

RESEARCH INVOLVING HUMAN FETAL TISSUE: LEGAL SURVEY AND ANALYSIS

BY

J. KYLE KINNER, J.D., M.P.A.

A. HISTORICAL OVERVIEW

Since at least the 1930s, American biomedical research has involved ex utero fetal tissue as both a medium, and increasingly, an object for experimentation.¹ The 1954 Nobel Prize for Medicine, for example, was awarded to American immunologists using cell lines obtained from human fetal kidney cells to grow poliovirus in cell cultures other than nerve tissue.² It was not until 1972, in a period that coincided with a larger societal debate over elective human abortion, that the use of ex utero fetal tissue for research (along with research involving fetuses generally) became controversial.³ In 1974, following the imposition a year earlier of a moratorium on federally-funded research on live fetuses, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (CPHSBBR).⁴ The Commission recommended guidelines applicable to research conducted or funded by DHHS

¹ See e.g. Gregory Gelfand & Toby R. Levin, “Fetal Tissue Research: Legal Regulation of Human Fetal Tissue Transplantation,” *Washington & Lee Law Review* 50 (1993): 668; Cory Zion, “Comment, The Legal and Ethical Issues of Fetal Tissue Research and Transplantation,” *Oregon Law Review* 75 (1996): 1282.

² See Gelfand & Levin, “Fetal Tissue Research,” 668; Edgar Driscoll, Jr., “Nobel Recipient John Enders, 88; Virus Work Led to Polio Vaccine,” *Boston Globe*, 10 September 1985: sec. Obituary; and Duke, Statement of the Population Crises Committee in Consultants to the Advisory Committee to the Director. National Institutes of Health, *Report of the Human Fetal Tissue Transplantation Research Panel* D112, D114 (vol II 1988) (hereinafter *HFTTRP Panel II*) (“For many years, the production and testing of vaccines, the study of viral reagents, the propagation of human viruses, and the testing of biological products have been dependent on the unique growth properties of fetal tissue”).

³ Proposed guidelines for fetal tissue research were released by NIH, DHHS (then DHEW) in 1973, 38 Fed. Reg. 31,738 (1973). See Gelfand & Levin, “Fetal Tissue Research,” 668. NIH, DHHS (then DHEW) also imposed a temporary moratorium on federally-funded research on live fetuses, *Id.*

⁴ See *National Research Act*, Public Law 93-348, Section 201(a), 88 Stat. 348 (1974).

(then DHEW) and in 1975, the Department adopted regulations governing fetal research while Congress passed similarly directed legislation.⁵

Controversy erupted again in October 1987 when NIH scientists presented Director James B. Wyngaarden with a request to fund research on Parkinson's disease involving fetal brain tissue transplantation, already approved by an internal NIH review board.⁶ Director Wyngaarden sought an opinion from DHHS Assistant Secretary Robert Windom, who responded by declaring a temporary moratorium on federally-funded transplantation research on fetal tissue from induced abortions.⁷ In March 1988, the Assistant Secretary asked NIH to establish an advisory committee to consider whether such research should be conducted and under what conditions.⁸ The twenty-one member Human Fetal Tissue Transplantation Research Panel (HFTTRP), composed of a cross-section of medical researchers, lawyers, ethicists, clergy, and politicians, deliberated until the Fall of 1988. The panel voted 19-2 to recommend continued funding for fetal tissue transplantation research, including guidelines to assure the ethical integrity of any experimental procedures.⁹ In November 1989, DHHS Secretary Louis Sullivan extended the moratorium indefinitely, adopting the position of minority panel-members who believed that

⁵ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Research on the Fetus: Report and Recommendations (Washington, D.C.: 1975), reprinted in 40 Fed. Reg. 33,526 (1975); 45 C.F.R. § 46.201-.211 (1997); 42 U.S.C. 274e (1997); 42 U.S.C. § 289g(a) (1997).

⁶ See James E. Goddard, "Comment, The NIH Revitalization Act of 1993 Washed Away Many Legal Problems with Fetal Tissue Transplantation Research But a Stain Remains," SMU Law Review 49 (1996): 383-84.

⁷ See Memorandum from Robert E. Windom, M.D., Assistant Secretary for Health, DHHS, to James B. Wyngaarden, M.D., Director of NIH, DHHS (22 March 1988) in A3 HFTTRP Panel II. See also Kenneth J. Ryan, "Symposium on Biomedical Technology and Health Care: Social and Conceptual Transformations: Technical Article: Tissue Transplantation from Aborted Fetuses, Organ Transplantation from Anencephalic Infants and Keeping Brain-Dead Pregnant Women Alive Until Fetal Viability," Southern California Law Review 65 (1991): 687 ("Although such approval [from the Assistant Secretary] was not required, the Assistant Secretary was consulted because of the scientific and ethical implications of the study").

⁸ Id. at 687 ("In the meantime the protocol was shelved and a moratorium placed on any use of NIH funding for such activities").

⁹ See Letter from Arlin M. Adams, Panel Chair, to James B. Wyngaarden, M.D., Director of NIH, DHHS (12 December 1988) in Consultants to the Advisory Committee to the Director. National Institutes of Health, Report of the Human Fetal Tissue Transplantation Research Panel A3 (vol I 1988) (hereinafter HPFTTR Panel I). See also Pedro F. Silva-Ruiz, "SECTION II: The Protection of Persons in Medical Research and Cloning of Human Beings," American Journal of Comparative Law 46 (1998): 278-279; Kimberly Fox Duguay, "Fetal Tissue Transplantation: Ethical and Legal Considerations," Buffalo Women's Journal of Law and Social Policy 1 (1992): 36.

such fetal tissue transplantation research would increase the incidence of elective abortion.¹⁰ Two attempts by Congress to override the Secretary's decision were vetoed by President Bush and were not enacted into law.¹¹

In October 1992, a consortium of disease advocacy organizations filed suit against DHHS Secretary Sullivan, alleging that the Hyde Amendment¹² (banning federal funding for abortions) did not apply to research on and transplantation of fetal tissue, and moreover, that the fetal tissue transplantation research ban was beyond DHHS's statutory authority under the law.¹³ This suit was mooted on January 22, 1993 when the new administration shifted national biomedical policy and directed DHHS Secretary Donna Shalala to remove the ban on federal funding for human fetal tissue transplantation research.¹⁴ On February 5, 1993, Secretary Shalala officially rescinded the moratorium, and in March 1993, NIH published interim guidelines for research involving human fetal tissue transplantation.¹⁵ Governing legislation was quickly proposed in Congress, and President Clinton signed the NIH Revitalization Act of 1993 into law on June 10, 1993.¹⁶

¹⁰ See Letter from Louis Sullivan, Secretary, DHHS, to William Raub, M.D., Acting Director of NIH, DHHS 3 (2 November 1989); Goddard, "NIH Revitalization Act," 384; a useful analysis of this debate is found at John A. Robertson, "International Symposium on Law and Science at the Crossroads: Biomedical Technology, Ethics, Public Policy, and the Law: Abortion to Obtain Fetal Tissue for Transplant," 27 Suffolk University Law Review (1993): 1362-69.

¹¹ See H.R. 2507, 102d Cong., 1st Sess. (1991) (amending Part G of Title IV of the Public Health Service Act); see also H.R. 5495, 102d Cong., 2nd Sess. (1992) (amending Part G of Title IV of the Public Health Service Act and incorporating the establishment of a federally-operated national tissue bank as provided by Exec. Order No. 12,806 (1992)). During this period, in an apparent attempt to find an alternative to fetal tissue derived from elective abortion, the Administration established (without success) a tissue bank to collect fetal tissue for research from ectopic pregnancies and miscarriages. Exec. Order No. 12,806, 57 Fed. Reg. 21,589 (1992). Because spontaneously aborted tissue may contain viral infection or pathological defect, the use of ectopic and miscarried abortuses is disfavored for transplantation and most other research.

¹² Departments of Labor, Health, Education, and Welfare Appropriations Act of 1977, Pub. L. 94-439, 209, 90 Stat. 1418, 1434 codified at U.S. Code, vol. 42, secs. ____ (1997).

¹³ Nikki Constantine Bell, "Regulating Transfer and Use of Fetal Tissue in Transplantation Procedures: The Ethical Dimensions," American Journal of Law & Medicine 20 (1994): 280.

¹⁴ See Memorandum on Fetal Tissue Transplantation Research, 29 Weekly Comp. Pres. Doc. 87 (22 January 1993), reprinted in 58 F.Reg. 7457 (22 January 1993).

¹⁵ DHHS. OPRR Reports, Human Subjects Protections: Fetal Tissue Transplantation—Ban on Research Replaced by New Statutory Requirements, by Gary B. Ellis, Director, OPRR (Bethesda, MD: 1994), 1-2. The NIH guidelines were withdrawn upon passage of Public Law 103-43 ("NIH Revitalization Act of 1993"), codified at NIH Revitalization Act of 1993, U.S. Code, vol. 42, secs. 289g-1 & 289g-2 (1997) as Section 498A of the Public Health Service Act.

¹⁶ Id. The Administration's policies on fetal tissue transplantation did not entirely quell public controversy or Congressional interest. See e.g., U.S. General Accounting Office. Report to the Chairmen and Ranking Minority

It is important to note that, throughout the period of controversy over the use of fetal tissue from induced abortions in transplantation, other areas of fetal tissue research continued to receive governmental funding and attention. One journalist has observed that “during the period of the moratorium, NIH—except for studies involving fetal material obtained from elective abortions [used in transplantation research]—continued to support human fetal tissue research. In 1992, this support totaled some \$12.4 million, more than 90 percent of which went toward extramural projects.”¹⁷

B. FEDERAL STATUTES

(1) *NIH Revitalization Act of 1993*

Codified at 42 U.S.C. § 289g-1 & g-2, the NIH Revitalization Act of 1993 includes most prior statutory and regulatory provisions on research involving fetal tissue transplantation. In substance, any tissue from any type or form of abortion may be used for research on transplantation, but only for “therapeutic purposes.”¹⁸ Note, however, that such research is not unfettered. First, it must be conducted in accordance with applicable State and local law (see discussion, infra).¹⁹ Second, a written statement must be obtained from the mother/donor verifying that (a) she is donating fetal tissue for therapeutic purposes; (b) no restrictions have been placed on the identity of the recipient; and (c) she has not been informed of the identity of the recipient.²⁰ Third, the attending physician must sign a written statement affirming five additional requirements about the abortion, effectively placing a “fire wall” between the decision

Members, Committee on Labor and Human Resources, U.S. Senate, and Committee on Commerce, House of Representatives: NIH-Funded Research: Therapeutic Human Fetal Tissue Transplantation Projects Meet Federal Requirements (Washington, D.C.: GPO, March 1997), 1-8.

¹⁷ Myrna E. Watanabe, “Research: With Five-Year Ban on Fetal Tissue Studies Lifted, Scientists are Striving to Make Up for Lost Time,” *The Scientist* 7 (4 October 1993): 1.

¹⁸ 42 U.S.C. § 289g-1(a)(1) (1997). See Goddard, “NIH Revitalization Act,” 390, 394 (“a huge problem... Congress neglected to define the term ‘therapeutic purposes’ ...”).

