many researchers because, unlike many other types of tissue, it appears to have this potential characteristic.\textsuperscript{61}

\textsuperscript{49} Ryan, supra note 30, at 684.
\textsuperscript{50} Gold & Lehrman, supra note 4, at 7.
\textsuperscript{51} Id.
\textsuperscript{52} Id.
\textsuperscript{53} Levine, supra note 17, at 62.
\textsuperscript{54} Id.
\textsuperscript{55} Id.
\textsuperscript{56} See id.; Ryan, supra note 30, at 684.
\textsuperscript{57} Gold & Lehrman, supra note 4, at 7.
\textsuperscript{58} Ryan, supra note 30, at 684.
\textsuperscript{60} Gelfand & Levin, supra note 5, at 656 n.53.
\textsuperscript{61} See John T. Hansen & John R. Sladek, Jr., Fetal Research, 246 Science 775, 777 (1989).
E. Availability

A particularly important advantage of fetal tissue is its availability. As of 1990 there were approximately 1.5 million abortions performed annually in the United States. The transplantable fetal tissue that could be removed from these aborted fetuses would more than adequately provide for the needs of researchers and patients.

IV. HISTORY OF FETAL TISSUE RESEARCH IN THE UNITED STATES

Fetal tissue transplantation research has been conducted in the United States since the 1930s but was relatively unheard of until 1973. That was a monumental year in this field of research; not only was it the year that Roe v. Wade was decided, it was also the year that scientists decapitated a dozen live fetuses and kept the fetal heads alive through artificial means. Around the same time, other researchers used saline solutions to keep aborted fetuses alive to determine if they could absorb oxygen. Because of public outcry over these experiments, the NIH halted all federally funded research unless it directly benefited the fetus.

All remained quiet on the fetal tissue front until 1988 when a group of NIH scientists requested approval from the Secretary of Health and Human Services (HHS) to use fetal brain tissue in a research protocol already sanctioned by the NIH's review board. In response to this request, Robert Windom, the HHS Assistant Secretary, imposed a temporary moratorium on fetal tissue research for transplantation purposes. This moratorium was intended to last until a twenty-one-member NIH panel studied and reported on the ethical, legal, and scientific issues.

63. See id.
64. Sanders, supra note 2, at 405.
66. This experiment was partially funded by the National Institutes of Health (NIH) and was designed to measure fetal metabolism. Id.
67. One fetus survived for nearly 24 hours. Id.
68. Gold & Lehrman, supra note 4, at 9.
69. Sanders, supra note 2, at 405.
70. The members of the panel were: the Honorable Arlin M. Adams, U.S. Court of Appeals (Ret.); Kenneth J. Ryan, Brigham and Women's Hospital, Boston; LeRoy Walters, Georgetown University, Kennedy Institute of Ethics; Rabbi J. David Bleich, Cardozo Law School; James Bopp, Jr., Esq.; James T. Burchnell, University of Notre Dame; Robert C. Cefalo, University of North Carolina School of Medicine, Chapel Hill; James F. Childress, University of Virginia, Charlottesville; K. Danner Clauser, Pennsylvania State University, Hershey; Dale Cowan, Marymount Hospital, Ohio; Jane Delgado, National Coalition of Hispanic and Human Services Organizations; Bernadine Healy, Cleveland Clinic Foundation; Dorothy I. Height, National Council of Negro Women; Barry J. Hoffer, University of Colorado, Denver; Patricia A. King, Georgetown University Law Center; Paul Lacy, Washington University School of Medicine, St. Louis; Joseph B. Martin, Massachusetts General Hospital, Boston; Aaron Moscona, University of Chicago; John Robertson, University of Texas School of Law; Daniel Robinson, Georgetown University; and Charles Swezey, Union Theological Seminary, Richmond, Va. Gold & Lehrman, supra note 4, at 10.
associated with this type of research. Despite the panel’s conclusion that the use of human fetal tissue for transplantation research was acceptable public policy, HHS Secretary Louis Sullivan extended the moratorium indefinitely on the grounds that this type of research would increase the incidence of induced abortions. This administrative declaration also ignored the panel’s additional recommendations that effective safeguards could be erected to ensure that abortions solely for research purposes would not occur. Thus, even though the human fetal tissue transplantation research panel represented a broad cross-section of American academia and medical professionals, its recommendations fell on deaf ears.

