

108TH CONGRESS
2D SESSION

S. 2968

To amend the Public Health Service Act to address the shortage of influenza vaccine, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 8, 2004

Mr. REED (for himself, Mr. KENNEDY, Mr. WARNER, Mr. DASCHLE, Ms. SNOWE, Mr. DODD, Mrs. CLINTON, Mr. DORGAN, Mr. BAYH, Mr. SCHUMER, Mr. JOHNSON, and Mr. DAYTON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to address the shortage of influenza vaccine, 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 “Emergency Flu Re-
5 sponse Act of 2004”.

6 **SEC. 2. EMERGENCY FLU RESPONSE.**

7 Title XXI of the Public Health Service Act (42
8 U.S.C. 300aa–1 et seq.) is amended by adding at the end
9 the following:

1 “Subtitle 3—Influenza Vaccine

2 **“SEC. 2141. DEFINITION.**

3 “In this subtitle, the term ‘priority group’ means a
4 group described as a priority group for vaccination with
5 influenza vaccine in recommendations entitled ‘Interim In-
6 fluenza Vaccination Recommendations—2004–2005 Influenza
7 enza Season’, dated October 5, 2004, or any successor to
8 such recommendations issued by the Secretary.

9 **“SEC. 2142. EMERGENCY ACCESS TO INFLUENZA VACCINE.**

10 “(a) DECLARATION OF EMERGENCY.—

11 “(1) IN GENERAL.—Under section 564(b)(1)(C)
12 of the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360bbb–3(b)(1)(C)), the Secretary shall im-
14 mediately declare the shortage of influenza vaccine
15 in the United States for the 2004–2005 influenza
16 season to be an emergency justifying an authoriza-
17 tion for a product under section 564 of such Act (21
18 U.S.C. 360bbb).

19 “(2) DETERMINATION.—For the purpose of
20 making determinations under section 564(b)(1)(C)
21 of such Act to carry out paragraph (1), the Sec-
22 retary—

23 “(A) shall deem the shortage to be a public
24 health emergency described in such section; and

1 “(B) shall deem influenza virus to be a bi-
2 ological agent.

3 “(3) CONSTRUCTION.—Nothing in this sub-
4 section shall be considered to invoke the authorities
5 described in section 319, or to limit the ability of the
6 Secretary to invoke such authorities.

7 “(b) SEEKING INFLUENZA VACCINE.—The Secretary
8 shall promptly consult with the health ministries of Can-
9 ada, countries that are members of the European Union
10 as of January 1, 2003, Japan, and Switzerland to assess
11 the availability of influenza vaccine for the 2004–2005 in-
12 fluenza season that—

13 “(1) has been approved, licensed, or otherwise
14 cleared for marketing by the relevant regulatory
15 agency in such a country; and

16 “(2) is in excess of the needs in such country
17 for the vaccination of persons at high risk for com-
18 plications from influenza.

19 “(c) ISSUANCE OF AUTHORIZATION.—

20 “(1) IN GENERAL.—The Secretary shall
21 promptly evaluate available influenza vaccine (as
22 identified under subsection (b)) to determine wheth-
23 er the vaccine meets the criteria for issuance of an
24 authorization under section 564(c) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–
2 3(c)).

3 “(2) CRITERIA.—For the purpose of making
4 determinations under section 564(c) of such Act to
5 carry out paragraph (1), the Secretary—

6 “(A) shall deem influenza virus to be an
7 agent that can cause a serious or life-threat-
8 ening disease or condition; and

9 “(B) shall deem the shortage described in
10 subsection (a)(1) to be sufficient evidence that
11 there is no alternative described in section
12 564(c)(3).

13 “(d) VACCINE PURCHASE.—Not later than 30 days
14 after the date of enactment of the Emergency Flu Re-
15 sponse Act of 2004, the Secretary shall purchase, at a rea-
16 sonable price, available influenza vaccine identified under
17 subsection (b) for which the Secretary has issued an au-
18 thorization under section 564(c) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3(c)).

20 “(e) VACCINE DISTRIBUTION.—Notwithstanding any
21 other provision of law, the Secretary shall promptly import
22 and distribute any influenza vaccine purchased under sub-
23 section (d), giving first priority to persons in priority
24 groups.

1 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 such sums as may be necessary for fiscal year 2005.

