

111TH CONGRESS
1ST SESSION

H. R. 2617

To amend the Federal Food, Drug, and Cosmetic Act to reduce human exposure to mercury through vaccines.

IN THE HOUSE OF REPRESENTATIVES

MAY 21, 2009

Mrs. MALONEY (for herself, Mr. SMITH of New Jersey, Mr. KENNEDY, Mr. BURTON of Indiana, and Mr. ACKERMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reduce human exposure to mercury through vaccines.

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 “Mercury-Free Vaccines
5 Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) In July 1999, the Public Health Service
9 and the American Academy of Pediatrics issued a
10 joint statement, which was later endorsed by the

1 American Academy of Family Physicians, pro-
2 claiming: “[The] Public Health Service, the Amer-
3 ican Academy of Pediatrics, and vaccine manufac-
4 turers agree that thimerosal-containing vaccines
5 should be removed as soon as possible. Similar con-
6 clusions were reached this year in a meeting at-
7 tended by European regulatory agencies, the Euro-
8 pean vaccine manufacturers, and the US FDA which
9 examined the use of thimerosal-containing vaccines
10 produced or sold in European countries.”.

11 (2) In July 2000, the Public Health Service,
12 the Advisory Commission on Immunization Prac-
13 tices, the American Academy of Pediatrics, and the
14 American Academy of Family Physicians issued a
15 joint statement, providing: “The AAFP, [the] AAP,
16 and the PHS in consultation with the ACIP reaffirm
17 the goal set in July 1999 to remove or greatly re-
18 duce thimerosal from vaccines as soon as possible
19 for the following reasons: (1) the removal or sub-
20 stantial reduction of thimerosal from vaccines is fea-
21 sible, (2) the progress in removal which has been
22 made to date is substantial, (3) the discussions be-
23 tween the Food and Drug Administration and the
24 vaccine manufacturers in removing thimerosal are
25 ongoing, and (4) the public concern about the use of

1 mercury of any sort remains high. Based on infor-
2 mation from the FDA and manufacturers, the PHS
3 projects that the United States will complete its
4 transition to a secure routine pediatric vaccine sup-
5 ply free of thimerosal as a preservative (i.e., at least
6 two vaccine products each for Hep B, Hib, and
7 DTaP) by the first quarter of 2001.”.

8 (3) The Institute of Medicine’s Immunization
9 Review Committee concluded that significant reasons
10 existed for continued public health attention to con-
11 cerns about thimerosal exposure and
12 neurodevelopmental disorders and recommended the
13 removal of thimerosal from vaccines administered to
14 children and pregnant women.

15 (4) Federal regulatory agencies and manufac-
16 turers have taken positive steps to remove thimer-
17 osal from some medical products, most notably rou-
18 tinely administered childhood vaccines.

19 (5) Considerable progress has been made in re-
20 ducing mercury exposures from childhood vaccines,
21 yet 10 years after the July 1999 statement, thimer-
22 osal remains in several nonroutinely administered
23 childhood vaccines and many pediatric and adult in-
24 fluenza vaccines.

1 (6) There is no law or regulation to prohibit the
2 reintroduction of thimerosal into any products from
3 which it has been removed, leaving open the possi-
4 bility that it may be reintroduced at some point in
5 the future in new vaccines or vaccines from which it
6 has already been removed.

7 (7) The Environmental Protection Agency has
8 estimated that as many as 1 in 6 infants are born
9 with a blood mercury level that exceeds the Agency’s
10 safety threshold.

11 (8) Cumulative exposures to mercury, a
12 neurotoxin, are known to cause harm, particularly in
13 young children and pregnant women.

14 (9) Taking steps to reduce mercury exposures
15 through vaccines is an important way to reduce di-
16 rect exposures to mercury and mercury compounds.

17 **SEC. 3. BANNED MERCURY-CONTAINING VACCINES.**

18 (a) PROHIBITION.—Section 501 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 351) is amended by
20 adding at the end the following:

21 “(j) If it is a banned mercury-containing vaccine
22 under section 351B of the Public Health Service Act.”.

23 (b) AMENDMENT TO PHSA.—Title III of the Public
24 Health Service Act (42 U.S.C. 241 et seq.) is amended
25 by inserting after section 351A the following:

1 **“SEC. 351B. BANNED MERCURY-CONTAINING VACCINES.**

2 “(a) IN GENERAL.—For purposes of section 501(j)
3 of the Federal Food, Drug, and Cosmetic Act, and subject
4 to subsection (b), a vaccine is a banned mercury-con-
5 taining vaccine under this section if 1 dose of the vaccine
6 contains 1 or more micrograms of mercury in any form.

7 “(b) PUBLIC HEALTH EMERGENCY EXCEPTION.—

8 “(1) EXCEPTION.—Section 501(j) of the Fed-
9 eral Food, Drug, and Cosmetic Act shall not apply
10 to a vaccine during the effective period of a declara-
11 tion issued by the Secretary for such vaccine under
12 this subsection.

13 “(2) DECLARATION.—The Secretary may issue
14 a declaration concluding that an actual or potential
15 bioterrorist incident or other actual or potential pub-
16 lic health emergency makes advisable the adminis-
17 tration of a vaccine described in subsection (a) not-
18 withstanding the mercury content of such vaccine.