Legislative attempts to overturn the moratorium passed in the House of Representatives in 1991 and in the Senate in 1992. But Congress failed to achieve the necessary two-thirds vote to overcome President George Bush’s veto. Soon after taking office in 1993, President William Clinton sent a memorandum to the Secretary of HHS ordering the end of the moratorium on fetal tissue transplantation research. Subsequent to this directive, the Secretary of HHS rescinded the prohibitory ban on federal funding of this research on February 5, 1993. Within days, a bill was presented in the Senate, amended by the House of Representatives, and rapidly passed by both houses of Congress on May 28, 1993. On June 10, 1993, President Clinton signed Public Law 103-43 into effect as the NIH Revitalization Act of 1993.

V. ASPECTS OF THE ETHICAL DEBATE OVER FETAL TISSUE TRANSPLANTATION RESEARCH

A. OPPONENTS TO FETAL TISSUE TRANSPLANTATION RESEARCH

The most well known opponent to the use of fetal tissue in transplantation research is James T. Burtchaell. He contends that fetal tissue transplantation research is improper under any circumstance. He

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71. See id. at 9, 10.
73. See Sanders, supra note 2, at 405.
75. Sanders, supra note 2, at 405.
76. President’s Message to the House of Representatives Returning Without Approval the National Institutes of Health Revitalization Amendments of 1992, 28 WEEKLY COMP. PREL. DOC. 1132 (June 23, 1992).
79. S. REP. NO. 2, supra note 8.
81. Burtchaell, a theologian at the University of Notre Dame, was a member of the human fetal tissue transplantation research panel. Gold & Lehrman, supra note 4, at 10.
believes that “one must decide at the outset not to exploit any human individuals to obtain prospective benefits for others,” which is the exact effect of fetal tissue transplantation research. Burtchaell argues that there are at least three strong objections to fetal tissue transplantation research on electively aborted fetuses: 1) once a woman has an abortion, she has abandoned her parental capacity to authorize research on the fetus; 2) any researcher acts with moral complicity in the destruction of the fetus after the fact if he or she participates in research on the tissue; and 3) there are other sources of fetal materials available for use in research (such as spontaneous abortions and ectopic pregnancies). For these reasons, Burtchaell adamantly opposes any federal legislation that favors fetal tissue transplantation research.

Kathleen Nolan also contends that fetuses from elective abortions should not be eligible as sources of transplantable tissue. She states that any woman who acts as the “agency of death” of a relative should not be able to act also as a decision-making proxy for that relative’s organ donation. The fetus, in her eyes, is a murder victim and since murderers cannot consent to the donation of their victim’s organs, aborting mothers should not be allowed to consent to the donation of the aborted tissue. She concludes that only tissue from spontaneous abortions and ectopic pregnancies should be used in fetal tissue transplantation.

The dissents found in the human fetal tissue transplantation research panel’s report also raised some interesting issues in opposition to this type of research. In his dissent, J. David Bleich argued against allowing fetal tissue transplantation research in this country. He stated that although the potential this research holds appears promising, it is diminished by two elements: 1) the therapeutic efficacy of the procedure is yet unknown, and 2) the benefits will only accrue to future patients. For Rabbi Bleich, a moral harm which outweighed the prospective benefits of fetal tissue transplantation research was certain to result if the panel’s recommendations were implemented.

Burtchaell authored a joint dissent with James Bopp in which they contended that fetal tissue transplantation research is ethically compromised by at least three factors: 1) the lack of authentic consent; 2) the complicity with the abortions; and 3) the incentives it will offer for more abortions. Due to these factors, Burtchaell and Bopp refused to conclude, as did all others on the panel except Rabbi Bleich, that fetal tissue transplantation research is morally appropriate.
B. PROONENTS OF FETAL TISSUE TRANSPLANTATION RESEARCH

The number of authors who favor fetal tissue transplantation research far outweigh the number of opponents. Most proponents believe that as long as ethical guidelines separate the decision to abort from the decision to donate fetal tissue, salvaging tissue from an aborted fetus is consistent with organ donation from any human cadaver and, therefore, is ethically appropriate. For them, the use of an electively aborted fetus in transplantation is more ethically correct than the alternative dispositions as organic trash which had been the prevailing method of aborted fetal tissue disposition prior to the enactment of the NIH Revitalization Act of 1993.