4 **“SEC. 2143. EFFECTIVE RESPONSES TO VACCINE SHORT-**
5 **AGES.**

6 “(a) IN GENERAL.—The Secretary shall award a
7 grant to each State to allow such State to develop and
8 implement a plan to respond to the shortage of influenza
9 vaccine in the United States for the 2004–2005 influenza
10 season.

11 “(b) USE OF FUNDS.—A State that receives a grant
12 under this section shall use the funds made available
13 through a grant under subsection (a) to develop—

14 “(1) a voluntary plan to ensure that the influ-
15 enza vaccine is, to the maximum extent possible, ad-
16 ministered to priority groups;

17 “(2) a system to notify health care providers
18 about revisions in guidelines for administering influ-
19 enza vaccine;

20 “(3) an awareness campaign to inform the pub-
21 lic about recommendations concerning groups that
22 are priority groups for vaccination with influenza
23 vaccine; and

24 “(4) procedures to allow for the voluntary dona-
25 tion of vaccine as described in section 2145.

1 “(c) AMOUNT.—The amount of a grant under sub-
2 section (a) shall be proportional to the population of the
3 State and the severity of the shortage of influenza vaccine
4 in such State, as determined by the Secretary.

5 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to carry out this section
7 such sums as may be necessary for fiscal year 2005.

8 **“SEC. 2144. EFFECTIVE MONITORING OF THE NATION’S IN-**
9 **FLUENZA VACCINE SUPPLY.**

10 “(a) MANUFACTURERS.—Not later than 15 days
11 after the date of enactment of the Emergency Flu Re-
12 sponse Act of 2004 and every 30 days thereafter, any per-
13 son who manufactures influenza vaccine for introduction
14 into interstate commerce shall prepare and submit to the
15 Secretary a summary report that lists—

16 “(1) each client, both public and private, who
17 purchased influenza vaccine from the manufacturer
18 during the period covered by the report; and

19 “(2) the number of doses of influenza vaccine
20 sold to each client during the period.

21 “(b) STATE PUBLIC HEALTH AGENCIES.—To be eli-
22 gible to receive a grant under section 2143(a), a State
23 through its public health agency shall, not later than 15
24 days after the date of enactment of the Emergency Flu
25 Response Act of 2004 and every 30 days thereafter, pre-

1 pare and submit to the Secretary a summary report de-
 2 scribing—

3 “(1) the number of doses of influenza vaccine
 4 available in the State during the period covered by
 5 the report;

6 “(2) the number of such doses that were given
 7 to each priority group during that period; and

8 “(3) to the extent that such information is
 9 readily obtainable by the State, the manner in which
 10 such doses were distributed to consumers during
 11 such period, such as by distribution through public
 12 health agencies or private health care providers.

13 **“SEC. 2145. CLEARINGHOUSES FOR VOLUNTARY DONATION**
 14 **OF INFLUENZA VACCINE.**

15 “The Centers for Disease Control and Prevention,
 16 and each State public health agency described in section
 17 2144(b), shall establish a clearinghouse to—

18 “(1) enable persons to voluntarily donate influ-
 19 enza vaccine doses; and

20 “(2) distribute the doses for administration to
 21 individuals in priority groups.

22 **“SEC. 2146. PURCHASES OF INFLUENZA VACCINE.**

23 “(a) IN GENERAL.—The Secretary shall establish a
 24 program through which the Secretary may—

1 “(1) purchase from private employers, vaccine
2 wholesalers, and other appropriate individuals and
3 entities, doses of influenza vaccine that are not need-
4 ed for the vaccination of priority groups; and

5 “(2) distribute the doses purchased under para-
6 graph (1) for administration to individuals in pri-
7 ority areas.

8 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
9 are authorized to be appropriated to carry out this section
10 such sums as may be necessary for fiscal year 2005.

11 **“SEC. 2147. USE OF INFLUENZA VACCINE.**

12 “(a) EXECUTIVE BRANCH.—The head of each Execu-
13 tive agency (as defined in section 105 of title 5, United
14 States Code) shall ensure that any influenza vaccine in
15 the possession of the head of the agency shall—

16 “(1) be administered only to employees of the
17 agency who are in priority groups; and

18 “(2) provide to the Secretary any doses of the
19 vaccine that are not needed for the vaccination of in-
20 dividuals in priority groups, so that the Secretary
21 can distribute the doses for administration to indi-
22 viduals in the priority groups.

