

to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of part 46 of title 45 of the Code of Federal Regulations and to report its finding to the Biomedical Ethics Board not later than 24 months after Nov. 4, 1988, which report was to be then transmitted to specified Congressional committees.

1988—Subsec. (c)(1). Pub. L. 100-607, §157(b), substituted “24 months after November 4, 1988” for “thirty months after November 20, 1985”.

Subsec. (c)(2). Pub. L. 100-607, §156(1), substituted “24-month period beginning on November 4, 1988” for “thirty-six month period beginning on November 20, 1985”.

Subsec. (c)(3). Pub. L. 100-607, §156(2), substituted “1990” for “1988”.

NULLIFICATION OF CERTAIN PROVISIONS

Section 121(c) of Pub. L. 103-43 provided that: “The provisions of Executive Order 12806 (57 Fed. Reg. 21589 (May 21, 1992)) [formerly set out below] shall not have any legal effect. The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect.”

EXECUTIVE ORDER NO. 12806. ESTABLISHMENT OF FETAL TISSUE BANK

Ex. Ord. No. 12806, May 19, 1992, 57 F.R. 21589, which established a human fetal tissue bank, was nullified by Pub. L. 103-43, title I, §121(c), June 10, 1993, 107 Stat. 133, set out above.

FEDERAL FUNDING OF FETAL TISSUE TRANSPLANTATION RESEARCH

Memorandum of President of the United States, Jan. 22, 1993, 58 F.R. 7457, provided:

Memorandum for the Secretary of Health and Human Services

On March 22, 1988, the Assistant Secretary for Health of Health and Human Services (“HHS”) imposed a temporary moratorium on Federal funding of research involving transplantation of fetal tissue from induced abortions. Contrary to the recommendations of a National Institutes of Health advisory panel, on November 2, 1989, the Secretary of Health and Human Services extended the moratorium indefinitely. This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson’s disease, Alzheimer’s disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

WILLIAM J. CLINTON.

§ 289g-1. Research on transplantation of fetal tissue

(a) Establishment of program

(1) In general

The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) Source of tissue

Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

(b) Informed consent of donor

(1) In general

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the woman providing the tissue

makes a statement, made in writing and signed by the woman, declaring that—

(A) the woman donates the fetal tissue for use in research described in subsection (a) of this section;

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) Additional statement

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician’s interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman’s medical care.

(c) Informed consent of researcher and donee

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to termi-

nate the pregnancy made solely for the purposes of the research.

(d) Availability of statements for audit

(1) In general

In research carried out under subsection (a) of this section, human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) of this section will be available for audit by the Secretary.

(2) Confidentiality of audit

Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) Applicability of State and local law

(1) Research conducted by recipients of assistance

The Secretary may not provide support for research under subsection (a) of this section unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) Research conducted by Secretary

The Secretary may conduct research under subsection (a) of this section only in accordance with applicable State and local law.

(f) Report

The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) of this section has been conducted in accordance with this section.

(g) “Human fetal tissue” defined

For purposes of this section, the term “human fetal tissue” means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

(July 1, 1944, ch. 373, title IV, §498A, as added Pub. L. 103-43, title I, §111, June 10, 1993, 107 Stat. 129.)

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

NULLIFICATION OF MORATORIUM

Section 113 of Pub. L. 103-43 provided that:

“(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act [this section] (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act [June 10, 1993].

“(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

“(1) IN GENERAL.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act [section 289a-1(b)(2) of this title] (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may not withhold funds for the research if—

“(A) the research has been approved for purposes of subsection (a) of such section 492A;

“(B) the research will be carried out in accordance with section 498A of such Act [this section] (as added by section 111 of this Act); and

“(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act [section 289g-2(a) of this title] (as added by section 112 of this Act).

“(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

“(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act (as added by section 101 of this Act); and

“(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

“(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

“(d) DEFINITION.—For purposes of this section, the term ‘human fetal tissue’ has the meaning given such term in section 498A(f) of the Public Health Service Act [subsec. (f) of this section] (as added by section 111 of this Act).”

REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS

Section 114 of Pub. L. 103-43 provided that, with respect to research on the transplantation of human fetal tissue for therapeutic purposes, the Comptroller General of the United States was to conduct an audit for the purpose of determining whether and to what extent such research conducted or supported by Secretary of Health and Human Services had been conducted in accordance with this section and whether and to what extent there have been violations of section 289g-2 of this title and directed the Comptroller General to complete the audit and report the findings to Congress, not later than May 19, 1995.

§ 289g-2. Prohibitions regarding human fetal tissue**(a) Purchase of tissue**

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.

(b) Solicitation or acceptance of tissue as directed donation for use in transplantation

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

(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

(2) the donated tissue will be transplanted into a relative of the donating individual; or

(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

(c) Solicitation or acceptance of tissue from fetuses gestated for research purposes

It shall be unlawful for any person or entity involved or engaged in interstate commerce to—

(1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue; or

(2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

(d) Criminal penalties for violations**(1) In general**

Any person who violates subsection (a), (b), or (c) shall be fined in accordance with title 18, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) Penalties applicable to persons receiving consideration

With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

(e) Definitions

For purposes of this section:

(1) The term “human fetal tissue” has the meaning given such term in section 289g-1(g) of this title.

(2) The term “interstate commerce” has the meaning given such term in section 321(b) of title 21.

(3) The term “valuable consideration” does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

(July 1, 1944, ch. 373, title IV, §498B, as added Pub. L. 103-43, title I, §112, June 10, 1993, 107 Stat. 131; amended Pub. L. 109-242, §2, July 19, 2006, 120 Stat. 570.)

AMENDMENTS

2006—Subsec. (c). Pub. L. 109-242, §2(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 109-242, §2(1), (3), redesignated subsec. (c) as (d) and substituted “(a), (b), or (c)” for “(a) or (b)” in par. (1). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 109-242, §2(1), (4), redesignated subsec. (d) as (e) and substituted “section 289g-1(g)” for “section 289g-1(f)” in par. (1).

§ 289g-3. Breast implant research**(a) In general**

The Director of NIH may conduct or support research to examine the long-term health implications of silicone breast implants, both gel and saline filled. Such research studies may include the following:

(1) Developing and examining techniques to measure concentrations of silicone in body fluids and tissues.

(2) Surveillance of recipients of silicone breast implants, including long-term outcomes and local complications.

(b) Definition

For purposes of this section, the term “breast implant” means a breast prosthesis that is implanted to augment or reconstruct the female breast.

(July 1, 1944, ch. 373, title IV, §498C, as added Pub. L. 107-250, title II, §215(b), Oct. 26, 2002, 116 Stat. 1615.)

BREAST IMPLANTS; STUDY BY COMPTROLLER GENERAL

Pub. L. 107-250, title II, §214, Oct. 26, 2002, 116 Stat. 1615, provided that:

“(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the following with respect to breast implants:

“(1) The content of information typically provided by health professionals to women who consult with such professionals on the issue of whether to undergo breast implant surgery.

“(2) Whether such information is provided by physicians or other health professionals, and whether the information is provided verbally or in writing, and at what point in the process of determining whether to undergo surgery is such information provided.

“(3) Whether the information presented, as a whole, provides a complete and accurate discussion of the risks and benefits of breast implants, and the extent to which women who receive such information understand the risks and benefits.

“(4) The number of adverse events that have been reported, and whether such events have been adequately investigated.