John Robertson has concluded that we have an ethical duty to cure diseases and alleviate suffering wherever possible. Since fetal tissue transplantation research accomplishes this task, as long as it is well-regulated, it is ethically correct. Professor Robertson believes that this type of research is not only morally appropriate, it is necessary. The necessity of fetal tissue transplantation research exists because it has the potential to cure many persons, and tissues available from spontaneous abortions will not be able to fulfill all the research needs involved. For him, and many others, the end justifies the means.

VI. FEDERAL LAW GOVERNING FETAL TISSUE TRANSPLANTATION RESEARCH

Although the primary law concerning fetal tissue transplantation research is currently located in the NIH Revitalization Act of 1993 (the relevant part of the Act is codified at, and hereinafter referred to as, 42 U.S.C. §§ 289g-1 & g-2), there are several other federal laws that have a...
significant impact on this type of research. Among these relevant federal laws are: cases, regulations, a uniform law, and additional federal statutes.

A. Case Law

1. Margaret S. v. Treen

This case questioned various provisions of a now-repealed Louisiana abortion statute. In 1980 the District Court for the Eastern District of Louisiana upheld the constitutionality of the statute as it related to the prohibition of experimentation, unless therapeutic, on a live or unborn child. In 1981, the Louisiana legislature amended the statute to include non-viable fetuses within its scope. The revision was subsequently found by the district court to be unconstitutional. The court concluded that the amended provision of the statute was "violative of the equal protection clause of the Fourteenth Amendment because it infringe[d] on the rights of physicians to participate in fetal research . . . ."

B. Federal Regulations


This regulation was originally promulgated in 1975 and as such is the earliest federal law on the issue. Its scope includes research involving "(1) the fetus, (2) pregnant women, and (3) human in vitro fertilization." Of particular interest to this Comment are sections 46.209 and 46.210, concerning fetuses that are out of the womb (ex utero). Section 46.209 focuses on viable and nonviable (but living) fetuses ex utero and allows research on them in a very limited set of circumstances.

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99. The amendment stated: "No person shall experiment on an unborn child or child born as a result of abortion, whether the unborn child or child is alive or dead, unless the experimentation is therapeutic to the unborn child or child." LA. REV. STAT. ANN. § 40:1299.35.13 (West Supp. 1982).
100. Margaret S. v. Treen, 597 F. Supp. at 676.
101. Id. at 675.
103. 45 C.F.R. § 46.201 (1994).
104. If an ex utero fetus is found to be viable, it is considered human and thus may only be experimented on as any other human. 45 C.F.R. § 46.209(c) (1994). If the viability of the fetus is yet to be determined, research will not be allowed unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or
The regulation also establishes two very narrow consent limitations that must be satisfied before research may be conducted on nonviable fetuses or fetuses whose viability has not yet been determined. First, informed consent must be obtained from the mother and father. Second, informed consent is only valid if both parents are "legally competent." Section 46.210 concerns itself only with "dead" fetuses and states that research may only be conducted on them "in accordance with any applicable State or local laws regarding such activities."  


This regulation merely states that all federal grants relating to fetal tissue transplantation research are subject to the provisions set forth in Part 46 of Title 45 in the Code of Federal Regulations relating to the protection of human subjects. Thus, to receive federal funding, all researchers desiring to perform fetal tissue transplantation research are required to conduct their research in accordance with the previously discussed regulation.  

C. THE UNIFORM ANATOMICAL GIFT ACT  

The Uniform Anatomical Gift Act was first proposed in 1968 and was later substantially revised to its present form, commonly referred to as the Uniform Anatomical Gift Act of 1987. This uniform law was established to govern tissue donation from all dead humans, including dead fetuses. The law permits the use of human tissue for the purpose of education, research, or the advancement of science. The law, however, requires that a physician determine the time of death and that in-
formed consent be obtained prior to the donation of any tissue. The fetus' parents have the highest decisional authority in granting the requisite consent.

The 1987 revision added section 10 which explicitly prohibits the actual sale or purchase of any human body parts for any consideration beyond that necessary to pay for expenses incurred in the removal, processing, and transportation of the tissue. Violation of this provision in the states that have adopted the 1987 version of the Uniform Anatomical Gift Act is considered a felony and carries a severe penalty. Within these limitations, some states have nonetheless added a clarification specifying that the donation of human tissue for transplantation is to be understood as a service and not as a sale.

