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Fetal Tissue Implants: An Explosive Technology Needs National Action

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I. Introduction

"Researchers hope that by implanting certain tissues of dead fetuses, which have been removed from the womb during abortions, they could dramatically improve the treatment of a score or more intractable afflictions, ranging from Parkinson's disease and diabetes to sickle-cell anemia, some forms of cancer and even strokes."[1]

The prospect of such fetal tissue implants, only recently deemed possible,[2] has refueled the on-going debate on abortion[3] and raised ethical[4] and legal[5] questions of enormous complexity. Imagine the following scenario: A child is diagnosed with juvenile diabetes. She must take daily insulin shots for the rest of her life.[6] She is at risk for a multitude of health problems as well as for a possible early death.[7] Her parents know that by conceiving another child, aborting it, and transplanting the fetal pancreatic eyelet cells into the pancreas of their daughter, a cure is quite possible.[8] Can they legally do this? If they can, should the law continue to allow it? If they cannot, is another source of fetal tissue legally available? If not, should there be?

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1. Clark, Gosnell, Hager, *Should Medicine Use the Unborn?*, NEWSWEEK, Sept. 14, 1987, at 62 [hereinafter *Should Medicine*].

2. *Id.*

3. Lewin, *Medical Use of Fetal Tissues Spurs New Abortion Debate*, N.Y. Times, Aug. 16, 1987, at A30, col. 5. (Statement of Dr. John C. Willke, president of the National Right-to-Life Committee that "people who kill these tiny developing babies, by virtue of the fact that they have done the killing, lose any moral right to use those tissues."). *Compare id.* at A30, col. 5. (Stating the fears of supporters of the right of a woman to have an abortion that the new technologies will be seen as evidence that the fetus is a person from the moment of conception.).

4. *See generally* Mahowald, Silver, Ratcheson, *The Ethical Options in Transplanting Fetal Tissue*, 17 HASTINGS CEN. REP. 9 (Feb. 1987) [hereinafter *Ethical Options*].

5. For a discussion of federal and state regulations that do not specifically address fetal implants, *see* Terry, *'Alas! Poor Yorick, I Knew Him Ex Utero': The Regulation of Embryo and Fetal Experimentation and Disposal in England and the United States*, 39 VAND. L. REV. 419 (1986).

6. W.B. SAUNDERS CO., DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 369 (26th ed. 1985).

7. 2 H.S. STUTTMAN, INC., FISHBEIN'S ILLUSTRATED MEDICAL AND HEALTH ENCYCLOPEDIA 456, 458 (1985).

8. Commentators have included diabetes as one of the diseases that may respond to fetal cell implants. A diabetic patient, Jerry Mispagel, had fetal eyelet cells transplanted along with a new kidney. He reports that the operation "made me so I could live a normal life." *Today* (NBC television broadcast, Oct. 7, 1987).

This Comment will examine the use of fetal tissue implants in humans.[9] It will focus upon the availability of using fetal tissue for implants in the United States once the procedures have proven effective. What follows is a survey of the federal and state regulations currently in place on this subject as well as the existing case law that may control the use of fetal tissue. Critical examination of these regulations and the case law interpreting them, illustrates the inadequacy of the current state of the law with regard to the use of this explosive new technology. The Comment concludes with recommendations for governmental action on a national scale.

II. Medical Possibilities

In April 1987, The New England Journal of Medicine reported a new breakthrough in the possible treatment of Parkinson's disease.[10] The new therapy involves transplanting tissue from the patient's own adrenal gland to the affected section of the patient's brain,[11] resulting in a dramatic and lasting improvement in symptoms.[12] Such neural transplantation has been done in animal models using fetal instead of adrenal tissue transplants.[13] In the animal models, the disease is essentially reversed.[14] While heralding the adrenal-to-brain transplants,[15] speculation continues that human fetal

9. Beyond the scope of this Comment are the legal restrictions in the United States upon the experimental research that is necessary to determine the possible use of fetal implants on the treatment of medical illnesses. Many of the restrictions discussed in this Comment make such research extremely problematic in the United States. *See generally* Terry, *supra* note 5; THE NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS, *reprinted in* 40 Fed. Reg. 33,530 (1975) [hereinafter RESEARCH ON THE FETUS]; Fletcher & Schulman, *Fetal Research: The State of the Question*, 15 HASTINGS CEN. REP. 6 (April 1985). Research now being done abroad indicates that it is likely that the technology will be perfected elsewhere. In West Germany, physicians have recently transplanted fetal kidneys into three patients. *See Should Medicine, supra* note 1, at 63. In the near future, researchers in Sweden are planning to use fetal brain transplants to treat some patients suffering from Parkinson's disease. Lewin, *supra* note 3, at A30, col. 2. Such treatment has recently been done in Mexico. *See infra* note 17 and accompanying text.

10. Madrazo, Drucker-Colin, Diaz, Martinez-Mata, Torres, Becerril, *Open Microsurgical Autograft of Adrenal Medulla to the Right Candidate Nucleus in Two Patients with Intractable Parkinson's Disease*, 316 NEW ENG. J. MED. 831 (1987). Parkinson's disease is a syndrome responsible for serious physical disability, especially among the elderly. Victims gradually lose their motor function and limbs can become rigid. Patients lose facial expression, have difficulty swallowing and speaking. Moore, *Parkinson's Disease — A New Therapy?*, 316 NEW ENG. J. MED. 872 (1987).

11. *Id.*

12. *Id.* at 873.

13. *Id.*

14. *Id.*

15. For articles in non-medical terms on the significance of the medulla to brain transplants, see Begley, Harmes, *Transplants in the Brain*, NEWSWEEK, April 13, 1987, at 64; Merz, *Adrenal-to-Brain Transplants Improve the Prognosis for Parkinson's Disease*, 257 J.

tissue implants promise even more success,[16] not only with Parkinson's disease but with a host of other neurological disorders as well. In early January, 1987 surgeons in Mexico City successfully grafted fetal tissue into the brains of two Parkinson's victims. Improvement has been dramatic in the two patients. Because abortion is illegal in Mexico, the tissue came from a miscarried fetus.[17] According to reports in the popular press, this technology also promises results with Alzheimer's disease, Huntington's Chorea, spinal cord injuries, diabetes, leukemia, blindness, aplastic anemia, stroke, brain damage from injury, and hypogonadism.[18]

Because of its unique characteristics, scientists perceive fetal tissue as better transplant material than other human tissue. It is immunologically reactive, meaning that it causes less rejection by the host body.[19] It grows much faster than adult tissue.[20] In addition, fetal cells are more adaptable and, therefore, they are able to make the new nerve connections necessary to render these therapies effective. The effectiveness of this remedy is due to the ability of the fetal cells to take over the functions of the unhealthy cells.[21]

A few reported instances of fetal cell use already show promising results.[22] Dr. Robert Gale of the University of California, Los Angeles used fetal liver cells with three of the victims he treated after the Chernobyl nuclear plant disaster in the Soviet Union. He hoped the cells would generate bone marrow; however, the patients died from burns before the results could be known.[23] Dr. Kevin Lafferty of the University of Colorado is implanting pre-insulin producing cells from fetal pancreases to treat diabetes.[24] Dr. Abraham Lieberman of New York University Medical Center says of fetal cell implants in brain transplants, "[t]his is to medicine what superconductivity is to physics."[25] Indeed, one researcher has pointed out that

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AM. MED. A. 2691 (1987); Lewin, *Brain Grafts Benefits Parkinson's Patients*, 236 SCIENCE, April 10, 1987, at 149.

