LEGAL AND REGULATORY ISSUES FOR NEURAL GRAFTS

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The use of neural grafts from fetuses is showing some success for the treatment of
disorders such as Parkinson's disease, and promise for the treatment of Alzheimer's disease as well. A potential advantage of using fetal tissue is that it is relatively undifferentiated, grows rapidly, and is less likely than other donor tissue to be rejected.\footnote{J. Fox, "Overview" in 2 NIH Report of the Human Fetal Tissue Transplantation Research Panel (1988) (hereinafter NIH Report) at A7-8.} The fact that in this country there are 0.5 million people with Parkinson's disease and 2.5 million Alzheimer's patients\footnote{N. Terry, "Politics and Privacy: Refining the Ethical and Legal Issues in Fetal Tissue Transplantation," 66 Wash U.L.Q. 523-551, 527-528 (1988).} indicates the pressing need for the development of a treatment. Currently, research on fetal neural tissue grafts is underway in the United States, Sweden, Mexico, Great Britain, and China.\footnote{Fox, supra note 1, at A1.}

The use of neural grafts from fetuses raises many ethical and legal issues. These include issues related to the protection of the human subjects who will be recipients of the grafts, the protection of the fetuses that will provide the grafts, and the proper characterization of the graft material itself.

I. Protection of the Subjects of the Research

A. General Legal and Ethical Principles Governing Human Research
Basic ethical and legal tenets govern experimentation on human beings. Many of these legal principles in this area have been developed in response to the abuses of research subjects that occurred in Nazi Germany during World War II. In addition, examples of unethical research in America further stimulated public discussion and policy considerations.

In the trials of Nazi physicians, the court set forth standards that should be complied with before and during research. Those standards, subsequently adopted by the United Nations General Assembly, are known as the Nuremberg Code. The tenets of the code significantly influenced subsequent state laws and federal regulations in the United States dealing with research.

5 The most well known examples of research abuses in the United States were the Willowbrook hepatitis study and the Tuskegee syphilis study. In the 1960s, institutionalized mentally disabled children at Willowbrook Institution were injected with live hepatitis virus in an effort to develop a vaccine. The researchers justified their procedures by noting that hepatitis ran rampant through the institution and that all children would eventually contract the disease. See S. Golby, "Experiments at the Willowbrook State School," 1 Lancet 749 (April 1971). From 1932 to 1972, a United States Public Health Service study of 400 black men suffering with syphilis deliberately deprived them of treatment in order to study the effects of allowing the disease to take its course, even though penicillin had been found to be an effective treatment. At least twenty-eight and as many as one hundred and seven men died. Tuskegee Syphilis Study Ad Hoc Panel to the Department of Health, Education and Welfare, Final Report (1973) and J. Jones Bad Blood: The Tuskegee Syphilis Experiment (New York: The Free Press, 1981).
6 Trials of War Criminals Before the Nuremberg Military Tribunals 2 The Medical Case 181 (1949). The Nazi doctors tried to defend themselves by pointing out the abuses in research that had occurred elsewhere, including ones in the United States. However, this defense did not succeed and 15 of the 23 doctors were found guilty of war crimes and crimes against humanity. A.M. Capron, "Human Experimentation," 1 BioLaw 10 217, 229 (1986).
8 The preamble to the California human experimentation law states that the law was necessary since the Nuremberg Code was not codified and thus is unenforceable. Cal. Health & Safety Code 24171(b) (West 1984).
The Nuremberg Code provides guidelines for assuring that participation in research is voluntary and that the risks of research are minimized. The Code provides that certain basic research and animal research must be done before human research is undertaken, that the research must be well-designed, that it must be undertaken only by scientifically qualified individuals, that the potential results must justify the level of risk involved in the performance of the research, and that those results must not be procurable by other means of study. The central tenet of the Nuremberg Code is that participation in research be voluntary, informed and uncoerced and that the subject have the right to bring the experimentation to an end. The Code also requires the minimization of research risks, through the appropriate design and conduct of the research as well as through the use of adequate preparation and facilities to protect the subject. Research is forbidden if there is an a priori reason to believe death or disabling injury will occur (although the Code does allow for a potential exception if the researchers also serve as subjects) and on-going research must be stopped if there is reason to believe that its continuation will lead to the injury, disability, or death of the subject.

Applying the ethical principles enunciated in the Nuremberg Code to the issue of fetal tissue grafts, a question of whether there has been sufficient animal research will arise. There have already been studies of fetal grafts in rodents and in monkeys. More animal research is necessary. Eventually, however, human subjects must be involved. Man is "the final test site."

10 For a review of the studies, see "Transplanted Cells: A Future Treatment for Parkinson's Disease?" 4 (2) Neurologic Consultant 1-8 (1987).
11 In a 1989 article, Gill and Lund note that more satisfactory animal models are needed for Parkinson's and similar diseases. T. Gill and R. Lund, "Implantation of Tissue Into the Brain: An Immunologic Perspective," 261 J.A.M.A. 2674-2676, 2675 (1989). They also note that certain additional information is needed about the neural system. They state that "the clinical use of neural tissue for transplantation in humans should be approached very cautiously until the appropriate fund of basic knowledge is acquired and evaluated." Id. at 2676.
13 Id. at 25.
Fetal tissue graft research also raises questions related to the informed consent of subjects. The likely recipients of experimental fetal tissue transplants may have impaired mental functioning. Much of the research will take place on people with Alzheimer's disease, for example. Thus, it is likely that some of the initial subjects in this field may be incapable of giving consent for themselves. Various guidelines have been suggested for research on subjects who are incapable of consenting. There is general agreement that such individuals should be allowed to participate in therapeutic research, the intent of which is to provide a health benefit to them. With respect to nontherapeutic research, some commentators suggest that such research should not be undertaken on people who cannot personally give a valid informed consent.14 Others suggest that it should be permissible to undertake important nontherapeutic research on incompetent individuals provided that there is proxy consent and there are minimal or no risks.15

Subsequent societal discussion of research in the four decades since the adoption of the Nuremberg Code has highlighted some additional ethical concerns. One concern is that selection of subjects for research be equitable;16 for example, a particular class or race of subjects should not serve as subjects for research that primarily benefits people of another class or race. Some commentators suggest that this should be particularly true in the case of subjects incapable of consenting17 (for example, research on an incompetent elderly subject should benefit other elderly people).

16 This requirement has been incorporated into the federal regulations. 45 C.F.R. 46.111(a)(3) (1989).
There has also been concern that research proposals be reviewed in advance by groups unrelated to the research project itself. This has led to the formation of Institutional Review Boards to assess the ethical ramifications of proposed research.\textsuperscript{18}

\textbf{B. Protection of the Recipients of Neural Grafts}

1. The Coverage of the DHHS Regulations Governing Research

The Department of Health and Human Services (DHHS) regulations apply to all research with human subjects that is federally funded or conducted by DHHS.\textsuperscript{19} These federal regulations have potential widespread application. The federal budget for the National Institutes of Health represents over one-third of all money spent on health-related research.\textsuperscript{20} In addition, the reach of the federal regulations can go beyond federally funded research, since the regulations are used widely as guidelines, even in institutions without federal funding.\textsuperscript{21}

The federal regulations apply to both therapeutic and nontherapeutic research.\textsuperscript{22} They define research as "a systematic investigation designed to develop or contribute to generalizable knowledge."\textsuperscript{23}

\textsuperscript{18} Institutional Review Board approval is necessary before a project will receive federal funding. 45 C.F.R. 46.103(b) (1989).
\textsuperscript{19} 45 C.F.R. 46.101 (1989).
\textsuperscript{22} 45 C.F.R. 46.101 to -.409 (1989); 21 C.F.R. 50.1 to -.48 (1989).
\textsuperscript{23} 45 C.F.R. 46.102(e) (1989). Some types of research are exempt from the federal regulations under certain conditions, such as educational research and research involving survey or interview procedures. 45 C.F.R. 46.101(b)(1) and (3) (1989).
Under the federal regulations, all human research projects must be reviewed and approved by an institutional review board (IRB). The IRB is required to conduct continuing review of the research which can include third party observation of the research. The intervals of continuing review are contingent upon the degree of risk involved in the experiment, but must not be less than once per year. The regulations provide that the risks of the proposed research must be minimized and must be reasonable in relation to anticipated benefits. They additionally provide for expedited review of research that involves minimal risk or minor changes in approved procedures.

The regulations require that selection of subjects be equitable. Informed consent must be obtained from each subject. The regulations provide the basic elements that must be included in informed consent and require that such consent be documented and provided in an understandable language. The regulations further provide that neither the researcher, the institution, nor the sponsor may be released from liability through the subject's oral or written consent. DHHS regulations also specifically address research involving fetuses, pregnant women, and human in vitro fertilizations. Moreover, separate provisions are included for research with children.

24 45 C.F.R. 46.103(b) (1989).
28 45 C.F.R. 46.110(b) (1989). "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater than those encountered in daily life or during the performance of routine physical or psychological tests. 45 C.F.R. 46.102(g) (1989). Research activities involving no more than minimal risk include, for example, collection of hair and nail clippings and recording of data that does not involve the invasion of the subject's privacy. 46 Fed. Reg. 8,392 (Jan. 26, 1981).
29 45 C.F.R. 46.110(b) (1989).
32 Id.
33 Id.
34 Id.
2. The Coverage of the FDA Regulation

Under the Food, Drug and Cosmetics Act, the Food and Drug Administration (hereinafter "FDA") enforces statutory safety requirements of health care products, including drugs, biologics, and medical devices. The FDA has authority to oversee clinical experimentation. After the commercial manufacturer has adequately demonstrated the safety and efficacy of the product and of the entire manufacturing process, the FDA may approve it for marketing.

The FDA generally does not sponsor research and thus its oversight of research is primarily retrospective. It may refuse to authorize the marketing of a new drug or device if the research is used to justify its approval did not comply with the FDA guidelines.

The Food and Drug Administration has promulgated regulations that track the DHHS regulations with minor differences. The subject must be informed that his or her records may be inspected by the FDA. The written consent requirement may be waived when it is determined that the research poses no more than "minimal risk" of harm to the subjects or where the procedure is one for which written permission is normally not required outside the research setting. The basic elements of informed consent are set forth with exemptions provided where the subject is confronted with a life-threatening situation or where informed

38 OTA, supra note 20, at 27, 38.
39 Capron, supra note 6, at 235.
42 21 C.F.R. 50.27, 56.109(c) (1989).
consent cannot be obtained because of an inability to communicate with the subject and there is not sufficient time to obtain consent from the subject's legal representative.\textsuperscript{45} As under the DHHS regulations, IRB review is required for all human subject research and the composition and duties of such IRBs are set forth.\textsuperscript{46}

The FDA also has authority to approve "new drug" experimentation that involves interstate commerce.\textsuperscript{47} A "new drug" is defined as an article intended to cure, mitigate, treat, or prevent disease.\textsuperscript{48} Fetal tissue transplant therapy would arguably fall under the purview of FDA regulations because the tissue that is inserted into the body is an article intended to cure or treat a disease.

3. The Coverage of State Laws and Regulations

In research programs where there is no federal involvement or influence, government oversight will depend on whether there are state statutes.\textsuperscript{49} Few states have statutes which comprehensively address human experimentation.\textsuperscript{50} Some states address human research as part of patients' rights statutes,\textsuperscript{51} or statutes protecting particular groups of research subjects.