Although the 1968 version of the Act was adopted by all fifty states and the District of Columbia, as of 1993 only fifteen states had incorporated the 1987 version within their statutes. In this context, it is important to recognize that uniform laws defer final control to the states and, as such, need to be ratified by the individual state legislatures to be legally binding and enforceable. Thus, the current version is law in only those fifteen states that have specifically adopted it.

D. Federal Statutes


This Act outlines the recommendations under which research involving living human fetuses may be conducted. It includes provisions applicable to both nonviable aborted fetuses and living human fetuses ex utero for whom viability has not yet been determined. The Act limits fetal research or experimentation to those projects that may enhance the well-being or health of the fetus, without imposing added risk, and whose pur-

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116. Id. § 3.
117. See UNIF. ANATOMICAL GIFT ACT § 10(a)-(b), 8A U.L.A. 58.
118. Id. § 10(c). A maximum civil fine of $50,000 is authorized through this section as well as a potential five-year jail sentence. Id.
119. Id. § 11 cmt., 8A U.L.A. 60.
120. TABLE OF JURISDICTIONS, UNIF. ANATOMICAL GIFT ACT OF 1968, 8A U.L.A. 63.
123. Section 289g(a) states:

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation -

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
pose is to develop important biomedical knowledge that is not obtainable by other means.\footnote{124}{Id.}


This statute prohibits the selling of any human organ for valuable consideration if the sell involves interstate commerce.\footnote{126}{Id. § 274e(a).} In 1988 Congress amended the definition of “human organ” to include fetal organs.\footnote{127}{Id. § 274e(c)(1).} Thus, the Act effectively prohibits the selling of fetal tissue for valuable consideration if the sale affects interstate commerce.


The NIH Revitalization Act of 1993 incorporates most of the prior federal statutory and regulatory provisions on fetal tissue transplantation to form a fairly comprehensive set of guidelines governing this type of research.\footnote{129}{Id. The Senate Report accompanying the bill contends that Congress intended “the guidelines in this bill be promulgated uniformly in both public and private sectors and monitored by the National Institutes of Health,” S. Rep. No. 2, supra note 8, at 23. Thus, although the Act, on its face, purports to be limited to federally-funded research, the legislative history of the Act states that the law is meant to address privately-funded research as well.} It also provides elaborate consent and documentation requirements to effectively separate the decision to abort from the decision to donate the fetal tissue.\footnote{130}{Id. at 22.} The relevant part of the Act consists of a series of requirements, a series of prohibitions, and a list of criminal and civil penalties.

\begin{itemize}
\item[a.] \textbf{Requirements}
\end{itemize}

The Act allows the tissue from any type of abortion to be used in fetal tissue transplantation research,\footnote{131}{42 U.S.C. § 289g-1(a)(2) states: “Human fetal tissue may be used in research regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.”} but the tissue can only be used for “therapeutic purposes.”\footnote{132}{Id. § 289g-1(a)(1).} Even though Congress has expressly authorized fetal tissue transplantation research to be conducted with electively-aborted tissue,\footnote{133}{Id. § 289g-1(a)(2) pronounces that: “Human fetal tissue may be used in research carried out [for therapeutic purposes] regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.”} federally-funded research must be performed in accordance with state law.\footnote{134}{Id. § 289g-1(e). Additionally, research that is conducted by the Department of Health and Human Services may only be conducted “in accordance with applicable State and local law.” Id.} Also, before tissue can be used for fetal tissue transplantation research, a written statement must be provided by the
mother of the fetus verifying that three requirements have been satisfied: 135 1) she is donating the tissue to be used only for therapeutic purposes; 136 2) there have been no restrictions placed on who may be a recipient of the tissue; 137 and 3) she has not been told who the recipient is. 138

Similarly, the attending physician who performs the abortion must sign a written statement certifying that five additional requirements were met before the abortion was conducted. 139 First, the mother’s consent for the abortion must have been “obtained prior to requesting or obtaining consent for a donation” for use in the transplantation research. 140 Second, there must have been “no alteration of the timing, method, or procedures used to terminate the pregnancy” so that higher quality tissue could be obtained. 141 Third, the abortion must have been “performed in accordance with applicable State law.” 142 Fourth, the tissue must have truly been donated in accordance with the requirements set out in the mother’s statement. 143 Last, the mother must have been fully informed of the doctor’s “interest . . . in the research to be conducted,” 144 and “risks to her privacy that might be associated with the donation of the tissue . . . .” 145