16. *See supra* note 1, at 62. For specific scientific articles on animal fetal cell implants, see *Ethical Options*, *supra* note 4, at 10.

17. Gorman, *A Balancing Act of Life and Death*, TIME, Feb. 1, 1988, at 49.

18. *Id.*; *Should Medicine*, *supra* note 1, at 62; Thorne, *Trade in Human Tissue Needs Regulation*, Wall St. J., Aug. 19, 1987, at 16, col. 3; Lewin, *supra* note 3.

19. *Ethical Options*, *supra* note 4, at 10; Lewin, *supra* note 3, at A30, col. 1.

20. *Ethical Options*, *supra* note 4, at 10.

21. *Should Medicine*, *supra* note 1, at 62.

22. *Id.* at 62-63. *See also supra* note 17 and accompanying text.

23. *Id.* at 62.

24. *Id.* at 63.

25. *Id.* at 62. In a recent interview, Dr. Lieberman amplified this thought:

> If you an unlock the secrets of why cells grow and how they grow and how they learn to make certain proteins and shut off certain proteins then you can

this technology "has proven to this point to reverse every kind of neurological disorder that has been placed before it."[26]

Obviously the possibilities inherent in such a technology raise a host of ethical and legal questions. A sampling from recent press reports addresses only some of the issues to be confronted.[27] For example, will this new technology make abortion more legitimate as right-to-life groups fear?[28] Will it exploit women?[29] Is it unethical to conceive in order to abort?[30] Is it unethical *not* to use a technology that is so beneficial?[31] If fetal tissue is used, is our society sliding down a slippery slope towards the utilitarian use of one life for the benefit of another?[32]

III. Current Legal Restrictions

Legal limits on this use of fetal tissue depend largely on how such tissue is defined, *i.e.*, the gestational age of the tissue required,[33] whether it is from a fetus or embryo,[34] and whether it is

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> start to reverse many of the neuro-degenerative diseases that we see: Parkinson's, Alzheimer's, spinal cord injury, people that have suffered stroke. And then you can say to yourself as you age and as you get older, and your reflexes slow down: "Why is that so?" Well, ultimately it's on a neural basis and the potential is there that you're going to open up the fountain of youth.

All Things Considered (National Public Radio broadcast, Aug. 23, 1987).

26. *All Things Considered* (National Public Radio broadcast, Aug. 23, 1987, interviewing Dr. John Slaydek, Chairman of the Neurobiology Department at the University of Rochester).

27. *See Should Medicine, supra* note 1, at 62; Thorne, *supra* note 17, at 16, col. 3; Lewin, *supra* note 3, at A1, col. 5.

28. *See* Lewin, *supra* note 3.

29. *See generally* Schiavoni, *Individual Reproductive Rights v. State Interest*, 59 WIS. BAR BULL., Sept. 1986, at 18 (summarizing recent developments in the law as they impact on women's reproductive rights, particularly when new technology, promoted as giving new choices to women, actually becomes compulsory).

30. Lewin, *supra* note 3, at A1, col. 5 (A woman called Arthur Caplan, director of the University of Minnesota Center for Biomedical Ethics, to ask if she could be artificially inseminated with her father's sperm, abort the resulting fetus, and use its brain tissue to relieve her father's suffering from Alzheimer's disease. Responding that it is not yet technically possible and also ethically wrong, Dr. Caplan said, "This is the ultimate issue of intergenerational justice. You're not just asking for the pocketbooks of the young — you're asking for body parts.").

31. *Today* (NBC television broadcast, Oct. 7, 1987) (interviewing Dr. Robert Gale: "If there is something available to help someone, to not do it is in a certain way unethical."). *See also* Lewin, *supra* note 3, at A1, col. 5 (also quoting Dr. Gale: "All of us that work in fetal research feel that, if someone has decided to have an abortion and gives permission, it is all right to use that tissue to help someone else. But despite our intellectual belief that this is right, we understand why there is controversy.").

32. *Ethical Options, supra* note 4, at 14.

33. The age of the tissue may be essential to achieve success. In experimentation with rats, the best results have been achieved by using tissue from mid-gestation or earlier. *Ethical Options, supra* note 4, at 10 *citing* Gage, Bjorklund, *Intracerebral Grafting of Neuronal Cell Suspensions into the Adult Brain*, 1984 CNS TRAUMA 45-56. There is yet no agreement on the age of tissue for best results with brain implants. Some doctors say a nine-week fetus is

taken in-utero or ex-utero.[35] Two major legal limitations on the use of fetal tissue implants depend largely upon whether such tissue is from a dead fetus or from a non-viable but living fetus[36] and how these implants are defined.[37] Because many of the proposed procedures call for tissue with a gestational age of under twelve weeks,[38] this Comment focuses upon the legalities of using tissue from a non-viable[39] fetus ex-utero. Such tissue has been compared to cadaver tissue;[40] however, there is a significant difference between the two because the fetal brain may not yet be dead.[41]

A. Fetal Tissue as Cadaver Tissue: Legal Implications

Federal regulations define a dead fetus as "a fetus ex-utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached)."[42] These regulations leave activities involving the dead fetus or fetal material to state and local regulation.[43] While there is specific state legislation governing the disposal of fetal remains,[44] the Uniform Anatomical Gift Act (UAGA),[45]

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optimal, while others believe an older fetus would be better. *See* Lewin, *supra* note 3, at A30, col. 2.

34. Fetuses and embryos have different legal status. Federal regulations define a fetus as "the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test) until a determination is made, following expulsion or extraction of the fetus, that it is viable," 45 C.F.R. § 46.203(d) (1986). The regulations do not apply these regimes to embryos. *See generally* Terry, *supra* note 5, at 456.

35. For a discussion on the differences in treatment, see RESEARCH ON THE FETUS, *supra* note 9.

36. 45 C.F.R. §§ 46.203(e), (f) (1986).

37. RESEARCH ON THE FETUS, *supra* note 9, at 33,532, 33,547-58.

38. *See supra* note 32.

39. Federal regulations define the terms, viable, non-viable, and dead. *See infra* notes 42, 113-14 and accompanying text. There is, however, no coherent medical and legal agreement on these terms. *See generally* Levine, *Viability and Death of the Human Fetus: Biologic Definitions*, 23 CLINICAL RESEARCH 211-76 (1975); Kass, *Determining Death and Viability in Fetuses and Abortuses*, NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, APPENDIX TO REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS 11 DHEW Pub. No. (OS) 76-128 (1975) [hereinafter *Appendix*]; Behrman, Rosen, *Report on Viability and Non-Viability of the Fetus, Appendix*, DHEW Pub. No. (OS) 76-128 (1975).

40. *Ethical Options, supra* note 4, at 10.

41. *Id.*

42. 45 C.F.R. § 46.203(f) (1986).

43. 45 C.F.R. § 46.210 (1986). "Activities involving the dead fetus, mascerated fetal material, or cells, tissue, — or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities." *Id.*

44. *See infra* notes 63-66 and accompanying text.

45. UNIF. ANATOMICAL GIFT ACT, 8A U.L.A. 15 (1983 & Supp. 1987) [hereinafter UAGA].

which addresses the use of organs and tissue from the dead,[46] may also be applicable.