\textsuperscript{45} Id., 50.23(a)(3).
\textsuperscript{46} 21 C.F.R. 56.107, 56.108 (1989).
\textsuperscript{47} 21 U.S.C. 355(a) (1982).
\textsuperscript{48} 21 U.S.C. 321(g) (1982).
\textsuperscript{49} Where the Department of Health and Human Services and the Food and Drug Administration regulations overlap state statutes, both state explicitly that they are not intended to preempt applicable state or local laws. 45 C.F.R. 46.101(g) (1989); 21 C.F.R. 50.25(e) (1989).
subjects such as the mentally disabled, 52 or professional ethics statutes that mandate obtaining patients' consent to experimentation. 53 The provisions range from a simple statement that individuals have the right to refuse to participate in experimental research 54 to statutes that explicitly list the elements of requisite informed consent to participation in experimentation. 55 Some statutes simply prohibit human experimentation that involves any significant risk of physical or psychological harm. 56 Often, the statutes use the terms "human research" and "human experimentation" interchangeably.


Only three states have enacted comprehensive legislation that specifically applies to all medical research with human subjects -- California, New York and Virginia.\textsuperscript{57} The statutes of both California and New York state that human experimentation is vital for the benefit of the human race, but that such experimentation must be undertaken with due respect to the right of individuals to determine what is done with their bodies.\textsuperscript{58}

All three of the comprehensive state statutes appear to regulate experimentation involving novel therapy on patients as well as research on healthy subjects. California, New York, and Virginia define human experimentation (research) within their statutes.\textsuperscript{59} Virginia defines "human research" as any medical research which departs from established methods using human subjects who might be exposed to possible injury as a consequence of their participation.\textsuperscript{60} This appears to encompass therapeutic experimentation. California and New York define human experimentation as experiments which are not necessary for treatment nor of direct benefit to the subject.\textsuperscript{61} Although these statutes appear to be primarily aimed at experimentation on healthy subjects, both include as an element of informed consent that the individual shall receive information concerning the disclosure of appropriate alternative procedures.\textsuperscript{62} As this information would not be relevant to the subject of purely nontherapeutic experimentation, it could be argued that these statutes also apply to therapeutic experimentation.

The California human experimentation statute provides penalties for those who violate the requirements. Liability extends to those who are primarily responsible for the conduct of medical experiments and representatives or employees of pharmaceutical companies who are directly responsible for contracting with the subjects. The statute sets forth fines and terms of imprisonment for those guilty of violating the human research requirements.

The New York and Virginia statutes provide that researchers conducting experimentation in compliance with federal regulations concerning protection of human subjects are not subject to the state requirements. California provides that researchers conducting investigations within institutions holding federal assurances and who obtain informed consent as required by federal regulations are exempt from the requirements except for provisions requiring that the subject receive a list of subjects' rights and penalties. The federal regulations provide that compliance with the federal regulations does not render state or local laws inapplicable. Therefore, in states that do not make provisions for the overriding applicability of federal regulations, researchers must observe both federal regulations and any state or local statutes or regulations.

54 Id.
55 Cal. Health & Safety Code 24176 (West 1984). Fines and terms of imprisonment are as follows:
For persons who negligently allow an experiment to be conducted without the subject’s informed consent -- a minimum of $50 and a maximum fine of $1000, to be determined by the court. For persons primarily responsible for the conduct of the experiment, who willfully fail to obtain the subject’s informed consent, a maximum fine of $5000. For persons primarily responsible for the conduct of a medical experiment, who willfully fail to obtain the subject’s informed consent, thereby exposing the subject to a known substantial risk of serious injury, either physical or psychological, a maximum fine of $10,000 or imprisonment for a maximum of one year, or both. A representative or employee of a pharmaceutical company, who is directly responsible for contracting for the conduct of the medical experiment and who has knowledge of the risks and hazards is subject to the same penalties.
58 Cal. Health & Safety Code 24172 (West 1984). The list of subject’s rights does not include information beyond that required in the federal regulations.
60 45 C.F.R. 46.101(g) (1989).
4. The Role of Institutional Review Boards

The federal regulations and some state laws provide for advance review of research proposals by institutional review boards (IRBs). This mechanism arose out of concern for the rights of human subjects who participate in medical research. The idea of requiring a review and approval of a research project before it was initiated grew out of a fear that relying on the investigator's sense of professional responsibility was an insufficient safeguard of the human subject's rights. Potential problems may exist in the inherent conflict between the researcher's goal of undertaking the experiment (which may lead to acquisition of knowledge, enhanced professional status and/or commercial gain) and the patient's rights. Because of this conflict, it was thought necessary to attempt to assure that proposed research is reviewed by an impartial body. When functioning properly, IRBs prevent premature experimentation with human subjects (by monitoring whether appropriate laboratory and animal research has been conducted) and serve to ensure that the subject has given fully informed consent.

73 Robertson, supra note 71, at 487.
Currently, the federal government requires that all research involving human subjects which is conducted by or funded by DHHS or the FDA be reviewed and approved by an institutional review board.\textsuperscript{74} Similarly, four states require institutional review board review of any research utilizing human subjects.\textsuperscript{75} Seven states and the District of Columbia provide specifically for review board approval of any research with the mentally disabled.\textsuperscript{76}

The federal regulations and the New York and Virginia statutes set forth the duties of the IRB which include evaluating the risks and benefits to the prospective subject(s) and ensuring that the risks are outweighed by the potential benefits to the subject or by the importance of the knowledge to be gained.\textsuperscript{77} These IRB's are also charged with the responsibility of deciding whether the persons proposing to conduct human research are qualified and competent, and must periodically investigate each project to ensure that it is being carried out according to the original proposal.\textsuperscript{78}

In any IRB review, the fundamental ethical guidelines for determining whether a therapy may be experimentally used on humans is to hold each person fundamentally entitled to respect as an individual\textsuperscript{79} and to proceed only if the benefits and risks of therapy are in

\textsuperscript{74} 45 C.F.R. 46.101 to -.409 (1989); 21 C.F.R. 56.107, 56.108 (1989).
\textsuperscript{78} The IRB must take the following factors into consideration in deciding whether or not to authorize human research: the adequacy of the researcher's description of the potential benefits and risks involved; the adequacy of the methodology of the research; whether any nontherapeutic research presents a hazardous risk to the human subject; whether the risks to the human subjects are outweighed by the potential benefits to them; the adequacy of the informed consent form; and whether the voluntary informed consent is to be obtained by adequate and appropriate methods.
favorable ratio.\textsuperscript{80} Specifically, this standard requires a thorough assessment of the probable outcome (in both its helpful and harmful aspects), which is weighed against the results of not using the treatment. For example, if a patient had a lethal disease and there were no known mitigating treatments, a therapy previously untested in humans that was not likely to cause serious or lethal harm to the patient might be approved for experimental use in the patient.

Only the federal regulations and the statutes of Delaware, New York, Missouri, and Virginia set forth the composition of the institutional review board.\textsuperscript{81} Under the federal law, for example, each IRB must include: at least five members with varying backgrounds (including racial and cultural backgrounds); a mixture of men and women; a member from a non-scientific discipline -- e.g., lawyer, ethicist; and a member who is not otherwise affiliated with the institution.\textsuperscript{82} Problems may arise where members of the IRB are associated with the institution. These individuals may not be able to be completely objective because of their identification with the researcher, their loyalty to the institutions and because any possible success will accrue indirectly to the associated review board members.\textsuperscript{83} One way to avoid this problem would be to require that the IRB include as members individuals who have no connection with the research institution.\textsuperscript{84} Some commentators argue that this proposal may promote unwarranted public interference with medical research\textsuperscript{85} and that membership on an IRB could become a matter of political appointment which could potentially threaten the


\textsuperscript{82} 45 C.F.R. 46.107 (1989).

\textsuperscript{83} Mulford, supra note 72, at 109.

\textsuperscript{84} Id.

\textsuperscript{85} Id.
academic freedom of researchers.\textsuperscript{86} However, in light of inherent difficulties involved in the objectivity of institutional associates, the possibility of political interference is outweighed by the necessity for outside input. The principle supporting the existence of IRB's assumes that the protection of the rights of human research subjects overrides the absolute freedom of the researcher to perform unrestricted experimentation.\textsuperscript{87}

5. The Requirements for Informed Consent

The doctrine of informed consent is related to the right of every individual to participate in decisions about his or her own medical care.\textsuperscript{88} Informed consent means the "knowing" consent of a person or, if the person is not competent to consent, his or her legally authorized representative.\textsuperscript{89} An individual cannot consent to participate as an experimental subject without understanding that for which he or she is volunteering.\textsuperscript{90} Adequate informed consent includes the transmission from the researcher to the prospective subject of any information that might influence the subject to participate or decline to participate.\textsuperscript{91}

The adequacy of consent for experimental therapy raises more issues than with proven treatment simply because less is known about the efficacy and risks involved in an experimental procedure.\textsuperscript{92} Although no absolute guarantee exists that an established treatment will be effective and will not cause harm, even fewer and possibly no guarantees exist when the proposed therapy is experimental.\textsuperscript{93} Therefore, a prospective subject must be made aware that

\textsuperscript{87} Id.
\textsuperscript{89} Greenwald, "Informed Consent," 79, 81 in Greenwald \textit{et al.}, supra note 9.
\textsuperscript{90} Id.
\textsuperscript{91} Id.
\textsuperscript{93} Id.
little is known about the possible risks and consequences involved in participation in experimentation. As the New York human experimentation law provides: "Every human being has the right to be protected against the possible conduct of medical or psychological research upon his body without his voluntary informed consent." The federal regulations and laws in California, New York, and Virginia provide that the information given for proper informed consent must include the following: an explanation of the procedures, drugs, or devices to be used in the experiment; a description of any possible risks and discomforts which might be expected; an explanation of possible benefits; a disclosure of appropriate alternative procedures, drugs, or devices; an offer to answer questions that the prospective subject may have concerning the experiment and its effect; and an instruction that the individual's consent to participate in the experiment may be withdrawn at any time without prejudice. There is virtually no disagreement concerning the requirement of these elements for informed consent.

Although the federal regulations and the statutes of California, New York, and Virginia specifically address the elements of informed consent, some states merely provide that informed consent be obtained. In all, the statutes of 24 jurisdictions contain provisions requiring some kind of informed consent before a person may participate in a research project

94 Id.
as a human subject. Of these statutes, 11 apply to research with the mentally disabled. Eleven of the "informed consent" statutes fail to specify what information must be provided. Of the remaining statutes, 10 provide only that the prospective subject has a right to refuse to participate in human experimentation.

When the subject is also a patient, it is important to provide a realistic assessment of the level of development of the therapy under consideration. Patients may tend to overestimate the benefits they will experience with an experimental treatment. To counter that tendency, it may be useful to provide information, when applicable, about the extent of previous research on the experimental treatment in animals and humans.


