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## **Federal and State Regulation of Research Involving Human Fetal Tissue**

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# Federal and State Regulation of Research Involving Human Fetal Tissue

## **Summary**

This report discusses federal and state regulation of research involving human fetal tissue. The NIH Revitalization Act of 1993 and the Health Research Extension Act of 1985 regulate the federal funding of fetal research and fetal tissue transplantation. The National Organ Transplant Act restricts the receipt or transfer of fetal organs. Additional fetal research statutes exist at the state level, but have been subject to challenges in federal courts. In general, the courts have found the state fetal research statutes to be unconstitutionally vague.

## Contents

Background .....	1
Federal Regulation of Research Involving Fetal Tissue .....	3
NIH Revitalization Act of 1993 .....	3
Health Research Extension Act of 1985 .....	5
National Organ Transplant Act .....	5
State Regulation of Research Involving Fetal Tissue .....	5

# Federal and State Regulation of Research Involving Human Fetal Tissue

Research involving human fetal tissue has provided significant medical developments. Fetal tissue research assisted with the creation of vaccines for polio and rubella.<sup>1</sup> Transplantation studies with human fetal tissue have shown promise in treating juvenile diabetes and other ailments.<sup>2</sup> However, despite these accomplishments, research involving human fetal tissue remains controversial. Because human fetal tissue is derived from aborted fetuses, such research is often entangled with the politics of abortion. Those who believe that a fetus is a human being consider research involving human fetal tissue to be unethical.<sup>3</sup>

Opposition to fetal tissue research and transplantation led to a moratorium on federal funding for fetal tissue transplantation research in 1988. This moratorium continued until the passage of the NIH Revitalization Act of 1993 (“NIH Act”). This report will review the federal government’s regulation of fetal tissue research and transplantation. The report will also discuss state regulation of fetal research and cases that have considered the legitimacy of such regulation.

## Background

The terms “fetal tissue research” and “fetal tissue transplantation research” are used to describe two distinct types of research involving human fetal tissue. The term “fetal tissue research” encompasses research with fetal tissue to develop therapies, evaluate risk factors, and develop cell lines.<sup>4</sup> The term “fetal tissue transplantation research” refers to research involving a procedure in which cells taken from a fetus are processed and injected into the faulty organs of people suffering from particular

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<sup>1</sup>See James E. Goddard, *The NIH Revitalization Act of 1993 Washed Away Many Legal Problems With Fetal Tissue Transplantation Research But A Stain Remains*, 49 SMU L. Rev. 375 (1996).

<sup>2</sup>See Jose L. Gonzalez, *The Legitimization of Fetal Tissue Transplantation Research Under Roe v. Wade*, 34 Creighton L. Rev. 895 (2001).

<sup>3</sup>See Goddard, *supra* note 1, at 376.

<sup>4</sup>See Gonzalez, *supra* note 2, at 896. In 1998, investigators at Johns Hopkins University published the results of their research with stem cells derived from aborted fetuses. The properties of these stem cells were found to be very similar to those of embryonic stem cells. For additional information on stem cell research, see (name redacted), *Stem Cell Research*, CRS Report RL31015.

diseases.<sup>5</sup> It is this latter type of research that prompted the moratorium on federal funding.

In 1988, a group of scientists at the National Institutes of Health ("NIH") sought approval from the Assistant Secretary of Health and Human Services ("HHS") to use human fetal tissue for transplantation in a research protocol.<sup>6</sup> In response to the request, the Assistant Secretary issued a temporary moratorium on the federal funding of fetal tissue transplantation research. The moratorium was intended to last until an NIH advisory panel could study and report on the ethical, legal, and scientific issues associated with fetal tissue transplantation research.<sup>7</sup> Although the panel eventually recommended continued funding for fetal tissue transplantation research pursuant to certain guidelines, the moratorium was extended indefinitely by the Secretary of HHS in 1989.<sup>8</sup> The Secretary maintained that fetal tissue transplantation research would increase the incidence of induced abortions.<sup>9</sup> Legislative attempts to override the Secretary's decision were either not enacted or were vetoed by President Bush.<sup>10</sup>

Shortly after assuming office, President Clinton instructed the Secretary of HHS to lift the ban on federal funding.<sup>11</sup> On February 5, 1993, the moratorium was officially rescinded. In March, 1993, NIH published interim guidelines for research involving the transplantation of human fetal tissue.<sup>12</sup> These guidelines were later incorporated into the NIH Act.

