

110TH CONGRESS
1ST SESSION

S. 2456

To amend the Public Health Service Act to improve and secure an adequate supply of influenza vaccine.

IN THE SENATE OF THE UNITED STATES

DECEMBER 12, 2007

Mr. REID (for Mrs. CLINTON (for herself and Mr. ROBERTS)) 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 improve and secure an adequate supply 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 Se-
5 curity Act of 2007”.

1 **TITLE I—MARKET GUARANTEES**

2 **SEC. 101. AMENDMENT TO THE PUBLIC HEALTH SERVICE**

3 **ACT.**

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

7 **“Subtitle 3—Influenza Vaccine**
8 **Security**

9 **“SEC. 2141. ESTABLISHMENT OF AN INFLUENZA VACCINE**
10 **TARGET AND STOCKPILE.**

11 “(a) ANNUAL TARGET.—The Secretary, in consulta-
12 tion with the Advisory Committee on Immunization Prac-
13 tices to the Centers for Disease Control and Prevention
14 (referred to in this subtitle as the ‘Advisory Committee’),
15 shall determine an annual production target for influenza
16 vaccine, based on the recommendations of the Advisory
17 Committee. Based on such target, the Secretary, acting
18 through the Centers for Disease Control and Prevention,
19 shall coordinate with the private market to encourage the
20 production of such vaccine in amounts that will meet the
21 annual target.

22 “(b) STOCKPILE.—Prior to the start of each annual
23 influenza season (as determined by the Secretary), the
24 Secretary is authorized to purchase and store from mul-
25 tiple manufacturers an amount not to exceed 10 percent

1 of the total amount of influenza vaccine, including one or
2 more active vaccine antigen ingredients in bulk or filled
3 form, that is designated for production by the Advisory
4 Committee for placement in the strategic national stock-
5 pile under section 121 of the Public Health Security and
6 Bioterrorism Preparedness and Response Act of 2002 (re-
7 ferred to in this subtitle as the ‘strategic national stock-
8 pile’). Such vaccine shall be held in reserve to be used in
9 the event of a vaccine shortage in a given influenza season.
10 The Secretary shall coordinate with the manufacturers in-
11 volved to ensure that reserving amounts of vaccine for the
12 stockpile does not interfere with the early season delivery
13 or early season administration of vaccine to high priority
14 populations (as defined by the Advisory Committee on Im-
15 munization Practices and the Centers for Disease Control
16 and Prevention) (referred to in this subtitle as ‘high pri-
17 ority populations’).

18 **“SEC. 2142. VACCINE BUYBACK PROGRAM.**

19 “(a) IN GENERAL.—The Secretary shall establish an
20 influenza vaccine buyback protocol under which the Sec-
21 retary may enter into buyback contracts with manufactur-
22 ers of influenza vaccine to purchase such manufacturers’
23 excess stocks of influenza vaccine so long as such vaccine
24 has been manufactured in accordance with the rec-

1 ommendations of the Advisory Committee for the produc-
2 tion of seasonal influenza vaccine.

3 “(b) MANUFACTURERS.—The Secretary shall have
4 the discretion to award buyback contracts under sub-
5 section (a) to several influenza vaccine manufacturers in
6 a manner consistent with the goal of providing stability
7 in the influenza vaccine market, as long as the Federal
8 Government purchases not more than 50 percent of the
9 excess influenza vaccine stock of any single manufacturer
10 at market price.

11 “(c) COOPERATION WITH MANUFACTURERS, DIS-
12 TRIBUTORS, AND WHOLESALERS.—As a condition of par-
13 ticipation in the buyback program under this section, the
14 Director of the Centers for Disease Control and Preven-
15 tion shall work in cooperation with influenza vaccine man-
16 ufacturers and wholesalers and distributors within the
17 chain of custody from factory to health care institution
18 or health care providers to share pertinent information
19 that will allow for the tracking of influenza vaccine, maxi-
20 mize the delivery and availability of influenza vaccines to
21 high priority populations, and ensure that influenza vac-
22 cine is delivered on an equitable basis, particularly in
23 times of vaccine shortages.