Informed consent should also include a statement of whether any alternative treatments exist so that the prospective subject can best evaluate the benefits/risks of participating. The subject should also be informed if the use of the experimental treatment will foreclose some of the alternatives. An example of this would be where the subject’s disease will have advanced too far after he or she has received experimental therapy to treat it with traditional therapy.\textsuperscript{102}

The use of fetal tissue transplants raises an additional unique issue about consent. Recipients should be told the source of the tissue -- i.e., that it was from an aborted fetus -- since that information may be material to their decision about whether or not to consent to have the tissue implanted in them.\textsuperscript{103}

There are also concerns about what should happen if the research subject is harmed in the study. According to the federal regulations and the California law, the subject should also be given an explanation of the availability of medical therapy in case of injury incurred as a result of the experiment.\textsuperscript{104} Where compensation for research injuries is not provided for, the prospective subject should be informed that any possible research related injuries will not be compensated.\textsuperscript{105} Where a subject has not been specifically informed that he or she bears the financial cost of potential physical injury, the informed consent is arguably not complete.\textsuperscript{106}

\textsuperscript{106} Id.
Research subjects should also be given an assurance that they are free to refuse to participate or to withdraw their consent at any time and to discontinue participation in the project without penalty or loss of benefits to which they are otherwise entitled.\textsuperscript{107} All ethical codes stipulate that subjects always be able to withdraw from an experimental project without prejudice or penalty.\textsuperscript{108} The right to withdraw is derived from the premise that the subject is doing something for the benefit of others and that such gratuitous acts are generally not obligatory.\textsuperscript{109}

If researchers do not provide adequate information to a subject before research is undertaken, they can be sued for damages when harm results.\textsuperscript{110} In addition, physician-researchers who do not obtain consent may be disciplined for unprofessional conduct.\textsuperscript{111} The California law also provides penalties for violation of the informed consent provision, including damages up to $1,000 for negligent failure to obtain informed consent,\textsuperscript{112} damages up to $5,000 for willful failure to obtain informed consent,\textsuperscript{113} and damages up to $10,000 and up to one year in jail for willful failure to obtain informed consent that exposes the subject to substantial physical or psychological risk.\textsuperscript{114} Additional protections are aimed against drug companies. A


\textsuperscript{108} Levine, supra note 102, at 85.

\textsuperscript{109} Id.

\textsuperscript{110} See, e.g., Halushka v. University of Saskatchewan, 53 D.L.R.2d 436 (Sask. 1968).

\textsuperscript{111} In the Jewish Chronic Disease Hospital case, twenty-two debilitated patients were injected with live cancer cells without first obtaining their voluntary informed consent. Mulford, supra note 72, at 99. The Attorney General of New York brought an action against the principal investigators to the Board of Regents Discipline Committee, which found the doctors guilty of fraud, deceit, and of unprofessional conduct. Id. at 100. The doctors were punished, not for performing experiments that resulted in harm to the patients, but because they did not obtain informed consent before proceeding.

\textsuperscript{112} Cal. Health & Safety Code 24176(a) (West 1984).

\textsuperscript{113} Id. at (b).

\textsuperscript{114} Id. at (c).
representative or employee of a pharmaceutical company who knows of substantial physical or psychological risks of an experiment and does not disclose them, can be imprisoned for up to a year and fined up to $10,000.\textsuperscript{115}

6. Grievance Handling and Nonrelease from Liability

The California statute provides a grievance mechanism for patients when an experiment goes awry. It requires that the subject be given the "name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment."\textsuperscript{116}

Like the federal regulations,\textsuperscript{117} the statutes in California, New York, and Virginia provide that any attempted or purported waiver of an individual's legal rights is void.\textsuperscript{118} The New York and Virginia statutes state that it is impermissible to release any individual, institution, or agency and any agents thereof from liability for negligence.\textsuperscript{119}

7. Protections for Particularly Vulnerable Subjects

Beyond statutes and regulations that apply to research on people generally, some statutes and regulations cover research on particularly vulnerable groups, such as the mentally disabled or children. Statutes concerning research on the mentally disabled may be relevant to experimental fetal tissue transplants into subjects with disorders such as Alzheimer's disease which may affect their mental functioning. The federal regulations provide that IRBs shall add appropriate additional safeguards if the potential subjects suffer from acute or severe physical or mental illness.\textsuperscript{120} Although the regulations do not describe what these additional protections

\begin{footnotesize}
\textsuperscript{115} Id. at (d).
\textsuperscript{117} 45 C.F.R. 46.116 (1989); 21 C.F.R. 50.20 (1989).
\textsuperscript{120} 45 C.F.R. 46.111(b) (1989).
\end{footnotesize}
might be, the National Institutes of Health have introduced guidelines on the issue for their own intramural research. The guidelines involve a procedure for proxy consent as well as for additional oversight for research that involves more than minimal risk. The guidelines also prohibit research of more than minimal risk if the patient is incapable of choosing a proxy decisionmaker and has no next of kin to seek court-appointed guardianship.

Twenty-five states and the District of Columbia specifically regulate human experimentation with the mentally disabled. Other states regulate experimentation on residents of nursing homes. See, e.g., Mo. Ann. Stat. 198.088(1)(b)(c) (Vernon Supp. 1989); Or. Rev. Stat. 441.385 (1987). The abundance of state legislation reflects a general concern that institutionalized persons are frequently used as experimental subjects because they are "administratively convenient" to the researcher, and that they are often taken advantage of, either due to their mental deficiencies or their guardians’ lack of interest in their welfare.


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124 Levine, supra note 102, at 172.

125 Annas, et al., supra note 7, at 140.
That state laws tend to pay close attention to the issue of informed consent for mentally ill patients is due to concerns not only about voluntariness, but also about the capacity to comprehend information.\textsuperscript{126}

Of the 25 jurisdictions that provide statutory guidelines for human experimentation with the mentally disabled, 14 states and the District of Columbia require that the informed consent of the patient or his or her guardian be obtained.\textsuperscript{127} Kansas and Wisconsin require the informed consent of both the mentally disabled person and his or her guardian.\textsuperscript{128} Five states provide only that mentally disabled patients have the right to refuse to participate in human experimentation projects.\textsuperscript{129}

In some states, the permissibility of research on mentally disabled individuals turns on its purpose and/or its level of risk. At least two states limit experimentation with the mentally deficient to that which poses no hazardous risks.\textsuperscript{130} Four states require that research must be intended to benefit the mentally ill subject.\textsuperscript{131} A similar approach, with more stringent provisions, is taken by the Delaware statute which prohibits the participation in experimental research of mentally ill persons who are incapable of giving voluntary consent -- except under specific circumstances.\textsuperscript{132} The requirements for informed consent may be waived where: an


attempt to obtain informed consent from the patient has failed; no other therapy exists or the patient has not responded to accepted therapies; the research would be in the best interests of the patient; and the waiver has been approved by the IRB and the patient's legal guardian or next-of-kin.\textsuperscript{133} The proposed waiver must then be approved by a court which has discretion to deny approval for any reason which it deems appropriate.\textsuperscript{134}

Other statutes specify a particular review mechanism that must be followed. Six states require the prior review and approval of any research projects by an IRB,\textsuperscript{135} while three jurisdictions require the review and approval of state boards before experiments are conducted with mentally disabled persons.\textsuperscript{136} Four states provide some sort of judicial determination of the necessity of an experimental procedure before it may be used on an incompetent person.\textsuperscript{137} Florida, New Jersey and North Dakota require that the patient be physically present at such a judicial hearing, represented by counsel, and provided the right and opportunity to confront and cross-examine witnesses.\textsuperscript{138} These three states also allocate the burden of proof to the party alleging the necessity of the treatment.

C. Protection of Donors of Neural Tissue

Since embryos and fetuses\textsuperscript{139} are the proposed sources of tissue for neural grafts,\textsuperscript{140} the federal regulations and state laws governing embryo and fetal research would apply. Some of these laws are sufficiently restrictive that experimental neural tissue transplants using fetal tissue would apparently be forbidden in these states. However, if neural grafts become accepted medical practice, the embryo and fetal research laws would no longer serve to prohibit the procedure.

The use of fetuses as a source of tissue for neural grafts raises complicated issues. In most instances, the tissue will come from dead fetuses. However, there may also be instances in which physicians intend to remove tissue from live, but nonviable fetuses. Moreover, experimental designs may include interventions involving the pregnant woman and her living \textit{in utero} fetus. For example, there may be instances in which the woman is asked to undergo an alternative abortion procedure in order to better preserve the fetal tissue or postpone the abortion until the fetus is more developed. Different laws will apply depending on whether the fetus is dead, alive \textit{ex utero}, or alive \textit{in utero} and depending upon whether the experiment presents risks to the pregnant woman as well.

Further issues are raised regarding maternal consent, centering on whether pregnant woman should have a right to prohibit or authorize use of their fetuses for experimentation. Some laws address this issue, as well as the role of the father in the consent process.

\textsuperscript{139} The terms "embryo" and "fetus" refer to the human conceptus at various stages of development. However, the terms are not used in a uniform manner by the medical and legal literatures. In scientific terms, a fertilized egg passes through the stages of being a zygote, morula and blastocyst and then, from about the end of the second week of development until the end of the 8th week, it is an embryo. For the rest of the pregnancy, it is a fetus. The legal writings have not been so precise, however. In legal contexts, the term "embryo" has been used to refer to the conceptus from fertilization until the end of the 8th week and the term "fetus" has been used to refer to the conceptus in all stages of development.

\textsuperscript{140} \textit{See, e.g.}, Gill and Lund, \textit{supra} note 11, at 2674, noting that abortuses of between 9 to 10 weeks of gestation are appropriate sources of tissue for grafting.
An additional, volatile issue addressed by fetal research laws is whether women should be able to receive payment for fetal tissue. Some of the laws banning compensation would extend to payment to third party intermediaries as well.

1. The Development of Federal Policy on Fetal Research

Federal activity with respect to the issue of fetal research has been extensive. In 1974, the year after the Roe v. Wade decision, \textsuperscript{141} Congress passed the National Research Act. \textsuperscript{142} This legislation established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research whose first charge was to investigate the scientific, legal, and ethical aspects of fetal research. The statute placed a prohibition on all federally funded nontherapeutic research on fetuses prior or subsequent to an abortion, remaining in effect until the Commission made its recommendations and regulations were adopted. In 1975, the Commission made its recommendations. \textsuperscript{143} In the next year, the Department of Health, Education and Welfare (HEW) adopted regulations for the federal funding of fetal research which for the most part comport with the recommendations of the Commission. \textsuperscript{144} Under these regulations, certain types of fetal research are allowed with constraints based on obtaining parental consent and minimizing risk to the pregnant woman and the fetus.