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<sup>5</sup>See Goddard, *supra* note 1, at 378. See also Cory Zion, *The Legal and Ethical Issues of Fetal Tissue Research and Transplantation*, 75 Or. L. Rev. 1281 (1996).

<sup>6</sup>Goddard, *supra* note 1, at 383.

<sup>7</sup>Goddard, *supra* note 1, at 383-84. See also Nat'l Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research - Volume I* (1999).

<sup>8</sup>Nat'l Bioethics Advisory Commission, *supra* note 7, at 31.

<sup>9</sup>*Id.* Most researchers believe that the success of fetal tissue transplantation research depends on tissue derived from induced abortions. Fetuses obtained from spontaneous abortions and ectopic pregnancies often contain genetic abnormalities that make the tissue unusable in transplantation research.

<sup>10</sup>See H.R. 2507, 102<sup>nd</sup> Cong. (1991); H.R. 5495, 102<sup>nd</sup> Cong. (1992); President's Message to the House of Representatives Returning Without Approval the National Institutes of Health Revitalization Amendments of 1992, 28 Weekly Comp. Pres. Doc. 1132 (June 23, 1992)

<sup>11</sup>See President's Memorandum for the Secretary of Health and Human Services, 58 Fed. Reg. 7457 (1993).

<sup>12</sup>Nat'l Bioethics Advisory Commission, *supra* note 7, at 31.

## Federal Regulation of Research Involving Fetal Tissue

Research involving fetal tissue is regulated primarily by three federal statutes. The restrictions imposed by these statutes are described in this section.

**NIH Revitalization Act of 1993.** Under the NIH Act, the Secretary of HHS may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes. The Secretary may provide support for research only if the applicant for financial assistance agrees to conduct the research in accordance with applicable state law.<sup>13</sup> Similarly, the Secretary may conduct research only in accordance with applicable state and local law.<sup>14</sup>

Fetal tissue that is used for transplantation research under the NIH Act may be obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.<sup>15</sup> However, before the fetal tissue may be used in research, written statements must be made by the woman providing the tissue, by the attending physician who obtains the tissue, and by the principal researcher. Each of these statements requires specific declarations.

In her written statement, the woman providing the tissue must declare that (1) she is donating the tissue for use in transplantation research for therapeutic purposes; (2) the donation is being made without any restriction on the recipient of the tissue; and (3) she has not been told of the identity of the recipient.<sup>16</sup> The physician's written statement must declare that (1) the woman's consent for the abortion was obtained prior to requesting or obtaining consent for the tissue donation; (2) there was no alteration of the timing, method, or procedures used to terminate the pregnancy for the purpose of obtaining the tissue; (3) the abortion was performed in accordance with applicable state laws; (4) the tissue was donated in accordance with the requirements set out in the mother's statement; and (5) the woman has been fully informed of the physician's interest, if any, in the research to be conducted and has been fully informed of any known medical risks or risks to her privacy as a result of the donation.<sup>17</sup>

Finally, the individual with the principal responsibility for conducting the research must declare that (1) he is aware that the tissue is human fetal tissue obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; (2) the tissue was donated for research purposes; (3) he has provided information about the tissue to other individuals involved with the research; (4) he will require, prior to obtaining consent from a transplantation recipient, written acknowledgment that the recipient

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<sup>13</sup>42 U.S.C. § 289g-1(e)(1).

<sup>14</sup>42 U.S.C. § 289g-1(e)(2).

<sup>15</sup>See 42 U.S.C. § 289g-1(a)(2).

<sup>16</sup>42 U.S.C. § 289g-1(b)(1).