The UAGA has been passed in some form by all fifty states.[47] In twenty-five of those states, the UAGA is the only regulation governing the use of dead fetal tissue.[48] The Act states that "[d]ecedent means a deceased individual and includes a still-born infant or fetus."[49] The definition of body part includes tissues.[50] The UAGA allows either parent to consent to such tissue donation as long as the other does not object.[51] It provides for the naming of a specific donee,[52] and mandates that the physician who certifies the death shall not participate in the procedures for removing or transplanting the body part.[53] The UAGA specifically leaves the issue of compensation for body parts, including tissue, to the states.[54]

Several problems are evident in using the UAGA to regulate the use of fetal tissue in brain transplants. As noted, the UAGA goes to great lengths to remove any possible conflict of interest between the physician certifying death and the physician transplanting the body part.[55] Although the Act permits the use of body parts from a stillborn fetus or infant if the parent consents, it is silent on the conflict of interest that might arise between the decision to elect an abortion and the decision to donate fetal tissue to a specific donee.[56] The potential for a conflict of interest is even greater when conception occurs with the intention of aborting and using the resulting

46. *Id.* § 1(b)-(e).

47. For a listing of jurisdictions adopting the UAGA, see UAGA, *supra* note 45, at 2.

48. Several states have passed legislation that restricts or bans the use of dead fetal tissue. *See infra* note 64 and accompanying text.

49. UAGA, *supra* note 45, at 30 (§ 1(b)).

50. *Id.* at 30 (§ 1(e)).

51. *Id.* at 34 (§ 2(b)(3)).

52. *Id.* at 41 (§ 3(4)).

53. *Id.* at 59 (§ 7(b)).

54. *Id.* at 41 (§ 3 comment). "The statutes in a few states specify that no donor shall ask compensation and no donee shall receive it. Several statutes provide that storage banks shall be non-profit organizations. On the other hand, most of the states have chosen not to deal with this question. The Uniform Act follows the latter course in this regard." *But see* National Organ Transplant Act, 42 U.S.C. § 273, § 274 (Supp. 1984) (prohibiting organ sales). *See also infra* notes 60-62 and accompanying text.

55. UAGA, *supra* note 45, at 59 (§ 7(b)).

56. While federal regulations mandate the informed consent of the mother when fetal research is to be conducted, this position has not been reached without heated debate. *See* RESEARCH ON THE FETUS, *supra* note 9, at 33,537-33,540 (summarizing the ethical debate presented to the Commission by reports and papers of ethicists). *See also Appendix, supra* note 39, at 2-10 (full text of these papers and reports). *But see* Horan, *Fetal Experimentation and Federal Regulation*, 22 VILL. L. REV. 325, 333-38 (1976-77) (arguing that parents do not have the right to consent to non-therapeutic medical procedures for their children and analogizing the living non-viable fetus ex utero to a child).

tissue for a brain transplant for a specific person.[57]

Another problem which may arise in applying the UAGA to fetal implants is the Act's requirement that a donee shall not accept a gift if the donee has notice that either the decedent or one of the parents opposes the gift.[58] As there are strong and opposing feelings about abortion, the reverse might also be true. It can be argued that a donee should be informed that fetal cells designated for their use came from an elected abortion.

Moreover, a problem with the UAGA has developed because of the lack of restrictions upon compensation for body parts.[59] In 1984, the National Organ Transplant Act addressed this issue by prohibiting the transfer of any human organ for valuable consideration.[60] The term organ, as defined in this section prohibiting compensation, does not include tissue.[61] Therefore, unless addressed by a state statute,[62] dead fetal tissue can be sold. If this area remains unregulated at a national level, the availability of fetal tissue for brain implants may depend upon one's geographical location.

Twenty-five states[63] have specific legislation which tends to un-

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57. *Ethical Options, supra* note 4, at 15, *citing* Warren, Maquire, Levine, *Can the Fetus Be an Organ Farm?*, 8 HASTINGS CEN. REP. 23 (Oct. 1978).

58. UAGA § 2(c), 8A U.L.A. 34 (1983).

59. *See generally* Note, *Regulating the Sale of Human Organs*, 71 VA. LAW REV. 1015 (1985) (summary of the congressional proceedings leading up to passage of the National Organ Transplant Act).

60. The National Organ Transplant Act, 42 U.S.C. § 274e (Supp. 1984).

> § 274e. Prohibition of organ purchases
>
> (a) It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.
>
> (b) Any person who violates subsection (a) shall be fined not more than $50,000 or imprisoned not more than five years, or both.
>
> (c) For purposes of subsection (a):
>
> (1) The term "human organ" means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye bone, and skin, and any other human organ specified by the Secretary of Health and Human Services by regulation.
>
> (2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.
>
> (3) The term "interstate commerce" has the meaning prescribed for it by section 201(b) of the Federal Food, Drug and Cosmetic Act [21 USCS § 321(b)].

61. *Id.*

62. *See infra* note 63.

63. ARIZ. REV. STAT. ANN. § 36.2302 (1986); ARK. STAT. ANN. §§ 82-436 to -441 (Supp. 1985); CAL. HEALTH & SAFETY CODE §§ 25956-25957 (West 1984); FLA. STAT. ANN. § 390.001(7) (West 1986); ILL. ANN. STAT. ch. 38, §§ 81-26, -32.1 (Smith-Hurd Supp. 1987); IND. CODE ANN. § 35-1-58.5-6 (Burns 1985); KY. REV. STAT. § 436.026 (1985); LA. REV.

dermine the uniformity of the UAGA as it relates to the donation of dead fetuses and fetal remains. Six of these statutes impose an absolute prohibition on the use of dead fetuses,[64] thereby overriding the provisions of the UAGA. Other states either adopt the provisions of the UAGA as they relate to the donation of dead fetuses[65] or modify those provisions slightly.[66]

If a fetus or fetal material is not specifically donated under the UAGA or the National Organ Transplant Act, but rather is left to the hospital or clinic for disposal, various state regulations and common law concepts may control. At early common law no property right existed in a dead body,[67] and the state's interest was limited to ensuring the public health.[68] In a recent case, *Georgia Lions Eye Bank, Inc. v. Lavant*,[69] the Georgia Supreme Court reiterated the current concept that relatives do have a quasi-property interest in bodies of their next of kin.[70] Such a right, however, is not constitu-

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STAT. ANN. § 40:1299.35.13 (West Supp. 1986); ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. GEN. LAWS ANN. ch. 112, § 12J (West 1983); MICH. STAT. ANN. §§ 14.15 (2688) (Callaghan 1980); MINN. STAT. ANN. §§ 145.421-422 (West Supp. 1984); MO. ANN. STAT. § 188.037 (Vernon 1983); MONT. CODE ANN. §§ 50-20-108(3)-108(4) (1987); NEB. REV. STAT. §§ 28-342 to -346 (1985); N.M. STAT. ANN. §§ 24-9A, -3, -5 (1986); N.D. CENT. CODE §§ 14-02.2-01 to -02 (1981); OHIO REV. CODE ANN. § 2919.14 (Baldwin 1986); OKLA. STAT. ANN. tit. 63, § 1-735 (West 1984); 18 PA. CONS. STAT. ANN. § 3216 (Purdon 1983); R.I. GEN. LAWS § 11-54-1 (Supp. 1987); S.D. CODIFIED LAWS ANN. § 34-23A-17 (1986); TENN. CODE ANN. § 39-4-208 (1982); UTAH CODE ANN. § 76-7-310 (1978); WYO. STAT. § 35-6-115 (1977).