In 1985, Congress again acted on the issue of fetal research. It passed a law which forbids federal conducting or federal funding of research on viable \textit{ex utero} fetuses; however, there is an exception for therapeutic research and for research that "will pose no added risk of suffering, injury, or death to the fetus and the purpose of which is the development of important

\textsuperscript{141} Roe v. Wade, 410 U.S. 113 (1973).
\textsuperscript{143} Research on the Fetus, supra note 17. This document is reprinted in 40 Fed. Reg. 33,530 (1975). The Commission also published, in a separate volume, Appendix: Research on the Fetus, supra note 15, the papers prepared for the Commission during its consideration of the fetal research issue.
\textsuperscript{144} 45 C.F.R. 46.201-211 (1989).
biomedical knowledge which cannot be obtained by other means."\textsuperscript{145} It also provides that for research on living fetuses in utero, the federal regulations must require that the risk standard be the same for fetuses which will be aborted and fetuses which will be carried to term.\textsuperscript{146} Simultaneously, Congress passed legislation creating a Biomedical Ethics Board, comprised of six members of the Senate and six members of the House of Representatives, with an outside Advisory Committee.\textsuperscript{147} Again, the issue of fetal research was the first order of business for the group. Under existing federal regulations, the Secretary of Health and Human Services may authorize research that does not comply with the regulations in certain instances of great need and great potential benefit.\textsuperscript{148} A recent statute, however, suspends that authority until the Biomedical Ethics Advisory Committee conducts a study of the "nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk provisions of the existing federal regulations on fetal research."\textsuperscript{149} Concerns over the abortion issue seem to have paralyzed the effects of the group and no report on fetal research has yet been undertaken.

Federal attention again turned to the issue of fetal research in 1988. The director of the National Institutes of Health, Dr. James Wyngaarden, requested permission to fund projects using fetal tissue for transplantation. On March 22, 1988, Dr. Robert Windom, the Assistant Secretary at the Department of Health and Human Services, denied the request on the grounds that the use of fetal grafts raised ethical and legal issues that should be addressed by an advisory committee. Dr. Wyngaarden convened such a committee, which subsequently made recommendations.\textsuperscript{150} The committee recommended lifting the moratorium on federal funding

\textsuperscript{145} 42 U.S.C.A. 289g(a) (West Supp. 1989).
\textsuperscript{146} 42 U.S.C.A. 289g(b) (West Supp. 1989).
\textsuperscript{148} 45 C.F.R. 46.211 (1989).
\textsuperscript{149} 42 U.S.C.A. 289g(c) (West Supp. 1989).
\textsuperscript{150} The deliberations and recommendations of the committee are reported in Report of the Advisory Committee to the Director, National Institutes of Health, \textit{Human Fetal Tissue Transplantation Research} (December 14, 1988). See also the reports of a consulting panel in 1 and 2 NIH Report, \textit{supra} note 1.
of human fetal tissue transplantation research using tissue from induced abortions and
emphasized that commercialization be prohibited and that the abortion procedure should be
separated from the procedure using fetal tissue.

2. Federal Regulations Governing Fetal Research

The federal regulations define the term fetus as a conceptus after implantation. With
respect to research on dead fetuses, the federal regulations defer to state laws on the subject.151
However, there is some dispute about whether another section of the statute, not specifically
applying to dead fetuses, should be read to apply, too, in the context of such research.152 That
section provides that "[n]o inducements, monetary or otherwise, may be offered to terminate
pregnancy for purposes of the activity."153 Even if the section on inducements were read into
the federal law about research on dead fetuses, this would not necessarily preclude
experimentation involving neural grafts from abortuses. Although some commentators have
alleged that the possibility of donating fetal tissue for experimental transplantation might lead
women to undergo abortion154 and thus is an "inducement," there is little evidence that women
would do so if there were prohibitions on payment for fetal tissue and on donation to a
relative.155 Moreover, there is support for the position that the term "inducement" means
valuable consideration and that the possibility of participating in research, without
compensation, would not be considered valuable consideration.156

152 See J. Areen, "Statement on Legal Regulation of Fetal Tissue Transplant," in 2 NIH Report,
supra note 1, at D21-D26.
154 Areen, supra note 152, at D22-D24 (describing and rejecting that approach).
Robertson points out that informing women who are ambivalent about abortion about the
chance to donate would not be an inducement unless specifically aimed at convincing the
woman to abort, particularly if no valuable consideration is offered. Id. at 470 and 482 n.81.
156 Id. at 471 n.82.
With respect to research on live fetuses, the federal regulations provide that appropriate studies must be done on animal fetuses before human studies are done.\textsuperscript{157} When research involving human fetuses is undertaken, the consent of the mother and father are required (unless the father's identity or whereabouts are not reasonably ascertainable, he is not reasonably available, or the pregnancy resulted from rape).\textsuperscript{158} To protect the pregnant woman and the fetus, the research must not alter a pregnancy termination procedure in a way that would cause greater than minimal risk to either.\textsuperscript{159}

To protect the fetus, the researchers must not have a role regarding the determination of the procedure to terminate the pregnancy or the assessment of whether the fetus is viable.\textsuperscript{160} In \textit{utero} fetal research may be undertaken if the research is designed to be therapeutic to the particular fetus and places the fetus at the minimum risk necessary to meet its health needs.\textsuperscript{161} It may also be undertaken if the research imposes minimal risks and "the purpose of the activity is the development of important knowledge which cannot be obtained by other means."\textsuperscript{162}

As to research on a live, \textit{ex utero} fetus, such activity may be undertaken if the vital functions of the fetus will not be artificially maintained, experimental activities terminating the heartbeat or respiration will not be employed, and the purpose of the research is, again, the development of important, otherwise unobtainable, biomedical knowledge.\textsuperscript{163} Where it is unclear whether the \textit{ex utero} fetus is viable, that fetus may not be the subject of research except if the purpose of the activity is to enhance its chances of survival or the research subjects the fetus to no additional risk and its purpose is to develop important, otherwise unobtainable, biomedical knowledge.

\textsuperscript{157} 45 C.F.R. 46.206(a)(2) (1989).
\textsuperscript{158} 45 C.F.R. 46.208(b) (1989) (research with \textit{in utero} fetuses); 45 C.F.R. 46.209(d) (1989) (research with \textit{ex utero} fetuses). For a criticism of requiring the father's consent, see Robertson, \textit{supra} note 155, at 465.
\textsuperscript{159} 45 C.F.R. 46.206(a)(3), (4) (1989).
\textsuperscript{161} 45 C.F.R. 46.208(a)(1) (1989).
\textsuperscript{162} 45 C.F.R. 46.208(a)(2) (1989).
\textsuperscript{163} 45 C.F.R. 46.209(b) (1989).
3. State Laws Governing Embryo and Fetal Research

The overwhelming majority of state legislatures have yet to address the issues associated with the experimental neural grafts from fetuses. Only Missouri has enacted legislation specifically directed toward fetal tissue transplants. Short of actually banning these procedures, the Missouri law makes it a crime for any physician to perform an abortion knowing that the woman is seeking it for the purpose of donating the fetal tissue for implantation, or for anyone to offer consideration for the conception of a fetus which will be aborted and used for implantation. This legislation addresses the concern that women will conceive fetuses to create tissue for themselves, for ailing family members, or for profit.

A proposed law in California takes a similar approach. While allowing the donation of a fetus for "medical research or therapeutic application," this law incorporates many guidelines suggested by the Human Fetal Tissue Transplantation research panel in its report to the Assistant Secretary for Health, Dr. Robert Windom. For example, the proposed law prohibits consideration as an inducement to undergo an abortion for the purpose of donating the tissue, it prohibits the naming of a specific recipient, and it prohibits any doctor "participating in the procedures resulting in the loss of a fetus" from participating in any research with the tissue.

166 Proposed amendment to Cal. Health & Safety Code 7151.8, S.B. No. 2425 (introduced by Senator Torres). For the complete text of this legislation, see Terry, supra note 2, at 532 n.45.
167 S.B. No. 2425.
168 See 1 N.I.H. Report, supra note 1, at 1-16.
169 S.B. No. 2425.
Although other states have not specifically addressed the issue of neural tissue grafts from fetuses, the general fetal research laws in effect in 25 states might affect the permissibility of undertaking this procedure.\textsuperscript{170} The state laws on fetal research are not as precise as the federal law. Some contain no definition of fetus, of death, or of research. Others include much broader definitions of the term fetus so that the laws cover not just post-implantation conceptuses, but the human conceptus beginning at fertilization. Indeed, "the uncertainties surrounding the reach of such state regulatory regimes may both create a dangerous chilling effect on even peripheral research, and leave the regimes exposed to constitutional attack."\textsuperscript{171}

Only one state -- New Mexico -- has adopted a law patterned on the federal regulations pertaining to fetal research.\textsuperscript{172} Other states have enacted a variety of regulatory approaches, with the permissibility of fetal research depending, in part, on the following factors: 1) whether the fetus is dead or alive; 2) whether the research involves a fetus prior to, during, or subsequent to an induced abortion; 3) whether the mother consented to the research; 4)


\textsuperscript{171} Terry, supra note 2, at 534 (footnote omitted). See I.D., infra, regarding constitutional challenges to the laws.

whether the fetus is in the womb or outside of the womb; and 5) whether the fetus has reached a point or acquired characteristics which would warrant treating it as a person or has acquired some characteristic such as the capability for experiencing pain, which would give it an important claim to protection (often this factor is put in terms of the fetus's viability or nonviability). Many states' fetal research laws do not apply to research which is potentially therapeutic to the fetus, but this exception is not applicable in the situation of neural grafts since the procedure is not being done for the benefit of the fetus. Nine states underscore their ban on experimentation on fetuses by prohibiting anyone from donating a fetus for experimentation.\footnote{Ark. Stat. Ann. 20-17-802 (c) (1987); Ky. Rev. Stat. 436-026 (1985) (only applies to live fetuses); Me. Rev. Stat. Ann. tit. 22, 1593 (1980) (only applies to live fetuses); Mass. Ann. Laws ch. 112, 121(a)(IV) (Michie/Law Co-op. 1985); Mich. Comp. Laws Ann. 333.2690 (West 1980); Neb. Rev. Stat. 28-342 (1985) (only applies to live fetuses); N.D. Cent. Code 14-02.2-02(4) (1989); R.I. Gen. Laws 11-54-1 (f) (Supp. 1988); Wyo. Stat. 35-6-115 (1988) (only applies to live or viable fetus). Other state statutes affecting transfers of fetal tissue are discussed in Section 1.C.3.c., infra.}

a. Research On Dead Fetuses

Under state law, research involving dead fetuses and fetal tissues is regulated under the Uniform Anatomical Gift Act (UAGA) which has been adopted by all 50 states and the District of Columbia.\footnote{For a more extensive discussion of the UAGA, see IIB, infra.} Research with dead fetuses is also regulated in some states by fetal research statutes. According to the provisions the UAGA, either parent might donate all or any part of a fetus "after or immediately before death," provided that the other parent does not present opposition to the gift.\footnote{Under the Uniform Anatomical Gift Act (UAGA), a 'decedent' is defined to include "a stillborn infant or fetus." Uniform Anatomical Gift Act (UAGA), 1(b), 8A. U.L.A. 30 (Master ed. 1983 & Supp. 1987). The Act covers the donation of all or any portions of the human body (1(e)) for purposes which include both educational and therapeutic benefits (3). Under the consent requirements of the UAGA, either parent might donate all or any part of a fetus "after or immediately before [its] death," provided that the other parent does not present opposition to the gift (2(c)).}
Of the 25 states that have more specific laws governing fetal research, 14 have provisions regulating research with dead fetuses. These laws deviate from the provisions of the UAGA either in their consent requirements or in the uses of dead fetal tissue they allow. Eight of these laws would require the mother's consent for research, but make no provision for consent or objection by the father. One statute that allows research with dead fetal tissue is silent on the issue of parental consent. The remaining five states diverge from the UAGA more radically by prohibiting any research with dead fetuses except for pathological examinations or autopsies. The divergences of these laws from the provisions of the UAGA are perhaps attributable to lawmakers' interests in regulating abortion and related practices. Of the 14 which regulate research with dead fetuses, 8 apply only to research with abortuses. Of the five statutes which prohibit any research except for pathological examinations, four apply exclusively to abortuses, and one puts more restrictions on research with dead fetuses resulting from an induced abortion.