24 “(d) CONFIDENTIALITY.—The information submitted
25 to the Centers for Disease Control and Prevention or its

1 contractors, if any, under subsections (c) and (d) shall re-
2 main confidential in accordance with the exception from
3 the public disclosure of trade secrets, commercial or finan-
4 cial information, and information obtained from an indi-
5 vidual that is privileged and confidential, as provided for
6 in section 552(b)(4) of title 5, United States Code, and
7 subject to the penalties and exceptions under sections
8 1832 and 1833 of title 18, United States Code, relating
9 to the protection and theft of trade secrets, and subject
10 to privacy protections that are consistent with the regula-
11 tions promulgated under section 264(c) of the Health In-
12 surance Portability and Accountability Act of 1996. None
13 of such information provided by a manufacturer, whole-
14 saler, or distributor shall be disclosed without its consent
15 to another manufacturer, wholesaler, or distributor, or
16 shall be used in any manner to give a manufacturer,
17 wholesaler, or distributor a proprietary advantage over its
18 competitors.

19 “(e) ABILITY TO NEGOTIATE.—The Secretary shall
20 have the ability to negotiate, on a case-by-case basis, the
21 submission of information under subsection (c), as long
22 as the information provided will achieve the goals of track-
23 ing of the influenza vaccine, maximizing the delivery and
24 availability of influenza vaccines to high priority popu-
25 lations, and ensuring that influenza vaccine is delivered

1 on an equitable geographical basis, particularly in times
2 of vaccine shortages.

3 “(f) NOTICE.—

4 “(1) IN GENERAL.—For purposes of maintain-
5 ing and administering the supply of vaccines de-
6 scribed under subsection (a), the Secretary shall by
7 contract require that a manufacturer of a vaccine in-
8 cluded in such supply provide not less than 12
9 months notice to the Secretary of a purposeful dis-
10 continuance of the manufacture of such vaccine by
11 the manufacture of the vaccine.

12 “(2) REDUCTION OF PERIOD OF NOTICE.—The
13 notification period required under paragraph (1)
14 shall not apply in a case in which vaccine production
15 is interrupted because of unforeseen manufacturing
16 concerns.

17 “(g) USE OF VACCINE POST BUYBACK.—Following
18 the buyback of vaccine under this section, the Secretary
19 shall direct that any vaccine purchased in such buyback
20 be used for the following activities:

21 “(1) Use in late-season mass vaccination exer-
22 cises conducted in coordination with Federal, State
23 or local agencies engaged in emergency preparedness
24 and bioterrorism preparedness activities. Such exer-
25 cises should be carried out in partnership with vol-

1 untary organizations working to improve emergency
2 preparedness and bioterrorism preparedness.

3 “(2) Promoting and carrying out late-season
4 vaccination through the Indian Health Service, the
5 Public Health Service, the Department of Veterans
6 Affairs, or through other federally funded health
7 care providers, such as community health centers
8 and rural health clinics.

9 “(3) Other activities approved by the Secretary.

10 **“SEC. 2143. CRITICAL SUPPLY PURCHASE PROGRAM.**

11 “(a) IN GENERAL.—The Secretary shall increase the
12 amount of antiviral medications, N-95 respirator masks,
13 and other protections and treatments, as determined nec-
14 essary by the Secretary as they become available, to treat
15 and prevent pandemic influenza, in the strategic national
16 stockpile. In increasing such amounts, the Secretary shall
17 consult with the Director of the Centers for Disease Con-
18 trol and Prevention and the Assistant Secretary for Pre-
19 paredness and Response, to determine the amounts that
20 are necessary to provide adequate protection to not less
21 than the number of individual who respond to an influenza
22 epidemic.

23 “(b) PEDIATRIC PROGRAMS.—The Secretary is en-
24 couraged to consult with all relevant Federal agencies and
25 the private sector to develop and approve N-95 respirators

1 and other protections and treatments, as determined nec-
2 essary by the Secretary, to treat and prevent pandemic
3 influenza, and shall ensure that such products are rep-
4 resented in adequate amounts in the strategic national
5 stockpile to provide adequate protection to pediatric popu-
6 lations in the United States.