Moreover, the person primarily responsible for the research to be performed on the fetal tissue must make a written statement declaring several things. 146 First, he must state that he is aware “the tissue is human fetal tissue” which “was donated for research purposes.” 147 Second, he must state that he has provided this information to others involved in the research. 148 Third, before the researcher gets consent from a recipient of the transplantation, he must obtain a written acknowledgment from that person that they are aware of the type of tissue to be used. 149 Last, the researcher must state that he “had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purpose of the research.” 150

136. Id. § 289g-1(b)(1)(A).
137. Id. § 289g-1(b)(1)(B).
138. Id. § 289g-1(b)(1)(C).
139. Id. § 289g-1(b)(2).
140. Id. § 289g-1(b)(2)(A)(i).
141. Id. § 289g-1(b)(2)(A)(ii).
142. Id. § 289g-1(b)(2)(A)(iii).
143. Id. § 289g-1(b)(2)(B).
144. Id. § 289g-1(b)(2)(C)(i).
145. Id. § 289g-1(b)(2)(C)(ii).
146. Id. § 289g-1(c).
147. Id. § 289g-1(c)(1)(A).
148. Id. § 289g-1(c)(1)(C).
149. Id. § 289g-1(c)(1)(B).
150. Id. § 289g-1(c)(3).
151. Id. § 289g-1(c)(4).
b. Prohibitions

Apart from the general prohibitions found in section 289g-1 for which no penalties are articulated, section 289g-2 lists four specific prohibitions to which heavy criminal and civil penalties are attached. The first prohibition is that there shall be no purchasing or selling of fetal tissue beyond reasonable preparation and handling costs. Second, soliciting or acquiring a donation of fetal tissue by promising the mother she can designate the donee is expressly prohibited. Also, it is unlawful for a person to promise the mother that the fetal tissue will be transplanted into one of her relatives so that she will donate the tissue. Similarly, the Act prohibits the solicitation or acquisition of donated tissue by the person who "has provided valuable consideration for the costs associated with [the] abortion." The one limitation placed on these prohibitions is that the transfer, solicitation, donation, or acquisition of the tissue must affect "interstate commerce." The statute expresses that "interstate commerce" has the same meaning attached to that term in 21 U.S.C. § 321(b).

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area." Any person who commits one of the offenses listed in the prohibitions section "shall be fined in accordance with Title 18, subject to paragraph (2)" or imprisoned for up to ten years or both. For those who transfer fetal tissue through interstate commerce and those who solicit or acquire the tissue after providing "valuable consideration for the costs associated with [the] abortion" a specific fine is to be imposed. Persons who fall within that group shall be fined at least twice as much as the amount of the "valuable consideration" they received.

VII. REMAINING PROBLEMS

The NIH Revitalization Act of 1993 solved many of the ethical and legal problems that existed with fetal tissue transplantation research prior to its enactment. But only an omniscient legislature could foresee all the potential scientific developments in a particular area or all the possible loopholes created by its legislation and thus provide a "perfect" statute on its first attempt. Unsurprisingly, Congress' first attempt at providing a comprehensive statute to cover fetal tissue transplantation research has kinks which need to be worked out of the statute over time. The following sections contemplate a few of the potential problems with the NIH Revitalization Act as enacted.

A. POSSIBLE ABUSES OF THE TECHNOLOGY

In section 289g-1(a), Congress stated that fetal tissue transplantation research may be conducted for therapeutic purposes. There is a huge problem with this section—Congress neglected to define the term "therapeutic purposes." This omission could lead to widespread abuse of fetal tissue transplantation technology.

Some have theorized that the technology may develop to the point where drugs could be produced from fetal tissue that will not only repair damaged tissue, but will have the ability to enhance the normal functioning of the body. Currently, researchers have discovered that fetal tissue injections can accelerate muscle healing in animals. It is foreseeable, then, that fetal injections could be used to "enhance—like steroids—the ability of athletes, thus raising the specter of Olympic competitors running on 'baby power.'" Thus, it is not a great leap to conceive of tissue being developed containing mind-altering substances, pheromones, adrenaline, or other materials meant to intensify existing human biological functions. All of these developments could result from research that was performed for "therapeutic purposes."

