

Service Act [42 U.S.C. 289a-1(b)(5)(B)(ii)] (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 [42 U.S.C. 289g-1(f)] (as added by section 111 of this Act).”

REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS

Pub. L. 103-43, title I, §114, June 10, 1993, 107 Stat. 132, 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.)

Editorial Notes

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.)

Statutory Notes and Related Subsidiaries

BREAST IMPLANTS; STUDY BY COMPTROLLER GENERAL

Pub. L. 107-250, title II, §214, Oct. 26, 2002, 116 Stat. 1615, which provided that the Comptroller General was

to conduct a study of information typically provided by health professionals to women on breast implant surgery and to report the findings of the study to Congress, was repealed by Pub. L. 111-8, div. G, title I, §1301(g), Mar. 11, 2009, 123 Stat. 829.

§ 289g-4. Support for emergency medicine research

(a) Emergency medical research

The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine, including—

- (1) the basic science of emergency medicine;
- (2) the model of service delivery and the components of such models that contribute to enhanced patient health outcomes;
- (3) the translation of basic scientific research into improved practice; and
- (4) the development of timely and efficient delivery of health services.

(b) Pediatric emergency medical research

The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine, including—

- (1) an examination of the gaps and opportunities in pediatric emergency care research and a strategy for the optimal organization and funding of such research;
- (2) the role of pediatric emergency services as an integrated component of the overall health system;
- (3) system-wide pediatric emergency care planning, preparedness, coordination, and funding;
- (4) pediatric training in professional education; and
- (5) research in pediatric emergency care, specifically on the efficacy, safety, and health outcomes of medications used for infants, children, and adolescents in emergency care settings in order to improve patient safety.

(c) Impact research

The Secretary shall support research to determine the estimated economic impact of, and savings that result from, the implementation of coordinated emergency care systems.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title IV, §498D, as added Pub. L. 111-148, title III, §3504(b), Mar. 23, 2010, 124 Stat. 521.)

§ 289g-5. Precision medicine initiative

(a) In general

The Secretary is encouraged to establish and carry out an initiative, to be known as the “Precision Medicine Initiative” (in this section referred to as the “Initiative”), to augment efforts to address disease prevention, diagnosis, and treatment.

(b) Components

The Initiative described under subsection (a) may include—

- (1) developing a network of scientists to assist in carrying out the purposes of the Initiative;
- (2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;
- (3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;
- (4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and
- (5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

(c) Authority of the Secretary

In carrying out this section, the Secretary may—

- (1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;
- (2) develop and utilize public-private partnerships; and
- (3) leverage existing data sources.

(d) Requirements

In the implementation of the Initiative under subsection (a), the Secretary shall—

- (1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;
- (2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;
- (3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;
- (4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;
- (5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and
- (6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such infor-