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108TH CONGRESS
2D SESSION

H. R. 4169

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 2, 2004

Mr. WELDON of Florida (for himself and Mrs. MALONEY) 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 2004''.

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 5 years after the July 1999 statement, thimerosal remains in several nonroutinely administered childhood 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.

(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:

''(h) 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(h) 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) 1 dose of the vaccine contains 1 or more micrograms of mercury in any form; or

''(2) the vaccine contains any quantity of thimerosal and is listed in the current version of the recommended childhood and adolescent immunization schedule of the Centers for Disease Control and Prevention.

''(b) PUBLIC HEALTH EMERGENCY EXCEPTION.—

''(1) EXCEPTION.—Subsection (h) of section 501 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 section.

''(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 or thimerosal 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 Secretary, 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.—

''(1) MERCURY-CONTAINING VACCINES.—In the case of a vaccine described in subsection (a)(1), the amendments made by this section apply only to vaccines introduced, or delivered for introduction, into interstate commerce on or after the following:

''(A) July 1, 2004, if the vaccine is an influenza vaccine.

''(B) January 1, 2005, if the vaccine (other than an influenza vaccine) is listed in the January–June 2004 version of the recommended childhood and adolescent immuniza-

tion schedule of the Centers for Disease Control and Prevention.

''(C) January 1, 2006, in the case of any vaccine not described in subparagraph (A) or (B).

''(2) THIMEROSAL-CONTAINING VACCINES.—In the case of a vaccine that is not described in subsection (a)(1), but is described in subsection (a)(2), the amendments made by this section apply only to vaccines introduced, or delivered for introduction, into interstate commerce on or after January 1, 2007.''.

SEC. 4. INFORMATION ON THIMEROSAL 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) THIMEROSAL 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 thimerosal, the materials include—

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

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

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

SEC. 5. 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. 6. 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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