182 In Illinois, research on dead fetuses is prohibited (Ill. Stat. Ann. ch. 38, para. 81-26(7) (Smith-Hurd Supp. 1989)), but a pathological examination is required (para. 81-32). However, with respect to a fetus whose death did not result from an induced abortion, research can be undertaken on its tissues or cells with the consent of one of the parents (para. 81-32.1).
b. Research on Living Fetuses

There may be instances in which an experimental protocol as a whole requires that some action be undertaken on a dying or about-to-be-aborted fetus in order to better prepare the fetus for use as a donor of tissue. There are significant ethical questions raised about whether such actions should be permissible. For example, some commentators argue that no research should be permitted on fetuses which are about to be aborted that would not be permissible on fetuses that would go to term.\textsuperscript{183}

Additionally, there are state statutory constraints on research on live fetuses. Even with respect to federally funded fetal research, the federal regulations provide that these state laws are still applicable.\textsuperscript{184} State laws governing research on live fetuses put considerable constraints on research which is not therapeutic to the fetus itself (thus covering neural graft research, which is not therapeutic to the fetus). Of the 24 state fetal research laws that regulate research on live ex utero fetuses,\textsuperscript{185} 21 would appear to prohibit research involving neural grafts (either because the procedure is not therapeutic to the fetus or because all experimentation on such

\textsuperscript{183} See Research on the Fetus, supra note 17, at 67.

\textsuperscript{184} 46 C.F.R. 46.201(b) (1989).

fetuses is prohibited). Of these 21 statutes, 5 permit diagnostic and remedial measures to preserve the life or health of the mother, perhaps leading to the incongruous result that the mother may donate fetal tissue to herself, but to no one else. Of the remaining statutes, two would appear to permit research involving a live ex utero fetus provided the mother has consented. The final statute only prohibits farming in vitro fertilized embryos for research purposes and any use of IVF embryos other than to create a pregnancy.


188 S.D. Codified Laws Ann. 34-23A-17 (1986); Tenn. Code Ann. 39-4-208(a) (1982). On its face, the Tennessee statute does not appear to apply to live fetuses, at least older ones. It prohibits any experimentation on, research with, and photographs of an aborted fetus with prior written maternal consent. Tenn. Code Ann. 39-4-208(a) (1982). However, when an infant is "born alive" (an undefined term) as a result of an abortion, the Tennessee Department of Human Services (DHS) automatically receives custody of the infant. Id., 39-4-207. Presumably the mother no longer has authority over an infant in DHS custody and any consents she has given previously are ineffective. Compare S.D. Codified Laws 34-23A-18 (1986) (requiring an abortion to be considered as evidence in dependency and termination proceedings). Note, however, that these statutes are probably not constitutional.

Of the 14 states regulating research on live in utero fetuses, 190 13 would appear to prohibit neural graft research (either because it is not therapeutic to the fetus itself or because all experimentation on such fetuses is prohibited). One state would apparently permit it, so long as the mother consented. 191

With respect to neural grafts, it may be necessary for a physician to keep a nonviable fetus artificially alive either to preserve its tissue or to promote its development until it may be utilized. Questions thus arise as to whether an ex utero nonviable fetus has rights, and whether the need for fetal tissue justifies treating an aborted fetus as a living organ bank. 192 Moreover, if tissue were retrieved from a live fetus before making a determination of death under normal heart-lung or brain death criteria, the removal could be prosecuted as a homicide if it were the cause of the fetus’ death. 193

c. Distinction Based on Whether the Research is Done in Connection with an Abortion

Under both the state fetal research laws dealing with dead fetuses and those dealing with live fetuses, the factor which seems most significant for regulating research and for determining the level of restriction imposed is whether the research concerns a fetus which is to be or has been intentionally aborted. Most of the state fetal research statutes were passed as a


192 See Terry, supra note 2, at 526.

193 Robertson, supra note 155, at 492.
part of abortion legislation. Twelve of the 25 laws apply to research only where it concerns a fetus prior to or subsequent to a planned abortion. Of the 13 that apply to fetuses more generally, 5 impose more stringent restrictions on fetal research in conjunction with an abortion.

Another tactic that has been taken to assure that fetal research does not encourage abortion is to prohibit the performance of an abortion where "part or all of the consideration for said performance is that fetal remains may be used for experimentation." There had been some concern in the Commission deliberations that free second trimester abortions were given to poor women in exchange for consent to participate in fetal research.

In the past, important scientific gains were made through experimentation in the context of an abortion. For example, the development of prenatal diagnosis techniques has involved pregnant patients about to undergo abortions.

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The development of chorionic villi sampling, for example, has relied on patients about to undergo first trimester abortions. L. Jackson, "Prenatal Genetic Diagnosis by Chorionic Villus Sampling (CVS)," 9 Seminars in Perinatology 209-218, 214 (April 1985).
The most appropriate tissue for neural grafts will probably come from elective, rather than spontaneous, abortions. Tissue from spontaneously aborted fetuses is likely not to be appropriate for neural grafts, since a fetal pathology may have lead to the miscarriage and since the fetus may have died in utero and deteriorated before being miscarried.

Some have argued that research involving fetuses resulting from planned abortions, whether the fetus be living or dead, is morally impermissible on the grounds that it constitutes cooperation with an immoral practice. Richard McCormick has made this point in the following way:

If one objects to most abortions being performed in our society as immoral, is it morally proper to derive experimental profit from the products of such an abortion system? Is the progress achieved through such experimentation not likely to blunt the sensitivities of Americans to the immorality (injustice) of the procedure that made such advance possible, and thereby entrench attitudes injurious and unjust to nascent life? This is, in my judgment, a serious moral objection to experimentation on the products of most induced abortions (whether the fetus be living or dead, prior to abortion or post abortional).199

Though McCormick himself acknowledged that this moral evaluation of the use of aborted fetuses for research is not widely shared and was therefore not feasible as a policy position in a morally pluralistic society, a great deal of discussion centered around this concern at the September 14-16, 1988 meeting of the Human Fetal Tissue Transplantation Research Panel Consultants to the Advisory Committee to the Director, NIH, and a number of the state laws seem to embody just this reasoning in their provisions.200


200 Many of the state fetal research laws regulate research only where it involves a fetus which is the subject of an abortion and some impose a stricter standard on research involving fetuses to be aborted than on research involving fetuses going to term.
Against this view it is possible to argue that even if abortion represents a moral wrong, the use of dead abortuses for certain types of research is not only morally legitimate but obligatory. Marc Lappe has argued that research with fetuses to be aborted is morally justified provided the research is aimed at deriving information potentially beneficial to other fetuses. According to Lappe, by allowing research intended to benefit future fetuses "what we have done is add a moral good to a morally tragic situation."\(^{201}\)

d. The Issue of Maternal Consent

Related to the issue of abortion is the issue of maternal consent. There appears to be widespread agreement that a woman should be able to refuse to allow her fetus to be used experimentally. Stephen Toulmin has argued this point on the grounds that failure to gain a woman’s informed consent to experimentation on her conceptus could have emotionally damaging effects. He asserts that "it would be morally wrong to disregard a woman's psychological investment in a pregnancy, and in the issue of that pregnancy. Whatever the circumstances in which a pregnancy is terminated, the mother should have confidence that the issue will be handled and disposed of, both before or after death, in a respectful and humane way; and the lack of such an assurance would be a legitimate source of grief and guilt."\(^{202}\)

There is more controversy, however, surrounding whether the mother should be able to authorize the use of her fetus in an experimental procedure, such as a neural graft. Some commentators have suggested that the laws allowing a woman to consent to research involving her abortus are inappropriate because the woman has shown her disregard for their fetus by aborting it. These commentators suggest that the woman who has decided to abort the child is

\(^{201}\) M. Lappe, "Balancing Obligations to the Living Human Fetus with the Needs for Experimentation" in Appendix: Research on the Fetus, supra note 15, at 4-6.

\(^{202}\) Toulmin, supra note 197, at 10-11.
not an appropriate person to give a proxy consent for research on the fetus. However, the Commission pointed out that since women have a constitutional right to abort, "basing maternal disqualification on the exercise of that right may be an unconstitutional penalty." Along those lines, a mother's consent to an abortion does not make her an unfit mother of the subsequently-born child for custody purposes.

In addition, as John Robertson points out, "As a product of her body and potential heir that she has for her own reasons chosen not to bring to term, she may care deeply about whether fetal remains are contributed to research or therapy to help others. Given that interest, there is good reason -- and no compelling contrary reason -- to respect her wishes, as current law presently does. Indeed, in cases of conflict between the mother and the father over disposition, one could argue that the mother's wishes should control because the fetus was removed from her body."

None of the fetal research laws which require maternal or parental consent provide consent requirements which are specific to fetal tissue transplants. Standards in this area are needed because a physician may need to perform a more dangerous abortion procedure in order to preserve the fetal tissue. He or she may also wish to postpone the procedure until the

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204 Research on the Fetus, supra note 17, at 26. See also A. Capron, "The Law Related to Experimentation with the Fetus," 13-1 in Appendix: Research on the Fetus, supra note 15: "Such attempts to take away parental custody and control on the grounds that the mother has abandoned the fetus or is unable to take account of its interests seem unwise (because of the burden placed on state officials which they are ill-equipped to handle), misguided (because it is based on misapprehension of the significance of the decision to abort), unnecessary (because the interests of such fetuses are already protected by the law from parental abuse to the same degree as those of other children), and perhaps unconstitutional (because it chills exercise of the right to have an abortion and operates arbitrarily through presumptions rather than actual facts about parental choices)."
205 Keith v. Daley, 764 F.2d 1265, 1271 (7th Cir. 1986); Wynn v. Carey, 599 F.2d 193, 195 (7th Cir. 1979).
206 Robertson, supra note 155, at 465 (footnotes omitted).
tissue has reached a desired level of maturity. In either case, the health of the woman who will undergo the abortion may be placed at an increased risk, thereby underscoring the necessity of her having informed consent.  

The timing of obtaining the woman's consent is an issue as well. It is recommended that the woman not be asked whether she wants to donate tissue until after she has consented to the abortion. But waiting until after the abortion may not be possible since the fetal tissue must be used quickly and the woman may be less able to give an informed consent (for example, due to anesthesia) immediately after the abortion is performed.  

The issue of informed consent raises an important policy issue in the context of abortion. The Fifth Circuit Court of Appeals upheld a district court ruling striking down a Louisiana law which required a physician to inform a woman who had undergone an abortion of the various methods which she could choose for disposal of the remains. While the court limited the application of its holding to the physician performing the abortion (thereby allowing a nurse or some other physician to give the same information), it also noted that the statute created a psychological burden and might thus impermissibly affect a woman's decision to have an abortion. The same could possibly be said about laws requiring the dissemination of information regarding fetal tissue implants. However, the arguments for requiring the informed consent of the mother outweigh those for denying it.