64. ARIZ. REV. STAT. ANN. § 36-2302A (1986); ILL. ANN. STAT. ch. 38, § 81-32 (Smith-Hurd Supp. 1987); IND. CODE ANN. § 35-58.5-6 (Burns 1985); LA. REV. STAT. ANN. § 40:1299.35.13 (West Supp. 1986) OHIO REV. CODE ANN. § 2919.14 (Baldwin 1986); OKLA. STAT. ANN. tit. 63 § 1-735A (West 1984).

65. KY. REV. STAT. § 436.026 (1985); ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MINN. STAT. ANN. § 145.421-.422 (West Supp. 1984); MO. ANN. STAT. § 188.037 (Vernon 1983); MONT. CODE ANN. § 50-20-108(3)-108(4) (1987); NEB. REV. STAT. § 28-342-346 (1985); N.M. STAT. ANN. § 24-9A, -3, -5 (1986); UTAH CODE ANN. § 76-7-310 (1978); WYO. STAT. § 35-6-115 (1977).

66. ARK. STAT. ANN. §§ 82-436 to -441 (Supp. 1985); CAL. HEALTH & SAFETY CODE §§ 25956-25957 (West 1984); FLA. STAT. ANN. § 390.001(6) (West 1986); MASS. GEN. LAWS ANN. ch. 112, § 12J (West 1983); MICH. STAT. ANN. §§ 14.15 (2688) (Callaghan 1980); N.D. CENT. CODE §§ 14-02.2-01 to -02 (1981); 18 PA. CONS. STAT. ANN. § 3216 (Purdon 1983); R.I. GEN. LAWS § 11-54-1 (Supp. 1987).

67. "But though the heir has a property in the monuments and escutcheons of his ancestors, yet he has none in their bodies or ashes; nor can he bring any civil action against such as indecently at least, if not impiously, violate and disturb their remains, when dead and buried." 2 W. BLACKSTONE, COMMENTARIES 429 (T. Cooley ed. 1899) *quoted in* Georgia Lions Eye Bank, Inc. v. Lavant, 255 Ga. 60, 61, 335 S.E.2d 127, 128 (1985), *cert. denied*, 106 S. Ct. 1464 (1986).

68. Seaton v. Commonwealth, 149 Ky. 498, 502, 149 S.W. 871, 873 (1912) (body may not be disposed of in a manner injurious to the health of the community).

69. 255 Ga. 60, 335 S.E.2d 127 (1985).

70. "It seems reasonably obvious that such 'property' is something evolved out of thin air to meet the occasion, and that in reality the personal feelings of the survivors are being protected, under a fiction likely to deceive no one but a lawyer." PROSSER & KEATON, PROSSER AND KEATON ON TORTS 63 (5th ed. 1984) *quoted in* Georgia Lions Eye Bank, Inc. v. Lavant, 255 Ga. 60, 61, 335 S.E.2d 127, 128 (1985).

tionally protected[71] and can be changed by legislative action.

In *Georgia*, the parents of a dead infant sued a hospital and an eyebank for wrongful removal of their infant's corneal tissue.[72] The removal occurred pursuant to a statute that permitted removal of the corneal tissue for transplant when no objection is made by the decedent in his life or by the next of kin after death.[73] While the parents did not object, there was no notice to them of the intended removal; therefore, they were not given a realistic opportunity to object.[74] In declaring the common law quasi-property right in dead bodies not to be of constitutional dimension, the court ruled that the legislature could vary common law as public health needs might dictate.[75] Thus, if fetal tissue becomes a needed public health resource, this case indicates that states could authorize its use for transplant without notice to the parents.

Before the advent of fetal tissue implant possibilities, fetal remains were of limited value.[76] State statutes that have addressed the question of fetal disposal[77] tend to be informational, report promoting procedures.[78] In 1983, however, the Supreme Court in *City of Akron v. Akron Center for Reproductive Health, Inc.*[79] struck down an ordinance which, among other provisions, required that "fetal remains be disposed of in a humane and sanitary manner."[80] Ruling that the provision was impermissibly vague,[81] the Court held that it

71. *See id.* at 61, 335 S.E.2d at 128.

72. *Id.* at 60, 335 S.E.2d at 128.

73. *Id.*

74. *Id.*

75. *Id.* at 60-61, 335 S.E.2d at 128-29. *See also* Florida v. Powell, 497 So. 2d 1188 (Fla. 1986); Tillman v. Detroit Receiving Hosp., 138 Mich. App. 683, 360 N.W.2d 275 (1984) (Both upholding similar statute permitting the post-mortem removal of cornea tissue without consent of the survivors.).

76. *See, e.g.*, RESEARCH ON THE FETUS, *supra* note 9, at 33,545 ("[A] final class of investigation (falling outside the present mandate of the Commission) has made use of tissues of the dead fetus, in accordance with accepted standards for treatment of the human cadaver. The Commission finds that, to the best of its knowledge, these types of research have not contravened accepted ethical standards.").

77. *E.g.*, ARK. STAT. ANN. § 82-436 (Supp. 1985); CAL. HEALTH & SAFETY CODE § 25957(a) (West 1984); FLA. STAT. ANN. § 390.001(7) (West 1986); ILL. ANN. STAT. ch. 38, § 81-32 (Smith-Hurd Supp. 1987); LA. REV. STAT. ANN. § 40:1299.35.14 (West Supp. 1986); UTAH CODE ANN. § 76-7-309 (1978). *Compare* statutes addressing experimentation or research, *infra* notes 136-39 and accompanying text.

78. *Contra* Planned Parenthood Ass'n v. Ashcroft, 462 U.S. 476, 486-90 (1983) (upholding a Missouri statute that mandated pathological examination of tissue from abortions and other surgery performed in hospitals).

79. 462 U.S. 416 (1983).

80. AKRON OHIO, CODIFIED ORDINANCES ch. 1870, § 1870.16 (1978), *quoted in City of Akron*, 462 U.S. at 424, n.7.

81. *City of Akron*, 462 U.S. at 451 (quoting the Sixth Circuit's opinion in the same case, 651 F.2d 1198, 1211 (6th Cir. 1981)).

was unclear that the stated intent to "preclude the mindless dumping of aborted fetuses into garbage piles"[82] did not also "mandate some sort of decent burial of an embryo at the earliest stages of formation."[83] Because criminal liability resulted, the level of uncertainty was fatal[84] to the statute.

In addition to the problem of vagueness, state disposal statutes have also been held unconstitutional on the grounds that they impermissibly burden a woman's decision to have an abortion. A Louisiana regulation that required a physician to tell a woman after an abortion that she must choose between burial and other means of disposal was struck down in *Margaret S. v. Treen*.[85] The regulation created the same psychological burden feared in a previous case, *Planned Parenthood Association v. Fitzpatrick*.[86] In *Fitzpatrick*, the court, while upholding a Pennsylvania statute providing for the humane disposal of fetal remains, went on to say that it is possible that future regulations might impermissibly burden the abortion decision.[87] Such an impermissible burden is exactly what the district court in *Treen* found. It held that the Louisiana statute requiring a woman to choose the method of disposal would have a chilling effect on a woman's decision to obtain an abortion and was thus unconstitutional.[88]

The Fifth Circuit Court of Appeals in affirming the *Treen* deci-

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82. *City of Akron*, 462 U.S. at 451 (quoting Planned Parenthood Assn. v. Fitzpatrick, 401 F. Supp. 554, 573 (E.D. Pa. 1975)), *aff'd. mem. sub. nom.* Franklin v. Fitzpatrick, 428 U.S. 901 (1976)).

