

109TH CONGRESS
1ST SESSION

S. 1828

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 6, 2005

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 2005”.

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 equal to not to exceed 10

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

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

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

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

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

22 “(d) CONFIDENTIALITY.—The information submitted
23 to the Centers for Disease Control and Prevention or its
24 contractors, if any, under subsections (c) and (d) shall re-
25 main confidential in accordance with the exception from

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

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

1 “(f) NOTICE.—

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

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

15 **“SEC. 2143. ANTIVIRAL PURCHASE PROGRAM.**

16 “(a) IN GENERAL.—The Secretary shall increase the
17 amount of antiviral medications contained in the strategic
18 national stockpile under section 121 of the Public Health
19 Security and Bioterrorism Preparedness and Response
20 Act of 2002, in such amounts as necessary, as determined
21 appropriate in consultation with the Director of the Cen-
22 ters for Disease Control and Prevention, to provide ade-
23 quate protection to not less than those responding to an
24 influenza epidemic.

1 “(b) PEDIATRIC ANTIVIRAL.—The Secretary is en-
2 couraged to work with all relevant Federal agencies and
3 the private sector to develop and approve an antiviral for
4 use in the pediatric population.

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

6 “‘There are authorized to be appropriated such sums
7 as may be necessary to carry out this subtitle in each of
8 fiscal years 2007 through 2011.’”.

9 **TITLE II—FOOD AND DRUG AD-**
10 **MINISTRATION ASSISTANCE**
11 **TO MANUFACTURERS**

12 **SEC. 201. AMENDMENT TO THE FOOD, DRUG, AND COS-**
13 **METIC ACT.**

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

17 **“SEC. 909. PROVISIONS RELATING TO INFLUENZA VACCINE**
18 **MANUFACTURERS.**

19 “(a) ASSISTANCE AND TECHNICAL TRAINING
20 BRANCH.—The Secretary shall expand and strengthen the
21 activities of the Manufacturer Assistance and Technical
22 Training Branch at the Center for Biologics Evaluation
23 and Research of the Food and Drug Administration to
24 provide for the dissemination of information, and to pro-
25 vide technical guidance, to entities seeking to comply with

1 regulations of the Secretary relating to the production of
2 biologic materials, particularly influenza vaccine.

3 “(b) TECHNICAL ASSISTANCE GRANTS.—

4 “(1) IN GENERAL.—The Secretary, in consulta-
5 tion with the Commissioner, shall award technical
6 assistance grants to entities seeking to—

7 “(A) enter the United States influenza vac-
8 cine market;

9 “(B) expand their vaccine production ca-
10 pacity for the United States influenza vaccine
11 market; or

12 “(C) improve their ability to remain within
13 the United States influenza vaccine market.

14 “(2) ACTIVITIES.—Amounts awarded under
15 grants under paragraph (1) shall be used for one or
16 more of the following activities:

17 “(A) Establishing or making capital im-
18 provements in technology, machinery, or pro-
19 duction capacity to vaccine manufacturing fa-
20 cilities located within the United States to en-
21 able such facilities to comply with the regula-
22 tions of the Food and Drug Administration.

23 “(B) The training of employees of United
24 States-based vaccine manufacturing facilities in
25 vaccine production methods.

1 “(C) Any other activities approved by the
2 Commissioner as assisting with the goal of in-
3 creasing manufacturer participation in the vac-
4 cine market and improving domestically-based
5 vaccine manufacturing capacity.

6 “(c) PROVISIONS RELATED TO THE EMERGENCY AC-
7 QUISITION OF VACCINES.—

8 “(1) INCREASED COMMUNICATION.—The Food
9 and Drug Administration shall carry out activities to
10 increase communication between the agency and the
11 scientific community regarding vaccine development
12 and regulation, including participation in con-
13 ferences on the science related to infectious diseases,
14 influenza, biologic manufacturing, and other issues
15 as determined appropriate by the Director of the
16 Center for Biologics Evaluation and Research.