7 **“SEC. 2144. AUTHORIZATION OF APPROPRIATIONS.**

8 “There are authorized to be appropriated such sums
9 as may be necessary to carry out this subtitle in each of
10 fiscal years 2008 through 2012.”

11 **TITLE II—FOOD AND DRUG AD-**
12 **MINISTRATION ASSISTANCE**
13 **TO MANUFACTURERS**

14 **SEC. 201. AMENDMENT TO THE FOOD, DRUG, AND COS-**
15 **METIC ACT.**

16 Chapter IX of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 391 et seq.) is amended by adding at the
18 end the following:

19 **“SEC. 909. PROVISIONS RELATED TO THE EMERGENCY AC-**
20 **QUISITION OF VACCINES.**

21 “(a) IN GENERAL.—

22 “(1) INCREASED COMMUNICATION.—The Food
23 and Drug Administration shall carry out activities to
24 increase communication between the agency and the
25 scientific community regarding vaccine development

1 and regulation, including participation in con-
2 ferences on the science related to infectious diseases,
3 influenza, biologic manufacturing, and other issues
4 as determined appropriate by the Director of the
5 Center for Biologics Evaluation and Research.

6 “(2) REGULATORY ROADMAP.—The Commis-
7 sioner, in consultation with the Director of the Cen-
8 ters for Disease Control and Prevention, the Sec-
9 retary, and other agencies or participants as deter-
10 mined appropriate by the Secretary, shall develop a
11 regulatory roadmap to address the following issues
12 surrounding emergency use authorization of influ-
13 enza vaccine, as determined by the Secretary during
14 a public health emergency involving an actual or im-
15 minent outbreak of naturally occurring or engi-
16 neered seasonal influenza:

17 “(A) Policies for the emergency use au-
18 thorization of influenza vaccine that is produced
19 and sold in other countries so that such vaccine
20 may be imported into the United States by the
21 United States Government during a vaccine
22 shortage.

23 “(B) Policies for the facilitation of the dis-
24 tribution of any such vaccine imported into the
25 United States during a vaccine shortage, in-

1 including the interstate transportation, allocation
2 and equitable distribution of vaccine among
3 high priority populations (as defined by the Ad-
4 visory Committee on Immunization Practices
5 and the Centers for Disease Control and Pre-
6 vention) during an emergency use situation.

7 “(C) Policies for the communication and
8 coordination of a response to an emergency use
9 authorization with State and local health de-
10 partments, including guidelines for notification
11 of such entities in such situations.

12 “(D) Policies for the emergency use au-
13 thorization of vaccines that are in clinical devel-
14 opment in both the United States and other
15 countries, including clarification of IND proto-
16 cols for such vaccines, particularly those using
17 new vaccine development technologies.

18 “(3) CONSULTATION.—In developing the road-
19 map under paragraph (2), the Commissioner shall
20 solicit input from private and nonprofit stakeholders,
21 including State and local health officials, and such
22 input shall include recommendations for developing
23 emergency use authorization guidelines that main-
24 tain the scientific and regulatory standards of the
25 Food and Drug Administration.

1 “(4) STANDING ORDERS.—

2 “(A) DEVELOPMENT.—The Secretary shall
3 direct the Centers for Disease Control and Pre-
4 vention, in conjunction with State and local
5 health departments and representatives of State
6 medical boards and nursing examiners, to de-
7 velop and publish a model standing order that
8 will, at a minimum, address the need for stand-
9 ing orders to administer influenza vaccine in
10 hospitals, community health centers, nursing
11 homes, and other assisted living facilities, and
12 by home health care providers. The Centers for
13 Disease Control and Prevention is encouraged
14 to expand such a model standing order to take
15 into account—

16 “(i) the administration of other Medi-
17 care covered vaccines; and

18 “(ii) the delivery of influenza vaccine
19 to patients in children’s hospitals or other
20 institutions serving the long-term care
21 needs of a pediatric population, including
22 those in a non-clinical setting.