23 “(b) LEGISLATIVE BRANCH.—The Attending Physi-
24 cian of the Capitol shall ensure that any influenza vaccine
25 in the possession of the Attending Physician shall—

1 “(1) be administered only to employees of the
2 legislative branch of the Federal Government who
3 are in priority groups; and

4 “(2) provide to the Secretary any doses of the
5 vaccine that are not needed for the vaccination of in-
6 dividuals in priority groups, so that the Secretary
7 can distribute the doses for administration to indi-
8 viduals in the priority groups.

9 **“SEC. 2148. ENHANCING EXISTING COUNTERMEASURES**
10 **AGAINST INFLUENZA.**

11 “(a) AUTHORIZATION TO PURCHASE.—The Secretary
12 may, subject to amounts appropriated under subsection
13 (d), purchase at a reasonable negotiated price, such addi-
14 tional amounts of any drug approved by the Commissioner
15 of Food and Drugs to treat influenza as are determined
16 necessary by the Secretary.

17 “(b) ADDITION TO STOCKPILE.—The Secretary shall
18 include any drug purchased under subsection (a) in the
19 stockpile established under section 121 of the Public
20 Health Security and Bioterrorism Preparedness and Re-
21 sponse Act of 2002.

22 “(c) INCREASING THE EFFECTIVENESS OF EXISTING
23 VACCINE SUPPLIES.—The Secretary, acting through the
24 Director of the National Institutes of Health, shall con-
25 duct a clinical trial or trials to determine whether influ-

1 enza vaccine can be diluted and continue to retain its ef-
2 fectiveness in preventing influenza in individuals in pri-
3 ority groups.

4 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this section
6 such sums as may be necessary for fiscal year 2005.

7 **“SEC. 2149. NATIONAL QUARANTINE COMPENSATION PRO-**
8 **GRAM.**

9 “(a) IN GENERAL.—There is established the National
10 Quarantine Compensation Program to be administered by
11 the Secretary under which compensation shall be paid to
12 individuals who are subjected to an order of quarantine
13 issued by a Federal or State health agency.

14 “(b) AMOUNT.—An individual’s compensation under
15 the National Quarantine Compensation Program shall be
16 equal to wages lost as a result of such individual being
17 subjected to the quarantine.

18 “(c) APPROPRIATIONS.—There are authorized to be
19 appropriated and there are hereby appropriated to carry
20 out subsections (a) and (b) such sums as may be nec-
21 essary.

22 **“SEC. 2150. EMPLOYMENT RIGHTS AND PROTECTIONS RE-**
23 **LATING TO FEDERALLY MANDATED HEALTH-**
24 **RELATED QUARANTINE.**

25 “(a) DEFINITIONS.—In this section:

1 “(1) EMPLOYER.—The term ‘employer’—

2 “(A) means any person engaged in com-
3 merce or in any industry or activity affecting
4 commerce; and

5 “(B) includes—

6 “(i)(I) any person who acts, directly
7 or indirectly, in the interest of a person de-
8 scribed in subparagraph (A) to any of the
9 employees of such person; or

10 “(II) any successor in interest of a
11 person described in subparagraph (A);

12 “(ii) any public agency, as defined in
13 section 3(x) of the Fair Labor Standards
14 Act of 1938 (29 U.S.C. 203(x));

15 “(iii) the Government Accountability
16 Office, the Government Printing Office,
17 and the Library of Congress; and

18 “(iv) all other legislative branch enti-
19 ties identified as employing offices in the
20 Congressional Accountability Act of 1995
21 (2 U.S.C. 1301 et seq.).

22 “(2) EMPLOYMENT BENEFITS.—The term ‘em-
23 ployment benefits’ means all benefits provided or
24 made available to employees by an employer, includ-
25 ing group life insurance, health insurance, disability

1 insurance, sick leave, annual leave, educational bene-
2 fits, and pensions, regardless of whether such bene-
3 fits are provided by a practice or written policy of
4 an employer or through an employee benefit plan, as
5 defined in section 3 of the Employee Retirement In-
6 come Security Act of 1974 (29 U.S.C. 1002).

7 “(3) SECRETARY.—

8 “(A) IN GENERAL.—Except as otherwise
9 provided in subparagraph (B), the term ‘Sec-
10 retary’ means the Secretary of Labor.

