

103<sup>D</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1175

To amend the Public Health Service Act to establish authorities and protections regarding the transplantation of human fetal tissue.

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IN THE HOUSE OF REPRESENTATIVES

MARCH 2, 1993

Mr. OBEY introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to establish authorities and protections regarding the transplantation of human fetal tissue.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Research on Human  
5 Fetal Tissue Amendments of 1993”.

1 **SEC. 2. ESTABLISHMENT OF AUTHORITIES AND PROTEC-**  
2 **TIONS REGARDING TRANSPLANTATION OF**  
3 **HUMAN FETAL TISSUE.**

4 Part G of title IV of the Public Health Service Act  
5 (42 U.S.C. 289 et seq.) is amended by inserting after sec-  
6 tion 498 the following new section:

7 “RESEARCH ON TRANSPLANTATION OF FETAL TISSUE

8 “SEC. 498A. (a) ESTABLISHMENT OF PROGRAM.—

9 “(1) IN GENERAL.—The Secretary may conduct  
10 or support research on the transplantation of human  
11 fetal tissue for therapeutic purposes.

12 “(2) SOURCE OF TISSUE.—Human fetal tissue  
13 may be used in research carried out under para-  
14 graph (1) regardless of whether the tissue is ob-  
15 tained pursuant to a spontaneous or induced abor-  
16 tion or pursuant to a stillbirth.

17 “(b) INFORMED CONSENT OF DONOR.—

18 “(1) IN GENERAL.—In research carried out  
19 under subsection (a), human fetal tissue may be  
20 used only if the woman providing the tissue makes  
21 a statement, made in writing and signed by the  
22 woman, declaring that—

23 “(A) the woman donates the fetal tissue  
24 for use in research described in subsection (a);

25 “(B) the donation is made without any re-  
26 striction regarding the identity of individuals

1           who may be the recipients of transplantations  
2           of the tissue; and

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

5           “(2) ADDITIONAL STATEMENT.—In research  
6           carried out under subsection (a), human fetal tissue  
7           may be used only if the attending physician with re-  
8           spect to obtaining the tissue from the woman in-  
9           volved makes a statement, made in writing and  
10          signed by the physician, declaring that—

11           “(A) in the case of tissue obtained pursu-  
12          ant to an induced abortion—

13           “(i) the consent of the woman for the  
14           abortion was obtained prior to requesting  
15           or obtaining consent for the tissue to be  
16           used in such research; and

17           “(ii) no alteration of the timing,  
18           method, or procedures used to terminate  
19           the pregnancy was made solely for the pur-  
20           poses of obtaining the tissue;

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

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

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

4           “(ii) any known medical risks to the  
5           woman or risks to her privacy that might  
6           be associated with the donation of the tis-  
7           sue and that are in addition to risks of  
8           such type that are associated with the  
9           woman’s medical care.

10       “(c) INFORMED CONSENT OF RESEARCHER AND  
11       DONEE.—In research carried out under subsection (a),  
12       human fetal tissue may be used only if the individual with  
13       the principal responsibility for conducting the research in-  
14       volved makes a statement, made in writing and signed by  
15       the individual, declaring that the individual—

16           “(1) is aware that—

17               “(A) the tissue is human fetal tissue;

18               “(B) the tissue may have been obtained  
19               pursuant to a spontaneous or induced abortion  
20               or subsequent to a stillbirth; and

21               “(C) the tissue was donated for research  
22               purposes;

23           “(2) has provided such information to other in-  
24           dividuals with responsibilities regarding the research;

1           “(3) will require, prior to obtaining the consent  
2 of an individual to be a recipient of a transplan-  
3 tation of the tissue, written acknowledgment of re-  
4 ceipt of such information by such recipient; and

5           “(4) has had no part in any decisions as to the  
6 timing, method, or procedures used to terminate the  
7 pregnancy made solely for the purposes of the re-  
8 search.

9           “(d) AVAILABILITY OF STATEMENTS FOR AUDIT.—

10           “(1) IN GENERAL.—In research carried out  
11 under subsection (a), human fetal tissue may be  
12 used only if the head of the agency or other entity  
13 conducting the research involved certifies to the Sec-  
14 retary that the statements required under sub-  
15 sections (b)(2) and (c) will be available for audit by  
16 the Secretary.

17           “(2) CONFIDENTIALITY OF AUDIT.—Any audit  
18 conducted by the Secretary pursuant to paragraph  
19 (1) shall be conducted in a confidential manner to  
20 protect the privacy rights of the individuals and enti-  
21 ties involved in such research, including such indi-  
22 viduals and entities involved in the donation, trans-  
23 fer, receipt, or transplantation of human fetal tissue.  
24 With respect to any material or information obtained  
25 pursuant to such audit, the Secretary shall—

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

4           “(B) not disclose or publish such material  
5           or information, except where required by Fed-  
6           eral law, in which case such material or infor-  
7           mation shall be coded in a manner such that  
8           the identities of such individuals and entities  
9           are protected; and

10           “(C) not maintain such material or infor-  
11           mation after completion of such audit, except  
12           where necessary for the purposes of such audit.