83. *City of Akron*, 462 U.S. at 451 (quoting the Sixth Circuit's opinion in the same case, 651 F.2d 1198, 1211 (6th Cir. 1981)).

84. *Id.* at 451; *Compare* Planned Parenthood Assn. v. Fitzpatrick, 401 F. Supp. 554, 572-73 (E.D. Pa. 1975), *aff'd. mem. sub. nom.* Franklin v. Fitzpatrick, 428 U.S. 901 (1976) (upholding a Pennsylvania disposal statute because the statute did not impose criminal liability, but rather, it only provided for regulations to implement the disposal requirement).

85. 597 F. Supp. 636 (E.D. La. 1984).

86. 401 F. Supp. 554 (E.D. Pa. 1975), *aff'd mem. sub. nom.* Franklin v. Fitzpatrick, 428 U.S. 901 (1976).

87. The court, while upholding the Pennsylvania statute providing for humane disposal of dead fetuses, went on to say:

> Of course, a regulation that requires expensive burial may very well invade the privacy of the pregnant woman and burden her decision concerning an abortion. However, no such regulation has been adopted to date pursuant to section 5(c), and we find that this section is not unconstitutional on its face. We, of course, do not foreclose a future challenge to any unconstitutional regulation adopted pursuant to this section.

Id. at 573.

88. "By requiring the physician to confront the woman with a choice on the method of disposal, the state suggests to the woman that it equates abortion with the taking of a human life . . . . This requirement thus penalizes those women who exercise their constitutional right in choosing abortion." *Treen*, 597 F. Supp. at 670.

sion,[89] did so on narrower grounds. The court held only that the requirement that the physician *personally* inform the woman after abortion about options for disposal of fetal remains made the statute unconstitutional.[90] The court specifically left open the question that a statute which allowed someone other than the attending physician to provide information about options for disposal would be constitutional.[91]

The *Treen* decision, when viewed in the light of *Georgia Eye Bank*, raises questions of informed consent by the mother to the use of dead fetal remains. If such consent is not required by due process standards, a discussion of any type of disposal by a physician may even be forbidden as having a chilling effect on the abortion decision. Civil tort cases have dovetailed with the decision in *Treen* by allowing recovery for intentional infliction of emotional distress when women have been given psychologically damaging information concerning the disposition of fetal remains.[92] These cases, however, occurred when hospitals contradicted a woman's decision rather than pre-empted it and also involved deaths at or shortly after birth rather than abortions.

If fetal remains are used for implants or other research without the woman's consent, or perhaps even her knowledge, other property issues are raised. In a pending California case, *Moore v. Regents of University of California*,[93] the plaintiff had his spleen removed as part of the treatment for a rare form of leukemia. The plaintiff's physician allegedly used the patient's blood without his knowledge or consent to create a cell line ultimately patented by the University of California.[94] The plaintiff is claiming that his blood cells were misappropriated and that he is entitled to a share in any profits derived

89. Margaret S. v. Edwards, 794 F.2d 994 (5th Cir. 1986).

90. *Id.* at 998.

91. *Id.*

92. *See* McCoy v. Georgia Baptist Hosp., 167 Ga. App. 495, 306 S.E.2d 746 (1983) (allowing recovery for intentional infliction of emotional distress when a woman, believing the hospital had disposed of her stillborn child, was informed that the body was in frozen storage and she could still pick it up); Johnson v. Woman's Hosp., 527 S.W.2d 133 (Tenn. Ct. App. 1975) (allowing recovery for breach of contract and punitive damages when, six weeks after believing the hospital had properly disposed of her premature baby who had died shortly after birth, a woman was shown the child floating in a jar of formaldehyde).

93. No. BO 21195 (Cal. Ct. App., filed May 15, 1986 & Aug. 28, 1986, consolidated Dec. 5, 1986).

94. *See generally* Comment, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207 (1986) (discussing property rights in human tissue and advocating that each person has the right to the commercial potential of his or her own body).

from any commercial uses of these cells.[95] This case, unless settled, will create valuable precedent in the area of property rights of human tissue and duties of the physician to inform a patient of possible uses of the patient's own tissue.

The ownership issue is also one of concern in using fetal tissue. One company, Hana Biologics, is using fetal tissue to grow neural and pancreatic cells.[96] The company expects to begin clinical trials with the pancreatic cells later this year.[97] If successful, profits are projected to be enormous in the next few years.[98] A spokesperson for the company, Nancy Peterson, stated that the tissue comes from "third-party non-profit procuring agencies."[99] One such agency is the subject of a recent investigation.[100] The Foundation on Economic Trends[101] charged the National Disease Research Interchange ("NDRI") in Philadelphia with obtaining fetal tissue from hospitals that did not perform all possible tests to determine if aborted fetuses were dead prior to removing organs and other materials.[102] In denying the allegations, Lee Ducat, president of NDRI, said that her group has proper death documentation on all tissue.[103]

Fetal tissue makes up less than one percent of all the material NDRI receives from a nationwide network of organ banks and hospitals.[104] Presently, fetal remains, unless specifically claimed, can be

95. *See generally New Developments in Biotechnology: Ownership of Human Tissues and Cells — Special Report*, OTA-BA 337 (Washington, D.C.: U.S. Govt. Printing Office, March 1987) (summarizing legal, ethical, policy, and economic considerations and suggesting options for congressional action in regard to property rights in one's own tissue. The report specifically states that it does not explore the special concerns arising from the use of fetal cells for research); Wagner, *Human Tissue Research: Who Owns the Results?*, 69 J. PAT. TRADEMARK OFF. SOC'Y 329 (1987) (arguing that human tissue belongs to no one and is rather available to all); Andrews, *My Body, My Property*, 16 HASTINGS CEN. REP. 28 (Oct. 1986) (arguing that people possess property rights in their own bodies, particularly the regenerative parts); Mathews, *Whose Body? People as Property*, 36 CURRENT LEGAL PROBS. 192 (1983) (arguing that while there can be no property right in a whole body, such rights do exist in parts of bodies).

96. Lewin, *supra* note 3, at A30, col. 5.

97. *Id.*

98. *Today* (NBC television broadcast, Oct. 7, 1987).

99. Lewin, *supra* note 3, at A30, col. 5.

100. Hilts, *NIH Probes Allegations of Live Fetal Tissue Use*, Washington Post, Sept. 9, 1987, at A4, col. 1.

101. *Id.* The foundation is a group headed by Jeremy Rifkin and is critical of research related to genetic engineering.

102. Leary, *Fetal-tissue Supplier Accused of Violations*, Philadelphia Inquirer, Sept. 9, 1987, at G1, col. 3. National Disease Research Interchange is a non-profit organization set up by the National Institute of Health to act as a clearing house for human tissue used in research. As such, it must comply with all federal regulations concerning research on live fetuses. *See infra* notes 114-23 and accompanying text. It must also comply with any state regulations concerning the use of dead fetuses. *See supra* notes 64-71 and accompanying text.