¹⁹ 42 U.S.C. § 289g-1(e) (1997).

²⁰ 42 U.S.C. § 289g-1(b)(1) (1997).

to abort and the decision to donate tissue for fetal research.²¹ Finally, the person principally responsible for the experiment must affirm his or her own knowledge of the source of the tissue, that others involved in the research are also aware of this fact, and that he or she had no part in the decision or timing of the abortion.²² The drafters included no specific penalties in 42 U.S.C. § 289g-1.

By contrast, 42 U.S.C. § 289g-2 provides significant criminal penalties for violation of four prohibited acts (relating to interstate commerce, for purposes of jurisdiction): (1) purchase or sale of fetal tissue “for valuable consideration” beyond “reasonable payments [for] transportation, implantation, processing, preservation, quality control, or storage ...”; (2) soliciting or acquiring fetal tissue through the promise that a mother/donor can designate a donee; (3) soliciting or acquiring fetal tissue through the promise that that the transplant will be made into a relative of the mother/donor; or (4) soliciting or acquiring fetal tissue after providing “valuable consideration” for the costs associated with the abortion itself.²³

(2) *Human Research Extension Act of 1985*

Codified at 42 U.S.C. § 289g, this statute provides guidance on fetal research generally, directing that no Federal research or support may be conducted on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been determined, unless (a) the research or experimentation may enhance the health, well-being, or probability of survival of the fetus itself; or (b) will pose no added risk of suffering, injury, or death to the fetus where the research or experimentation is for “the development of important biomedical

²¹ 42 U.S.C. § 289g-1(b)(2) (1997).

²² 42 U.S.C. § 289g-1(c) (1997).

²³ 42 U.S.C. § 289g-2(a)-(c) (1997). But see Goddard, “NIH Revitalization Act,” 393-94 (criticizing vague terms; questioning constitutionality of ban on recipient designation).

knowledge which cannot be obtained by other means.”²⁴ In either instance, the risk standard must be the same for fetuses carried to term as for those intended to be aborted.²⁵

(3) *National Organ Transplant Act*

The National Organ Transplant Act (NOTA), 42 U.S.C. §§ 273-274e, prohibits the sale of any human organ for “valuable consideration” if the sale involves interstate commerce.²⁶ In 1988, the Congress amended NOTA to include fetal organs within the definition of “human organ,” effectively prohibiting the sale of fetal tissue within interstate commerce.²⁷

C. FEDERAL REGULATIONS²⁸

(1) *45 C.F.R. §§ 46.201-211, Subpart B*

Located within the general protections for biomedical research subjects provided by federal regulation, 45 C.F.R. § 46.201-211, Subpart B speaks directly to research involving the human fetus.²⁹ First promulgated in 1975, this regulatory section covers research on “(1) the fetus, (2) pregnant women, and (3) human in vitro fertilization” and applies to all DHHS “grants and contracts supporting research, development, and related activities directed towards those

²⁴ Human Research Extension Act of 1985, U.S. Code, vol. 42, sec. 289g (1997).

²⁵ 42 U.S.C. § 289g(b) (1997).

²⁶ National Organ Transplant Act, U.S. Code, vol. 42, sec. 274e(a) (1997). “Valuable consideration” is defined at 42 U.S.C. § 274e(c)(2) (1997) by its negation: “‘valuable consideration’ does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.” A similar definition (excluding donor costs) is provided at 42 U.S.C. § 289g-2(d)(3) (1997).

²⁷ Organ Transplants Amendment Act of 1988, U.S. Code, vol 42, sec. 274(e)(c)(1) (1997); Senator Gordon Humphrey’s amendment was specifically intended to prevent the “sale or exchange for any valuable consideration” of fetal organs and tissue. 134 Cong. Rec. S10, 131 (daily ed. July 27, 1988).

²⁸ Note: federal regulations are applicable only to federal agencies and the expenditure of federal research funds. Cf. 45 C.F.R. § 46.123(b) (regulation permitting HHS Secretary to terminate all federal funding to any institution if the Secretary determines that researchers have “materially failed [their] responsibility for the protection of the rights and welfare of human subjects”).

²⁹ Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization, Code of Federal Regulations, Title 45, Vol. 1, Part 46.201-211 (1997).

subjects.³⁰ The regulation states explicitly that “the purpose of this subpart [is] to ... assure that [applicable research] conform[s] to appropriate ethical standards and relate[s] to important societal needs.”³¹ Like its statutory counterpart at 42 U.S.C. §§ 289g, 289g-1 & g-2, 45 C.F.R. § 46.201-211 attempts to address the particular concerns inherent in fetal research and to reduce attendant risks. These protections include (1) provision for stringent IRB review;³² (2) pre-studies on animals and non-pregnant individuals;³³ (3) an assessment of minimal risk to the fetus (except where the research purpose is intended “to meet the health needs” of the mother or the fetus);³⁴ (4) separation of researchers from the decision to terminate or any assessment of fetus viability;³⁵ (5) prohibition on inducements to terminate for purposes of the research.³⁶ Specific restrictions are imposed on the inclusion of pregnant women or fetuses in utero in research activities.³⁷

Of special relevance to fetal tissue research, 45 C.F.R. §§ 46.209 and 210 address requirements for federal funding of activities directed towards fetuses ex utero, including nonviable fetuses.³⁸ Section 46.209 focuses on viable and nonviable (but still living) fetuses.³⁹ Until a determination has been made of fetal viability, no research may occur unless (1) there is no additional risk to the fetus and the purpose is the development of important biomedical knowledge that cannot be obtained elsewhere; or (2) the purpose is to enhance the viability of the particular fetus to the point of survival.⁴⁰ Once viability is determined, the regulation specifies

³⁰ 45 C.F.R. § 46.201(a) (1997).

³¹ 45 C.F.R. § 46.202 (a) (1997).

³² 45 C.F.R. § 46.205(a) (1997).

³³ 45 C.F.R. § 46.206(a)(1) (1997).

³⁴ 45 C.F.R. § 46.207(a) (1997).

³⁵ 45 C.F.R. § 46.206(a)(3) (1997).

³⁶ 45 C.F.R. § 46.206(a)(4) (1997).

³⁷ 45 C.F.R. § 46.208 (1997).

³⁸ 45 C.F.R. § 46.209-210 (1997).

³⁹ 45 C.F.R. § 46.209 (1997). According to 45 C.F.R. § 46.203(d) (1997), “viable as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration ... If a fetus is viable after delivery, it is a premature infant.” At 45 C.F.R. § 46.203(e) (1997) “nonviable fetus means a fetus ex utero which, although living, is not viable,” and at 45 C.F.R. § 46.203(f) (1997) “dead fetus means a fetus ex utero which exhibits neither heart beat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).”

⁴⁰ 45 C.F.R. § 46.209(a)(1)-(2) (1997); this language is essentially equivalent to 42 U.S.C. § 289g(a)(1)-(2) (1997).

that research on a nonviable fetus may only occur where (1) vital functions of the fetus are not artificially maintained; (2) experimental activities that would themselves terminate heartbeat or respiration are not employed; and (3) the underlying purpose of the research is the development of important biomedical knowledge that cannot be obtained elsewhere.⁴¹ Where a fetus ex utero is determined to be viable, its status is protected under 45 C.F.R. § 46.101 et seq. as a human subject.⁴² Note finally that research on fetuses for which viability has not been determined, or fetuses that have been deemed nonviable, may occur only where the mother and father are legally competent and have given their informed consent, or where only the mother consents if the father's identity or whereabouts cannot be ascertained; he is not reasonably available; or the pregnancy resulted from rape.⁴³

45 C.F.R. § 46.210 provides fewer limitations and deals exclusively with research involving the dead fetus, fetal material derived from dead fetuses, or the placenta.⁴⁴ The regulation states that “activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.”⁴⁵ As commentary infra suggests, at least some analysts, perhaps including the DHHS General Counsel, conclude that 45 C.F.R. § 46.210 is the *only* regulatory component of Subpart B that is applicable in the context of fetal tissue transplant research or research in which fetal cellular material or tissue is separated from the fetus as a whole for experimentation (commentators like Judith Areen (discussed infra) arguing from textual analysis of Subpart B, others concluding on a practical basis that it is not possible to extract tissue for research purposes from living, non-viable or viability undetermined fetuses in a way that involves “minimal risk”). Interested members of the NIH community, in commenting on this paper in its draft form, agree that living, non-viable or viability undetermined fetuses should not

⁴¹ 45 C.F.R. § 46.209(b)(1)-(3) (1997).

⁴² 45 C.F.R. § 46.209(c) (1997).

⁴³ 45 C.F.R. § 46.209(d) (1997).

⁴⁴ 45 C.F.R. § 46.210 (1997). See note 38 supra for definitions.

⁴⁵ Id.

be considered a source of fetal material for research of the type contemplated here (for the practical reasons described supra), but argue that other protective elements within Subpart B are nevertheless applicable in the context of fetal tissue research in addition to Section 46.210.⁴⁶ Uncertainty over whether and to what degree individual sections of Subpart B are determinative for fetal-derived stem cell research may cloud efforts to pursue study in this area.

(2) *45 C.F.R. §§ 201-210, Subpart B -- Proposed Rule*

On May 20, 1998, the Department of Health and Human Services released for public comment its proposal to revise and rewrite 45 C.F.R. §§ 46.201-210, Subpart B, “Additional DHHS Protections for Pregnant Women, Human Fetuses, and Newborns Involved as Subjects in Research, and Pertaining to Human In Vitro Fertilization.”⁴⁷ The changes contained in the proposed rule are the product of an intensive 14-month review of existing Subpart B regulations by the NIH Office for Protection from Research Risks (OPRR) Public Health Service Human Subject Regulation Drafting Committee.⁴⁸ The newly revised regulations have not been finalized by the Department and do not presently supercede the original 1975 Subpart B (discussed supra). While the regulations have been substantially reorganized under the proposed rule, in general there are only a few changes that are material to fetal tissue research as it is discussed here.

Four revisions are worth noting. First, new 45 C.F.R. § 46.201(b) applies the categories of noncontroversial research deemed exempt from regulation in Subpart A at 45 C.F.R. §

⁴⁶ They point to a series of reports prepared by the NIH Office of Science Policy in 1987-92 that purport to show that NIH has applied 45 C.F.R. § 46, Subpart B restrictions broadly against a range of categories of fetal research. This position may be supported in a 1988 memorandum from Director Wyngaarden to Assistant Secretary for Health Robert E. Windom (“as you know, the NIH conducts all human fetal tissue research in accordance with Federal Guidelines (45 C.F.R. 46)”) and the accompanying 1987 summary of fetal tissue research at NIH (“NIH-supported human fetal tissue research is conducted in compliance with all Federal ... regulations regarding the use of human fetal tissue. These regulations include restrictions on tissue procurement [Subpart B] that are intended to prevent possible ethical abuses.” The paragraph further cites as applicable 45 C.F.R. § 46.206(a)(3) and 46.206(b). See Memorandum from NIH Director James B. Wyngaarden, M.D. (signed by William F. Raub, Ph.D.) to DHHS Assistant Secretary for Health Robert E. Windom, M.D. (2 February 1988): 2; National Institutes of Health, Summary Highlights of FY 1987 Human Fetal Tissue Research Supported by the NIH (1987): 1.