11 “(B) EXCEPTIONS.—In the case of actions
12 brought regarding employees—

13 “(i) of the Government Accountability
14 Office, the term ‘Secretary’ means the
15 Comptroller General of the United States;

16 “(ii) of the Government Printing Of-
17 fice, the term ‘Secretary’ means the Public
18 Printer;

19 “(iii) of the Library of Congress, the
20 term ‘Secretary’ means the Librarian of
21 Congress; and

22 “(iv) of any other legislative branch
23 employer, the term ‘Secretary’ means the
24 Office of Compliance.

1 “(b) EMPLOYMENT RIGHTS, BENEFITS, AND PRO-
2 TECTION FROM DISCRIMINATION.—

3 “(1) RESTORATION TO POSITION.—Any indi-
4 vidual subjected to an order of quarantine issued by
5 a Federal or State health agency shall be entitled,
6 on return from such quarantine—

7 “(A) to be restored by the employer of
8 such individual to the position of employment
9 held by the individual when the quarantine of
10 such individual commenced; or

11 “(B) to be restored to an equivalent posi-
12 tion with equivalent employment benefits, pay,
13 and other terms and conditions of employment.

14 “(2) BENEFITS.—An individual restored to
15 such individual’s position, or equivalent position,
16 pursuant to paragraph (1) shall be entitled to the
17 seniority and other rights and benefits that the indi-
18 vidual had on the date when the quarantine of such
19 individual commenced, plus the additional seniority
20 and rights and benefits that the individual would
21 have attained had the individual not been subjected
22 to a federally mandated health-related quarantine.

23 “(3) PROTECTION FROM DISCRIMINATION.—It
24 shall be unlawful for an employer to discharge or in
25 any other manner discriminate against any indi-

1 vidual on the basis of such individual's being, or
2 having been, subjected to a federally mandated
3 health-related quarantine.

4 “(c) INVESTIGATIVE AUTHORITY; ENFORCEMENT.—

5 “(1) IN GENERAL.—The Secretary shall ensure
6 compliance with the provisions of subsection (b) and
7 enforce violations of subsection (b).

8 “(2) SAME AUTHORITIES.—In order to carry
9 out paragraph (1), the Secretary shall have the same
10 authorities as provided to the Secretary under sec-
11 tions 106 and 107 of the Family and Medical Leave
12 Act of 1993 (29 U.S.C. 209 and 210) to ensure
13 compliance with and enforce violations of the Family
14 and Medical Leave Act of 1993.

15 “(d) STATE AND LOCAL LAWS.—Nothing in this sec-
16 tion shall be construed to supersede any provision of any
17 State or local law that provides greater rights than the
18 rights established under this section.”.

19 **“SEC. 2151. ASSURING THAT INDIVIDUALS IN PRIORITY**
20 **GROUPS RECEIVE VACCINES.**

21 “(a) DETERMINATIONS.—Not later than 30 days
22 after the date of enactment of the Emergency Flu Re-
23 sponse Act of 2004, and every 30 days thereafter, the Sec-
24 retary shall review the effectiveness of measures taken
25 under sections 2142 through 2147 and determine whether

1 the measures have ensured the distribution of influenza
2 vaccine for administration to individuals in priority
3 groups. If the Secretary determines that the measures
4 have not ensured that distribution, the Secretary—

5 “(1) may take the actions described in sub-
6 section (b) if the Secretary determines that such ac-
7 tions are needed to protect the public health; and

8 “(2) shall notify the appropriate committees of
9 Congress of such determination.

10 “(b) ASSURING THE INDIVIDUALS IN PRIORITY
11 GROUPS RECEIVE VACCINES.—On making the determina-
12 tion described in subsection (a), the Secretary may require
13 that a person, not including a person that is a manufac-
14 turer of influenza vaccine, who possesses influenza vaccine
15 sell such person’s supply of the influenza vaccine to the
16 Federal Government, as an exercise of the Federal Gov-
17 ernment’s power to take private property for public use,
18 for just compensation.

19 “(c) PRIORITIZATION.—The Secretary shall dis-
20 tribute the doses of influenza vaccine obtained under sub-
21 section (b) in a manner determined appropriate by the
22 Secretary to ensure that such vaccine is administered to
23 individuals in priority groups.”.

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