17 “(2) REGULATORY ROADMAP.—The Commis-
18 sioner, in consultation with the Director of the Cen-
19 ters for Disease Control and Prevention, the Sec-
20 retary, and other agencies or participants as deter-
21 mined appropriate by the Secretary, shall develop a
22 regulatory roadmap to address the following issues
23 surrounding emergency use authorization of influ-
24 enza vaccine, as determined by the Secretary during
25 a public health emergency involving an actual or im-

1 minent outbreak of naturally occurring or engi-
2 neered seasonal influenza:

3 “(A) Policies for the emergency use au-
4 thorization of influenza vaccine that is produced
5 and sold in other countries so that such vaccine
6 may be imported into the United States by the
7 United States government during a vaccine
8 shortage.

9 “(B) Policies for the facilitation of the dis-
10 tribution of any such vaccine imported into the
11 United States during a vaccine shortage, in-
12 cluding the interstate transportation, allocation
13 and equitable distribution of vaccine among
14 high priority populations (as defined by the Ad-
15 visory Committee on Immunization Practices
16 and the Centers for Disease Control and Pre-
17 vention) during an emergency use situation.

18 “(C) Policies for the communication and
19 coordination of a response to an emergency use
20 authorization with State and local health de-
21 partments, including guidelines for notification
22 of such entities in such situations.

23 “(D) Policies for the emergency use au-
24 thorization of vaccines that are in clinical devel-
25 opment in both the United States and other

1 countries, including clarification of IND proto-
2 cols for such vaccines, particularly those using
3 new vaccine development technologies.

4 “(3) CONSULTATION.—In developing the road-
5 map under paragraph (2), the Commissioner shall
6 solicit input from private and nonprofit stakeholders,
7 including State and local health officials, and such
8 input shall include recommendations for developing
9 emergency use authorization guidelines that main-
10 tain the scientific and regulatory standards of the
11 Food and Drug Administration.

12 “(4) STANDING ORDERS.—

13 “(A) DEVELOPMENT.—The Secretary shall
14 direct the Centers for Disease Control and Pre-
15 vention, in conjunction with State and local
16 health departments and representatives of State
17 medical boards and nursing examiners, to de-
18 velop and publish a model standing order that
19 will, at a minimum, address the need for stand-
20 ing orders to administer influenza vaccine in
21 hospitals, nursing homes, and by home health
22 care providers. The Centers for Disease Control
23 and Prevention is encouraged to expand such a
24 model standing order to take into account—

1 “(i) the administration of other Medi-
2 care covered vaccines; and

3 “(ii) the delivery of influenza vaccine
4 to patients in children’s hospitals or other
5 institutions serving the long-term care
6 needs of a pediatric population.

7 “(B) IMPLEMENTATION.—Not less than 1
8 year after the publication of the standing order
9 under paragraph (A), States shall be required
10 to implement such standing order in order to be
11 eligible to receive grants under this Act.

12 “(C) RULE OF CONSTRUCTION.—Nothing
13 in this paragraph shall be construed as pre-
14 cluding the application of State laws, so long as
15 such laws don not restrict the implementation
16 of this requirements of the Influenza Vaccine
17 Security Act of 2005 (and the amendments
18 made by such Act).

19 “(d) AUTHORIZATION OF APPROPRIATIONS.—

20 “(1) IN GENERAL.—There are authorized to be
21 appropriated to carry out this section, \$75,000,000
22 for each of fiscal years 2007 through 2011.

23 “(2) USE OF FUNDS.—The Secretary shall en-
24 sure that \$5,000,000 of the amount appropriated
25 under paragraph (1) for fiscal year 2007, and such

1 sums as may be necessary for each of fiscal years
 2 2008 through 2011, shall be made available for the
 3 purpose of increasing the ability of the Food and
 4 Drug Administration to provide the technical assist-
 5 ance and take advantage of the training opportuni-
 6 ties as designated in this section.”.

7 **TITLE III—VACCINE DEVELOP-**
 8 **MENT RESEARCH AND CO-**
 9 **ORDINATION**

10 **SEC. 301. INCREASED FUNDING FOR NEW AND EXISTING**
 11 **VACCINE DEVELOPMENT RESEARCH.**

12 Subpart 6 of part C of title IV of the Public Health
 13 Service Act (42 U.S.C. 285f et seq.) is amended by adding
 14 at the end the following:

15 **“SEC. 447C. INCREASED FUNDING FOR NEW AND EXISTING**
 16 **VACCINE DEVELOPMENT RESEARCH.**

17 **“(a) NEW RESEARCH.—**

18 **“(1) SOLICITATION OF PROPOSALS.—**The Insti-
 19 tute shall solicit proposals for research into improved
 20 technologies for influenza vaccine development, in-
 21 cluding a permanent influenza vaccine. The Sec-
 22 retary, acting through the Director of the Institute
 23 may award grants to fund such proposals.