⁴⁷ See Fed. Reg. 27794-27804 (20 May 1998).

⁴⁸ Id. at 27794.

46.101(b)(1)-(6) to Subpart B.⁴⁹ Second, the regulations governing fetal research have been rewritten, but not substantively changed, to reflect (i) “fetuses may be involved in research where the risk is not greater than minimal”⁵⁰; or (ii) “any risk to the fetus which is greater than minimal is caused solely by activities designed to meet the health needs of the mother or her fetus”⁵¹; (iii) “any risk is the least possible for achieving the objectives of the research”⁵²; (iv) IRBs are no longer obligated to determine the purpose of the research (e.g. whether it involves “the development of important biomedical knowledge which cannot be obtained by other means”)⁵³; (v) “consent of the father is not required”; rather, “consent of the mother *or* her legally authorized representative is required” [after she is] ... “informed of the reasonably foreseeable impact of the research on the fetus.”⁵⁴ Third, parental consent requirements for ex utero

⁴⁹ Id. at 27803, proposed rule 45 C.F.R. § 46.201(b). “(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. (4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.” 45 C.F.R § 46.101(b)(1)-(6).

⁵⁰ See Fed. Reg. 27803-04, proposed rule 45 C.F.R. § 46.204 and 204(b).

⁵¹ Id.

⁵² Id. at 27804, proposed rule 45 C.F.R. § 46.204(c).

⁵³ Language in 45 C.F.R. § 46.209 referencing this standard has been omitted in the proposed rule 45 C.F.R. § 46.204-206.

⁵⁴ See Fed. Reg. 27804, proposed rule 45 C.F.R. § 46.204(e) and Table 1, “Current and Proposed 45 C.F.R. 46, Subpart B,” at 27798, explanatory text.

nonviable and viability-undetermined fetuses were amended somewhat.⁵⁵ Finally, 45 C.F.R. § 46.206 relating to dead fetal and placental material, like its predecessor § 46.210, retains the supremacy of state regulation codified in the earlier 1975 rule, but appends a new and unrelated paragraph (b) directing that any living individual who becomes personally identified as a result of research on dead fetal or placental material must be treated as a research subject and accorded the protections of 45 C.F.R. §§ 46.101 et seq.⁵⁶

D. UNIFORM ACTS

*Uniform Anatomical Gift Act (UAGA)*⁵⁷

Originally promulgated to encourage organ availability for transplantation, the Uniform Anatomical Gift Act (UAGA) has been widely enacted into law by the States.⁵⁸ First proposed in 1968 in a version enacted by all fifty states and the District of Columbia, a 1987 revision has been enacted by twenty-two states.⁵⁹ The uniform Act is relevant not only because Federal fetal tissue statutes and regulations explicitly condition funding and authority on compliance with State and local laws, but also because private researchers are bound by State statute even absent Federal authority. In its 1987 definition, UAGA defines a “decedent” as a “deceased individual [that]

⁵⁵ See Fed. Reg. 27804, proposed rule 45 C.F.R. § 46.205(a)(2), 205(b)(4) and Table 1, “Current and Proposed 45 C.F.R. 46, Subpart B,” at 27798, explanatory text (“Research involving newborns of uncertain viability”: “Consent of the mother *or* the father is required, *or* that of a legally authorized representative of the mother *or* father if both parents are unavailable, temporarily incapacitated, or incompetent”; “Research involving nonviable newborns”: “Consent of the mother and father are required, *unless* one is unavailable, incompetent, or temporarily incapacitated. Consent of a legally authorized representative is prohibited”).

⁵⁶ See Fed. Reg. 27804, proposed rule 45 C.F.R. § 206.

⁵⁷ Uniform Anatomical Gift Act secs. 1-17, 8A U.L.A. 29 (1994).

⁵⁸ See National Conference of Commissioners on Uniform State Laws, “A Few Facts About THE REVISED UNIFORM ANATOMICAL GIFT ACT (1987),” Fact Sheet 1 (1998); Zion, “Legal and Ethical Issues,” 1292.

⁵⁹ According to NCCUSL Fact Sheet, 1, the following states have enacted the 1987 revision: Arizona, Arkansas, California, Connecticut, Hawaii, Idaho, Indiana, Iowa, Minnesota, Montana, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Virginia, Washington, Wisconsin. The two important new sections in the 1987 revision are Section 10 (criminal prohibition on the purchase or sale of body parts, discussed infra) and Section 4 (presumption of willingness to donate tissue or organs in the absence of known objection after reasonable efforts to discern patient/next-of-kin intent, not applicable in the context of fetal tissue derived from elective abortion). Gelfand & Levin, “Fetal Tissue Research,” 671-75.

includes a stillborn infant or fetus.”⁶⁰ The law permits the use of human tissue for the purposes of education, research, or the advancement of science.⁶¹ It requires that an attending physician determine the time of death, and like 42 U.S.C. § 289g-1(b), the Act provides that informed consent must be obtained prior to the donation of any tissue.⁶² Like 45 C.F.R. § 46.209(d), the parents of the fetus have the ultimate authority to decide whether to make a donation.⁶³

Several sections of UAGA may be materially different from existing Federal law and regulation. For example, an entire body or parts of a body may be donated as an “anatomical gift” to a recipient, including individual donees.⁶⁴ This section is consistent with 42 U.S.C. §§ 289g-1(b)(1)(B)-(C) and 289g-2(b)(1) only where designation by the mother/donor of a donee/recipient for aborted fetal tissue means a designated researcher or research facility (since designation or even knowledge of an individual recipient is prohibited), or where fetal tissue is donated for research not involving transplantation.⁶⁵ In addition, the Act provides that “neither the physician or surgeon who attends the donor at death nor the physician or surgeon who determines the time of death may participate in the procedures for ... transplanting a part.”⁶⁶ This section, although waivable, appears slightly more stringent than statutory and regulatory restrictions at 42 U.S.C. § 289g-1(c)(4) and 45 C.F.R. § 46.206(3) on researcher involvement in the decision or act of abortion, prohibiting researchers’ physical presence or assistance at the

⁶⁰ Unif. Anatomical Gift Act sec. 1(3). But note Zion, “Legal and Ethical Issues,” 1293 (“UAGA ... does not differentiate between a fetus donated from a miscarriage or one given through an elective abortion. Presumably, either type of donation is included, but a certain determination is difficult”).

⁶¹ Unif. Anatomical Gift Act sec. 6(a)(1)-(2).

⁶² Unif. Anatomical Gift Act secs. 8(b); 5.

⁶³ Unif. Anatomical Gift Act sec. 3 (preceded in order of proxy donation by spouse or adult child of the decedent); See Gelfand & Levin, “Fetal Tissue Research,” 679 (“UAGA makes the mother’s consent determinative unless the father objects, and ... does not provide for notice to the father. The federal regulations [at 45 C.F.R. § 46.209(d)] require the father’s consent, unless he is ‘unavailable’ to consent”). Note that members of the NIH Office of Science Policy have argued in comments to this paper that no use of fetal tissue for research purposes from living, non-viable or viability undetermined fetuses is possible under the regulations (no tissue extraction could be deemed “minimal risk”). As a result, parental consent at 45 C.F.R. § 46.209(d) is not operative.

⁶⁴ Unif. Anatomical Gift Act secs. 1(a); 6.

⁶⁵ See Zion, “Legal and Ethical Issues,” 1293 (“The act may need an amendment that prohibits specification of a donee ...”); accord Gelfand & Levin, “Fetal Tissue Research,” 673.

⁶⁶ Unif. Anatomical Gift Act sec. 8(b).

clinical procedure from which fetal tissue for research is derived.⁶⁷ Finally, commentators have noted that, unlike 45 C.F.R. § 46.209(b) which addresses living but nonviable fetuses, UAGA apparently does not. “UAGA does not apply to tissue donations from live persons, such as blood donations, skin donations, bone marrow, or kidney donations, so there may be no applicable law for fetal donation in such cases.”⁶⁸ The authors suggest that “UAGA is probably best applied by analogy until an amendment can resolve this point.”⁶⁹

In other areas, UAGA closely tracks federal statutory provisions and, as a result, may share similar difficulties. Sections 10(a)-(b) of the uniform Act, included in the 1987 revisions, prohibit the actual sale or purchase of any human body parts for any consideration beyond that amount necessary to pay for expenses incurred in removal, processing, and transportation of the tissue.⁷⁰ This is essentially the same proscription included at 42 U.S.C. § 289g-2(a) barring the acquisition or transfer of fetal tissue for “valuable consideration,” with the same exceptions.⁷¹ One commentator has argued that the Federal provision (and by extension UAGA) is unenforceably vague in its definition of reasonable processing fees, “leav[ing] ... room for unscrupulous tissue processors to abuse the law”⁷² Drafters on the Federal level and in the states that have enacted UAGA’s 1987 no-sale provision have attempted to address this concern

⁶⁷ See e.g. 45 C.F.R. § 46.206(3) (“Individuals engaged in the activity [of research] will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy”); see also Zion, “Legal and Ethical Issues,” 1294 (“These provisions create a ‘Chinese Wall’ between the individuals effecting the abortion and those conducting fetal tissue research and transplantation ... While this language standing alone would likely preclude most undue influence, the UAGA also provides for the waiver of the ‘Chinese Wall’ [R]evision may be necessary”).

⁶⁸ See Gelfand & Levin, “Fetal Tissue Research,” 671. At least one commentator has suggested that UAGA may not govern *any* fetal tissue donation, Jonathan Hersey, “Comment, Enigma of the Unborn Mother: Legal and Ethical Considerations of Aborted Fetal Ovarian Tissue and Ova Transplantations,” *UCLA Law Review* 43 (1995): 174 (“[I]n the vast majority of abortion procedures, the woman is alive. Therefore, if one believes that a fetus maintains few or no rights independent of the woman, the UAGA statutes are inapplicable to fetal tissue donations”).

⁶⁹ *Id.*

⁷⁰ Unif. Anatomical Gift Act secs. 10(a)-(b).

⁷¹ 42 U.S.C. § 289g-2(a) (1997); NOTA prohibits sale of organs for “transplantation,” while UAGA’s somewhat broader proscription includes “transplantation *or therapy*, if the removal of the part is intended to occur after the death of the decedent” (italics added).

⁷² See Goddard, “NIH Revitalization Act,” 394.

by making violation of the section a felony with substantial penalties.⁷³ Some states have added a further clarification in their enactment to indicate that the donation of human tissue for transplantation is to be understood as a service and not a sale.⁷⁴

E. CASE LAW

Any consideration of court-derived law in the area of fetal tissue research and transplantation will conclude that litigation directly related to this subject is relatively uncommon. A wide range of cases deserve mention however, including those affecting privacy and reproductive freedom generally;⁷⁵ donative autonomy;⁷⁶ informed consent;⁷⁷ self-determination and surrogate decision-making;⁷⁸ determination of brain death and/or viability;⁷⁹ allocation of

⁷³ 42 U.S.C. § 289g-2(c) (1997); discussion of state laws, *infra*. *But see* Hersey, “Enigma,” 113 (“Only the 1987 version of the UAGA explicitly prohibits sales of procured organs. Thus, unless the states still enforcing the 1968 version have supplementary statutes banning the purchase and/or sale of fetal tissue and organs, the specter of a cottage industry of fetal reproductive organs looms ...”).