208 Robertson, supra note 155, at 469.
209 Id.
211 794 F.2d at 998.
212 Id.
213 Robertson, supra note 155, at 466.
Indeed, failure to ask for a woman's informed consent to undertake research on her fetus may lead to a tort action for emotional distress if the research is undertaken. Courts have recognized the great emotional investment that women have in how their dead fetuses are treated. In *McCoy v. Georgia Baptist Hospital*, for example, a woman recovered damages for intentional infliction of emotional distress when, after thinking that the body of her stillborn child had been properly disposed of, she was told that the body had been frozen.

**e. The Issue of Payment in Connection with Fetal Experimentation**

Perhaps the greatest ethical concern regarding neural grafts -- and the concern which state legislatures are most likely to address first -- is the notion that the need for fetal tissue will encourage women to conceive for the sole purpose of donating tissue to relatives, or selling it for profit. This could lead to the exploitation of women and patients. Currently, 16 state fetal research statutes prohibit the sale of fetal tissue, 7 for any purpose and 9 for research purposes. Some of these statutes only apply to an aborted fetus, and thus would not preclude the sale of a miscarried fetus for tissue transplantation. The penalties for some of these laws

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are very stiff. Selling a live or viable abortus for experimentation in Wyoming, for example, subjects a person to a fine of not less than $10,000 and imprisonment of one to fourteen years.\textsuperscript{219} Several states have nonuniform UAGA provisions that prohibit transfer of organs or tissues, including fetal organs and tissues, for value.\textsuperscript{220} Moreover, certain states have laws that would forbid the sale of fetuses even when they are not being used for research purposes, thus covering payment for neural grafts in the clinical setting.\textsuperscript{221}

Viewed in light of the existence of biotechnology companies which create cell lines from fetal tissue,\textsuperscript{222} this fact raises the possibility that a woman may donate fetal tissue to a company which might then commercially exploit it.\textsuperscript{223} The fact that a corporation might profit from fetal tissue while at the same time the woman is prevented from receiving consideration for it seems to violate the principle of Moore v. Regents of University of California,\textsuperscript{224} where the court held that an individual has a protectable monetary interest in products made from his or her genetic material.\textsuperscript{225} While some state laws might prevent this practice,\textsuperscript{226} it is possible that because a cell line is new tissue produced from the genetic material of, but not originally a part of, the aborted fetus, laws proscribing the sale of fetal tissue may not apply. In fact, a Minnesota law prohibits the sale of living conceptuses or nonrenewable organs but does allow "the buying and selling of a cell culture line or lines taken from a non-living human conceptus...."\textsuperscript{227} In contrast,

\begin{footnotesize}
\begin{itemize}
  \item[\textsuperscript{219}] Wyo. Stat. 35-6-115 (1988).
  \item[\textsuperscript{220}] The applicability of these provisions to neural graft procedures will be discussed in II.C., infra.
  \item[\textsuperscript{221}] See II. C., infra.
  \item[\textsuperscript{222}] Sheehan, supra note 103, at 906.
  \item[\textsuperscript{223}] Id.
  \item[\textsuperscript{225}] Id.
  \item[\textsuperscript{226}] See, e.g., Tenn. Code Ann. 39-4-208 (1982) (prohibiting any "person, agency, corporation, partnership or association" from giving or receiving anything of value for an aborted fetus).
  \item[\textsuperscript{227}] Minn. Stat. Ann. 145.1627(3) (West 1989).
\end{itemize}
\end{footnotesize}
Nevada's broadly worded statute making it a crime for anyone to use or "make available...the remains of an aborted embryo or fetus for any commercial purpose" could conceivably outlaw the production of cell lines from fetal tissue.\textsuperscript{228}

f. Transfer of a Fetus for Research Purposes or Possession of Fetal Tissue

Some state statutes also contain restrictions on the transfer of fetal tissues from state to state. An Indiana law, for example, forbids transporting a fetus from an induced abortion to another state "for experimental purposes."\textsuperscript{229}

In Arkansas, there is a ban on "possession" of the organ, tissue or material of an aborted fetus.\textsuperscript{230} However, the Arkansas statute expressly exempts from its provisions physicians and the instructional and research programs of institutions of higher education.\textsuperscript{231}

g. Alternatives to the Use of Fetal Tissue

The ethical dilemmas of experimentation involving fetuses may eventually be resolved through the use of laboratory-maintained fetal cell lines or even through the development of drugs that supply those biological factors that the neural grafts are being used to provide.\textsuperscript{232}

D. Potential Constitutional Challenges to Restrictions on Research

\textsuperscript{229} Ind. Code Ann. 35-1-58.5-6 (West 1986).
\textsuperscript{232} Statement of Dr. William Moscona, NIH Panel on Fetal Tissue Transplantation Research (Sept. 21, 1988), cited in J. Robertson, supra note 155, at 446.
Not all regulations on research are constitutional. Laws restricting research may be struck down as too vague or as violating the equal protection clause. Those applying in the abortion context may violate the right to privacy. In addition, some legal commentators posit that there is a constitutional right to undertake or participate in research. Even if undertaking and participating in research were constitutionally protected, however, certain restrictions on research to further health and safety would be constitutionally permissible.

A law governing research must meet certain standards of clarity in order to be constitutional. In Louisiana, a law prohibited nontherapeutic experimentation on fetuses. A federal appeals court declared the law unconstitutional because the term "experimentation" was so vague it did not give researchers adequate notice about what type of conduct was banned. The court said that the term "experimentation" was impermissibly vague since physicians do not and cannot distinguish clearly between medical experimentation and medical tests. The court noted that "even medical treatment can be reasonably described as both a test and an experiment." This is the case, for example, "whenever the results of the treatment are observed, recorded, and introduced into the data base that one or more physicians use in seeking better therapeutic methods."

233 For example, bans on experimentation on fetuses might be unconstitutional as a violation of the woman's right to privacy. See Note, "State Prohibition of Fetal Experimentation and the Fundamental Right to Privacy," 88 Colum. L. Rev. 1073-97 (1988).
234 Margaret S. v. Edwards, 794 F.2d 994, 999 (5th Cir. 1986).
235 Id.
236 Id. A concurring judge found this analysis to be contrived and opined that the provision was not unconstitutionally vague. Id. at 1000 (Williams, J., concurring). Instead, he suggested that the prohibition was unconstitutional because "under the guise of police regulation the state has actually undertaken to discourage constitutionally privileged induced abortions." Id. at 1002, citing Thornburgh v. American College of Obstetricians and Gynecologists, 106 S. Ct. 2169, 2178 (1986). The concurring judge pointed out that the state had "failed to establish that tissue derived from an induced abortion presents a greater threat to public health or other public concerns than the tissue of human corpses [upon which experimentation is allowed]." Id. Moreover, the state had not shown a rational justification for prohibiting experimentation on fetal tissue from an induced abortion, rather than a spontaneous one. Id.
237 Margaret S. v. Edwards, 794 F.2d 994, 999 (5th Cir. 1986).
238 Id.
Although there is no specifically enumerated right to research in the U.S. Constitution, commentators such as John Robertson argue that support for such a right could be derived from the fourteenth amendment right to personal liberty\textsuperscript{239} and the first amendment right to free speech.\textsuperscript{240} This right to research consists of the freedom to pursue knowledge and the freedom to choose the means to achieve that knowledge.\textsuperscript{241} The Supreme Court stated in \textit{Meyer v. Nebraska}\textsuperscript{242} that the right to liberty guaranteed by the fourteenth amendment encompassed freedom to "acquire useful knowledge . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men."\textsuperscript{243} This language arguably applies not only to the researcher's right to scientific inquiry, but also to an individual's right to participate as a research subject.\textsuperscript{244}

Robertson hinges most of his argument on the first amendment's protection of free speech which he believes includes a right to learn new information. However, Robertson distinguishes the freedom to pursue knowledge from the right to choose the method for achieving that knowledge, since the method itself may permissibly be regulated.\textsuperscript{245} Although Robertson argues that the government may not prohibit research in an attempt to prevent the development of new knowledge, he recognizes that it may restrict or prohibit the means used by researchers which intrude on interests in which the state has a legitimate concern.\textsuperscript{246} Therefore, both the federal government and the state may regulate the researcher's methods in order to

\textsuperscript{239} Robertson, "The Scientist's Right to Research: A Constitutional Analysis," \textit{51 S. Cal. L. Rev.} 1203-79, 1213 (1977). Robertson argues that the right to participate as a research subject is protected by the fourteenth amendment's right to privacy as recognized in \textit{Roe v. Wade}, 410 U.S. 113 (1973). This right arises from an individual's privacy interest in autonomous decision-making concerning the use of his or her body in an experiment designed to further medical knowledge or to be of personal benefit. \textit{Id.}

\textsuperscript{240} \textit{Id.} at 1212.

\textsuperscript{241} \textit{Id.} at 1204.

\textsuperscript{242} \textit{Meyer v. Nebraska}, 262 U.S. 390 (1923).

\textsuperscript{243} \textit{Id.} at 399.

\textsuperscript{244} Robertson, supra note 239, at 1212 (the language of \textit{Meyer} could be interpreted to support an individual's right to help acquire knowledge by participating as an experimental subject).

\textsuperscript{245} \textit{Id.}

\textsuperscript{246} \textit{Id.} at 1253.
protect the rights of research subjects and community safety.\textsuperscript{247} Research may be restricted, for example, to protect the subject's right to autonomy and welfare by requiring informed, free and competent consent.\textsuperscript{248} However, the state cannot arbitrarily regulate research solely because it deems the knowledge sought to be obtained distasteful or subject to harmful use.\textsuperscript{249} 

II. Regulation of the Transplantation Material Itself

Once fetal tissue grafts evolve from an experimental to a clinical procedure, questions will arise about how to classify the transplant material. Various analogies come to mind -- to organs, fetal remains, blood donations, and so forth. Various laws in these analogous areas have implications for the practice of fetal tissue grafts.

A heated debate took place when blood transfusions began to be used extensively, focusing on whether blood should be viewed as a product or a service. The outcome of the debate was important, since it would determine the legal liability of blood banks and hospitals when a patient got infected blood. If blood was viewed as a product, there would be strict liability. If blood were viewed as a service, the infected patient could recover damages only if he or she proved that the blood bank or hospital was negligent. The latter approach was ultimately taken, with state statutes adopting laws designating the provision of blood to be a service.\textsuperscript{250} See, e.g., Iowa Code Ann. 142A.8 (West 1989); Minn. Stat. Ann. 525.928 (West 1975); N.C. Gen. Stat. 130A-410 (1986) ("whether or not any renumeration is paid").

\textsuperscript{247} Id. at 1254.
\textsuperscript{248} Id. at 1256.
\textsuperscript{249} Id. at 1253.
\textsuperscript{250} Some states provide that donation of tissues in general is a service, not a sale.
Nevertheless, in more recent years, concern for the quality of blood -- and, even more recently, of donated sperm -- has led the FDA and some states to adopt standards for donated blood and sperm. Along those lines, the FDA could adopt quality assurance standards applying to the collection and dissemination of fetal tissue and the development and dissemination of cell lines from fetal tissue.