19 “(3) LIMITATION.—The Secretary—

20 “(A) shall specify in any declaration under
21 this section the beginning and ending dates of
22 the effective period of the declaration; and

23 “(B) may not specify any such effective pe-
24 riod that exceeds 12 months.

25 “(4) RENEWALS.—At the end of the effective
26 period of any declaration under this section, the Sec-

1 retary, subject to paragraph (3), may issue another
2 declaration for the same incident or public health
3 emergency.

4 “(5) PUBLICATION.—The Secretary shall
5 promptly publish each declaration under this section
6 in the Federal Register.

7 “(c) EFFECTIVE DATES.—This section applies only
8 to the introduction, or delivery for introduction, of a
9 banned mercury-containing vaccine into interstate com-
10 merce on or after the earlier of the following:

11 “(1) January 1, 2010, if the vaccine is listed in
12 the January 2009 version of the recommended child-
13 hood and adolescent immunization schedule of the
14 Centers for Disease Control and Prevention (other
15 than an influenza vaccine).

16 “(2) January 1, 2011.”.

17 **SEC. 4. RESTRICTIONS ON ADMINISTRATION OF MERCURY-**
18 **CONTAINING INFLUENZA VACCINES TO CHIL-**
19 **DREN AND PREGNANT WOMEN.**

20 (a) APPLICATION.—This section applies only to a vac-
21 cine that—

22 (1) is a banned mercury-containing vaccine (as
23 that term is defined in section 351B(a) of the Public
24 Health Service Act (as amended by section 3));

25 (2) is an influenza vaccine; and

1 (3) is manufactured for use in the 2009–2010
2 influenza season or any subsequent period.

3 (b) RESTRICTIONS ON ADMINISTRATION OF VACCINE
4 TO CHILDREN.—Any approval by the Secretary of Health
5 and Human Services of a biologics license under section
6 351 of the Public Health Service Act (42 U.S.C. 262) for
7 any vaccine described in subsection (a) shall provide that
8 such vaccine is being approved as a biological product sub-
9 ject to subpart H of part 314 of title 21, Code of Federal
10 Regulations (or any successor regulations). Under such
11 subpart H, the Secretary shall establish the following re-
12 strictions on the distribution of the vaccine:

13 (1) Effective July 1, 2009, the vaccine shall not
14 be administered to any child under the age of 3
15 years old.

16 (2) Effective July 1, 2009, if the vaccine con-
17 tains thimerosal, the vaccine shall not be adminis-
18 tered to any pregnant woman.

19 (3) Effective July 1, 2010, the vaccine shall not
20 be administered to any child under the age of 6
21 years old.

22 (c) TRANSITIONAL PROVISION.—In the case of a bio-
23 logics license under section 351 of the Public Health Serv-
24 ice Act (42 U.S.C. 262) that was approved before the date

1 of the enactment of this Act for a vaccine described in
2 subsection (a)—

3 (1) at the request of the holder of the license,
4 the Secretary shall modify the license to include the
5 restrictions described in subsection (b); or

6 (2) if the holder of the license fails to submit
7 such a request, the Secretary shall revoke the license
8 as applied to vaccines manufactured for use in the
9 2009–2010 influenza season or any subsequent pe-
10 riod.

11 (d) PUBLIC HEALTH EMERGENCY EXCEPTION.—
12 This section shall not apply to a vaccine during the effec-
13 tive period of a declaration issued by the Secretary for
14 such vaccine under section 351B(b) of the Public Health
15 Service Act (as amended by section 3).

16 **SEC. 5. INFORMATION ON MERCURY CONTENT.**

17 Section 2126 of the Public Health Service Act (42
18 U.S.C. 300aa–26) is amended by adding at the end the
19 following:

20 “(e) MERCURY CONTENT.—Not later than 2 months
21 after the date of the enactment of this subsection, the Sec-
22 retary shall revise the vaccine information materials devel-
23 oped and disseminated under this section to ensure that,
24 in the case of any vaccine described in subsection (a) that
25 contains mercury, the materials include—

1 “(1) a statement indicating the presence of
2 mercury in the vaccine;

3 “(2) information on the availability of any mer-
4 cury-free or mercury-reduced alternative vaccine and
5 instructions on how to obtain such alternative vac-
6 cine; and

7 “(3) a recommendation against administration
8 of any mercury-containing vaccine to a pregnant
9 woman.”.

10 **SEC. 6. SENSE OF CONGRESS.**

11 It is the sense of the Congress that the Director of
12 the Centers for Disease Control and Prevention should in-
13 clude, in any information disseminated by the Centers to
14 the public or to health care providers relating to the ad-
15 ministration of vaccines, a recommendation against ad-
16 ministration of any thimerosal-containing vaccine to a
17 pregnant woman.

18 **SEC. 7. REPORT TO CONGRESS.**

19 Not later than 1 year after the date of the enactment
20 of this Act, and annually thereafter, the Commissioner of
21 Food and Drugs shall submit a report to the Congress
22 annually on the progress of the Commissioner in removing
23 mercury from vaccines.

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