⁷⁴ Defining the transaction as a service rather than a sale may assist regulators and the courts in better distinguishing between reasonable overhead (permitted under 42 U.S.C. § 289g-2(d)(3) and Unif. Anatomical Gift Act 10) and profit (not permitted). It would certainly still be the case under UAGA that the mother/donor could not be compensated beyond reasonable expenses for donation of fetal tissue, although such payments may be permissible under Federal law for research separated from interstate commerce (42 U.S.C. §§ 289g-2(a); 274(e)(a)), *see* discussion, *infra*.

⁷⁵ *See e.g.* Griswold v. Connecticut, 381 U.S. 479 (1965); Roe v. Wade, 410 U.S. 113 (1973); Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

⁷⁶ *See e.g.* Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914); McFall v. Shrimp, 10 Pa. D. & C.3d 90-92 (1978); Matter of Storar and Matter of Eichner, 420 N.E.2d 64 (N.Y. 1981).

⁷⁷ *See e.g.* Salgo v. Leland Stanford Jr. University Board of Trustees, 154 Cal. App. 2d 560, 317 P.2d 170 (1957); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972).

⁷⁸ *See e.g.* Matter of Conroy, 98 N.J. 321, 486 A.2d 1209 (1985); In re Quinlan, 70 N.J. 10, 355 A.2d 647 (1976), *cert. denied*, 429 U.S. 922 (1976); Brophy v. New England Sinai Hospital, Inc., 497 N.E.2d 626 (Mass. 1986); Matter of Jobs, 108 N.J. 294, 429 A.2d 434 (1987); Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990); In re A.C., 573 A.2d 1235 (D.C. App. 1990); Matter of Baby K, 16 F.3d 590 (4th Cir. 1994), *cert. denied*, 115 S.Ct. 91 (1994); Carey v. Population Services International, 431 U.S. 678 (1977); Brotherton v. Cleveland, 923 F.2d 477 (6th Cir. 1991); State v. Powell, 497 So.2d 1188 (Fla. 1986), *cert. denied*, 481 U.S. 1059 (1987).

⁷⁹ *See e.g.* Youman v. McConnell & McConnell, Inc., 7 La. App. 315 (1927); Porter v. Lassiter, 91 Ga. App. 712, 716, 87 S.E.2d 100, 103 (1955); Hogan v. McDaniel, 204 Tenn. 235, 319 S.W.2d 221 (1958); West v. McCoy, 233 S.C. 369, 105 S.E.2d 88 (1958); Endresz v. Friedberg, 24 N.Y.2d 478, 248 N.E.2d 901, 301 N.Y.S.2d 65 (1969); Presley v. Newport Hosp., 117 R.I. 177, 365 A.2d 748 (1976) (Kelleher, J., dissenting); Wascom v. American Indem. Corp., 348 So. 2d 128 (La. App. 1977); Wallace v. Wallace, 120 N.H. 675, 421 A.2d 134 (1980); Danos v. St. Pierre, 402 So. 2d 633 (La. 1981); Witty v. American Gen. Capital Distributions, Inc., 727 S.W.2d 503 (Tex. 1987); Webster v. Reproductive Health Services, 109 S.Ct. 3040 (1989); In re T.A.C.P., 609 So.2d 588 (Fla. 1992); Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833 (1992).

parental authority among competing parties;⁸⁰ fetal tort rights;⁸¹ biological property interests;⁸² and the ability of Congress to regulate fetal tissue use or transfer in interstate commerce among others.⁸³

Only a few cases touch directly on the subject of fetal tissue research itself.⁸⁴ While numerous states (see discussion, *infra*) have enacted laws affecting or regulating fetal experimentation, an important statute to face scrutiny on that issue was enacted by Louisiana in 1978. La.Rev.Stat. Ann. § 40:1299.31 *et seq.* forbade virtually all research or study involving the

⁸⁰ See e.g. In the Matter of Baby M, 109 N.J. 396, 537 A.2d 1227 (1988); Johnson v. Calvert, 5 Cal. 4th 84, 851 P.2d 776, 19 Cal. Rptr. 2d 494 (1993); Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992), *cert. denied*, 113 S.Ct. 1259 (1993); Hecht v. Superior Court (Kane), 16 Cal. App. 4th 836, 20 Cal. Rptr. 2d 275 (1993).

⁸¹ See e.g. Dietrich v. Northampton, 138 Mass. 14 (1884); Allaire v. St. Luke's Hosp., 184 Ill. 359, 56 N.E. 638 (1900) (Boggs, J., dissenting); Amann v. Faidy, 415 Ill. 422, 114 N.E.2d 412 (1953) (overruling Allaire); Bonbrest v. Kotz, 65 F. Supp. 138 (D.D.C. 1946); Verkennes v. Corniea, 229 Minn. 365, 38 N.W.2d 838 (1949); Wallace v. Wallace, 120 N.H. 675, 421 A.2d 134 (1980); Presley v. Newport Hosp., 117 R.I. 177, 365 A.2d 748 (1976).

⁸² See e.g. York v. Jones, 717 F.Supp. 421 (E.D. Va. 1989); Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992), *cert. denied*, 113 S.Ct. 1259 (1993); Hecht v. Superior Court (Kane), 16 Cal. App. 4th 836, 20 Cal. Rptr. 2d 275 (1993); Moore v. Regents of the University of California, 51 Cal.3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991); Brotherton v. Cleveland, 923 F.2d 477 (6th Cir. 1991); Georgia Lions Eye Bank v. Lavant, 255 Ga. 60, 335 S.E.2d 127 (1985); State v. Powell, 497 So.2d 1188 (Fla. 1986), *cert. denied*, 481 U.S. 1059 (1987); Tillman v. Detroit Receiving Hospital, 138 Mich.App. 683, 360 N.W.2d 275 (1984).

⁸³ See 42 U.S.C. §§ 289g-2(a); 273-274; S.H.D., "Note, Regulating the Sale of Human Organs," Virginia Law Review 71 (1985): 1015, 1025 (suggesting that "the courts ... will probably continue their broad construction of Congress' Commerce Clause power and will find that intrastate organ sales do 'affect interstate commerce'") *citing generally*, Heart of Atlanta Motel v. United States, 379 U.S. 241 (1964); Katzenbach v. McClung, 379 U.S. 294 (1964); Wickard v. Filburn, 317 U.S. 111 (1942); *but see* U.S. v. Lopez, 514 U.S. 549 (199_) (restricting Congress' ability to regulate pursuant to the Commerce Clause);

⁸⁴ See e.g., Doe v. Rampton, 366 F.Supp. 189, 194 (D.Utah 1973) (suggesting in dicta that statute provision prohibiting research on live fetus may not be otherwise unconstitutional), vacated and remanded, 410 U.S. 950 (1973) (directing further consideration in light of Roe); Wolfe v. Schroering, 388 F.Supp. 631, 638 (W.D. Ky. 1974), *affd. in part, rev'd in part on other grounds*, 541 F.2d 523 (6th Cir. 1976) (upholding prohibition on experimentation on a viable fetus due to state's interest in fetus after viability); Planned Parenthood Association v. Fitzpatrick, 401 F.Supp. 554 (E.D.Penn. 1975), *aff'd, without opin. sub. nom.*, Franklin v. Fitzpatrick, 428 U.S. 901 (1976) (affirming legitimate state interest in disposal of fetal remains); Wynn v. Scott, 449 F.Supp. 1302, 1322 (N.D. Ill. 1978) (medical researchers have no fundamental rights under the Constitution to perform fetal experiments), *aff'd on other grounds sub nom.*, Wynn v. Carey, 599 F.2d 193 (7th Cir. 1979) (upholding state's rational interest in regulating medicine as to viable fetus); Leigh v. Olson, 497 F.Supp. 1340 (D.N.D. 1980) (striking fetal disposal statute as vague where it left "humane disposal" undefined and required mother to determine method of disposal); Akron Center for Reproductive Health, Inc., 462 U.S. 416 (1983) (struck down local ordinance that, *inter alia*, mandated humane and sanitary disposal of fetal remains, finding the provision impermissibly vague because it was unclear whether it mandated a decent burial of the embryo at the earliest stages of formation); Planned Parenthood Association v. City of Cincinnati, 822 F.2d 1390, 1391 (6th Cir. 1987) (struck down on other grounds, the court noted in dicta that the wording used by the municipal code regulating disposal of aborted fetal tissue might be precise enough to survive scrutiny); Planned Parenthood of Minnesota v. Minnesota, 910 F.2d 479 (8th Cir. 1990) (upholding Minnesota's fetal disposal statute against challenge of vagueness and infringement of privacy).

fetus or fetal tissue (“a live child or unborn child”) not “therapeutic” to that child.⁸⁵ The statute protected the fetus in utero, but did not address ex utero fetal tissue except by implication. In 1981, the Louisiana legislature expanded the Act’s scope to include aborted fetal tissue in its prohibition.⁸⁶ In its initial review, the court considered only the pre-1981 act (without the fetal tissue amendment), holding that plaintiffs’ failure to demonstrate the statute’s negative impact on the right of privacy left the court to conclude that “no obstacle has been placed in the path of the woman seeking abortion.”⁸⁷ Under the resulting rational basis analysis, the court found that the statute was rational because it protected the state’s citizens from the “dangers of abuse inherent in any rapidly developing field.”⁸⁸ The statute was challenged again after the 1981 amendment, and included a showing by plaintiffs that a prohibition on research did burden the right of privacy.⁸⁹ Reversing its earlier decision, the court found that the revised statute infringed on the fundamental right of privacy, and applied strict scrutiny analysis. The court concluded that a research ban did not further the state’s compelling interest in protecting the health of the woman, and that its interest in the potential life of the unborn did not continue past the death of the

⁸⁵ La.Rev.Stat. Ann. § 40:1299.35.13 (19__).

⁸⁶ La.Rev.Stat. Ann. § 40:1299.35.13 (19__). See Marilyn Clapp, “Note, State Prohibition of Fetal Experimentation and the Fundamental Right of Privacy,” Columbia Law Review 88 (1988): 1076-77 (“The Louisiana statute effectively prohibits any research, experimentation, or even observational study on any embryo, fetus, or aborted fetal tissue. The ban encompasses a range of activities, including studies of the safety of ultrasound and pathological study of fetal tissues removed from a woman for the purpose of monitoring her health. Research on in vitro fertilization is likewise barred. Since the aborted pre-viable fetus is not living or cannot survive for long, no procedure performed upon it could be considered ‘therapeutic,’ and therefore use of this tissue is likewise prohibited. If performed on tissues from a miscarriage, such experimentation would be acceptable under the statutory scheme”) (footnotes omitted).