<sup>17</sup>42 U.S.C. § 289g-1(b)(2).

is aware of the kind of tissue to be used; and (5) he had no part in determining the timing, method, or procedures used to terminate the pregnancy.<sup>18</sup>

In addition to requiring written statements, the NIH Act also prohibits the knowing acquisition, receipt, or transfer of any human fetal tissue for valuable consideration if the transfer affects interstate commerce.<sup>19</sup> Moreover, the NIH Act provides:

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

- (1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;
- (2) the donated tissue will be transplanted into a relative of the donating individual; or
- (3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.<sup>20</sup>

Persons violating these restrictions shall be subject to fines, imprisonment for not more than ten years, or both.<sup>21</sup> Violations involving the payment of valuable consideration shall result in fines reflecting not less than twice the amount of the valuable consideration received.<sup>22</sup>

Although the NIH Act responded to numerous concerns involving fetal tissue transplantation research, it also aroused criticism for its ambiguity. For example, it has been argued that Congress' failure to define the term "therapeutic purposes" could result in the transplantation of fetal tissue to enhance the body's normal functioning.<sup>23</sup> It has also been argued that the Act's use of the term "valuable consideration" could result in abuse by those who transport or process human fetal tissue.<sup>24</sup> Uncertainty about what constitutes "reasonable payments" could result in

<sup>18</sup>42 U.S.C. § 289g-1(c).

<sup>19</sup>42 U.S.C. § 289g-2(a).

<sup>20</sup>42 U.S.C. § 289g-2(b).

<sup>21</sup>42 U.S.C. § 289g-2(c)(1).

<sup>22</sup>42 U.S.C. § 289g-2(c)(2).

<sup>23</sup>See Goddard, *supra* note 1, at 393 ("Currently, researchers have discovered that fetal tissue injections can accelerate muscle healing in animals. It is foreseeable, then, that fetal injections could be used to 'enhance - like steroids - the ability of athletes . . .').")

<sup>24</sup>Goddard, *supra* note 1, at 394. See 42 U.S.C. § 289g-2(d)(3) (The term "valuable consideration" is defined to exclude "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.").

fetal tissue transporters and processors charging excessive amounts and declaring such amounts to be “reasonable.”

**Health Research Extension Act of 1985.** The Health Research Extension Act of 1985 (“Extension Act”) restricts research or experimentation on nonviable living human fetuses ex utero and living human fetuses ex utero whose viability has not been determined.<sup>25</sup> Under the Extension Act, the Secretary of HHS may conduct or support research or experimentation on the specified fetuses in only two situations. The Secretary may conduct or support research or experimentation that enhances the well-being of the fetus or enhances the probability of its survival.<sup>26</sup> The Secretary may also conduct or support research or experimentation that is undertaken to develop important biomedical knowledge that cannot be obtained by other means.<sup>27</sup> This type of research or experimentation must pose no added risk of suffering, injury, or death to the fetus.<sup>28</sup>

**National Organ Transplant Act.** The National Organ Transplant Act (“NOTA”) makes it unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration if the transfer affects interstate commerce and the organ is to be used in transplantation.<sup>29</sup> The term “human organ” includes fetal organs.<sup>30</sup> Reasonable payments associated with the removal, transportation, processing, and storage of the organs are excluded from the definition of “valuable consideration.”<sup>31</sup> Violation of NOTA’s prohibition shall result in fines not to exceed \$50,000, imprisonment for not more than five years, or both.

## State Regulation of Research Involving Fetal Tissue

Under the NIH Act, federally-funded research on fetal tissue transplantation must comply with applicable state laws.<sup>32</sup> Laws relating to the use of human tissue exist in all states. The Uniform Anatomical Gift Act, first proposed in 1968, sought to govern tissue donation from all dead humans and fetuses.<sup>33</sup> The Act permits the use of human tissue for the purpose of education, research, or the advancement of science.<sup>34</sup> However, while the original Act was adopted by all fifty states and the

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<sup>25</sup>See 42 U.S.C. § 289g.

<sup>26</sup>42 U.S.C. § 289g(a)(1).

<sup>27</sup>42 U.S.C. § 289g(a)(2).

<sup>28</sup>*Id.*

<sup>29</sup>42 U.S.C. § 274e(a).

<sup>30</sup>42 U.S.C. § 274e(c)(1).

<sup>31</sup>42 U.S.C. § 274e(c)(2).

<sup>32</sup>42 U.S.C. § 289g-1(e)(1).

<sup>33</sup>See Goddard, *supra* note 1, at 388.