23 “(B) IMPLEMENTATION.—Not less than 1
24 year after the publication of the standing order
25 under paragraph (A), States shall be required

1 to implement such standing order in order to be
2 eligible to receive grants under this Act.

3 “(C) RULE OF CONSTRUCTION.—Nothing
4 in this paragraph shall be construed as pre-
5 cluding the application of State laws, so long as
6 such laws do not restrict the implementation of
7 this requirements of the Influenza Vaccine Se-
8 curity Act of 2007 (and the amendments made
9 by such Act).

10 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
11 are authorized to be appropriated to carry out this section,
12 \$5,000,000 for fiscal year 2008, and such sums as may
13 be necessary for each of fiscal years 2009 through 2012,
14 to be made available to the Food and Drug Administration
15 to provide the technical assistance and take advantage of
16 the training opportunities as designated in this section.”.

17 **TITLE III—VACCINE EDUCATION,**
18 **OUTREACH, AND COORDINA-**
19 **TION**

20 **SEC. 301. AUTHORITY OF THE NATIONAL CENTER FOR IM-**
21 **MUNIZATION AND RESPIRATORY DISEASES**
22 **FOR COORDINATION, EDUCATION, OUT-**
23 **REACH, AND COMMUNICATION ACROSS HHS.**

24 Section 2102 of the Public Health Service Act (42
25 U.S.C. 300aa–2) is amended—

1 (1) in subsection (a), by adding at the end the
2 following:

3 “(10) COORDINATION OF SUPPORT.—The Di-
4 rector of the Center, in consultation with the Direc-
5 tor of the National Institute for Allergy and Infec-
6 tious Disease, shall—

7 “(A) coordinate efforts in regard to all in-
8 fluenza vaccine education, outreach, surveil-
9 lance, and research activities within the Depart-
10 ment in support of the goal of—

11 “(i) increasing overall influenza vac-
12 cination rates in the United States, par-
13 ticularly those of high priority populations
14 (as defined by the Advisory Committee on
15 Immunization Practices and the Centers
16 for Disease Control and Prevention) and
17 health care providers;

18 “(ii) increasing vaccination rates
19 among medically underserved populations
20 with low vaccination rates; and

21 “(iii) any other vaccine promotion ac-
22 tivities as directed by the Secretary;

23 “(B) coordinate educational efforts under
24 this paragraph with the National Vaccine Pro-
25 gram Office, State and local health depart-

1 ments, the National Institutes of Health, and
 2 all other relevant Federal and other entities as
 3 designated by the Director; and

4 “(C) provide an annual report to Congress
 5 on the progress being made toward the goals
 6 described in subparagraph (A).”; and

7 (2) by adding at the end the following:

8 “(c) APPROPRIATIONS FOR COORDINATION OF IN-
 9 FLUENZA VACCINE OUTREACH ACTIVITIES.—There is au-
 10 thorized to be appropriated to carry out activities under
 11 subsection (a)(10), \$2,000,000 for each of fiscal years
 12 2008 through 2012.”.

13 **TITLE IV—INCREASED INFLU-**
 14 **ENZA VACCINE AND OUT-**
 15 **BREAK SURVEILLANCE AC-**
 16 **TIVITIES**

17 **SEC. 401. TRACKING NETWORK AND DEMONSTRATION**
 18 **GRANTS.**

19 Title III of the Public Health Service Act is amended
 20 by inserting after section 319B (42 U.S.C. 247d–2) the
 21 following:

22 **“SEC. 319B–1. TRACKING NETWORK AND DEMONSTRATION**
 23 **GRANTS.**

24 “(a) TRACKING SYSTEM.—

1 “(1) ESTABLISHMENT.—Not later than 2 years
2 after the date of enactment of this section, the Di-
3 rector of the Centers for Disease Control and Pre-
4 vention, in conjunction with State and local public
5 health officials and health provider and nonprofit or-
6 ganizations, shall establish an electronic tracking
7 system through which the Director and such officials
8 can determine the amount of influenza vaccine with-
9 in a 24-hour window that is available for distribution
10 to patients, as well as the need for such vaccine on
11 a county-by-county basis, and the progress of vac-
12 cine delivery and distribution efforts at the State
13 and local level.