⁸⁷ Margaret S. v. Edwards, 488 F.Supp. 181, 220 n.124 (E.D. La. 1980) [hereinafter Margaret S. I]. This suit was a class action brought on behalf of pregnant women who sought abortions, three physicians who performed abortions, and five clinics that provided abortion facilities.

⁸⁸ Id. at 221.

⁸⁹ Margaret S. v. Treen, 597 F.Supp. 636 (E.D. La. 1984), aff’d sub nom. Margaret S. v. Edwards, 794 F.2d 994 (5th Cir. 1986) [hereinafter Margaret S. II]. See Clapp, “State Prohibition,” 1078-79 (the court “specifically not[ed] that reproductive choice was ‘not limited to abortion decisions . . . but extends to both childbirth and contraception.’ Prohibiting experimentation on fetal tissues could deny a woman knowledge that would influence her own future pregnancies, as well as prohibit procedures of immediate medical benefit such as pathological examination of tissues. The court also found that the prohibition curtailed the development and use of prediagnostic techniques, including amniocentesis. This result constituted a ‘denial of health care’ and a ‘significant burden’ on choice made during the first trimester”) (footnotes omitted).

fetus.⁹⁰ Finally, the district court addressed the statute's vagueness, noting that it was not possible, *ex utero*, to distinguish between fetal and maternal tissue or the products of spontaneous and induced abortions.⁹¹ On appeal to the Fifth Circuit, the court ignored the district court's analysis entirely, finding instead that the term "experiment" as used in the statute's prohibition against fetal experimentation was unconstitutionally vague.⁹² "The whole distinction between experimentation and testing, or between research and practice, is ... almost meaningless," such that "experiment" is not adequately distinguishable from "test."⁹³ As a criminal prohibition without effective standards, the statute was deemed void.⁹⁴

A less stringent Utah statute was examined by the Tenth Circuit in 1995 in Jane L. v. Bangerter and rejected on similar grounds⁹⁵ Unlike the Louisiana law, Utah Code Ann. § 76-7-310 (1995) permitted discretionary experimentation aimed at acquiring genetic information about the embryo or fetus. A lower court upheld the statute by narrowly interpreting "experimentation" to mean "tests or medical techniques which are designed solely to increase a researcher's knowledge and are not intended to provide any therapeutic benefit to the mother or child."⁹⁶ The Tenth Circuit disagreed, arguing that the district court "blatantly rewrote the statute,

⁹⁰ Margaret S. II, at 674-75. See Clapp, "State Prohibition," 1079, n.48 ("The court further suggested the statute would fail even a rational relation test because it failed to serve its own stated purpose of treating the fetus like a human being, since it treated fetal tissue differently from other human tissue" Id. at 674-75).

⁹¹ Margaret S. II, at 675-76.

⁹² Margaret S. v. Edwards, 794 F.2d 994, 999 (5th Cir. 1986) [hereinafter Margaret S. III]. Note the court's concurring opinion that "criticized the majority for avoiding the real constitutional issue raised — that any statutory ban on experimentation would inevitably limit the kinds of tests available to women and their physicians and thus could not help but infringe on fundamental rights. Id. at 999-1002 (Williams, J., concurring)." Clapp, "State Prohibition," 1080, n.50.

⁹³ Margaret S. III at 999 ("every medical test that is now 'standard' began as an 'experiment'"). But see Clapp, "State Prohibition," 1080, n.54 ("the court hypothesized that the statute was intended 'to remove some of the incentives for research-minded physicians ... to promote abortion' and was therefore 'rationally related to an important state interest.' This language suggests that if the statute had not been vague, the court would have applied less than strict scrutiny to a ban on fetal research. The court also implied, in dicta, that the rationale was based on the 'peculiar nature of abortion and the state's legitimate interest in discouraging' it, relying on H.L. v. Matheson, 450 U.S. 398, 411-13 (1981)").

⁹⁴ Margaret S. III at 999.

⁹⁵ 61 F.3d 1493 (10th Cir. 1995).

⁹⁶ Jane L. v. Bangerter, 794 F.Supp. 1528 (D. Utah 1992).

choosing among a host of competing definitions for ‘experimentation.’”⁹⁷ The court further concluded that the word “benefit” was itself ambiguous: “If the mother gains knowledge from a procedure that would facilitate future pregnancies but inevitably terminate the current pregnancy, would the procedure be deemed beneficial to the mother? Does the procedure have to be beneficial to the particular mother and fetus that are its subject?”⁹⁸ Without clear boundaries between permissible action and criminal conduct, the statute was deemed unconstitutionally vague and invalid.⁹⁹

Finally, an Illinois district court in Lifchez v. Hartigan¹⁰⁰ considered a claim by a class of reproduction and infertility specialists seeking to invalidate a criminal misdemeanor statute that prohibited “experiment[ation] upon a fetus produced by the fertilization of a human ovum by a human sperm unless such experimentation is therapeutic to the fetus thereby produced.”¹⁰¹ Plaintiffs claimed that the words “experimentation” and “therapeutic” rendered the statute vague and unconstitutional, and the district court agreed. “[P]ersons of common intelligence will be forced to guess at whether or not their conduct is unlawful [T]here is no single accepted definition of ‘experimentation’ in the scientific and medical communities.”¹⁰² The court observed that experimental procedures evolve quickly into routine diagnostic and therapeutic interventions, and tests to obtain information about a fetus’ development often aren’t therapeutic to the fetus in the sense meant by that term.¹⁰³ The court was also troubled that without a bounded definition, a term like “therapeutic” might prohibit assisted-reproduction technologies generally, or impede the detection or novel treatment of disorders that are considered life-threatening to the mother.¹⁰⁴ On this basis, the court decided that a scienter (knowledge or intent)

⁹⁷ Id. at 1501.

⁹⁸ Id. at 1502.

⁹⁹ Id.

¹⁰⁰ 735 F. Supp. 1361 (N.D. Ill. 1990).

¹⁰¹ Ill.Rev.Stat., Ch. 38 para 81-26, § 6(7) (1989).

¹⁰² Lifchez at 1364.

¹⁰³ Id. at 1366-67.

¹⁰⁴ Id. at 1367-70.

requirement included in the Illinois statute did not mitigate vagueness where the law “has no core meaning to begin with.”¹⁰⁵ Rather, the court expanded its vagueness argument to conclude that potential restrictions on a woman’s reproductive decision arising out of the law’s broad effect and definitional uncertainty were an encroachment on the essential right of privacy as outlined by the Supreme Court in Griswold and Roe.¹⁰⁶

F. STATE LAW

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G. COMMENTARY

(1) *Directed Donation*

The issue of recipient-specified (or “directed”) donation of fetal tissue for research or transplantation is an area of ambiguity under the law that deserves further consideration. Under statute, 42 U.S.C. § 289g-2(c)(1) provides a fine and/or incarceration for any person who “solicit[s] or knowingly acquire[s], receive[s], or accept[s] a donation of human fetal tissue for the purposes of transplantation ... into another person [where] the donation will be or is made pursuant to a promise ... that the donated tissue will be transplanted into a recipient specified by such individual.” (42 U.S.C. § 289g-2(b)(1)). The law also proscribes any inducement to donate on the basis of a promise that “the donated tissue will be transplanted into a relative of the donating individual,” (42 U.S.C. § 289g-2(b)(2)). Three qualifying criteria are necessary for this statute to apply: the solicitation or acquisition must be “for the purpose of transplantation ... into another person,” (42 U.S.C. §§ 289g-2(b)); where the donation “affects interstate commerce,” (42 U.S.C. § 289g-2(b)); and the tissue “will be or is obtained pursuant to an induced abortion,” (42 U.S.C. § 289g-2(b)).

¹⁰⁵ Lifchez at 1372.

¹⁰⁶ Id. at 1376-77. See also note ___, supra.

In its enactment, Congress has attempted to isolate the decision to abort from any consideration that the aborted tissue may benefit someone known to the donor, fearing that such knowledge would influence the initial termination decision.¹⁰⁷ This is demonstrated more generally at 42 U.S.C. § 289g-1(b)(1), requiring that the donor, prior to donation, affirm in writing that such decision “is made without any restrictions regarding the identity of individuals who may be the recipients of transplantations of the tissue; and [that] the [donor] has not been informed of the identity of any such individuals.” A written statement must be supplied from the attending physician affirming, *inter alia*, that the donor’s decision to abort was separated from (and prior to) the decision to donate tissue, and that the statements contained in the donor’s written affirmation were in fact true (42 U.S.C. § 289g-1(b)(2)). Researchers involved in fetal tissue transplantation are permitted to use donated material from any source on the condition that they also affirm, *inter alia*, that the researcher “has had no part in any decisions as to timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research” (42 U.S.C. § 289g-1(c)).¹⁰⁸ Researchers are also subject to the aforementioned criminal penalties for procuring fetal tissue for directed donations at 42 U.S.C. § 289g-2(b).

The real difficulty with directed donation resides not so much in the text of 42 U.S.C. § 289g-2 or in federal law generally, but in the apparent conflict both in language and in spirit with

¹⁰⁷ See Robertson, “Symposium,” at 1369 (“The federal law ... reflects the prevailing consensus that the NIH advisory panel and other ethical review bodies have reached: fetal tissue transplantation research or therapy is acceptable as long as the donated fetal tissue is not the product of an abortion induced for donation purposes, but is the by-product of abortions that would be occurring anyway”).

¹⁰⁸ This statutory subsection is also the subject of an expression of Congressional concern over DHHS General Counsel Harriet Rabb’s memorandum to NIH Director Harold Varmus analyzing various legal issues related to stem cell research (see discussion, *infra*). (“The Rabb memo also ignores the policy reflected in current law on fetal tissue transplantation research using tissue from intentionally aborted children. While that law is itself open to criticism, it at least bans the use of fetal tissue in federally funded research if abortion was induced for the purpose of providing the tissue. Under current law, federal funds may not be used for fetal tissue transplantation experiments following an abortion if the timing and method of the abortion were altered solely for the purpose of providing usable tissue for research. Yet, in the embryonic stem cell research which NIH proposes to fund, the timing, method, and procedures for destroying the embryonic child would be determined solely by the federally funded researcher’s need for usable stem cells”). Letter from Seventy Members of the U.S. House of Representatives to Donna E. Shalala, Secretary of Health and Human Services (11 February 1999) at 2.

Section 6(a)(3) of the Uniform Anatomical Gifts Act (UAGA).¹⁰⁹ The UAGA provides that permissible donees for organ transplant or research are “(a)(1) a hospital, physician, surgeon, or procurement organization for transplantation, therapy, medical or dental education, research, or advancement of medical or dental science; (a)(2) an accredited medical or dental school, college, or university for education, research, advancement of medical or dental science; or (a)(3) a designated individual for transplantation or therapy needed by that individual.” No comparable restrictions to 42 U.S.C. §§ 289g-1(b) or 289g-2(b) are present anywhere in the UAGA, a widely adopted model act whose core tenet “require[s] that the intentions of a donor be followed.”¹¹⁰ The conflict between federal statutes and regulations and state law incorporating the UAGA is not an easy one. Ordinarily, one or more theories of legislative preemption would conclude that federal statutes supercede without question those of the subordinated states. However, both 42 U.S.C. § 289g-1(e) (applicable to DHHS and its grantees) and 45 C.F.R. § 46.210 (applicable to DHHS and its grantees whose research involves dead fetuses or fetal material) explicitly condition research access to fetal tissue on compliance with “applicable State or local laws regarding such activities.”