162. 42 U.S.C. § 289g-2(c)(1).
163. Id. § 289g-2(c)(2).
164. Id. § 289g-2(c)(2).
165. Woodward, supra note 65, at 53.
166. See id.
167. Id.
B. VAGUENESS OF THE CONSIDERATION PROVISIONS

The Act explicitly states: "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration . . . ."168 The Act also contends that "'valuable consideration' does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."169 Thus, the Act purports to allow the sale of tissue for valuable consideration if only "reasonable" handling costs are charged. This leaves a lot of room for unscrupulous tissue processors to abuse the law and reap large financial rewards while providing inferior quality tissue.

Consequently, the Act's very purpose (making quality fetal tissue available to researchers) is undermined by the vagueness of such a provision. It is not hard to imagine an organization that processes fetal tissue cutting every conceivable corner so that they have minimal overhead for a piece of tissue, but charging the greatest possible amount in the name of "reasonable" processing fees. Imagine a firm in California deciding to go into business as a fetal tissue processing plant. The plant receives all of the discarded fetal tissue from abortions performed in the area. The plant then performs minimal preparation to turn the discarded tissue into apparently transplantable tissue. After this, they throw the tissue into a freezer that they have purchased at a garage sale. Up to this point, entire preparation costs total twenty-five dollars.

Next, a researcher in New York asks that transplantable tissue be shipped to him for transplantation into a Parkinson's patient. The inadequately prepared tissue is then mailed to the researcher in a small styrofoam cooler that costs the processors five dollars. The handling costs for this transaction total thirty dollars.

The researcher, however, is not charged thirty dollars. He is charged one thousand dollars for "reasonable" processing and shipping fees. After all, one thousand dollars is not entirely unreasonable when one considers all the costs involved in adequately preparing tissue for transplantation.170 The firm would thus have a $970 profit for each transaction. If the firm were to make such a transaction just once a day, it would have a yearly profit of over $350,000. In addition to the cost problem, the transplantation will likely be unsuccessful because the tissue was

169. Id. § 289g-2(d)(3).
170. In the above example, the unethical California firm could claim the following expenses:
   1) Processing - $300;
   2) Quality Control - $200;
   3) Preservation - $100;
   4) Storage - $100; and
   5) Transportation - $300.
These expenses, while potentially accurate if the tissue were properly handled and shipped, are grossly disproportionate to the cost actually incurred by the hypothetical California firm.
inadequately processed and shipped. This may lead many to believe that transplantations do not work; even though they could work if performed with adequately prepared tissue.

C. CONSTITUTIONAL IMPLICATIONS OF THE CRIMINAL BAN ON DESIGNATED DONATION

The NIH Revitalization Act of 1993 states:

It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, 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 person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.171

This section effectively makes it illegal for a woman to get pregnant for the sole purpose of creating fetal tissue for transplantation.172

In a recent article, John Robertson contends that this section makes the Act unconstitutional.173 Professor Robertson argues that the decision to abort solely to obtain tissue for transplantation involves a woman’s "fundamental rights of privacy, bodily integrity, and procreative autonomy."174 For Robertson, the fact that the Act does not, by its own terms, prohibit abortions to obtain tissue for transplantation is irrelevant.175 Although the prohibition in the Act appears directed at the physician or researcher who will obtain the tissue from the woman who aborts, the prohibition infringes on a woman’s fundamental right to have an abortion.176

According to Professor Robertson, this is true for two reasons: 1) the purpose of the prohibition infringes on a woman’s fundamental right to abort, and 2) the prohibition unduly burdens women who desire to abort so they can donate fetal tissue to loved ones.177 Robertson claims that the "purpose of the law appears clearly to be to reduce or stop abortions to obtain tissue for transplant."178 This purpose, he says, is invalid be-

172. An example being a woman getting pregnant solely to provide fetal tissue for her father who is suffering from Parkinson’s disease. See Jenn S. Bregman, Comment, Conceiving to Abort and Donate Fetal Tissue: New Ethical Strains in the Transplantation Field - A Survey of Existing Law and a Proposal for Change, 36 UCLA L. REV. 1167 (1989).
173. See Robertson, supra note 14.
174. Id. at 29.
175. Id.
176. Id. at 30.
177. Id.
cause Roe v. Wade\textsuperscript{179} and Planned Parenthood v. Casey\textsuperscript{180} reveal that "a woman is free to abort for any reason."\textsuperscript{181} The Act is unduly burdensome because it has the clear "effect of stopping women who wish to donate fetal tissue to loved ones from doing so, by removing their ability to effectuate a purpose or reason in seeking the abortion."\textsuperscript{182}