103. *Id.* at G1, col. 4.

104. *Id.*

given by hospitals to non-profit groups such as NDRI and used by companies like Hana Biologics as a foundation for profit-making products. These products would also presumably have an equally enormous therapeutic value. Questions are thus raised concerning the commercial value of fetal tissue. If women are prohibited from making money from a sale of fetal tissue, many feel that companies should be precluded as well.[105] However, without a profit incentive, the benefits of such a therapy may never be realized.

B. Fetal Tissue from Non-Viable Fetuses Ex-Utero

In the wake of *Roe v. Wade*,[106] stories surfaced in the press of live but aborted fetuses being used for medical research in objectionable ways.[107] Responding to the public outrage, Congress passed the National Research Act[108] which contained two provisions regarding research on the fetus. The first created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Congress gave this Commission a mandate, with a deadline of four months, to investigate research involving the fetus and to recommend whether and under what circumstances such research should be supported by the Department of Health, Education and Welfare.[109] In addition, the law contained a ban on fetal research until the Commission made its recommendations, except when such research was intended to preserve the life of that specific fetus.[110] The result of this mandate was a report entitled *Research on the Fetus*[111] which later became the basis for federal regulations.[112]

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105. Lewin, *supra* note 3, at A30, col. 5, *quoting* Professor Nadine Taub of the Women's Rights Litigation Clinic at the Rutgers University Law School: "It's a hard one, whether fetuses should be treated as renewable body tissue that can be sold, or as organs that can't be. I don't think fetal tissue should be saleable. And it seems to me that if women can't make money off it, companies shouldn't be able to make money off it, either."

106. 410 U.S. 113 (1973).

107. Cases of objectionable research are objectively surveyed by Mahoney, *The Nature and Extent of Research Involving Living Human Fetuses*, in *Appendix, supra* note 39, 1-1 to 1-48.

108. Pub. L. No. 93-348, Title II, § 213, 88 Stat. 353 (1974).

109. *Id.*

110. *Id.* For a discussion of the events leading up to the National Research Act, see Fletcher and Schulman, *supra* note 9, at 6. For a discussion of the impact of this moratorium on fetal research and the impact of the Commission's report, see Levine, *The Impact on Fetal Research of the Report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 22 VILL. L. REV. 367 (1976-77).

111. RESEARCH ON THE FETUS, *supra* note 9. For a survey of recent fetal research and how the regulations affect such endeavors, see Fletcher and Schulman, *supra* note 9.

112. Protection of Human Subjects, Subpart B — Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization, 45 C.F.R. § 46.201-.211 (1986).

These federal regulations define a non-viable fetus as "a fetus ex utero which although living is not viable."[113] "Viable" is defined as "being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration."[114] If a fetus is viable, it is treated like a premature infant.[115] If it is non-viable, the regulations require that it cannot be used as a subject of research unless the following four conditions are met: 1) vital functions will not be artificially maintained; 2) experimental activities which would terminate the heartbeat or respiration of the fetus will not be employed; 3) the purpose is the development of important biomedical knowledge which cannot be obtained by other means; and 4) the mother and father are legally competent and have given their informed consent.[116] The father's consent is not necessary if his whereabouts are unknown, he is not reasonably available, or the pregnancy resulted from rape.[117]

In addition, the issue of fetal research is also addressed by general sections of the Basic Policy for Protection of Human Research Subjects.[118] Pursuant to these regulations, each project must be approved by an Institutional Review Board.[119] The criteria for approval require that the risks to the subject are minimized and bear a reasonable relationship to the anticipated benefits.[120] General limitations also apply,[121] some with parallels to the UAGA. For example, individuals engaged in the research activity are not permitted to take part in the decision, timing, or method of terminating the pregnancy or the determination of the viability of the fetus.[122] Obviously this is intended to minimize any potential conflict of interest between the physician and patient. Nonetheless, these regulations fail to anticipate the potential conflict inherent when conception occurs for the purpose of abortion.

Another important regulation which imposes further limitations

113. 45 C.F.R. 46.203(e) (1986).

114. 45 C.F.R. 46.203(d) (1986). This section also specifies that "[T]he Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a fetus is viable for purposes of this subpart." *Id.*

115. *Id.*

116. 45 C.F.R. 46.209(b)-(d) (1986).

117. 45 C.F.R. 46.209(d) (1986).

118. Basic Policy for Protection of Human Research Subjects, Subpart A, 45 C.F.R. § 46.101-46.124 (1986).

119. 45 C.F.R. § 46.102(h) (1986).

120. 45 C.F.R. § 46.111(a)-(b) (1986).

121. 45 C.F.R. § 46.206 (1986).

122. 45 C.F.R. § 46.206(3) (1986).

on the area of fetal research is the restriction placed upon facilities funded by the Department of Health and Human Services. This regulation provides that "no inducements monetary or otherwise may be offered to terminate pregnancy for purposes of the activity."[123] Thus, it appears that the sale of fetal tissue may be prohibited if the research is at all funded by Health and Human Services. If such funding is not a consideration, and unless prohibited by state statute, the restriction is inapplicable.

In attempting to apply these regulations to the use of fetal tissue implants, several problems are apparent. These regulations define research as "a systematic investigation designed to develop or contribute to generalizable knowledge."[124] This definition differs from the specific recommendations of the Commission that distinguished between therapeutic and non-therapeutic research[125] involving fetuses. As finally adopted, the regulations on fetal research contained no such distinctions.

While the distinction between therapeutic and non-therapeutic is not made explicit in a definition section, it can be inferred from a careful reading of the regulations. Activities are not permitted on a viable fetus ex-utero unless there will be no added risk *and* the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means or the survival of that particular fetus.[126] The regulations concerning the non-viable fetus only state that the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means.[127]

When the Commission made its recommendations and adopted the Department of Health regulations, this kind of technology was unknown. As stated, the purpose of the recommendations was to control a perceived exploitation of fetuses in the wake of *Roe v.*

123. 45 C.F.R. § 46.206(4)(b) (1986).

124. 45 C.F.R. § 46.102(e) (1986).

125. RESEARCH ON THE FETUS, *supra* note 9, at 33,545-33,548. These distinctions have sparked vigorous debate. *See* Horan, *Fetal Experimentation and Fetal Regulation*, 22 VILL. L. REV. 325 (1976-77) (arguing that therapeutic research is a contradiction in terms — that all non-therapeutic research involving unborn whether in-utero or ex-utero should be prohibited. The author advocates using only the term research and analyzing any proposal without the confusion of terms therapeutic or non-therapeutic research.). *See also* RESEARCH ON THE FETUS, *supra* note 9, at 33,550-33,551 (concurring statement of Commissioner); Lebacoz, *Reflections on the Report and Recommendations of the National Commission: Research on the Fetus*, 22 VILL. L. REV. 357 (1976-77) (essentially agreeing with the conclusion that this distinction obscures the nature of the research).

126. 45 C.F.R. § 46.209(1) (1986).

127. 45 C.F.R. § 46.209(b)(3) (1986).

Wade.[128] While permitting non-therapeutic research or experimentation on the non-viable fetus ex-utero, the regulations are silent with regard to therapeutic use. Depending upon the type of tissue needed for implants, it may be necessary to violate the prohibition against maintaining artificial functions. It is also impossible not to violate the second condition that activities which would terminate the heartbeat and respiration of the fetus cannot be employed.