A review of presently enacted UAGA statutes reveals only one state, Vermont, that has omitted the conflicting subsection (a)(3) from its enactment.¹¹¹ The remaining jurisdictions, including the District of Columbia, permit designated donation of organs or tissue for transplant, research, or other purposes. It is not necessarily the case, however, that the apparent conflict in law is irremediable. Rather, one could reasonably argue that what state statutes uniformly permit

¹⁰⁹ Christie A. Seifert, “Comment, Fetal Tissue Research: State Regulation of the Donation of Aborted Fetuses Without the Consent of the ‘Mother’” 31 John Marshall Law Review (1997): 290 (“All fifty states have adopted a version of the UAGA. Approximately half of the states, however, have chosen to supplement the UAGA with laws that specifically address issues revolving around the use of fetal tissue for research. Of these states which have chosen to further regulate the use of fetal tissue research, roughly half have laws requiring the consent of the aborting woman prior to the donation and subsequent use of the fetus. Although these supplementary laws exist, the controlling law with respect to the donation of fetal tissue for research purposes is still the state-adopted UAGA”) (footnotes omitted).

¹¹⁰ Unif. Anatomical Gift Act prefatory note, 1994 main volume.

¹¹¹ Id. at sec. 6, “Historical Notes – Action in Adopting Jurisdictions.” See also, Unif. Anatomical Gift Act (1968), sec. 3(4) [predecessor to sec. 6(a)(3) (1987)] “Historical Notes – Action in Adopting Jurisdictions.”

(recipient designation), is nevertheless prohibited in the limited context of fetal tissue donations for transplantation research or therapy conducted by agency scientists or extramural grantees. The explicit statutory subordination to state law at 42 U.S.C. § 289g-1(e) and 45 C.F.R. § 46.210 may create the perception of some analytic circularity in this approach, but it seems extremely unlikely that permission from countervailing state statutes could enable agency conduct that federal statutory language expressly forbids. Commentators who have considered the question have rightly noted that this statutory conflict would appear to be ripe for resolution.¹¹² Given the wide prevalence of enacted UAGA statutes throughout the states, it would be significantly more feasible for Congress to amend 42 U.S.C. § 289g-1(e) in a way that clarifies the preemptive status of federal jurisdiction on the narrow question of directed donation.¹¹³

(2) *Statutory and Regulatory Research Limitations*

¹¹² See generally Bell, “Regulating Transplantation,” at 282 (“Many proponents of fetal tissue transplantation suggest that regulations should not allow the woman who donates fetal remains to designate the recipient of the fetal tissue. Additionally, it would be desirable to maintain the anonymity of both the pregnant woman and the tissue recipient. This precaution would eliminate the possibility that a woman would conceive a fetus in order to terminate the pregnancy and donate the fetal tissue. This measure would also ensure against the recipient seeking to reward the woman with gifts or fervent displays of gratitude after transplantation. Likewise, it would discourage tissue donation by a woman who might otherwise donate tissue hoping for a grateful response from the recipient”) (footnotes omitted); accord Duguay, “Fetal Tissue,” at 41, citing Childress, “Disassociation from Evil: The Case of Human Fetal Tissue Transplantation Research,” *Social Responsibility* (1990): 32, 37 (designated donation creates risk of exploitation and pressure); HPFTTR Panel I, at 2, 3, 8; Joanna H. Kinney, “Restricting Donative Choice: Fetal Tissue Transplantation and Respect for Human Life,” 10 *Journal of Law and Health* (1995): 261; S.C. Hicks, “The Regulation of Fetal Tissue Transplantation: Different Legislative Models for Different Purposes,” 27 *Suffolk University Law Review* (1993): 1623-1629; T.M. Hess-Mahan, “Human Fetal Tissue Transplantation Research: Entering a Brave New World,” 23 *Suffolk University Law Review* (1989): 818.

¹¹³ But see supporting a state-initiated UAGA amendment Frankowska, “A Proposal to Amend UAGA,” at 1116 (“The states should amend the UAGA to prohibit either parent from designating the recipient of tissue from an electively aborted fetus”); accord Mark W. Danis, “Fetal Tissue Transplants: Restricting Recipient Designation,” *Hastings Law Journal* 39 (1988): 1079; Seifert, “State Regulation,” at 296; Zion, “Legal and Ethical Issues,” at 1293-94; Beverly Burlingame, “Note, Commercialization in Fetal-Tissue Transplantation: Steering Medical Progress to Ethical Cures,” 68 *Texas Law Review* (1989): 236-37; Hersey, “Enigma,” at 206; Gelfand & Levin, “Fetal Tissue Research,” at 673; and see opposing designated donation restrictions generally Shirley K. Senoff, “FOCUS: ISSUES IN BIOETHICS: Canada’s Fetal-Egg Use Policy, The Royal Commission’s Report on New Reproductive Technologies, and Bill C-47,” 25 *Manitoba Law Journal* (1997): 29 (“Women who have undergone abortions may, in some cases, be allowed to designate recipients for fetal eggs While mandatory counseling for both the donating woman and the recipient would safeguard against the possibility that a woman may be coerced into aborting, the decision to designate a recipient would ultimately be that of the woman”); Robertson, “Symposium,” at 1361 (“the ban on designation of fetal tissue recipients unconstitutionally infringes upon the fundamental right to abortion ... [but] a set of procedural safeguards should be required to ensure that women freely consent to such donations”).

The scope of federal authority to pursue various types of research involving human fetal tissue is not altogether straight-forward under the statutes or accompanying regulations. For analytical purposes, it is useful to divide fetal-involved research activities into three broad categories: (a) therapeutic fetal tissue transplant research; (b) fetal tissue research not involving transplantation; and (c) non-therapeutic fetal tissue transplant research. We will consider each category in turn.

(a) *therapeutic fetal tissue transplant research*

Federal statutory and regulatory guidance is somewhat less ambiguous in this research category. For pragmatic purposes, the NIH Revitalization Act of 1993 divides research science relating to transplantation into public and private sectors. 42 U.S.C. § 289g-1 is directed exclusively at those activities which the Department of Health and Human Services may in its discretion conduct through its own scientists or through extramural grantees. The statute permits “the [DHHS] Secretary ... [to] conduct or support research on the transplantation of human fetal tissue for therapeutic purposes ... regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or ... stillbirth.” 42 U.S.C. § 289g-1(a). Accordingly, the mechanisms included in 42 U.S.C. § 289g-1 to ensure that a firewall exists between donor and researcher are applied only in those instances where DHHS or its subordinates perform research of a type described in the act. Regrettably, the statute fails to define the term “therapeutic” or to articulate the scope of what it means by “transplantation.”¹¹⁴

¹¹⁴ In its FY 1996-97 and FY 1993-95 reports to Congress on fetal tissue transplantation (filed pursuant to 42 U.S.C. § 289g-1(f)), NIH adopts the interpretation that “projects involving the transplantation of human fetal tissue into humans are classified as therapeutic or clinical research if they are conducted on human subjects and are aimed at the development of therapeutic approaches for the cure or amelioration of diseases and disorders.” “Therapeutic research” is the third in a spectrum of activities that NIH groups with “basic research,” (“advancement of knowledge of basic biological processes”) and “pre-clinical investigation,” (that “further[s] therapeutic research through transplantation studies in animals or the development of improved methodologies for processing and preserving tissue”). See Department of Health and Human Services. National Institutes of Health, Therapeutic Human Fetal Tissue Transplantation Research Activities Funded by the National Institutes of Health in FY 1996-97: Report to Congress (Bethesda, MD: 1998), 1 [hereinafter Department II]; Department of Health and Human Services. National

By contrast, 42 U.S.C. § 289g-2 applies more broadly to include both public and private-sector research, covering “any person,” (42 U.S.C. § 289g-2(a)-(b)) irrespective of funding status or governmental affiliation, who acquires fetal tissue. The prohibition on sale of tissue at Section 2(a) covers *all* transactions involving human fetal tissue, irrespective of purpose or category, and is applicable where a transfer occurs “[1] for valuable consideration [2] if the transfer affects interstate commerce.” Section 2(b) imposes additional donative limits (described supra) and covers “any person” who acquires human fetal tissue “[1] for the purpose of transplantation of such tissue into another person [2] if the donation affects interstate commerce, [and] [3] the tissue will be or is obtained pursuant to an induced abortion ...” (42 U.S.C. § 289g-2(b)). Inasmuch as most or all research transactions will involve interstate commerce, the determinative criterion for 42 U.S.C. § 289g-2(a) is: (1) valuable consideration; and the criteria for 42 U.S.C. § 289g-2(b) are (1) transplantation into a human recipient; and (2) induced abortion as the tissue source. No mention was included by the drafters of any restrictions on the “therapeutic” purpose or intent of research conducted under 42 U.S.C. § 289g-2.

The question of regulatory limitations is somewhat clouded. In her 1988 study for the Human Fetal Tissue Transplantation Research Panel, Judith C. Areen documents “four quite different interpretations of the current regulations”¹¹⁵ The problem Areen identified, and one which remains unresolved, is how to determine whether individual subsections of 45 C.F.R. Section 46 are applicable to human fetal tissue transplantation research. Most obviously, there is 45 C.F.R. § 46.210 which covers activities involving “the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus,” and provides that such activities are controlled by State or local laws where applicable.¹¹⁶ This “single section interpretation,” is contrasted with “double,” “triple,” and “four section” interpretations that purport to include, respectively,

Institutes of Health, Therapeutic Human Fetal Tissue Transplantation Research Activities Funded by the National Institutes of Health in FY 1993-95: Report to Congress (Bethesda, MD: 1997), 1 [hereinafter Department I].

¹¹⁵ Judith C. Areen, “Statement on Legal Regulation of Fetal Tissue Transplantation for the Human Fetal Tissue Transplantation Research Panel,” D21 in HFTTRP Panel II.

¹¹⁶ Id. at D21.

sections 46.206 (general limitations); 46.205 (additional duties for the IRB); and 46.209 (regulations applicable to viable and viability-undetermined fetuses ex utero).¹¹⁷ On the basis of her own textual analysis, Areen concludes that the “one section” theory is correct and that only 45 C.F.R. § 46.210 applies to fetal tissue transplantation research.¹¹⁸ This position was recently supported, at least by implication, by the DHHS General Counsel’s office.¹¹⁹ Areen notes that the Association of American Medical Colleges had conversely adopted the “double section” theory.¹²⁰ It appears from available commentary that other writers have not considered the issue carefully, with some adopting a modified “double section” theory that applies as relevant only sections 46.209 and 46.210 while others appear to agree with Areen.¹²¹ The author aptly concludes that “it is imperative that the Department clarify which of the [interpretations] is correct.”¹²²

(b) *fetal tissue research not involving transplantation*

This is an area of research that has not been particularly controversial. DHHS and NIH have funded and continue to fund research of this type with Congressional oversight and seeming approval. Research involving human fetal tissue that excludes transplantation is not addressed by 42 U.S.C. § 289g-1 and 289g-2(b) and is otherwise more generally regulated at 42 U.S.C. §§ 289g, 289g-2(b), 274e and 45 C.F.R. Section 46, Subpart B. While this conclusion is

¹¹⁷ Id. at D22-23.