A. Fetal Remains Laws

Every jurisdiction makes some provision for the registration of deaths (usually by death certificate) and disposition of dead bodies.\textsuperscript{251} Most of these statutes also specify when fetal deaths must be registered and how to dispose of fetal remains. In addition, some states make separate provision for reporting fetal deaths and/or disposing of fetal remains.\textsuperscript{252} These statutes are important, not only because they provide penalties for unauthorized uses of dead bodies,\textsuperscript{253} See, e.g., Cal. Health & Safety Code 7200 et. seq. (West 1980) (30-day holding period); Fla. Stat. Ann 245.06 et. seq. (West 1989) (embalming requirement).

\textsuperscript{251} Most states have a vital statistics statute governing death registration and issuance of permits for transporting or disposing of dead bodies and a separate statute governing the disposition of dead bodies. See e.g. Ala. Code 22-9-1 et seq. (1984) (vital statistics), 22-19-1 et seq. (1984). A few states have delegated authority over these matters to some administrative agency, typically the state health department. See, e.g., S.C. Code Ann. 44-63-1 (Law Co-op. Supp. 1988). In most states, dead bodies must be disposed of in an authorized manner within a specified period of time (usually 72 hours of death). Any disposition of a dead body usually requires a permit, which generally issues only after a death certificate has been filed.


\textsuperscript{253} The two most common sources of authority to conduct research are research statutes (in case of neural grafts, fetal research statutes) and the UAGA. In addition, many states establish an administrative agency to distribute unclaimed dead bodies for scientific and educational purposes. Since these statutes typically require a lengthy holding period and/or embalming of the body, they do not provide useful authority for the use of fetal tissue in neural grafts.
Anyone who conducts fetal research that is not authorized by one of these states may be charged with corpse abuse or unauthorized dissection. The most common corpse abuse statute follows Model Penal Code 250.10 and prohibits any use of a corpse that would offend "family sensibilities." See e.g., Ala. Code 13A-11-13(1)(1982); Ark. Stat. Ann. 5-60-101 (1987); Colo. Rev. Code 18-13-101(1)(b)(1986); Hawaii Rev. Stat. 711.1108(1)(1985); Ky. Rev. Stat. 525.120 (1985); Ohio Rev. Code Ann. 2927.01(a)(Baldwin 1986); 18 Pa. Cons. Stat. Ann. 5510 (Purdon 1983). For a discussion of the inapplicability of these statutes to authorized research, see the comments following the Ohio and Pennsylvania statutes. Oregon defines "corpse abuse" as any treatment of a corpse that is not recognized by the generally accepted standards of the community or, if by a professional, that is not recognized by other members of the profession as indicated by the rules applicable to that profession. Or. Rev. Stat. 160.085 (1987).


254 Failure to comply with these registration and disposition statutes carries a variety of penalties. For example, Alabama penalizes a failure to complete or file a death certificate, or to obtain a permit before disposing of a body, by a fine up to $50 and/or 10 days in county jail. Ala. Code 22-9-79 (1984). Illinois makes the same violations felonies. Ill. Ann. Stat. ch. 111 1/2, para. 73-27 (Smith-Hurd 1988). Idaho and Louisiana punish dispositions of dead bodies without a permit by fines up to $1,000 and/or imprisonment up to 1 year. Idaho Code 39-273(b)(3) (1985); La. Rev. Stat. Ann. 40:61(B) (West Supp. 1989).
Most jurisdictions exempt fetuses in early stages of development from death certification and registration requirements. These states define "fetal deaths" or "stillbirths" requiring registration in terms of a minimum gestational period, a minimal weight, or both.\textsuperscript{255} One state leaves the registration of the deaths of younger fetuses to be determined by regulation.\textsuperscript{256} Eight states apparently require fetal death certificates regardless of the age or weight of the fetus.\textsuperscript{257} Of the statutes that require fetal death certificates, at least five exempt deaths resulting from induced abortions.\textsuperscript{258} Finally, 13 states do not require death certificates for fetuses of any


particular age or weight, but do require at least some fetal deaths to be reported.\textsuperscript{259} Three of the statutes requiring some report of fetal deaths make special provision for reporting deaths resulting from induced abortions.\textsuperscript{260}

Some states require disposition permits, regardless of the age or weight of the fetus.\textsuperscript{261} At least six states directly exempt young fetuses from permit requirements.\textsuperscript{262} Eighteen other states apparently reach the same result indirectly by anticipating that permits will issue only on


the filing of a death certificate, but exempting younger fetuses from death certification requirements.\textsuperscript{263} In a few states, whether a permit is required depends on the kind of disposal planned, rather than on any characteristics of the fetus.\textsuperscript{264}

The most common kind of disposition that can be made of fetal remains is "burial, cremation, entombment, and other authorized disposition."\textsuperscript{265} One state apparently allows only burial of fetal remains.\textsuperscript{266} At least 16 statutes anticipate that a health care institution will dispose of fetal remains and require the institution to report these dispositions.\textsuperscript{267} Finally,

\begin{itemize}
  \item Ky. Rev. Stat. 213.160 (Supp. 1988) (requiring institutions to record the name of "the funeral director removing the body for burial.")
\end{itemize}
seven states that provide for fetal death certificates or death reports either explicitly exclude young fetuses from disposition requirements, make no specific provision for fetal remains, or authorize an administrative agency to decide what disposition is appropriate.  

At least seven of the statutes governing the general disposition of dead bodies make some provision for parental consent to the disposition of fetal remains. Five statutes require parental consent for any disposition of a dead fetus, regardless of gestational age. One of the five statutes requires the mother's, but not the father's consent, when the mother is unmarried. The two remaining statutes only require parental consent in certain circumstances. In addition to the laws governing the registration and disposition of dead bodies, the manner in which fetal remains are disposed of are also covered under the statutes of some states. The California penal statute clearly does not affect neural grafts; it merely prohibits

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disposition of fetal remains in sites open to public view. The California Health and Safety Code provision requires fetal remains to be incinerated at the conclusion of research, but does not apply to educational institutions. The Arkansas statute requires physicians performing abortions to ensure that fetal remains are disposed of in a similar manner to other human tissue, i.e., by "incineration, cremation, burial, or other sanitary means prescribed by the state health department." The laws of Florida, Georgia, Minnesota, and North Dakota allow any manner of disposition approved by the state health department. The Florida statute also requires the health department to promulgate rules consistent with the disposition of other human tissues. Whether neural grafts are allowed in these states depends on what regulations are currently in force. Finally, the Massachusetts statute requires fetal remains to be disposed of at the parent's direction, either by burial, entombment, or cremation, or, if the hospital or attending physician is to dispose of the remains, by any method that does not create a public health hazard. In addition, the statute requires the hospital or attending physician to inform parents of their right to direct disposition and of any hospital policy governing disposition of fetal remains.

277 Id., 20-17-801(a). The hospital or institution actually disposing of the fetal remains is required to hold them for 48 hours unless the mother or her spouse consents in writing to a speedier disposition.
278 Fla. Stat. Ann. 390.001(7) (West 1986) (sanitary and appropriate manner in accordance with standard health practices, as provided by health department rules); Ga. Code Ann. 26-1202.1(a)(1) (Harrison 1988) (cremation, interment, or other manner approved by the commissioner of human resources); Minn. Stat. Ann. 145.1621(2), (4) (West 1989) (when a fetus has reached the stage of development where cartilaginous or skeletal structures or fetal parts are apparent, remains must be disposed of by cremation, burial, or manner directed by the commissioner of health); Miss. Code Ann. 41-39-1 (1981) (incineration, cremation, burial, or other sanitary method approved by the state board of health); N.D. Cent. Code 14.02.1-08 (1981) (in humane fashion under health department regulations).
The fetal remains laws in some states have been subject to successfully constitutional challenges, however. The Supreme Court, in City of Akron v. Akron Center for Reproductive Health, Inc., held that an ordinance requiring fetal remains to be disposed of in a humane and sanitary manner was impermissibly vague. In addition, laws that specifically required that a woman decide, in advance of her abortion, whether her aborted fetus be buried, cremated, or disposed of at the hospital’s discretion have been struck down as unconstitutionally interfering with the woman’s right to privacy.

B. The Uniform Anatomical Gift Act

The Uniform Anatomical Gift Act, having been adopted in all 50 states and the District of Columbia, is the only uniform body of law which might regulate fetal tissue implants. In fact, in the 25 states which lack fetal research statutes, the U.A.G.A. is the primary legislation which would affect this technology.

Specifically, the U.A.G.A. affects fetal tissue implants by including "a stillborn infant or fetus" in the definition of "decedent;" and by stating that "parts" include "tissues." According to the uniform version of the act, either parent may consent to donation of fetal tissue, but in reality the consent of both parents is necessary because if either objects, then a

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285. Sheehan, supra note 103, at 900.
287. Id., 1(e).
288. Id., 2(b)(3).
donee who knows of the objection may not accept the gift.\textsuperscript{289} The U.A.G.A. would appear to allow the parents of an aborted or stillborn fetus to designate a donee.\textsuperscript{290} This possibility is in direct opposition to the recommendations contained in the Report of the Human Fetal Tissue Transplantation Research Panel.\textsuperscript{291} The panel expressed concern that such a practice might encourage abortions in order to donate fetal tissue for the treatment of relatives, and, due to the genetic nature of diseases such as diabetes and Parkinson's disease, might actually jeopardize the effectiveness of the transplant by implanting cells which possess the same defect which the procedure is supposed to ameliorate.\textsuperscript{292}

In adopting the UAGA, many states have added sections designed to facilitate and regulate the donation of tissue. The most common nonuniform provisions found in state laws either require hospitals to adopt an organ procurement protocol, which is designed to facilitate the procurement of donor tissue while recognizing the sensitivity of the relatives who must consent to the donation,\textsuperscript{293} or simply require hospital personnel to request from the relative of a suitable decedent that the individual's organs be made available for donation.\textsuperscript{294} In either case,

\textsuperscript{289} Id., 2(c).
\textsuperscript{290} Id., 3(4), 4(c).
\textsuperscript{291} 1 NIH Report, supra note 1, at 8.
\textsuperscript{292} Id.
these laws would require physicians desiring to obtain fetal tissue to go about obtaining parental consent in a professional and sensitive manner. Those laws which require consent be obtained, however, would require doctors to inform all abortion patients of the possibility of donation for transplants, and might conceivably influence a woman’s decision to undergo an abortion. For this reason, the Fetal Tissue Transplantation Research panel recommends that the decision to obtain an abortion precede any request for consent to donate tissue for implantation.295

In addition, the laws of at least eight states would serve to protect recipients of fetal tissue by requiring all donors of tissue to be tested for HIV,296 and an additional two states, while not requiring HIV testing of donors, establish standards which decrease the likelihood that AIDS-infected tissue will be made available for donation.297

Overall, the Uniform Anatomical Gift Act and its various manifestations provide some guidelines in the area of fetal tissue transplants. Because this act was drafted before this technology became known, however, it is obviously not designed to address the specific and unique problems which implants raise. For this reason, there is clearly a need for a new uniform act which is drafted along the guidelines of the NIH panel on fetal tissue transplants.