There is a possibility of a waiver of some of these specific requirements.[129] All funded projects involving human subjects must be reviewed and approved by an Institutional Review Board (IRB).[130] In addition, the regulations involving fetuses, pregnant women and in-vitro fertilization provide for the establishment of a national Ethical Advisory Board (EAB).[131] Upon request of an IRB, the EAB can recommend waiving or modifying the specific requirements, but only after public comment.[132] The Secretary of Health and Human Services then makes a final determination by considering "whether the risks to the subject are so outweighed by the sum of the benefit *to the subject* and the importance of the knowledge to be gained as to warrant such modification or waiver . . . ."[133] This waiver possibility is unlikely to occur in the case of fetal tissue implants because it requires a showing that the subject will benefit. Clearly these anticipated technologies cannot be used in compliance with the regulations if the fetal implants require the removal of tissue from a non-viable but not yet dead fetus ex-utero. Federal funding would therefore be impossible.

C. *State Regulations on Fetal Research*

The federal regulations provide that compliance in no way renders inapplicable any state laws also covering fetal research.[134] In addition, the regulations only govern those activities funded or conducted by the Department of Health and Human Services.[135] As be-

128. 410 U.S. 113 (1973).
129. 45 C.F.R. § 46.211 (1986).
130. *See supra* notes 118-19 and accompanying text.
131. 45 C.F.R. § 46.204 (1986).
132. 45 C.F.R. § 46.211 (1986).
133. *Id.* (emphasis added). The role of the Ethical Review Board is thoroughly discussed by Fletcher and Schulman, *supra* note 9, at 7-11. They note that fetal research has been greatly hampered by the fact that the Ethical Advisory Board ("EAB") was allowed to lapse when its charter and funding expired in 1980. Noting that lack of an EAB has created a gulf between local and national considerations of fetal research, they urgently call for its reestablishment. *Id.*
134. 45 C.F.R. § 46.201(b) (1986).
135. 45 C.F.R. § 46.201(a) (1986). Except to the extent that a funded research institu-

fits such a controversial topic, twenty-five state legislatures have enacted statutes regulating fetal research.[136]

Nineteen states ban *any* non-therapeutic research on a living abortus.[137] At the other extreme, two states, Arkansas and Utah, permit all types of fetal research on a living abortus.[138] The other four states either precondition such research on maternal consent[139] or on the lack of risk to the abortus.[140] The lack of uniformity among the state regulations is apparent given the various approaches outlined in these statutes.

Furthermore, even states which have similar regulations cannot agree on their interpretation. For example, in *Wynn v. Scott*,[141] an Illinois case, the court upheld a state statute prohibiting experimentation on dead fetuses, while the Louisiana case of *Margaret S. v. Treen* struck down a similar statute.[142] The district court in *Treen* held the statute unconstitutional because it limited medical information obtainable through experiments on the dead fetuses that might prove beneficial to the mother.[143] The prohibition thus burdened the exercise of a woman's fundamental right to an abortion.[144]

The *Treen* court distinguished its decision from the *Wynn* rationale by pointing out that the court in *Wynn* found no evidence of an infringement of a fundamental right and that the statute ques-

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tion must gain approval for "[a] statement of principles governing the institution in discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution regardless of source of funding" (45 C.F.R. 46.103(b)(1)), there is no interference with research conducted without federal funds.

136. *See supra* note 63. *See also* Baron, *Fetal Research: The Question in the States*, 15 HASTINGS CEN. REP. 12 (1985) (giving a history of state legislative action and the resulting variability in state statutes).

137. ARIZ. REV. STAT. ANN. § 36.2302A (1986); CAL. HEALTH & SAFETY CODE § 25956(a) (West 1984); FLA. STAT. ANN. § 390.001(6) (West 1986); ILL. ANN. STAT. ch. 38, §§ 81-26(3) (Smith-Hurd Supp. 1987); IND. CODE ANN. § 535-1-58.5-6 [10-112] (Burns 1985); KY. REV. STAT. § 436.026 (1985); LA. REV. STAT. ANN. § 40:1299.35.13 (West Supp. 1986); ME. REV. STAT. ANN. tit. 22, § 1593 (1980); MASS. GEN. LAWS ANN. ch. 112, § 12J(a)(I) (West 1983); MICH. STAT. ANN. §§ 14.15 (2685) (Callaghan 1980); MO. ANN. STAT. § 188.037 (Vernon 1983); MONT. CODE ANN. § 50-20-108(3) (1985); NEB. REV. STAT. §§ 28-342 (1979); N.D. CENT. CODE § 14-01.2-01 (1981); OHIO REV. CODE ANN. § 2919.14(A) (Baldwin 1986); OKLA. STAT. ANN. tit. 63, § 1-735 (West 1984); 18 PA. CONS. STAT. ANN. § 3216 (Purdon 1983); R.I. GEN. LAWS § 11-54-1 (Supp. 1987); WYO. STAT. § 35-6-115 (1978).

138. ARK. STAT. ANN. § 82-437 (Supp. 1985); UTAH CODE ANN. § 76-7-310 (1978).

139. S.D. COMPILED LAWS ANN. § 34-23A-17 (1977); TENN CODE ANN. § 39-4-208 (1982).

140. N.M. STAT. ANN. § 24-9-A-4 (1986); MINN. STAT. ANN. § 145.422(1) (West Supp. 1985).

141. 449 F. Supp. 1302 (1978) (N.D. Ill.), *appeal dismissed for want of jurisdiction sub. nom.* Carey v. Wynn, 439 U.S. 8 (1978), *aff'ing*, 599 F.2d 193 (7th Cir. 1979).

142. 597 F. Supp. 636 (E.D. La. 1984).

143. Margaret S. v. Treen, 597 F. Supp. 636, 673 (E.D. La. 1984).

144. *Id.*

tioned in *Wynn*, while banning experimentation, specifically provided for the pathological examination of tissue that might lead to information beneficial to the mother.[145] In affirming the *Treen* decision, the court of appeals limited its holding to the fact that the terms "experiment" and "experimentation" made the statute unconstitutionally vague because it offered no guidance to a physician as to the distinction between a medical test and a medical experiment.[146]

In light of these decisions, state regulation of fetal research and experimentation may be contingent upon whether such regulation, by limiting a woman's access to medical information that might bear on future pregnancy decisions, unconstitutionally burdens the abortion decision. Many of these statutes, as they apply only to aborted fetuses or discriminate between an induced or natural abortion, may also be unconstitutionally vague. These statutes address research or experimentation, either therapeutic or non-therapeutic. It is not clear under what definition, if any, the beneficial use of fetal tissue would fall.