<sup>34</sup>*Id.*



District of Columbia, fewer states adopted a revised 1987 version of the Act. Instead, many states enacted alternate legislation to specifically regulate fetal research.<sup>35</sup>

At least nineteen states restrict fetal research.<sup>36</sup> For example, North Dakota law provides: “A person may not use a fetus or fetal organs or tissue resulting from an induced abortion in animal or human research, experimentation, or study, or for animal or human transplantation except for diagnostic or remedial procedures.”<sup>37</sup> The validity of state laws that restrict fetal research has been considered in four federal circuits.<sup>38</sup> In general, the courts have concluded that the language of the state fetal research statutes is unconstitutionally vague.<sup>39</sup> These courts have found that the statutes’ use of the terms “experiment,” “experimentation,” or “investigation” fail to provide adequate guidance on the conduct that is prohibited.

In *Forbes v. Napolitano*, the U.S. Court of Appeals for the Ninth Circuit found Arizona’s fetal research statute unconstitutionally vague under the due process clause of the Fourteenth Amendment.<sup>40</sup> The court indicated that the statute “provides no guidance as to where the state should draw the line between experiment and treatment and gives doctors no constructive notice.”<sup>41</sup> Moreover, the statute failed to give police, prosecutors, and judges any standards to “focus the statute’s reach.”<sup>42</sup>

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<sup>35</sup>See Gonzalez, *supra* note 2, at 905.

<sup>36</sup>Ariz. Rev. Stat. Ann. § 36-2302 (1993); Ark. Code Ann. § 20-17-802 (2000); Cal. Health & Safety Code § 123440 (1996); Fla. Stat. Ann. § 390.0111 (1998); 720 Ill. Comp. Stat. Ann. 510/12.1 (1993); Ky. Rev. Stat. Ann. § 436.026 (1999); La. Rev. Stat. Ann. § 40:1299.35.13 (2001); Me. Rev. Stat. Ann. tit. 22, § 1593 (1992); Mass. Gen. Laws Ann. ch. 112, § 12J (1996); Minn. Stat. Ann. § 145.422 (1998); Mo. Ann. Stat. § 188.036 (1996); N.D. Cent. Code §§ 14-02.2-01, 14-02.2-02 (1997); Ohio Rev. Code Ann. § 2919.14 (1999); Okla. Stat. Ann. tit. 63, § 1-735 (1997); R.I. Gen. Laws § 11-54-1 (2000); S.D. Codified Laws § 34-23A-17 (1994); Tenn. Code Ann. § 39-15-208 (1997); Utah Code Ann. § 76-7-310 (1999); Wyo. Stat. Ann. § 35-6-115 (2001). See note 38 (The Arizona, Illinois, Louisiana, and Utah statutes have been found unconstitutional.).

<sup>37</sup>N.D. Cent. Code § 14-02.2-02.2.

<sup>38</sup>See *Margaret S. v. Edwards*, 794 F.2d 994 (5<sup>th</sup> Cir. 1986); *Lifchez v. Hartigan*, 735 F.Supp. 1361 (N.D. Ill. 1990), *aff’d* mem., 914 F.2d 260 (7<sup>th</sup> Cir. 1990); *Forbes v. Napolitano*, 236 F.3d 1009 (9<sup>th</sup> Cir. 2000); *Jane L. v. Bangerter*, 61 F.3d 1493 (10<sup>th</sup> Cir. 1995), *Rev’d* and remanded on other grounds sub. nom., *Levitt v. Jane L.*, 518 U.S. 137 (1996).

<sup>39</sup>See *Forbes*, 236 F.3d at 1011 (“The due process clause of the Fourteenth Amendment guarantees individuals the right to fair notice of whether their conduct is prohibited by law . . . Although only constructive rather than actual notice is required, individuals must be given a reasonable opportunity to discern whether their conduct is proscribed so they can choose whether or not to comply with the law.”).

<sup>40</sup>236 F.3d 1009 (9<sup>th</sup> Cir. 2000).

<sup>41</sup>*Forbes*, 236 F.3d at 1013.

<sup>42</sup>*Id.*

Despite the invalidation of various state fetal research statutes, opponents of fetal tissue research and transplantation maintain that the vagueness problems identified by the courts can be overcome.<sup>43</sup> If such statutes were to withstand constitutional challenge, it would appear that federally-supported fetal tissue transplantation research could be restricted in states with fetal research laws.

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<sup>43</sup>See *AG Finds Fetal Tissue Research May Be Banned By State If Law Properly Drafted*, 9 Health L. Rep. (BNA) No. 10, at 338 (March 9, 2000).

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