24 **“(2) PRIORITY.—**In funding proposals sub-
 25 mitted under paragraph (1), the Institute shall give

1 priority to proposals for research that contributes to
2 the goal of providing marketable influenza vaccine
3 alternatives within the 10-year period after the date
4 of enactment of this section.

5 “(b) EXISTING RESEARCH.—

6 “(1) IN GENERAL.—The Director of the Insti-
7 tute, acting jointly with the Director of Intramural
8 Research at the Institute and the Scientific Director
9 of the Vaccine Research Program at the Institute,
10 and in consultation with any other officials deter-
11 mined appropriate by the Director, shall review vac-
12 cine development research that is being conducted
13 under grants awarded by the Institute to identify re-
14 search that could provide the United States with im-
15 proved technologies for vaccine production that could
16 be marketed within the United States within the 10-
17 year period beginning on the date of enactment of
18 this section.

19 “(2) SUPPLEMENTARY FUNDING.—The Direc-
20 tor of the Institute shall provide supplementary
21 grant funding to the research identified under para-
22 graph (1) that the Director determines could result
23 in the production described in such paragraph.

24 “(3) AUTHORIZATION OF APPROPRIATIONS.—

25 There is authorized to be appropriated to carry out

1 this section, \$100,000,000 for each of fiscal years
2 2007 through 2011.”.

3 **SEC. 302. AUTHORITY OF THE NATIONAL IMMUNIZATION**
4 **PROGRAM FOR COORDINATION OF, EDU-**
5 **CATION, OUTREACH, AND COMMUNICATION**
6 **ACROSS HHS.**

7 Section 2102 of the Public Health Service Act (42
8 U.S.C. 300aa-2) is amended—

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

11 “(10) COORDINATION OF SUPPORT.—The Di-
12 rector of the Program shall—

13 “(A) coordinate education, outreach, and
14 communication efforts in regard to all influenza
15 vaccine research activities within the Depart-
16 ment in support of the goal of—

17 “(i) increasing overall influenza vac-
18 cination rates in the United States, par-
19 ticularly those of high priority populations
20 (as defined by the Advisory Committee on
21 Immunization Practices and the Centers
22 for Disease Control and Prevention) and
23 health care providers,

24 “(ii) ensuring that safe and effective
25 marketable vaccines produced with im-

1 proved technologies that supplement the
2 current egg-based system of production
3 shall be available within the 10-year period
4 after the enactment of this paragraph; and

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

7 “(B) coordinate educational efforts under
8 this paragraph with the National Vaccine Pro-
9 gram Office, State and local health depart-
10 ments, the National Institutes of Health, and
11 all other relevant Federal and other entities as
12 designated by the Director; and

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

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

17 “(c) APPROPRIATIONS FOR COORDINATION OF IN-
18 FLUENZA VACCINE OUTREACH ACTIVITIES.—There is au-
19 thorized to be appropriated to carry out activities under
20 subsection (a)(10), \$2,000,000 for each of fiscal years
21 2007 through 2011.”.

1 **TITLE IV—INCREASED INFLU-**
2 **ENZA VACCINE AND OUT-**
3 **BREAK SURVEILLANCE AC-**
4 **TIVITIES**

5 **SEC. 401. TRACKING NETWORK AND DEMONSTRATION**
6 **GRANTS.**

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

10 **“SEC. 319B–1. TRACKING NETWORK AND DEMONSTRATION**
11 **GRANTS.**

12 “(a) TRACKING SYSTEM.—

13 “(1) ESTABLISHMENT.—Not later than 2 years
14 after the date of enactment of this section, the Di-
15 rector of the Centers for Disease Control and Pre-
16 vention, in conjunction with State and local public
17 health officials, shall establish an electronic tracking
18 system through which the Director and such officials
19 can determine the amount of influenza vaccine that
20 is available for distribution to patients, as well as
21 the need for such vaccine on a county-by-county
22 basis, and the progress of vaccine delivery and dis-
23 tribution efforts at the State and local level.