IV. What Needs To Be Done

As noted, *Research on the Fetus* came as a result of a dramatic societal change in 1973 — the legalization of abortion.[147] The formation of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, along with its research, hearings, and final recommendations, were a reasoned and measured response to this change. Although there is not total agreement with the resulting regulations, there is no quarrel with the process employed to develop them.[148] This process, however, occurred over twelve years ago. Although the Commission attempted to provide for some flexibility, the use of fetal tissue for brain or other implants was not contemplated and, as such, cannot be properly addressed under the current federal regulatory scheme.[149] Moreover, as illustrated above, state laws that supplement the federal regulations vary widely and generally do not address this technology.[150]

It is thus imperative to appoint another commission with a similar mandate to make recommendations on the use of fetal tissue and

145. *Id.*
146. Margaret S. v. Edwards, 794 F.2d 994, 999 (5th Cir. 1986).
147. Roe v. Wade, 410 U.S. 113 (1973).
148. *See generally* Fletcher & Schulman, *supra* note 9; Horan, *supra* note 56; Nathan, *Fetal Research: An Investigator's View*, 22 VILL. L. REV. 384 (1976-77).
149. *Id.*
150. *See supra* notes 114-46 and accompanying text.

any other related technologies that have developed since the earlier report. Like the first diverse group that made up the original Commission, the members must be from medical, legal, and ethical fields and possess the highest qualifications. Only by such a reasoned approach on a national scale can the benefits of fetal tissue implants be fully realized in this country.

As this Comment demonstrates, access to such technology now depends largely upon the state location of the medical facility and the absence of federal funding. This situation cannot continue if the benefits of these techniques prove to be as dramatic as anticipated. Changes in the regulatory scheme must occur at a federal level and these laws must not be viscerated by state legislatures.

The issues which must be addressed by a future commission and Congress are similar to those questions addressed by the original Commission and do not lend themselves to easy resolution. Nevertheless, several prohibitions and requirements must be addressed.

Foremost, under no circumstances should consent of the mother be waived. Whether the tissue needed is from a dead fetus or a nonviable fetus ex-utero, it must not be obtained without the informed consent of the mother. Such informed consent need not result in the constitutional concerns expressed in *Margaret S. v. Treen.*[151] A woman decides, with a physician's advice, many medical issues concerning her abortion, including the method and the time. Rather than mandating that the physician inform the woman, someone other than the doctor could be allowed to discuss the donation option, a procedure left open by the court of appeals in affirming *Treen.*[152] An informed donation of fetal tissue is no more problematic than what is currently prescribed by the UAGA[153] or National Organ Transplant Act.[154]

A new law which became effective last October may serve as a model for such consent.[155] The law requires that hospitals may not participate in Medicare or Medicaid, unless they establish "written protocols for the identification of potential organ donors."[156] Hospitals must assure that families of potential donors are informed of

151. 597 F. Supp. 636 (E.D. La. 1984). *See also supra* notes 85-92 and accompanying text.

152. Margaret S. v. Edwards, 794 F.2d 994, 998 (5th Cir. 1986). *See also supra* notes 89-91 and accompanying text.

153. UAGA, *supra* note 45, at 34 (§ 2).

154. 2 U.S.C. § 274e (Supp. 1984).

155. Hospital Protocols for Organ Procurement and Standards for Organ Procurement Agencies, 100 Stat. 2009 (1986).

156. *Id.*

their option to donate organs and their option to decline. The protocols must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of such families. The term organ is defined as a human kidney, liver, heart, lung, pancreas and *any other organ or tissue specified by the Secretary.*[157] If fetal tissue becomes a resource for transplants, there appears to be no reason why it could not be included within this law.

Without such consent, however, there are possibilities for tort recoveries for emotional distress if a woman should discover such tissue was obtained without her permission.[158] A decision to have an abortion, whether for medical or other reasons is not a casual one. Indeed, it can be argued that knowledge that fetal tissue may be used against her wishes or without her knowledge would be an impermissible burden upon a woman's decision to choose an abortion.

The method of and timing for an abortion is a woman's decision. It is possible that the type of abortion most suitable for preserving fetal tissue may not be the recommended method for a particular woman. Only she, in consultation with her physician, should be able to decide to elect one procedure over another.

Another important restriction that a commission should consider is a prohibition upon the sale of fetal tissue. The coercion inherent in a monetary inducement may effectively deprive a woman of informed consent. Additionally, if the sale of such tissue is permitted, people will be willing to produce it for monetary gain. The potential for exploitation of women in such a situation is unacceptable. Because they are biologically able to reproduce, women could potentially become part of a commodity market, particularly in third world nations. Dr. Arthur Caplan[159] summed up the Orwellian possibilities inherent in fetal tissue sales in a recent interview:

> It doesn't take a whole lot of imagination to put yourself in the situation of the third world where people could go around offering ten cents, five cents, to women to serve as fetal farms for tissue donation. I don't think that's a practice that we want to be encouraging. I think part of the objection here, the ethics concern, is that whatever we're doing between mothers and fetuses, we don't want them thinking of the fetus as a thing, an entity, a piece of property simply to chop up and parse out to whoever happens to have a need or to whoever happens to want

157. *Id.* (emphasis added).
158. *See supra* note 92.
159. *See supra* note 30.

to pay for it.[160]

In addition to banning the sale or purchase of fetal tissue, a donor must be barred from any participation in the selection of the donee. Such an action prohibits the hypothetical couple, mentioned at the beginning of this Comment, from donating fetal tissue to their daughter. Any incentive to conceive with the intention of aborting and donating the tissue is thus removed. Also removed is any familial pressure, real or perceived, upon women to conceive in order to help an ill family member.

Such a prohibition has been suggested for live organ donors because of increased success with cadaver transplants.[161] The use of the anti-rejection drug cyclosporin has almost equalized the rejection rate between randomly matched organs and donors and those transplants done between family members.[162] Such an equalization is more likely for fetal tissue because it is so less likely to be rejected.[163]

With 1.2 million abortions performed each year in this country, supply of fetal tissue is not likely to become a problem.[164] While mandating informed consent by the mother may restrict the availability, it may also increase it. Because an exact tissue match is not required for success, eliminating a donor's ability to designate a donee would not significantly alter the effectiveness of the implant. Such a restriction would, however, place a check on conception in order to abort.

Though feelings differ concerning the morality of abortion, there is nevertheless a recognition that a fetus is different from other body parts. Such a recognition is the foundation upon which the *Research on the Fetus* recommendations, as well as state and federal regulatory schemes, are built. Conception with the intention of using the resulting fetal tissue is not an action to be encouraged. Fortunately, the current state of technology does not force someone to make the choice between an intentional conception for the purpose of abortion or the endurance of a family member's suffering. If fetal tissue transplants prove to be as beneficial as anticipated, such tissue can be obtained without encouraging conception in order to abort.

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160. *Today* (NBA television broadcast, Oct. 7, 1987).

161. Starzl, *Will Live Organ Donations No Longer Be Justified?*, 15 HASTINGS CEN. REP. 5 (April 1985).

162. *Id.*

163. *See supra* notes 19-21 and accompanying text.

164. Thorne, *supra* note 18, at 16, col. 4.

V. Conclusion

The use of fetal tissue for transplants in humans has incredible potential to reverse or significantly improve many neurological and other diseases. The current state of both federal and state law, however, does not adequately address how and under what conditions such tissue could be obtained and used.

Without intervention on a national scale, there is the danger of an industry developing that deals in fetal tissue for profit. The resulting potential for the exploitation of women and the trivialization of a fetus in its non-viable state are unacceptable. National action must be taken before such an industry is in place. Such national action must mandate informed consent of the woman involved, prohibit the purchase or sale of fetal tissue, and preclude donors from designating a specific person as donee. Only such action will avoid an ad hoc random approach that ultimately will subordinate individual choices to the demands of technology. For competing interests and benefits to be reconciled and realized, there must be opportunity for these concerns to be addressed, debated, and resolved in a national forum.

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