¹¹⁸ Id. at D23-24.

¹¹⁹ See Memorandum from Harriet S. Rabb, HHS General Counsel, to Dr. Harold Varmus, M.D., NIH Director (15 January 1999): 5 (“45 C.F.R. [§] 46.210, Subpart B ... would apply to certain human pluripotent stem cells, including those derived from the primordial germ cells of non-living fetuses”).

¹²⁰ Areen, at D22 in HFTTRP Panel II. It appears from the Summary Highlights of FY 1987 Human Fetal Tissue Research Supported by NIH, and accompanying memorandum, see note ___ supra, that NIH may have supported this “double section” interpretation in 1987-88 (note that NIH’s present position is undetermined).

¹²¹ See e.g. Goddard, “NIH Revitalization Act,” at 387 (modified “double section”); Danis, “Restricting Recipient Designation,” at 1086 (implicit agreement with Areen); Ania M. Frankowska, “Note, Fetal Tissue Transplants: A Proposal to Amend the Uniform Anatomical Gift Act,” 1989 University of Illinois Law Review (1989): 1105 (also seems to agree with Areen); but see Gelfand & Levin, “Fetal Tissue Research,” 670 (highlighting 45 C.F.R. §§ 46.203 (definitions); 46.209; 46.210; and 46.206(a)(3) (donor-researcher separation provisions)).

¹²² Areen, at D24 in HFTTRP Panel II.

not stipulated in statutory or regulatory text (other than DHHS's broad enabling statutes), it was accepted practice even during the fetal tissue transplant moratorium that other types of non-transplant research involving fetal tissue would still receive funding on an uninterrupted basis.¹²³ Inasmuch as it is widely believed that Congress did not act to constrict the scope of permissible fetal tissue research in this area when it enacted the NIH Revitalization Act of 1993, it can be reasonably surmised that those activities which NIH funded or conducted prior to the moratorium's having been lifted could legitimately be funded or conducted thereafter.

From this analysis, one might conclude that research of the type conducted by Drs. Shablott and Gearhart et al.—in which primordial germ cells were cultured from “gonadal ridges and mesenteries of 5- to 9-week postfertilization human [fetal] embryos (obtained as a result of therapeutic termination of pregnancy ...)”¹²⁴ but not intended for transplant—would not be regulated by 42 U.S.C. § 289g-1's transplant “firewall” or the donative limitations at 42 U.S.C. § 289g-2(b) (excepting 42 U.S.C. § 289g-2(a)'s general prohibition of tissue sale, which is applicable). Rather, researchers pursuing this type of basic science in the future could proceed outside 42 U.S.C. § 289g-1 and 289g-2(b), subject to regulations that limit their ability to use cells extracted from a living, non-viable fetus (42 U.S.C. § 289g; 45 C.F.R. § 46.209); by state law where applicable (42 U.S.C. § 46.210, see discussion, supra); or where their research matures to a point that can be described as intended for transplantation. Seeming to support this analysis, NIH Director Harold Varmus has stated that the development of transplantation science is only one reason for conducting fetal-derived stem cell research; other areas include “how stem cells differentiate into specific types of cells ... which, in turn, could lead to the discovery of new ways to prevent and treat birth defects and even cancer”; and “pharmaceutical development ... study[ing] the beneficial and toxic effects of candidate drugs in many different cell types and

¹²³ See note ___, supra.

¹²⁴ Michael J. Shablott, John Gearhart, et al., “Derivation of pluripotent stem cells from cultured human primordial germ cells,” Proceedings of the National Academy of Sciences 95 (November 1998): 13726.

potentially reduce the numbers of animal studies and human clinical trials required for drug development.”¹²⁵

In formulating Commission policy on this question, it is worth considering that the Gearhart exclusion argument is not uniformly accepted. DHHS General Counsel Harriet Rabb, in a January 1999 memorandum to NIH Director Varmus, concludes somewhat inexplicably that “[t]o the extent human pluripotent stem cells are considered human fetal tissue by law, they are subject to ... the restrictions on fetal tissue transplantation research that is conducted or funded by DHHS, as well as to the federal criminal prohibition on the directed donation of fetal tissue.”¹²⁶ General Counsel Rabb examines the definition of “fetal tissue” at 42 U.S.C. § 289g-1(g) which “means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth” and observes that “some stem cells, for example those derived from the primordial germ cells of non-living fetuses, would be considered human fetal tissue for purposes of [federal law].”¹²⁷ Having concluded (we think correctly) that primordial germ cells extracted from non-living fetuses are a type of fetal tissue, the General Counsel goes on to apply, without explanation, the prohibition on sale of fetal tissue at 42 U.S.C. § 289g-2(a); firewall restrictions at 42 U.S.C. § 289g-1; the remaining donative limitations at 42 U.S.C. § 289g-2(b); and the single section 46.210 of 45 C.F.R.¹²⁸ While it is certainly clear from the text of the statute that 42 U.S.C. § 289g-2(a)’s prohibition on fetal tissue sale was intended to apply broadly,

¹²⁵ Statement of Harold Varmus, M.D., NIH Director, Before the Senate Appropriations Subcommittee on Labor, Health, and Human Services, Education, and Related Agencies (26 January 1999) at 1. It is unclear from his public statements whether Dr. Varmus regards 42 U.S.C. § 289g-1 and 289g-2(b) as applicable to stem cell research involving fetal tissue. See e.g., id. at 1 (“Dr. Gearhart’s work could have been supported with federal funds ... Federal laws and regulations already exist that govern research on fetal tissue”); Testimony of Harold Varmus, M.D., NIH Director, Before the National Bioethics Advisory Commission (19 January 1999) at 15, 16, 18 (“[quoting the Rabb memorandum] [fetal-derived] stem cells ...are subject to the existing statutes’; that is, there will be no reason to exclude Federal support or work with those cells as long as statutes and laws are obeyed ... there are restrictions on fetal tissue transplantation research, and those restrictions are good ... At present the Federal government can support derivation of pluripotent stem cells from fetal germ cells I would point out the Administration does not at this time seek any changes in the law”).

¹²⁶ See Memorandum from Harriet S. Rabb, HHS General Counsel, to Dr. Harold Varmus, M.D., NIH Director (15 January 1999): 1.

¹²⁷ Id. at 4.

¹²⁸ Id. at 4-5. For 45 C.F.R. § 46.210, see discussion, supra.

both 42 U.S.C. § 289g-1 and 289g-2(b), like NOTA's prohibition at 42 U.S.C. § 274e(a), are explicitly limited to the narrow research context of transplantation. It would appear that the General Counsel believes that research of the type conducted by Drs. Shablott and Gearhart et al. presently constitutes transplantation research mature enough to qualify for regulation under the statutes, but no argument or analysis is presented to support this conclusion.

(c) *non-therapeutic fetal tissue transplant research*

Without question, this category represents an area of potentially important research science that deserves greater clarity. The statutes and regulations themselves are essentially silent on non-therapeutic fetal tissue transplantation and the scope of research activity that can be considered permissible. The same broad regulations that affect the prior category (42 U.S.C. § 289g; 289g-2(a); one or more subsections of 45 C.F.R. Section 46, Subpart B; and State and local laws where appropriate, see 45 C.F.R. § 46.210) are almost certainly applicable here. Further, given the language of 42 U.S.C. § 289g-1 and 289g-2, it seems clear that scientists in the private sector are able to pursue non-therapeutic transplant research, including transplantation into a human recipient, subject to the tissue sale prohibition at 42 U.S.C. § 289g-2(a) and the donative restrictions at 42 U.S.C. § 289g-2(b), discussed supra. However, the structure and language of § 289g-1 and 289g-2 leave unanswered the question of whether federal intramural scientists or extramural grantees could conduct research (or even ignore firewall restrictions) where the transplantation is not “for therapeutic purposes.” This uncertainty is particularly acute given the absence of criminal penalties at 42 U.S.C. § 289g-1 concomitant with those provided at 42 U.S.C. § 289g-2(c). It might be argued that U.S.C. § 289g-1 permits one type of transplant research (“therapeutic”), is silent as to the other (“non-therapeutic”), and lacks an enforcement mechanism to police the difference even if it is assumed that the latter research activity was intended to be forbidden.

This is almost certainly an anomalous interpretation given the statutes' origin as a Congressional action to lift the predecessor moratorium and provide comprehensive guidelines for transplantation of human fetal tissue.¹²⁹ Normal rules of construction would probably dictate that use of a specific term like “therapeutic” to permit what had otherwise been forbidden limits the scope of permissible action to the general meaning of that term. The Congress appears to have intended to apply more stringent regulations to governmental or governmentally-supported transplantation research than to those restrictions applied in the private sector. By including the term “therapeutic,” Congress expressed its desire to prohibit federal or federally-funded *non-therapeutic* transplantation research, irrespective of tissue source (induced, spontaneous, or stillbirth) while failing entirely to explain what this means. The provision seemingly limits the scope of permissible transplant research on the federal level to only those procedures whose primary or intended purpose is to provide therapeutic benefit to the transplant recipient herself. Congress' failure to include penalties in 42 U.S.C. § 289g-1 like those applied in § 289g-2 should rather be attributed to its assumption that simple oversight would be sufficient to ensure compliance by the executive agency and its extramural research grantees.

¹²⁹ See historical discussion, *supra*.

It appears that NIH and the Department have attempted to interpret for themselves this puzzling statute, and may arguably have received tacit support both from Congress and from the General Accounting Office in their interpretation. In its reports to Congress on fetal tissue transplant research (FY 1996-97 and FY 1993-95), NIH describes three categories of research involving human fetal tissue:

Basic research involving human fetal tissue focused on the advancement of knowledge of basic biological processes Pre-clinical investigations aim[ed] [at] ... further therapeutic research through transplantation studies in animals or the development of improved methodologies for processing and preserving tissue [and] ... Projects involving the transplantation of human fetal tissue into humans [and] classified as therapeutic or clinical research if they are conducted on human subjects and are aimed at the development of therapeutic approaches for the cure or amelioration of diseases and disorders.¹³⁰

The reports are mandated by 42 U.S.C. § 289g-1(f) and require the Department to tell Congress what research it supports pursuant to 42 U.S.C. § 289g-1(a) (the subsection that includes the Department's enabling language and the terms "therapeutic" and "transplantation"). All of the research grants that NIH reported to Congress under section 289g-1(a) were characterized as falling in the third category, either actual transplantation of human fetal tissue into other humans, or follow-up studies on patients whose treatment had included fetal tissue transplants.¹³¹ In its FY 1993-95 combined report, NIH described a quality-of-life study on Parkinson's patients that it had funded at three universities, stating that "since this research does not involve the actual transplantation of tissue, the funds for the study are not included in the total [fetal tissue transplant] funding figure for the year."¹³² By its own reporting, its earlier definitional categories, and this admission, NIH seems to imply that (a) it presently supports what may be variously described as therapeutic or non-therapeutic transplant research; and (b) that such research is only deemed to be controlled by the enabling language and term "therapeutic" as a limiter where the

¹³⁰ See Department I at 1, and Department II at 1.