13           “(e) APPLICABILITY OF STATE AND LOCAL LAW.—

14           “(1) RESEARCH CONDUCTED BY RECIPIENTS  
15           OF ASSISTANCE.—The Secretary may not provide  
16           support for research under subsection (a) unless the  
17           applicant for the financial assistance involved agrees  
18           to conduct the research in accordance with applica-  
19           ble State and local law.

20           “(2) RESEARCH CONDUCTED BY SECRETARY.—  
21           The Secretary may conduct research under sub-  
22           section (a) only in accordance with applicable State  
23           and local law.

24           “(f) DEFINITION.—For purposes of this section, the  
25           term ‘human fetal tissue’ means tissue or cells obtained

1 from a dead human embryo or fetus after a spontaneous  
2 or induced abortion, or after a stillbirth.”.

3 **SEC. 3. PURCHASE OF HUMAN FETAL TISSUE; SOLICITA-**  
4 **TION OR ACCEPTANCE OF TISSUE AS DI-**  
5 **RECTED DONATION FOR USE IN TRANSPLAN-**  
6 **TATION.**

7 Part G of title IV of the Public Health Service Act,  
8 as amended by section 2 of this Act, is amended by insert-  
9 ing after section 498A the following new section:

10 “PROHIBITIONS REGARDING HUMAN FETAL TISSUE

11 “SEC. 498B. (a) PURCHASE OF TISSUE.—It shall be  
12 unlawful for any person to knowingly acquire, receive, or  
13 otherwise transfer any human fetal tissue for valuable con-  
14 sideration if the transfer affects interstate commerce.

15 “(b) SOLICITATION OR ACCEPTANCE OF TISSUE AS  
16 DIRECTED DONATION FOR USE IN TRANSPLANTATION.—  
17 It shall be unlawful for any person to solicit or knowingly  
18 acquire, receive, or accept a donation of human fetal tissue  
19 for the purpose of transplantation of such tissue into an-  
20 other person if the donation affects interstate commerce,  
21 the tissue will be or is obtained pursuant to an induced  
22 abortion, and—

23 “(1) the donation will be or is made pursuant  
24 to a promise to the donating individual that the do-  
25 nated tissue will be transplanted into a recipient  
26 specified by such individual;

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

3           “(3) the person who solicits or knowingly ac-  
4 quires, receives, or accepts the donation has provided  
5 valuable consideration for the costs associated with  
6 such abortion.

7           “(c) CRIMINAL PENALTIES FOR VIOLATIONS.—

8           “(1) IN GENERAL.—Any person who violates  
9 subsection (a) or (b) shall be fined in accordance  
10 with title 18, United States Code, subject to para-  
11 graph (2), or imprisoned for not more than 10  
12 years, or both.

13           “(2) PENALTIES APPLICABLE TO PERSONS RE-  
14 CEIVING CONSIDERATION.—With respect to the im-  
15 position of a fine under paragraph (1), if the person  
16 involved violates subsection (a) or (b)(3), a fine shall  
17 be imposed in an amount not less than twice the  
18 amount of the valuable consideration received.

19           “(d) DEFINITIONS.—For purposes of this section:

20           “(1) The term ‘human fetal tissue’ has the  
21 meaning given such term in section 498A(f).

22           “(2) The term ‘interstate commerce’ has the  
23 meaning given such term in section 201(b) of the  
24 Federal Food, Drug, and Cosmetic Act.

1           “(3) The term ‘valuable consideration’ does not  
2 include reasonable payments associated with the  
3 transportation, implantation, processing, preserva-  
4 tion, quality control, or storage of human fetal tis-  
5 sue.”.

6 **SEC. 4. REPORT BY GENERAL ACCOUNTING OFFICE ON**  
7 **ADEQUACY OF PROTECTIONS.**

8           (a) IN GENERAL.—With respect to research on the  
9 transplantation of human fetal tissue for therapeutic pur-  
10 poses, the Comptroller General of the United States shall  
11 conduct an audit for the purpose of determining—

12           (1) whether and to what extent such research  
13 conducted or supported by the Secretary of Health  
14 and Human Services has been conducted in accord-  
15 ance with section 498A of the Public Health Service  
16 Act (as added by section 2 of this Act); and

17           (2) whether and to what extent there have been  
18 violations of section 498B of such Act (as added by  
19 section 3 of this Act).

20           (b) REPORT.—Not later than May 19, 1995, the  
21 Comptroller General of the United States shall complete  
22 the audit required in subsection (a) and submit to the  
23 Congress a report describing the findings made pursuant  
24 to the audit.

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