
The Fair Labeling and Informed Consent Act (Introduced in House) HR XXXX

110th CONGRESS

H. R. XXXX

IN THE HOUSE OF REPRESENTATIVES

xx (month) yy (day), 2008

Mr. xxxx introduced the following amendment to the [Federal Food, Drug and Cosmetic Act], which was referred to the Committee on [Energy and Commerce]

A BILL

To amend labeling requirements and informed consent procedures for all vaccines and medical products using aborted fetal material in any form including but not limited to cells, cell lines, tissues, DNA, recombinant DNA, monoclonal antibodies, blood, proteins or components thereof, in manufacturing or development.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as ‘F.L.I.C.A.’

SEC. 2. PURPOSES.

It is the purpose of this Act to--

- (1) require the manufacturers and distributors to provide information if the development or manufacture of their product uses aborted fetal material in any form including but not limited to cells, cell lines, tissues, DNA, recombinant DNA, monoclonal antibodies, blood, proteins or components thereof, in manufacturing or development.
- (2) specifically, require the manufacturers and distributors to provide such information the product label; and
- (3) require the revision of the Vaccine Information Statement (VIS) currently provided under 42 USC, § 300AA-26, prior to vaccination, to include the information as described in (1).

4) protect the legal right of patients to give their valid informed consent by requiring that attending physicians, nurses, midwives, pharmacists or any other health care provider with the appropriate knowledge, shall provide all such information to patients before dispensing any product or treatment that contains human cell lines, tissues, proteins, DNA, recombinant DNA, monoclonal antibodies or any other components derived from elective abortion by amending the Vaccine Information Sheet. (VIS) as required under 42 USC § 300AA-26.

5) protect the legal right of physicians, nurses, midwives, pharmacists or any other health care professional to receive and provide valid informed consent for themselves and their patients prior to purchasing or dispensing any product or treatment that contains human cell lines, tissues, proteins, DNA, recombinant DNA, monoclonal antibodies or any other components derived from elective abortion, by amending the manufacturer package insert and VIS.

6) protect the civil rights of all such individuals when the use of such drugs and vaccinations would violate a person's religious or moral convictions; and to prohibit all forms of discrimination, coercion, or liability upon such persons by reason of such refusal.

SEC 3: ENACTMENT

a) Revision of Package Insert (See Sec. 7 Addendum 1.)

All vaccines and medical products using aborted fetal material in any form including but not limited to cells, cell lines, tissues, DNA, recombinant DNA, monoclonal antibodies, blood, proteins or components must include the term **“from elective abortion”** in the package insert description, immediately following these ingredients.

b) Revision of the Federal Food, Drug and Cosmetic Act, 502 (e) to the end of paragraph (iii) the word “and”, followed by new paragraph:

(iv) the term **“from elective abortion”** must appear next to any ingredients including, but not limited to human cell lines, tissues, proteins, DNA, recombinant DNA, monoclonal antibodies or any other components that take their origin in elective abortion.

c) Revision of Vaccine Information Statement (VIS) to include section of Informed Consent on any product using aborted fetal materials as described in Paragraph (a) (See Sec. 7 Addendum 2)

d) Revision of US Code: 42 USC §300aa-26, paragraph (c) ‘Information requirements’

(4) a statement of Informed Consent when aborted fetal materials are used in any current or future vaccines or drugs, and

e) Revision of US Code: 42 USC §300aa-26 to add paragraph (e)
(E) VIS shall be prepared and required for all vaccines or drugs utilizing aborted fetal materials as described in Section (a).

SEC. 4: CURRENT POLICY

a) It is the current policy of the United States through the Federal Food and Drug and Administration to provide information on the ingredients in the labeling of all prescription and non-prescription drugs including, but not limited to the descriptions found in the Code of Federal Regulations 21 CFR Part 201, Labeling and 42 USC, § 300aa-26 and the Federal Food, Drug and Cosmetic Act, 502 (e).

b) In accordance with such procedures of 21 CFR 201.56 and 201.57, all prescription and non-prescription drugs and vaccinations must be labeled in the required format to include: "Description", "Clinical Pharmacology", "Indications and Usage", "Warnings", "Precautions", "Adverse Reactions", "Drug Abuse and Dependence", "Overdose", Dosage and Administration and "How Supplied". Section 201.57 specifies the exact information that is required to appear in these sections.

c) It is the current policy of the United States under US Code, Title 15, Chapter 39, §1451 that, 'Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.'

d) It is the current policy of the Federal and State laws of 48 states and the District of Columbia to allow religious and or philosophical exemptions to vaccination when the use of such products would violate religious beliefs, tenets or practices. (DS Form 122.1 and related State exemption laws)

