I

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.

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

---

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.

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 ''Vaccine Shortage Preparedness Act of 2008''.

SEC. 2. SALES FROM 6-MONTH SUPPLY.

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

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

SEC. 3. ONE-YEAR NOTICE ON DISCONTINUING MANUFACTURE OF VACCINE.

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

''SEC. 506D. DISCONTINUANCE OF VACCINE.

''(a) IN GENERAL.—

''(1) NOTICE TO SECRETARY.—A manufacturer of a vaccine approved by the Secretary shall notify the Secretary of a discontinuance of the manufacture of the vaccine at least 12 months prior to the date of the discontinuance.

''(2) DIRECTOR OF CENTERS FOR DISEASE CONTROL AND PREVENTION.—Promptly after receiving a notice under paragraph (1), the Secretary shall inform the Director of the Centers for Disease Control and Prevention of the notice. Promptly after determining that a reduction under subsection (b) ap-

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

''(3) RELATIONSHIP TO SEPARATE NOTICE PROGRAM.—In the case of a vaccine that is approved by the Secretary and is a drug described in section 506C(a), this section applies to the vaccine in lieu of section 506C.

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

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

''(2) a biomaterials shortage prevents the continuation of the manufacturing for the 12-month period;

''(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 12-month period;

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

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

''(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the manufacture of vaccines to appropriate physician and patient organizations.''.

SEC. 4. CERTAIN AUTHORITIES REGARDING INFLUENZA AND OTHER VACCINES.

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

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

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

''SEC. 317A. CERTAIN AUTHORITIES REGARDING INFLUENZA AND OTHER VACCINES.

''(a) DECLARATION.—The Secretary may declare a public health emergency if—

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

''(2) there is a significant risk of a significant outbreak of such disease.

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

gency under subsection (a), each person who is a manufacturer or distributor of such vaccine shall provide to the Secretary such information as the Secretary may require with respect to the location of supplies of the vaccine, including supplies in the possession of the person, supplies scheduled to be received by the person, and supplies sold by the person. Any such person who fails to comply with an order of the Secretary under the preceding sentence is liable to the United States for a civil penalty not exceeding $1,000 for each day for which the person is in violation of the order.

''(c) AVAILABILITY TO STATES.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, at the request of a State, provide to the State information collected by the Secretary under subsection (b).

''(2) RESTRICTION; CONFIDENTIALITY.—The Secretary may provide to a State information collected by the Secretary under subsection (b) only if the State agrees—

''(A) to restrict its use of the information to facilitating access to vaccines; and

''(B) to otherwise keep such information confidential.''.

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

○