24 “(2) ESTIMATES.—The tracking system estab-
25 lished under paragraph (1) shall collect estimates of

1 the size of high priority populations (as defined by
2 the Advisory Committee on Immunization Practices
3 and the Centers for Disease Control and Prevention)
4 (referred to in this section as ‘high priority popu-
5 lations’) in each county in the United States, so as
6 to better determine where influenza vaccine re-
7 sources may need to be directed in the case of an
8 emergency.

9 “(3) PROVISION OF INFORMATION.—To be eli-
10 gible to participate in buyback programs the vaccine
11 manufacturer shall provide information to the track-
12 ing system as the Director of the Centers for Dis-
13 ease Control and Prevention determines appropriate
14 in accordance with subtitle 3 of title XXI.

15 “(4) DATABASE.—In consultation with manu-
16 facturers, distributors, wholesalers, and State and
17 local health departments, the Secretary shall develop
18 guidelines for the development and use of a database
19 in order to maintain confidentiality and ensure that
20 none of the information provided under paragraph
21 (3) and contained in the database can be used to
22 provide a proprietary advantage within the vaccine
23 market while allowing State and local health officials
24 such information to maximize the delivery and avail-
25 ability of vaccines to high priority populations.

1 “(b) EXPANSION OF CURRENT SYSTEMS AND ACTIVI-
2 TIES.—

3 “(1) SURVEILLANCE SYSTEM.—Not later than
4 4 years after the date of enactment of this section,
5 the Director of the Centers for Disease Control and
6 Prevention shall upgrade the influenza surveillance
7 system of the Centers for Disease Control and Pre-
8 vention to report influenza data from State and local
9 health departments into the tracking system estab-
10 lished under subsection (a)(1).

11 “(2) EDUCATIONAL MATERIALS.—The tracking
12 system shall contain information to assist users in
13 accessing influenza education, outreach, and commu-
14 nications tools, such as those developed and financed
15 under the Influenza Vaccine Security Act of 2005
16 (and the amendments made by such Act).

17 “(3) EMERGENCY PROVIDER DATABASE.—The
18 Director of the Centers for Disease Control and Pre-
19 vention shall coordinate access to, in conjunction
20 with State and local health departments and State
21 licensing boards for health professionals, a database
22 registry of medical personnel who can provide serv-
23 ices in the event of a health emergency, including
24 pandemic influenza or an influenza vaccine shortage.

1 Such information shall be made available through
2 the tracking network.

3 “(c) DEMONSTRATION GRANTS.—

4 “(1) IN GENERAL.—The Director of the Cen-
5 ters for Disease Control and Prevention shall award
6 demonstration grants to State and local health de-
7 partments to enable such departments to enter into
8 contract with hospitals, community health centers,
9 long-term care facilities, physicians’ offices, and
10 health care facilities operated or funded by such de-
11 partments to assist such entities in upgrading their
12 information technology, infrastructure, and work-
13 force in a manner that will allow such entities to im-
14 prove their ability to report and track influenza vac-
15 cine dissemination.

16 “(2) PRIORITY.—In awarding grants under
17 paragraph (1), priority shall be given to entities that
18 serve high priority populations in medically under-
19 served areas.

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated—

22 “(1) to carry out subsection (a), \$100,000,000
23 for each of fiscal years 2007 through 2011, of which
24 \$500,000 for each fiscal year shall be made available
25 to implement subsection (b)(3); and

1 “(2) to carry out subsection (c), \$100,000,000
2 for each of fiscal years 2007 through 2011.”.

3 **TITLE V—FLU VACCINE**
4 **OUTREACH AND EDUCATION**

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

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

9 **“SEC. 319B–2. IMMUNIZATION EDUCATIONAL EFFORTS AND**
10 **GRANTS.**

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

19 “(b) INFLUENZA VACCINE EDUCATION AND OUT-
20 REACH.—

21 “(1) IN GENERAL.—In order to achieve an opti-
22 mal balance in the influenza vaccine market, and to
23 ensure that the recommendations of the Advisory
24 Committee on Immunization Practices to the Cen-
25 ters for Disease Control and Prevention for vaccine

1 administration are carried out to the maximum ex-
2 tent possible, the Director of the Centers for Disease
3 Control and Prevention, in conjunction with State
4 and local health departments, shall carry out influ-
5 enza immunization education and outreach activities
6 that target physicians and other health care pro-
7 viders, health insurance providers, health care insti-
8 tutions and patients, particularly those in high pri-
9 ority populations (as defined by the Advisory Com-
10 mittee on Immunization Practices and the Centers
11 for Disease Control and Prevention) (referred to in
12 this section as ‘high priority populations’).