14 “(2) ESTIMATES.—The tracking system estab-
15 lished under paragraph (1) shall collect estimates of
16 the size of high priority populations (as defined by
17 the Advisory Committee on Immunization Practices
18 and the Centers for Disease Control and Prevention)
19 (referred to in this section as ‘high priority popu-
20 lations’) in each county in the United States, so as
21 to better determine where influenza vaccine re-
22 sources may need to be directed in the case of an
23 emergency.

24 “(3) PROVISION OF INFORMATION.—To be eli-
25 gible to participate in buyback programs the vaccine

1 manufacturer shall provide information to the track-
2 ing system as the Director of the Centers for Dis-
3 ease Control and Prevention determines appropriate
4 in accordance with subtitle 3 of title XXI.

5 “(4) CONFIDENTIALITY.—The information sub-
6 mitted to the Secretary (or a contractors, if any)
7 under this section or under any other section of this
8 Act related to vaccine distribution information shall
9 remain confidential in accordance with the exception
10 from the public disclosure of trade secrets, commer-
11 cial or financial information, and information ob-
12 tained from an individual that is privileged and con-
13 fidential, as provided for in section 552(b)(4) of title
14 5, United States Code, and subject to the penalties
15 and exceptions under sections 1832 and 1833 of title
16 18, United States Code, relating to the protection
17 and theft of trade secrets, and subject to privacy
18 protections that are consistent with the regulations
19 promulgated under section 264(c) of the Health In-
20 surance Portability and Accountability Act of 1996.
21 None of such information provided by a manufac-
22 turer, wholesaler, or distributor shall be disclosed
23 without its consent to another manufacturer, whole-
24 saler, or distributor, or shall be used in any manner

1 to give a manufacturer, wholesaler, or distributor a
2 proprietary advantage.

3 “(5) GUIDELINES.—The Secretary, in order to
4 maintain the confidentiality of relevant information
5 and ensure that none of the information contained
6 in the systems involved may be used to provide pro-
7 prietary advantage within the vaccine market, while
8 allowing State, local, and tribal health officials ac-
9 cess to such information to maximize the delivery
10 and availability of vaccines to high priority popu-
11 lations, during times of influenza pandemics, vaccine
12 shortages, and supply disruptions, in consultation
13 with manufacturers, distributors, wholesalers and
14 State, local, and tribal health departments, shall de-
15 velop guidelines permitting the Department of
16 Health and Human Services to carry out paragraphs
17 (1) and (2) and (3).

18 “(b) EXPANSION OF CURRENT SYSTEMS AND ACTIVI-
19 TIES.—

20 “(1) SURVEILLANCE SYSTEM.—Not later than
21 4 years after the date of enactment of this section,
22 the Director of the Centers for Disease Control and
23 Prevention shall upgrade and enhance the influenza
24 surveillance system of the Centers for Disease Con-
25 trol and Prevention to report influenza data from

1 State and local health departments into the tracking
2 system established under subsection (a)(1).

3 “(2) EDUCATIONAL MATERIALS.—The tracking
4 system shall contain information to assist users in
5 accessing influenza education, outreach, and commu-
6 nications tools, such as those developed and financed
7 under the Influenza Vaccine Security Act of 2007
8 (and the amendments made by such Act).

9 “(c) DEMONSTRATION GRANTS.—

10 “(1) IN GENERAL.—The Director of the Cen-
11 ters for Disease Control and Prevention shall award
12 demonstration grants to State and local health de-
13 partments to enable such departments to enter into
14 contract with hospitals, community health centers,
15 long-term care facilities, physicians’ offices, and
16 health care facilities operated or funded by such de-
17 partments to assist such department and entities in
18 upgrading their information technology, infrastruc-
19 ture, and workforce in a manner that will allow such
20 departments and entities to improve their ability to
21 report and track influenza vaccine dissemination.

