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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

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A BILL

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

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 the ''Mercury-Free Vaccines Act of 2009''.

SEC. 2. FINDINGS.

The Congress finds as follows:

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

American Academy of Family Physicians, proclaiming: ''[The] Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible. Similar conclusions were reached this year in a meeting attended by European regulatory agencies, the European vaccine manufacturers, and the US FDA which examined the use of thimerosal-containing vaccines produced or sold in European countries.''.

(2) In July 2000, the Public Health Service, the Advisory Commission on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians issued a joint statement, providing: ''The AAFP, [the] AAP, and the PHS in consultation with the ACIP reaffirm the goal set in July 1999 to remove or greatly reduce thimerosal from vaccines as soon as possible for the following reasons: (1) the removal or substantial reduction of thimerosal from vaccines is feasible, (2) the progress in removal which has been made to date is substantial, (3) the discussions between the Food and Drug Administration and the vaccine manufacturers in removing thimerosal are ongoing, and (4) the public concern about the use of

mercury of any sort remains high. Based on information from the FDA and manufacturers, the PHS projects that the United States will complete its transition to a secure routine pediatric vaccine supply free of thimerosal as a preservative (i.e., at least two vaccine products each for Hep B, Hib, and DTaP) by the first quarter of 2001.''.

(3) The Institute of Medicine's Immunization Review Committee concluded that significant reasons existed for continued public health attention to concerns about thimerosal exposure and neurodevelopmental disorders and recommended the removal of thimerosal from vaccines administered to children and pregnant women.

(4) Federal regulatory agencies and manufacturers have taken positive steps to remove thimerosal from some medical products, most notably routinely administered childhood vaccines.

(5) Considerable progress has been made in reducing mercury exposures from childhood vaccines, yet 10 years after the July 1999 statement, thimerosal remains in several nonroutinely administered childhood vaccines and many pediatric and adult influenza vaccines.

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

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

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

(9) Taking steps to reduce mercury exposures through vaccines is an important way to reduce direct exposures to mercury and mercury compounds.

SEC. 3. BANNED MERCURY-CONTAINING VACCINES.

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

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

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

"SEC. 351B. BANNED MERCURY-CONTAINING VACCINES.

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

"(b) PUBLIC HEALTH EMERGENCY EXCEPTION.—

"(1) EXCEPTION.—Section 501(j) of the Federal Food, Drug, and Cosmetic Act shall not apply to a vaccine during the effective period of a declaration issued by the Secretary for such vaccine under this subsection.

"(2) DECLARATION.—The Secretary may issue a declaration concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a vaccine described in subsection (a) notwithstanding the mercury content of such vaccine.

"(3) LIMITATION.—The Secretary—

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

"(B) may not specify any such effective period that exceeds 12 months.

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

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

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

''(c) EFFECTIVE DATES.—This section applies only to the introduction, or delivery for introduction, of a banned mercury-containing vaccine into interstate commerce on or after the earlier of the following:

''(1) January 1, 2010, if the vaccine is listed in the January 2009 version of the recommended childhood and adolescent immunization schedule of the Centers for Disease Control and Prevention (other than an influenza vaccine).

''(2) January 1, 2011.''.

SEC. 4. RESTRICTIONS ON ADMINISTRATION OF MERCURY-CONTAINING INFLUENZA VACCINES TO CHILDREN AND PREGNANT WOMEN.

(a) APPLICATION.—This section applies only to a vaccine that—

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

(2) is an influenza vaccine; and

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

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

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

(2) Effective July 1, 2009, if the vaccine contains thimerosal, the vaccine shall not be administered to any pregnant woman.

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

(c) TRANSITIONAL PROVISION.—In the case of a biologics license under section 351 of the Public Health Service Act (42 U.S.C. 262) that was approved before the date

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

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

(2) if the holder of the license fails to submit such a request, the Secretary shall revoke the license as applied to vaccines manufactured for use in the 2009–2010 influenza season or any subsequent period.

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

SEC. 5. INFORMATION ON MERCURY CONTENT.

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

''(e) MERCURY CONTENT.—Not later than 2 months after the date of the enactment of this subsection, the Secretary shall revise the vaccine information materials developed and disseminated under this section to ensure that, in the case of any vaccine described in subsection (a) that contains mercury, the materials include—

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

''(2) information on the availability of any mercury-free or mercury-reduced alternative vaccine and instructions on how to obtain such alternative vaccine; and

''(3) a recommendation against administration of any mercury-containing vaccine to a pregnant woman.''.

SEC. 6. SENSE OF CONGRESS.

It is the sense of the Congress that the Director of the Centers for Disease Control and Prevention should include, in any information disseminated by the Centers to the public or to health care providers relating to the administration of vaccines, a recommendation against administration of any thimerosal-containing vaccine to a pregnant woman.

SEC. 7. REPORT TO CONGRESS.

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

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