

109TH CONGRESS  
1ST SESSION

# S. 1422

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

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IN THE SENATE OF THE UNITED STATES

JULY 19, 2005

Mr. HAGEL introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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 2005”.

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 substan-  
20 tial reduction of thimerosal from vaccines is feasible,  
21 2) the progress in removal which has been made to  
22 date is substantial, 3) the discussions between the  
23 Food and Drug Administration and the vaccine  
24 manufacturers in removing thimerosal are ongoing,  
25 and 4) the public concern about the use of mercury

1 of any sort remains high. Based on information from  
2 the FDA and manufacturers, the PHS projects that  
3 the United States will complete its transition to a  
4 secure routine pediatric vaccine supply free of thi-  
5 merosal as a preservative (i.e. at least two vaccine  
6 products each for Hep B, Hib, and DTaP) by the  
7 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 5 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.—Subsection (j) of section  
9 501 of the Federal Food, Drug, and Cosmetic Act  
10 shall not apply to a vaccine during the effective pe-  
11 riod of a declaration issued by the Secretary for  
12 such vaccine under 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) July 1, 2006, if the vaccine is listed in the  
 12      January–June 2005 version of the recommended  
 13      childhood and adolescent immunization schedule of  
 14      the Centers for Disease Control and Prevention  
 15      (other than an influenza vaccine).

16           “(2) January 1, 2009.”.

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 2006–2007  
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, 2006, the vaccine shall not  
14           be administered to any child under the age of 3  
15           years old.

16           (2) Effective July 1, 2006, if the vaccine con-  
17           tains thimerosal, the vaccine shall not be adminis-  
18           tered to any pregnant woman.

19           (3) Effective July 1, 2007, 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 2006–2007 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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