22 “(2) PRIORITY.—In awarding grants under
23 paragraph (1), priority shall be given to departments
24 and entities that serve high priority populations in
25 medically underserved areas.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated—

3 “(1) to carry out subsection (a), \$100,000,000
4 for each of fiscal years 2008 through 2012, of which
5 \$500,000 for each fiscal year shall be made available
6 to implement subsection (b)(3); and

7 “(2) to carry out subsection (c), \$100,000,000
8 for each of fiscal years 2008 through 2012.”.

9 **TITLE V—FLU VACCINE**
10 **OUTREACH AND EDUCATION**

11 **SEC. 501. EDUCATIONAL EFFORTS AND GRANTS.**

12 Title III of the Public Health Service Act is amended
13 by inserting after section 319B–1 (as added by section
14 401) the following:

15 **“SEC. 319B–2. IMMUNIZATION EDUCATIONAL EFFORTS AND**
16 **GRANTS.**

17 “(a) IN GENERAL.—The Director of the Centers for
18 Disease Control and Prevention, in conjunction with State
19 and local health departments, shall revise and expand the
20 influenza-related educational materials to the Centers for
21 Disease Control and Prevention, and facilitate the use of
22 such materials by health care providers and patients. The
23 Director is authorized to coordinate such educational ef-
24 forts with nonprofit provider and patient advocacy groups.

1 “(b) INFLUENZA VACCINE EDUCATION AND OUT-
2 REACH.—

3 “(1) IN GENERAL.—In order to achieve an opti-
4 mal balance in the influenza vaccine market, and to
5 ensure that the recommendations of the Advisory
6 Committee on Immunization Practices to the Cen-
7 ters for Disease Control and Prevention for vaccine
8 administration are carried out to the maximum ex-
9 tent possible, the Director of the Centers for Disease
10 Control and Prevention, in conjunction with State
11 and local health departments, shall carry out influ-
12 enza immunization education and outreach activities
13 that target physicians and other health care pro-
14 viders, health insurance providers, health care insti-
15 tutions and patients, particularly those in high pri-
16 ority populations (as defined by the Advisory Com-
17 mittee on Immunization Practices and the Centers
18 for Disease Control and Prevention) (referred to in
19 this section as ‘high priority populations’).

20 “(2) TYPES OF ACTIVITIES.—The education
21 and outreach activities under paragraph (1) shall in-
22 clude—

23 “(A) activities to encourage voluntary par-
24 ticipation in influenza vaccination programs,
25 with the goal of increasing overall influenza

1 vaccination rates in the United States, achiev-
2 ing full influenza vaccination of all high priority
3 populations, and full use of each season’s influ-
4 enza vaccine supply and late season vaccination;

5 “(B) the provision of information on influ-
6 enza prevention, including to medically under-
7 served communities with low vaccination rates;

8 “(C) activities to increase the number of
9 healthcare providers who receive influenza vac-
10 cines each year; and

11 “(D) other influenza educational efforts
12 determined appropriate by the Director.

13 “(c) GRANTS.—The Director of the Centers for Dis-
14 ease Control and Prevention may award grants to State
15 and local health departments to carry out activities to en-
16 courage individuals, particularly those from high priority
17 populations, to seek out influenza vaccinations.

18 “(d) COLLABORATION.—State and local health de-
19 partments that receive grants under subsection (b) are en-
20 couraged to collaborate on projects with physicians and
21 other health care providers, health insurance providers,
22 health care institutions, and groups representing high pri-
23 ority populations.

24 “(e) AUTHORIZATION OF APPROPRIATIONS.—In ad-
25 dition to any amounts otherwise available through the Sec-

1 retary for influenza outreach and education, there is au-
2 thorized to be appropriated to carry out this section,
3 \$10,000,000 for each of fiscal years 2008 through 2012.”.

○