13 “(2) TYPES OF ACTIVITIES.—The education
14 and outreach activities under paragraph (1) shall in-
15 clude—

16 “(A) activities to encourage voluntary par-
17 ticipation in influenza vaccination programs,
18 with the goal of increasing overall influenza
19 vaccination rates in the United States, achiev-
20 ing full influenza vaccination of all high priority
21 populations, and full use of each season’s influ-
22 enza vaccine supply;

23 “(B) the provision of information on influ-
24 enza prevention;

1 “(C) activities to increase the number of
2 healthcare providers who receive influenza vac-
3 cines each year; and

4 “(D) other influenza educational efforts
5 determined appropriate by the Director.

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

11 “(d) COLLABORATION.—State and local health de-
12 partments that receive grants under subsection (b) are en-
13 couraged to collaborate on projects with physicians and
14 other health care providers, health insurance providers,
15 health care institutions, and groups representing high pri-
16 ority populations.

17 “(e) AUTHORIZATION OF APPROPRIATIONS.—In ad-
18 dition to any amounts otherwise available through the Sec-
19 retary for influenza outreach and education, there is au-
20 thorized to be appropriated to carry out this section,
21 \$10,000,000 for each of fiscal years 2007 through 2011.”.

1 **TITLE VI—COMPENSATION**

2 **SEC. 601. COMPENSATION.**

3 Section 224 of the Public Health Service Act (42
4 U.S.C. 233) is amended by adding at the end the fol-
5 lowing:

6 “(q) MANUFACTURE, ADMINISTRATION, AND USE OF
7 PANDEMIC INFLUENZA TECHNOLOGIES.—

8 “(1) DEFINITIONS.—In this subsection:

9 “(A) COVERED PERSON.—The term ‘cov-
10 ered person’ means—

11 “(i) a manufacturer of a qualified
12 pandemic influenza technology;

13 “(ii) a distributor of a qualified pan-
14 demic influenza technology;

15 “(iii) a hospital, clinic, and other
16 healthcare entity under whose auspices a
17 qualified pandemic influenza technology is
18 administered;

19 “(iv) a licensed health care profes-
20 sional or other individual authorized to ad-
21 minister a qualified pandemic influenza
22 technology under State law; and

23 “(v) any official, agent, or employee of
24 any of the entities described in clauses (i)
25 through (iv), or of a State or locally ad-

1 ministered health plan, or a volunteer act-
2 ing under a publicly funded health pro-
3 gram, who is acting within the scope of his
4 or her agency or employment.

5 “(B) PANDEMIC INFLUENZA TECH-
6 NOLOGY.—The term ‘pandemic influenza tech-
7 nology’ means any vaccine product developed or
8 procured for the specific purpose of preventing
9 or treating pandemic influenza or any vaccine
10 product limiting the harm such pandemic might
11 otherwise cause.

12 “(C) QUALIFIED PANDEMIC INFLUENZA
13 TECHNOLOGY.—The term ‘qualified pandemic
14 influenza technology’ means a pandemic influ-
15 enza technology that has been designated by the
16 Secretary in accordance with paragraph (2).

17 “(2) DESIGNATION BY SECRETARY.—

18 “(A) IN GENERAL.—The Secretary may
19 designate a pandemic influenza technology as a
20 qualified pandemic influenza technology if the
21 Secretary determines that there is a public
22 health emergency involving an actual or immi-
23 nent outbreak of naturally occurring or engi-
24 neered pandemic influenza and requiring the

1 manufacture, distribution, and administration
2 of pandemic influenza technology.

3 “(B) RECOMMENDED DESIGNATION.—A
4 person may recommend to the Secretary at any
5 time the designation of a technology under sub-
6 paragraph (A) and may provide data and infor-
7 mation to support such recommendation.

8 “(C) EFFECTIVE PERIOD.—The Secretary
9 shall specify in a designation under this para-
10 graph the beginning and ending dates of the ef-
11 fective period of such designation, and may sub-
12 sequently amend such designation to shorten or
13 extend such effective period.

