

110TH CONGRESS  
2D SESSION

# H. R. 4991

To amend the Social Security Act, the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act to ensure a sufficient supply of vaccines, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 16, 2008

Mr. WAXMAN (for himself and Ms. ROYBAL-ALLARD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Social Security Act, the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act to ensure a sufficient supply of vaccines, and for other purposes.

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 “Vaccine Shortage Pre-  
5 paredness Act of 2008”.

6 **SEC. 2. SALES FROM 6-MONTH SUPPLY.**

7 Section 1928(d)(6) of the Social Security Act (42  
8 U.S.C. 1396s(d)(6)) is amended by inserting before the

1 last sentence the following: “The Secretary may sell such  
2 quantities of vaccines from such supply to public health  
3 departments or back to the vaccine manufacturers as the  
4 Secretary determines appropriate. Proceeds received from  
5 such sales shall be available to the Secretary only for the  
6 purposes of procuring pediatric vaccine stockpiles under  
7 this section and shall remain available until expended.”.

8 **SEC. 3. ONE-YEAR NOTICE ON DISCONTINUING MANUFAC-**  
9 **TURE OF VACCINE.**

10 Subchapter A of chapter V of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
12 ed by inserting after section 506C the following section:

13 **“SEC. 506D. DISCONTINUANCE OF VACCINE.**

14 “(a) IN GENERAL.—

15 “(1) NOTICE TO SECRETARY.—A manufacturer  
16 of a vaccine approved by the Secretary shall notify  
17 the Secretary of a discontinuance of the manufac-  
18 ture of the vaccine at least 12 months prior to the  
19 date of the discontinuance.

20 “(2) DIRECTOR OF CENTERS FOR DISEASE  
21 CONTROL AND PREVENTION.—Promptly after receiv-  
22 ing a notice under paragraph (1), the Secretary shall  
23 inform the Director of the Centers for Disease Con-  
24 trol and Prevention of the notice. Promptly after de-  
25 termining that a reduction under subsection (b) ap-

1       plies with respect to such a notice, the Secretary  
2       shall inform such Director of the reduction.

3               “(3) RELATIONSHIP TO SEPARATE NOTICE PRO-  
4       GRAM.—In the case of a vaccine that is approved by  
5       the Secretary and is a drug described in section  
6       506C(a), this section applies to the vaccine in lieu  
7       of section 506C.

8               “(b) REDUCTION IN NOTIFICATION PERIOD.—The  
9       notification period required under subsection (a) for a  
10       manufacturer may be reduced if the manufacturer certifies  
11       to the Secretary that good cause exists for the reduction,  
12       such as a situation in which—

13               “(1) a public health problem may result from  
14       continuation of the manufacturing for the 12-month  
15       period;

16               “(2) a biomaterials shortage prevents the con-  
17       tinuation of the manufacturing for the 12-month pe-  
18       riod;

19               “(3) a liability problem may exist for the manu-  
20       facturer if the manufacturing is continued for the  
21       12-month period;

22               “(4) continuation of the manufacturing for the  
23       12-month period may cause substantial economic  
24       hardship for the manufacturer; or

1           “(5) the manufacturer has filed for bankruptcy  
2           under chapter 7 or 11 of title 11, United States  
3           Code.

4           “(c) DISTRIBUTION.—To the maximum extent prac-  
5           ticable, the Secretary shall distribute information on the  
6           discontinuation of the manufacture of vaccines to appro-  
7           priate physician and patient organizations.”.

8   **SEC. 4. CERTAIN AUTHORITIES REGARDING INFLUENZA**  
9                                   **AND OTHER VACCINES.**

10          (a) AUTHORITIES.—Part B of title III of the Public  
11          Health Service Act (42 U.S.C. 243 et seq.) is amended—

12                  (1) by redesignating section 317A as section  
13                  317A–1; and

14                  (2) by inserting after section 317 the following  
15          section:

16   **“SEC. 317A. CERTAIN AUTHORITIES REGARDING INFLU-**  
17                                   **ENZA AND OTHER VACCINES.**

18          “(a) DECLARATION.—The Secretary may declare a  
19          public health emergency if—

20                  “(1) there is a shortage of an approved vaccine  
21                  for an infectious disease; and

22                  “(2) there is a significant risk of a significant  
23                  outbreak of such disease.

24          “(b) REQUIREMENT.—If the Secretary publishes in  
25          the Federal Register a declaration of a public health emer-

1 gency under subsection (a), each person who is a manufac-  
2 turer or distributor of such vaccine shall provide to the  
3 Secretary such information as the Secretary may require  
4 with respect to the location of supplies of the vaccine, in-  
5 cluding supplies in the possession of the person, supplies  
6 scheduled to be received by the person, and supplies sold  
7 by the person. Any such person who fails to comply with  
8 an order of the Secretary under the preceding sentence  
9 is liable to the United States for a civil penalty not exceed-  
10 ing \$1,000 for each day for which the person is in violation  
11 of the order.

12 “(c) AVAILABILITY TO STATES.—

13 “(1) IN GENERAL.—Subject to paragraph (2),  
14 the Secretary shall, at the request of a State, pro-  
15 vide to the State information collected by the Sec-  
16 retary under subsection (b).

17 “(2) RESTRICTION; CONFIDENTIALITY.—The  
18 Secretary may provide to a State information col-  
19 lected by the Secretary under subsection (b) only if  
20 the State agrees—

21 “(A) to restrict its use of the information  
22 to facilitating access to vaccines; and

23 “(B) to otherwise keep such information  
24 confidential.”.

1           (b) STUDY ON REALLOCATION OF VACCINE.—Not  
2 later than 1 year after the date of the enactment of this  
3 Act, the Secretary of Health and Human Services shall  
4 complete a study and submit a report to the Congress on  
5 successful models and alternatives for tracking and facili-  
6 tating, in consultation with State and local health officials,  
7 reallocation of vaccine at the local level in times of short-  
8 age or emergency.

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