Professor Robertson contends that intrinsic in the right to abort is "the right to designate a recipient because the power to do so is central to the decision itself to abort."\textsuperscript{183} Without an abortion, there will be no fetal tissue to dispose of.\textsuperscript{184} "But the abortion will not occur, unless the woman is guaranteed the right to determine who receives fetal remains."\textsuperscript{185}

Robertson contends that Congress had two possible interests to protect in promulgating this prohibition, but neither interest is sufficient to meet a "compelling interest/less restrictive alternative standard necessary to justify infringement of fundamental constitutional rights."\textsuperscript{186} Congress' first interest in establishing the prohibition was "to minimize abortions in order to protect fetuses."\textsuperscript{187} But Roe and Casey reveal that such an interest does not create sufficient justification to override a woman's fundamental right to abort.\textsuperscript{188} Robertson also believes that the Act was meant "to prevent women from being pressured or coerced into having abortions for family members."\textsuperscript{189} He contends that this might be a legitimate interest, but there are less restrictive means available to protect this interest.\textsuperscript{190} As Professor Robertson says, "[t]he mere fact that some pressuring might occur is no reason to ban all designated donations."\textsuperscript{191}

VIII. WHAT SHOULD BE DONE?

A. Define "Therapeutic Purposes" and Provide Penalties for Non-Therapeutic Uses

The potential for the abuse of fetal tissue transplantation technology is great, but it could easily be curbed by adding two provisions to the Act. First, Congress should amend section 289g-1 to include a definition of "therapeutic purposes." Second, criminal penalties should be attached to non-therapeutic uses by including such uses in the prohibitions of section 289g-2.

An example of a proper definition of "therapeutic purposes" is:

\begin{itemize}
\item \textsuperscript{179} 410 U.S. 959 (1973).
\item \textsuperscript{180} 112 S. Ct. 2791 (1992).
\item \textsuperscript{181} Robertson, supra note 14, at 30 (emphasis added).
\item \textsuperscript{182} Id. at 30-31.
\item \textsuperscript{183} Id. at 32.
\item \textsuperscript{184} Id. at 33.
\item \textsuperscript{185} Id.
\item \textsuperscript{186} Robertson, supra note 14 at 33-34.
\item \textsuperscript{187} Id. at 33.
\item \textsuperscript{188} Id.
\item \textsuperscript{189} Id. at 34.
\item \textsuperscript{190} Id.
\item \textsuperscript{191} Id.
\end{itemize}

This definition clearly establishes that fetal tissue transplantation should only be performed for the benefit of those inflicted with certain maladies, which have caused them to function below a normal level. The second sentence of the definition also clarifies that fetal tissue transplantation research may not be performed in order to develop substances that are meant merely to enhance a healthy person’s physiological functioning. This definition would effectively eliminate the vagueness that presently accompanies the Act’s use of the term “therapeutic purposes.”

As well, certain penalties should be made to attach to those who choose, in spite of this definition, to abuse the technology. The Act should be amended to make it a criminal offense to create or use any substance formed from fetal tissue for “non-therapeutic purposes.” In other words, those who abuse the technology should be harshly fined, jailed, or both.\footnote{Section 289g-2(c)(1) currently reads: “Any person who violates subsection (a) or (b) of this section shall be fined in accordance with Title 18, subject to paragraph (2), or imprisoned for not more than 10 years, or both.” \textit{Id.} To affect the recommended change, Congress could merely change this subsection to read: Any person who violates subsection (a) or (b) of this section or subsection (a) of § 289g-1 shall be fined in accordance with Title 18, subject to paragraph (2), or imprisoned for not more than 10 years, or both.}}