C. Compensation for Fetal Tissue in a Nonresearch Setting

295. 1 NIH Report, supra note 1, at 3.
There is much concern about the payment to women for fetal tissue for transplant purposes. Nicholas P. Terry points to "the fear that permitting the commercialization of the fetal tissue transplantation system will result in the exploitation of the women who bear tissue for profit and of the critically ill patients who want to acquire it." The NIH panel recommended that sale of fetal tissue not be allowed so as not to influence a woman's decision to abort, or to induce an abortion facility to use a more dangerous abortion procedure so that it may profit from the sale of tissue. The federal prohibition on payment to organ donors may provide a mechanism for prohibiting payment to women for donating tissue from their fetuses. In addition, a variety of state statutes may have this result.

The federal National Organ Transplant Act, passed under Congress' commerce clause authority, bans the sales of certain listed organs (including certain fetal organs and their subparts) and then provides that the Secretary of Health and Human Services may list other organs. Since the brain is not listed as one of the organs, the payment for use of fetal brain parts for transplantation will not be banned until the Secretary so designates.

In addition to the 16 state fetal research statutes which prohibit the sale of fetal tissues for purposes including research, 7 other state laws forbid the sale of fetuses or fetal material. The Florida statute places a flat ban on selling, purchasing or transferring a human embryo for

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298. Terry, supra note 2 at 525.
299. 1 NIH Report, supra note 1, at 9.
valuable consideration, and offering or advertising to do so.\textsuperscript{302} Nevada prohibits any commercial use of an aborted fetus or fetal material resulting from an abortion.\textsuperscript{303} Missouri prohibits knowingly offering or receiving any valuable consideration for the organs or tissues of an abortus, except payments for burial or other final disposition and for pathological exams.\textsuperscript{304} Utah prohibits sales and purchases, or offers to buy or sell, unborn children.\textsuperscript{305} The Georgia statute prohibits buying or selling a human fetus or fetal part.\textsuperscript{306} The prohibition does not apply to donations under the UAGA,\textsuperscript{307} reimbursement of a living donor's actual expenses, and payment of costs associated with collecting, storing, and implanting a donated part.\textsuperscript{308} Similarly, the Texas statute prohibits knowing and intentional transfers of fetal tissue for valuable consideration but excludes from "valuable consideration" fees paid to physicians, hospitals, and clinics for services rendered in the usual course of medical practice, reimbursement of legal or medical fees incurred to benefit the ultimate receiver of the tissue, and the donor's travel and housing expenses and lost wages.\textsuperscript{309} Finally, in an unusual provision, Kentucky prohibits selling or purchasing a child for adoption or any other purpose.\textsuperscript{310} Since the statute specifically excludes from its coverage in vitro fertilization where the genetic donors are a married couple and the fertilized ovum is to be implanted in the wife,\textsuperscript{311} the Kentucky legislators seem to have intended "child" to include the human organism from conception and "any purpose" to include medical and scientific procedures. Thus, this statute could be used to prohibit any agreement to pay the mother for fetal tissue made while the fetus is still alive.

\textsuperscript{305} Utah Code Ann. 76-7-311 (1978).
\textsuperscript{307} Ga. Code Ann. 48-401 et seq. (Harrison 1989) (UAGA). Georgia has no statute prohibiting sales of organs; 'donations' for consideration may be possible under its anatomical gift act.
\textsuperscript{309} Tex. Penal Code 48.02 (Vernon 1989).
\textsuperscript{311} Id.
In addition, at least 18 jurisdictions have laws forbidding payment to organ donors.\textsuperscript{312} Ten of the statutes are nonuniform UAGA provisions.\textsuperscript{313} The Delaware UAGA provision clearly does not prohibit payment to the mother for fetal tissue: it applies only to payments to a donor for disposition of his or her own body.\textsuperscript{314} Whether the nine remaining UAGA provisions prohibit payment to the mother depends on two factors: whether any or all of the payment can be considered as a reasonable costs associated with the use of the tissue; and when the tissue will be removed.

The nonuniform provisions of California, Connecticut, Hawaii, Idaho, Illinois, New York, North Dakota, Virginia, and West Virginia all prohibit the purchase or sale of organs or tissue for valuable consideration, but exclude from the definition of "valuable consideration" the costs of removing, transporting, inspecting, preserving, and reimplanting the organ or tissue.\textsuperscript{315} However, Connecticut, New York, and West Virginia go on to exclude from "valuable consideration" "the expenses of travel, housing, and lost wages" incurred by the "donor".\textsuperscript{316} This suggests that the mother cannot be reimbursed for nonmedical losses and expenses without


specific statutory authority. Moreover, under the UAGA, the term "donor" applies only to "an individual who makes a gift of all or part of his body."\(^{317}\) The mother is not a donor, but someone authorized to consent to the gift of a "decedent's remains,"\(^{318}\) in the case of the fetuses. Thus, the mother may not be paid for agreeing to transfer the fetus' remains, even under the more generous Connecticut, New York, and West Virginia laws.\(^{319}\)

Under the nonuniform provisions of four states, California, Hawaii, Idaho, and North Dakota, payment to the mother may be banned for another reason. These states prohibit sales and purchases of an organ and tissue for valuable consideration, when the organ or tissue is to be removed after the decedent's death.\(^{320}\) Unless the fetal tissue is to be removed while the fetus is still alive (which may be forbidden under the state's fetal research or other statute), payment to the mother is forbidden under these anatomical gift act provisions. The California Anatomical Gift Act is supplemented by a penal provision that prohibits a person from knowingly acquiring, receiving, selling, or promoting the transfer or otherwise transferring any organ for transplantation for valuable consideration.\(^{321}\) It also prohibits the use of an organ known to have been transferred for valuable consideration.\(^{322}\) The law is directed against brokering organs rather than the direct selling from a donor to a recipient. There is an exception allowing purchase by the person who receives the transplant from "the person from whom the organ is removed, ... or those persons' next-of-kin who assisted in obtaining the organ for purposes of transplantation."\(^{323}\)

\(^{317}\) U.A.G.A. 1(c).
\(^{318}\) Compare Ill. Stat. Ann. ch. 110 1/2, para. 308.1a (Smith-Hurd Supp. 1989) (prohibiting payments to donor or person authorized to consent to an anatomical gift for making or consenting to the gift).
\(^{322}\) Id., 367(b).
Of the eight statutes remaining that prohibit the sale of organs but are not part of the state UAGA,\textsuperscript{324} one clearly does not prohibit payments to the mother. The Tennessee statute only prohibits transfers of organs for valuable consideration that "affect commerce"\textsuperscript{325} and is presumably aimed at brokers. The law of the District of Columbia clearly prohibits such payments: it excludes nothing of value from the definition of valuable consideration.\textsuperscript{326} The remaining statutes are similar to the nonuniform anatomical gift act provisions previously discussed: six allow reimbursement of reasonable expenses associated with the removal, preservation, and use of the donated organ;\textsuperscript{327} four make an additional allowance for the donor’s losses and expenses.\textsuperscript{328}

The federal and state laws prohibiting payment to organ donors would ban more than just a cash payment to women. They would also cover the payment of the woman’s abortion expenses in order that the woman donate fetal tissue.\textsuperscript{329} The reach of some state laws may also extend to payment to agencies that retrieve and process the fetal tissue. These agencies would not be able to "sell" tissue to physicians or patients; however, they would be able to recover their costs and overhead for obtaining the tissue.\textsuperscript{330}


\textsuperscript{326} D.C. Code Ann. 6-2601(b) (1989).


\textsuperscript{329} Robertson, supra note 154, at 476.

\textsuperscript{330} See e.g. N.Y. Pub. Health Law 4307 (McKinney 1985); W.Va. Code 16-19-7a (Supp. 1989). Both of these statutes explicity exclude from the definition of "valuable consideration" reimbursement of expenses incurred by nonprofit agencies and corporations in offering services related to the location, maintenance, and distribution of the donated organ.
Most of the statutes prohibiting transfers of organs for value define organ quite broadly and would cover most types of tissues and organs to be transplanted from fetuses. Other statutes are more limited in the body parts they cover and would require regulatory agency action to cover brain tissue. The Florida statute bans the sale of the kidney, liver, heart, lung, pancreas, bone, and skin or any other organ or tissue specified by rules adopted by the Department of Health and Rehabilitative Services. The New York statute begins with a larger list of items and then provides for regulatory expansion. It defines "human organ" as "the human kidney, liver, heart, lung, bone marrow, and any other human organ or tissue as may be designated by the commissioner but shall exclude blood." To the New York list, Wisconsin adds the pancreas, cornea, eye, bone, skin, and any other organ specified by the department except blood, blood products, and semen. Michigan has by far the most comprehensive list: "human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, cartilage, dura mater, ligaments, tendons, fascia, pituitary gland, and middle ear structures and any other human organ specified by rule promulgated by the department."

Finally, ten states prohibit "trafficking" in dead bodies, i.e., transferring dead bodies for valuable consideration. These statutes are arguably drafted broadly enough to prohibit payment to and/or receipt of payment by the mother for the use of fetal remains. Only one statute explicitly covers all bodies and bodily parts. The remaining either cover bodies but do

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not refer to parts or limit their coverage to unclaimed bodies (those that have not been claimed for burial). The majority of states ban both purchases and sales of dead bodies, but three states only prohibit sales and one state more broadly proscribes "delivering or receiving for speculation or pecuniary profit." In addition, five statutes prohibit transporting dead bodies out of state.

D. Regulation of Cell Lines

An attempt is being made to culture cell lines. For example, Hana Biologics, Inc. of California, is growing fetal cell lines in the lab, which could obviate the need to use fresh tissue from abortuses. Once cell lines are established, the state and federal fetal research laws would not apply to their use (even in experimental therapies). However, the use of cell lines could be regulated by the FDA.

345. The Minnesota fetal research statute already excludes the purchase or sale of all culture lines taken from dead fetuses from its prohibition on selling fetuses and nonreusable organs. Minn. Stat. Ann. 145.422(3) (West Supp. 1989).
III. Potential Policy Directions

There are several grounds for federal action in this area. To the extent that federal funds are used to support research involving fetal neural grafts, or to pay for the clinical use of such procedures, federal regulations may establish mandatory policies governing the conduct of such research. Even if federal funds are not used, the federal government has powers under the commerce clause to regulate fetal neural grafts that involve transfers of tissue from state to state or otherwise implicate interstate commerce.

The U.S. Constitution, Article I, Section 8 gives Congress the authority to "regulate Commerce with foreign Nations, and among the several States, and with the Indian tribes." Congress has such a broad power to enact legislation that reasonably regulates interstate commerce that "judicial review of the affirmative authorization for congressional action is largely a formality."346

This power has served as the basis for the establishment of the Food and Drug Administration, the prohibition on payment to organ donors for transplantation involving interstate commerce, and the regulation of medical laboratories engaged in interstate commerce.

Some existing federal policies governing experimentation and organ transplantation could affect tissue transplants. However, the federal regulations on fetal research and the federal law on transplantation were developed before the extensive, recent debate on fetal tissue transplantations. It might be appropriate to amend the existing policies to address more directly the concerns raised by neural grafts. In particular, the federal regulations and law might be modified to provide that a woman not be paid for fetal tissue for transplantation and

not be allowed to designate a donor. The federal regulations might also be amended to assure that the health care professionals undertaking counselling and abortion procedures are not also involved in the harvest and transplantation of fetal tissue.