¹³¹ Id.

¹³² See Department I at 4.

“research ... involves the actual transplantation of tissue.”¹³³ After reporting twice to the House Committee on Commerce and the Senate Committee on Health, Education, Labor, and Pensions, it may be assumed that the committees have at least impliedly concurred in the NIH’s definition of its authority. Finally, the General Accounting Office, in its March 1997 report to the Chairmen and Ranking Minority Members, considered NIH’s compliance with 42 U.S.C. § 289g-1 and 289g-2 and concluded that “the requirements of the act are being complied with.” It must be admitted that the GAO did not consider the definitional issue in the form described here, but it read the law closely and its assessment of NIH’s performance was favorable.

The net effect of all of this seems to be that NIH as a research and granting agency can and will fund (a) any *therapeutic* fetal tissue transplant research, subject to statutory and regulatory restrictions and reporting obligations (where the “research ... involves the actual transplantation of tissue ... conducted on human subjects and ... aimed at the development of therapeutic approaches for the cure or amelioration of diseases and disorders”); (b) any fetal tissue research (therapeutic or non-therapeutic) *not involving transplantation*, subject to substantially fewer statutory and regulatory restrictions; and theoretically exclude (c) *non-therapeutic* fetal tissue transplant research. In simpler terms, almost any project that involves “the actual transplantation of tissue” will generally be styled as “therapeutic transplantation” and treated under the aforementioned section (a) (NIH’s narrow definition of “transplantation” would exclude every procedure not involving than physical implantation of fetal tissue into a human). The NIH definition of “therapeutic” is quite broad, and practically speaking, any injection of human fetal cells into a human recipient is not likely to be approved if it isn’t also at least

¹³³ Id.

“therapeutic” in the inclusive sense that NIH understands the term.¹³⁴ As a result, a narrow definition of “transplantation,” a broad definition of “therapeutic,” and the reality of human subjects protections will effectively avoid the application of an inferred prohibition against non-therapeutic fetal tissue transplantation for almost any conceivable research proposal involving human fetal tissue. Following this logic, any project that does not involve “the actual transplantation of tissue” should be categorized as *not transplantation* under the NIH definition (since no cell matter is actually injected into a human recipient) and may be legitimately funded outside the restrictions established in 42 U.S.C. § 289g-1 and 289g-2(b). Note finally that this interpretation makes the General Counsel’s sweeping analysis even more difficult to understand or to reconcile; the research conducted by Drs. Shablott and Gearhart *et al.* did not involve “the actual transplantation of tissue” (a fact that should remove it from the transplant category entirely, according to NIH).

(3) *Prohibition on Sale of Fetal Tissue*

A number of issues related to the federal statutory, regulatory, and UAGA prohibitions on sale of human fetal tissue present areas for further consideration. 42 U.S.C. § 289g-2 broadly states that “it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.” Fetal tissue is defined to mean “tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth” 42 U.S.C. § 289g-2(d)(1) (by reference to 42 U.S.C. § 289g-1(g)). “Valuable consideration” is defined by its negation at 42

¹³⁴ Recall that NIH describes “therapeutic” somewhat elliptically in its qualifying definition as including projects that “are conducted on human subjects and are aimed at the development of therapeutic approaches for the cure or amelioration of diseases and disorders.” Department I, at 1; Department II, at 1. For human subjects protections, see generally 45 C.F.R. Section 46, Protection of Human Subjects, and 45 C.F.R. § 46.111(a), Criteria for IRB approval of research (“risks to subjects are minimized ... do not unnecessarily expose subjects to risk ... whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes; ... risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result ...”).

U.S.C. § 289g-2(d)(3) as “not includ[ing] reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.” A complementary prohibition at 42 U.S.C. § 289g-2(b), more narrowly limited to “donation ... for the purpose of transplantation,” makes it unlawful to solicit or acquire fetal tissue by “provid[ing] valuable consideration for the costs associated with ... abortion,” (42 U.S.C. § 289g-2(b)(3)). DHHS departmental regulations at 45 C.F.R. § 46.206(b), applicable to DHHS scientists and extramural grantees, provides that “no inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the [research] activity.” The National Organ Transplant Act (NOTA) at 42 U.S.C. § 274e prohibits acquisition or transfer of “any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.” NOTA states that “the term ‘human organ’ means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the [DHHS] Secretary by regulation.” 42 U.S.C. § 274e(c)(1). The statute’s definition of “valuable consideration” at 42 U.S.C. § 274e(c)(2) is effectively the same as 42 U.S.C. § 289g-2(d)(3), supra.

The 1987 revision of the Uniform Anatomical Gifts Act (UAGA) at section 10 directs that “(a) a person may not knowingly, for valuable consideration, purchase or sell a part for transplantation or therapy, if removal of the part is intended to occur after the death of the decedent.” Further, “(b) valuable consideration does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of a part.” The UAGA § 10(c), like its federal counterparts at 42 U.S.C. § 289g-2(c), and § 274e(b), provides substantial criminal penalties for violation. A review of the enacted UAGA legislation discloses two substantive changes by state legislatures: New Mexico and Nevada omit the phrase “if removal of the part is intended to occur after the death of the decedent” from § 10(a), and both Oregon and Connecticut omit entirely the section prohibiting

sale of human organs. The effect of the former has little bearing on fetal tissue research except to the extent that it may impact work involving living, nonviable fetuses in those states adopting that redaction, and the latter reflects the apparent consensus among states (only 22 having enacted the post-1987 UAGA revision) that organ sale not be made illegal.

The unwillingness of states like Oregon and Connecticut to include prohibition of organ sale in their statutes reflects a wider and unexplained state practice generally on this subject. Whether the legislatures of the remaining 28 states and the District of Columbia have consciously chosen to forgo state-enacted bans on organ sale is not known; it is quite possible that, given an existing version of the UAGA that predates the 1987 revision, inertia has precluded enactment of the newer prohibition or simply that the state legislators believe federal prohibitions (discussed, supra) are sufficient. On the latter justification, there is some question as to whether this rationale actually works. Without getting deeply enmeshed in the current legal debate over Congress' ability to regulate state activity through the commerce clause, it is definitely the case that the Supreme Court has begun to place limits on this power that did not exist when NOTA or the NIH Revitalization Act of 1993 were enacted.¹³⁵ Available commentary on this subject does not adequately address whether fully *intrastate* research activity would be prohibited under federal law, nor has any court considered the question.¹³⁶ Combining this potential for federal jurisdictional incapacity with the majority of state legislatures' not having enacted prohibitions on organ sale, it is at least possible that the sale of human fetal tissue for research or transplant may legally occur now or in the future in at least some states.¹³⁷

¹³⁵ See note __, supra.

¹³⁶ See e.g., note __, supra, S.H.D. (“suggesting that “the courts ... will probably continue their broad construction of Congress' Commerce Clause power and will find that intrastate organ sales do ‘affect interstate commerce’ ” but written well before the Court began to revise its understanding of the commerce clause).

¹³⁷ See Hersey, “Enigma,” at 113 (“Only the 1987 version of the UAGA explicitly prohibits sales of procured organs. Thus, unless the states still enforcing the 1968 version have supplementary statutes banning the purchase and/or sale of fetal tissue and organs, the specter of a cottage industry of fetal reproductive organs looms ...”).

Finally, it is probably worth noting what numerous commentators have already observed: the statutes are not clearly written.¹³⁸ For example, the reference in 42 U.S.C. § 289g-2 and other statutes to “valuable consideration” lacks meaningful content. While its purpose is generally understandable, the statutes’ use of this ambiguous term leaves real questions unanswered about the scope of permissible activity under the law. And as cases like Margaret S., Jane L., and Lifchez demonstrate, definitional ambiguity in this area can be fatal.¹³⁹ One tactical difficulty inherent in the definition is the degree to which various entities, including a range of intermediaries, are permitted to profit from their participation in the harvest of tissue or its subsequent use in research or transplantation. On its face, the statutes appear to exclude payments to the donor/mother for any commercial value the tissue may hold, nor may researchers under 42 U.S.C. § 289g-2(b)(3) provide reimbursement for the cost of the induced abortion. Beyond the donor/mother, however, the issue becomes much less clear. Are the intermediaries who collect and process the tissue, heretofore not-for-profit foundations, expected to recoup costs only or are future commercial entities permitted to charge more? How much more? May researchers or their institutional partners who immortalize valuable cell lines from fetal tissue legally transfer them for profit? May cell banks?

In an ambiguity specific to the National Organ Transplant Act (NOTA) at 42 U.S.C. § 274e, one commentator aptly observed that “the statute ... fails to state clearly what exactly is included in fetal organs and ‘any subparts thereof.’ At the time of transplantation, many organs, such as the pancreas and liver, are not yet developed. Thus, what is being transplanted, from a medical standpoint, are not organs or organ subparts, but precursor cells and tissues.”¹⁴⁰ Moreover, “because NOTA does not specifically list, for instance, whether the brain is a

¹³⁸ See e.g. Hersey, “Enigma,” at 117; Zion, “Legal and Ethical Issues,” at 1291; Burlingame, “Commercialization in Fetal-Tissue Transplantation,” at 226.

¹³⁹ See generally, discussion *supra*.

¹⁴⁰ See Zion, “Legal and Ethical Issues,” at 1292 (footnotes omitted). See also Marjory Spraycar, ed., Stedman’s Medical Dictionary, 26th Edition (Baltimore: Williams & Wilkins, 1995) at 1257 (“Organ ... Any part of the body exercising a specific function, as of respiration, secretion, digestion”).

controlled organ, it is unknown whether it is exempt.”¹⁴¹ It would almost certainly be the case that the gonadal ridges and mesenteries of 5- to 9-week postfertilization embryos used by Drs. Shablott and Gearhart et al. in their research on the primordial germ cell would be difficult to categorize developmentally as organs,¹⁴² nor are they listed as such by 42 U.S.C. § 274e or by any departmental guidelines promulgated pursuant to 42 U.S.C. § 274e(c)(1). It may, however, one day be the case that differentiated successors to pluripotent stem cell cultures will be made to specialize for transplantation in a way that qualifies them for organ tissue status. Under the circumstances, Congressional action to clarify the definitional issues brought about by medical and technological advances would appear to be appropriate.¹⁴³

¹⁴¹ See Zion, “Legal and Ethical Issues,” at 1292 (footnotes omitted).

¹⁴² See Shablott & Gearhart, et al., “Derivation of pluripotent stem cells,” at 13726.

¹⁴³ See Zion, “Legal and Ethical Issues,” at 1292 (“Unanswered questions such as these suggest that NOTA requires further amendments”).