

108TH CONGRESS  
2D SESSION

# H. R. 5243

To amend the Public Health Service Act to provide for emergency distributions of influenza vaccine.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 7, 2004

Mr. DEFAZIO (for himself, Ms. WOOLSEY, Mr. GEORGE MILLER of California, Mr. BOSWELL, Mr. COSTELLO, Mr. ABERCROMBIE, Mr. SANDERS, Mr. SCOTT of Virginia, Mr. CROWLEY, Mr. BAIRD, Mr. HINCHEY, Mr. HOLDEN, Mr. GUTIERREZ, Mrs. CHRISTENSEN, Mrs. MALONEY, Ms. NORTON, Mr. ETHERIDGE, Ms. MCCOLLUM, Ms. DELAURO, Ms. MCCARTHY of Missouri, Mr. CONYERS, Mr. MOORE, Mr. PALLONE, Mr. WEXLER, Mr. FILNER, and Mr. FORD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Public Health Service Act to provide for emergency distributions of influenza vaccine.

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 “Influenza Vaccine  
5 Emergency Act”.

1 **SEC. 2. EMERGENCY DISTRIBUTIONS OF INFLUENZA VAC-**  
2 **CINE.**

3 Part B of title III of the Public Health Service Act  
4 (42 U.S.C. 243 et seq.), as amended by section 102 of  
5 Public Law 106–505 (114 Stat. 2315), is amended—

6 (1) by redesignating sections 319A through  
7 319G as sections 319B through 319H, respectively;  
8 and

9 (2) by inserting after section 319 the following  
10 section:

11 “EMERGENCY AUTHORITIES REGARDING SUPPLY OF  
12 INFLUENZA VACCINE

13 “SEC. 319A. (a) CONTINGENCY CLAUSES IN SALES  
14 CONTRACTS.—In entering into a contract for the sale of  
15 influenza vaccine in interstate commerce, a manufacturer  
16 or distributor of such vaccine shall include in the contract  
17 a provision in writing expressing the policy that the sale  
18 to the purchaser under the contract is subject to the fol-  
19 lowing conditions:

20 “(1) If the Secretary publishes in the Federal  
21 Register a declaration that there is a public health  
22 emergency by reason of a shortage of influenza vac-  
23 cine, the Secretary has the authority, in lieu of such  
24 purchaser, to take title to such quantities of the vac-  
25 cine as the Secretary determines to be necessary for

1 purposes of the public health, subject to subsection  
2 (c)(2).

3 “(2) If by reason of the Secretary using the au-  
4 thority under paragraph (1) the purchaser does not  
5 receive, or loses possession of, a quantity of influ-  
6 enza vaccine for which the purchaser has made pay-  
7 ment, the manufacturer or distributor (as the case  
8 may be) will provide to the purchaser a refund for  
9 such quantity.

10 “(b) COMPENSATION.—In the case of a contract for  
11 the sale of influenza vaccine with respect to which the Sec-  
12 retary uses the authority referred to in subsection (a)(1),  
13 the Secretary shall pay to the manufacturer or distributor  
14 involved the same amount as, under the contract, the man-  
15 ufacturer or distributor received or would have received  
16 for the quantity of vaccine involved.

17 “(c) AGENCY PROCEDURES.—With respect to the in-  
18 fluenza season involved:

19 “(1) If the Secretary makes an emergency dec-  
20 laration under subsection (a)(1), the Secretary shall  
21 determine the extent of compliance with guidelines  
22 for the distribution of influenza vaccine that have  
23 been established by the Secretary.

24 “(2) The Secretary may not use the authority  
25 referred to in subsection (a)(1) with respect to any

1 contract unless the Secretary has published in the  
2 Federal Register, not earlier than 30 days after  
3 making the emergency declaration under such sub-  
4 section, a determination that the extent of compli-  
5 ance with such guidelines has not been sufficient to  
6 constitute an adequate response to the emergency.

7 “(d) DISTRIBUTION OF VACCINE.—If the Secretary  
8 meets the condition described in subsection (c)(2) for the  
9 use of the authority referred to in subsection (a)(1):

10 “(1) The Secretary may, in lieu of such author-  
11 ity, order any manufacturer or distributor of influ-  
12 enza vaccine to honor its contracts with States or  
13 political subdivisions of States for the sale of such  
14 vaccine, in any case in which the manufacturer or  
15 distributor has conflicting obligations under its con-  
16 tracts for sale of the vaccine.

17 “(2) Any influenza vaccine to which the Sec-  
18 retary takes title under subsection (a)(1) shall be  
19 provided—

20 “(A) to States and political subdivisions of  
21 States in accordance with the immunization  
22 program under section 317(j); and

23 “(B) to such other public or private enti-  
24 ties as the Secretary determines to be appro-  
25 priate as a response to the emergency involved.

1 “(e) RULES OF CONSTRUCTION.—

2 “(1) EMERGENCY DECLARATION.—The Sec-  
3 retary shall be considered to have made an emer-  
4 gency declaration under subsection (a)(1) if the Sec-  
5 retary publishes in the Federal Register a declara-  
6 tion described in such subsection.

7 “(2) EMERGENCY SHORTAGE.—

8 “(A) OVERALL QUANTITY VS. DELIVERY  
9 WAITING TIME.—Without regard to whether the  
10 Secretary considers as adequate the total quan-  
11 tity of influenza vaccine that has been or is  
12 being manufactured for the influenza season in-  
13 volved, the Secretary may make an emergency  
14 declaration under subsection (a)(1) if the Sec-  
15 retary determines that the delivery waiting time  
16 for States or political subdivisions of States to  
17 receive the vaccine for the season is a period  
18 whose duration constitutes a significant threat  
19 to children, adolescents, or adults who are  
20 served by the immunization program under sec-  
21 tion 317(j).

22 “(B) DELIVERY WAITING TIME.—A deliv-  
23 ery waiting time under subparagraph (A) for a  
24 State or political subdivision of a State to re-  
25 ceive influenza vaccine is the time elapsing be-

1           tween the date on which the State or subdivi-  
2           sion enters into a contract to purchase such  
3           vaccine and the date on which the State or sub-  
4           division (or other entity designated under the  
5           contract) takes custody of the vaccine, less any  
6           period in which payment is due under the con-  
7           tract and the State or subdivision has not made  
8           payment, or in which the State or subdivision  
9           otherwise is in significant violation of the con-  
10          tract.

11          “(f) DEFINITIONS.—For purposes of this subsection,  
12          the terms ‘influenza season’ and ‘influenza vaccine’ have  
13          the meanings given such terms by the Secretary.”.

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