SEC. 5: DEFINITIONS

a) "Health care provider" means any public or private corporation, partnership, association, organization, agency or other legal entity that is involved directly or indirectly in providing health care services, including, without limitation, any public or private hospital, clinic, medical center, research facility, medical school, nursing school or other medical training institution, laboratory or diagnostic facility, physician's office, infirmary, dispensary, ambulatory surgical treatment center, public health center or school administering vaccinations, prescription or non-prescription drugs or medical treatments.

b) "Prescription or non-prescription drug" means any medical product or treatment prescribed by or administered by health care personnel to patients.

c) "Patient" means any human being or any parent or legal guardian of a person acting in behalf of a human being, receiving a prescription or non-prescription drug, vaccination or medical treatment subject to the regulations of this Act.

d) "Elective abortion" means: "All the measures which impair the viability of the zygote [newly-conceived embryo] at any time from the moment of fertilization through the completion of labor constitute, in the strict sense, procedures for inducing abortion," as defined in the U.S. Public Health Service Leaflet, #1066, US Department of Health, Education & Welfare, 1963, Pg 27.

e) "Fair labeling" shall mean that the human fetal or embryonic cell lines, proteins, DNA, recombinant DNA, monoclonal antibodies or any other components derived from elective abortion shall be clearly labeled as such and listed under the product's "Description" in the manufacturer package insert.

f) "Informed consent" means that patients, attending physicians, nurses, midwives, pharmacists or any other health care professional are provided with the appropriate foreknowledge through the amended VIS in order to freely decide to receive, produce, or dispense any product or treatment that contains human fetal or embryonic tissue, cell lines, proteins, DNA, recombinant DNA monoclonal antibodies or any other components derived from elective abortion.

SEC. 6: FREEDOM OF CONSCIENCE

a) All persons have the right not to receive, produce, provide, perform, assist, or participate in directly or indirectly the use of health care products as described herein that would be contrary to their religious or moral convictions or conscience.

b) No individual shall be civilly or criminally, legally or administratively liable to any person for any refusal to produce, provide, use, assist, or participate directly or indirectly in the use of health care products as described herein that violate one's religious or moral convictions or conscience.

c) No person shall discriminate against, penalize, discipline, or retaliate against any individual in employment, privileges, benefits, remuneration, promotion, termination of employment; or in eligibility for, admission to, renewal or participation in, or graduation from any educational, study, or training program; or in any grant, contract, research or other program because of his or her refusal or unwillingness to provide, use, perform, assist, or participate directly or indirectly in the use of health care products as described herein that violate his or her religious or moral convictions or conscience.

d) It shall be unlawful for any person, public or private institution, or public official to discriminate against any person, association, health official or corporation refusing to provide health care products as described herein that violate his or her religious or moral convictions or conscience in any manner, including but not limited to, deprivation, or disqualification of financial aids, assistance, benefits, or any other privileges.

SEC. 6: AUTHORITY TO ENFORCE THIS ACT

a) The United States may bring an action for injunctive or declaratory relief to enforce compliance with this Act including but not limited to: (1) Suspension of product licensing, and (2) Criminal penalties and fines as recorded in 21 USC, FDC Act, Chapter 9, Subchapter III, § 333(a)(2)

b) No rule or regulation shall impair or delay any person who believes that his or her or its rights under this Act have been violated from bringing an action in any State or Federal court.

Sec. 7: ADDENDUM

1) SAMPLE PACKAGE INSERT REVISION - MMR VACCINE:

MERUVAX II (Rubella Virus Vaccine Live), the Wistar RA 27/3 strain from elective abortion of live attenuated rubella virus propagated in WI-38 human diploid lung fibroblasts from elective abortion.

2) SAMPLE VIS CHANGE FOR POLIO VACCINE - INSERT PARAGRAPH - INFORMED CONSENT-

Informed Consent

Is there anything else I should know?

Informed Consent Doctrine requires that health care professionals provide patients with all relevant information about a proposed procedure including: the nature of the procedure, the risks, the benefits and the availability of alternative treatment, (including no treatment) and the risks and benefits thereof.

Informed consent protects the patient by providing him/her with complete information on which to make an informed decision.

Because some patients may have religious or moral concerns about abortion, you are entitled to know that some[polio] vaccines are propagated on cell lines obtained from electively aborted fetuses. Those vaccines contain residual DNA, cell components and proteins from the aborted fetal cell line.

There are also other versions of [IPV] available in the US using non-human cell lines. Ask your doctor for more information on these alternatives. See Section 1 for more information on the disease.

- End VIS Revision-