B. \textbf{REQUIRE FETAL TISSUE PROCESSORS TO OBTAIN A PERMIT IN ORDER TO CHARGE FOR PROCESSED TISSUE}

The problem of unscrupulous tissue processors abusing the Act by “selling” inadequately processed tissue could be answered with a permit requirement. Congress should amend the Act to include such a requirement so that this abusive practice will be prevented in the future. A proper amendment would require that every fetal tissue processor satisfy three requirements: 1) they must have quality processing equipment to be able to produce transplantable tissue;\footnote{In tandem with this requirement, a regulation should be promulgated containing a list of devices, any combination of which would be considered quality processing equipment sufficient to produce transplantable fetal tissue.} 2) they must keep accurate records of all procedures performed on the tissue; and 3) they must report, on a monthly basis, all fetal tissue related procedures, with resulting costs, to the Department of Health and Human Services.
Such a permit program would be beneficial for at least three reasons. First, the program would ensure that all processing plants have at least the minimal quality of equipment necessary to develop transplantable tissue. Second, such a permit requirement would make data available to the proper agency concerning the type of procedures that have been performed on tissue, and the amounts of money that have been spent on these procedures. This would allow proper fines to be assessed against organizations for charging greater than "reasonable" processing fees for fetal tissue. Third, the government could inspect the facilities of each processor to be certain that proper processing procedures are being undertaken at each facility, and to fine those facilities that have reported false information or that evidence an inadequate processing of the tissue.

Additionally, the information obtained from the monthly reports could be used to establish regulations that would set limits on what qualify as "reasonable" processing fees. As data are collected by the Department of Health and Human Services, national expense numbers can be promulgated within the federal regulations that represent the average cost of each procedure to fetal tissue processors. These numbers could then be used as the guidelines for prosecuting tissue processors who charge substantially above these amounts for processed fetal tissue. The permit program coupled with the nationally promulgated "reasonable processing cost" regulations would effectively resolve the vagueness problem with the Act's consideration provisions as they currently exist.

C. AMEND THE ACT TO INCLUDE THE LEAST RESTRICTIVE MEANS AVAILABLE TO PREVENT WOMEN FROM BEING COERCED TO ABORT

Professor Robertson suggests that Congress could resolve the apparent unconstitutionality of the prohibition on designated donations through "the development of procedures to minimize coercion and undue influence on women who could produce the fetal tissue that family members need to protect their health."195 This could easily be accomplished by amending section 289g-2(b) to read:

It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and the donating individual was coerced into donating the tissue.

This amended provision would allow the government to use its prosecutorial discretion in charging individuals for violating this section, while at the same time causing no intrusion into a woman's fundamental right to abort. Thus, the amended provision would be constitutionally valid because it is the least restrictive means available to protect the

195. Robertson, supra note 14, at 35.
aborting individual’s interest of being free from coercion in making her decision to abort and donate the resulting fetal material.

IX. CONCLUSION

Congress should be commended for being able to accomplish something many before them were unable to do—provide a federal law that allows fetal tissue transplantation research to be conducted and federally supported in the United States. At the same time, however, Congress should be chastised for creating such a sloppy law. They have left the door wide open for a multitude of abuses of the technology and the law, and in the process, may have infringed on a woman’s fundamental right to have an abortion. In their attempts to assist in the development of cures for diseases, they have created the opportunity for unethicals persons to use the technology to their ultimate advantage regardless of whom it may hurt.

By making three relatively minor alterations, Congress could avoid these problems. If they merely define the term “therapeutic purposes” they could avoid the possibility of future abuse of the fetal tissue transplantation research technology. If they promulgate a permit program to be applied to those seeking to process fetal tissue for use in research, they could effectively deter unscrupulous processors from reaping huge financial rewards from inadequate preparation of the tissue. Finally, if Congress merely provides that it shall be unlawful to use fetal tissue that has been obtained pursuant to an abortion where the mother was coerced into donating the resulting tissue, the Act would not infringe on a woman’s fundamental right to have an abortion and donate the resulting material.

Because of the volatile nature of this subject, it is imperative that Congress reevaluate its prior legislation. This is not likely to happen, however, until someone brings a constitutional challenge against the Act itself. This Comment presents some possible approaches persons could take in challenging the Act, but there would still remain several jurisdictional problems if such a challenge were brought, e.g., standing, ripeness, mootness. Due to these factors, it is unlikely that Congress will choose to discuss amending the Act for quite some time. In the meantime, it is apparent that fetal tissue transplantation research technology can be, and probably will be, abused.

It is not too late. With a little prodding by the right person or persons, Congress could make a few minor adjustments to the Act and to the federal regulations that could resolve several problems within the existing Act. These minor alterations would allow Congress to produce the law that they intended in 1993.