14 “(D) PUBLICATION.—The Secretary shall
15 provide for the publication of each designation
16 under this paragraph, and each amendment
17 thereto, in the Federal Register. Such designa-
18 tion or amendment shall take effect imme-
19 diately upon such publication and shall not be
20 subject to the provisions of section 553 of title
21 5, United States Code, concerning prior notice
22 and opportunity for comment.

23 “(E) VACCINE INJURY COMPENSATION
24 PROGRAM.—Nothing in this Act shall be con-
25 strued to supersede the authority of the Vaccine

1 Injury Compensation Program in regards to
2 vaccine products on the table, such as trivalent
3 influenza vaccine.

4 “(3) LIABILITY OF UNITED STATES.—

5 “(A) IN GENERAL.—For purposes of this
6 section, a covered person shall be deemed to be
7 an employee of the Public Health Service with
8 respect to liability for personal injury or death
9 arising out of the manufacture, administration,
10 or use of a qualified pandemic influenza tech-
11 nology. The liability of the United States under
12 this subsection shall be as set forth in section
13 1346(b) and chapter 171 of title 28, United
14 States Code, except—

15 “(i) as otherwise provided in this sec-
16 tion; and

17 “(ii) that the liability of the United
18 States may be based on any cause of ac-
19 tion seeking compensation for harm alleg-
20 edly arising out of the manufacture, ad-
21 ministration, or use of a qualified pan-
22 demic influenza technology, regardless of
23 whether such cause of action is alleged as
24 negligence, strict liability in tort, breach of
25 warranty, failure to warn, or other action.

1 “(B) SCOPE.—For purposes of this sec-
2 tion, any activity reasonably related to the man-
3 ufacture, distribution, or administration of a
4 qualified pandemic influenza technology shall be
5 considered to be a medical, surgical, dental, or
6 related function within the scope of the covered
7 person’s employment by the Public Health
8 Service.

9 “(C) GOVERNING LAW.—Notwithstanding
10 the provisions of section 1346(b)(1) and chap-
11 ter 171 of title 28, United States Code, as they
12 relate to governing law, the liability of the
13 United States as provided in this subsection
14 shall be in accordance with the law of the place
15 of injury.

16 “(D) MILITARY PERSONNEL AND UNITED
17 STATES CITIZENS OVERSEES.—

18 “(i) MILITARY PERSONNEL.—The li-
19 ability of the United States as provided in
20 this subsection shall extend to claims
21 brought by United States military per-
22 sonnel.

23 “(ii) CLAIMS ARISING IN A FOREIGN
24 COUNTRY.—Notwithstanding the provisions
25 of section 2680(k) of title 28, United

1 States Code, the liability of the United
2 States as provided in this subsection shall
3 extend to claims based on injuries arising
4 in a foreign country where the injured
5 party is a member of the United States
6 military, is the spouse or child of a mem-
7 ber of the United States military, or is a
8 United States citizen.

9 “(iii) GOVERNING LAW.—With regard
10 to all claims brought under clause (ii), and
11 notwithstanding the provisions of section
12 1346(b)(1) and chapter 171 of title 28,
13 United States Code, and of subparagraph
14 (C), as they relate to governing law, the li-
15 ability of the United States as provided in
16 this subsection shall be in accordance with
17 the law of the claimant’s domicile in the
18 United States or most recent domicile
19 within the United States.

20 “(4) EXCLUSIVITY OF REMEDY.—The remedy
21 provided for by this section shall be exclusive of any
22 other civil action or proceeding against a covered
23 person, for personal injury or death arising out of
24 the manufacture, administration, or use of a quali-

1 fied pandemic influenza technology during the effec-
2 tive period of the designation under paragraph (2).

3 “(5) COVERED PERSON TO COOPERATE WITH
4 UNITED STATES.—

5 “(A) IN GENERAL.—A covered person shall
6 cooperate with the United States in the proc-
7 essing and defense of a claim or action under
8 this subsection based upon the acts or omis-
9 sions of such person.

10 “(B) CONSEQUENCES OF FAILURE TO CO-
11 OPERATE.—Upon the motion of the United
12 States or any other party and upon a finding
13 that a covered person has failed to cooperate
14 with the United States as provided for in sub-
15 paragraph (A)—

16 “(i) the court shall substitute such
17 person as the party defendant in place of
18 the United States and, upon motion, shall
19 remand any such suit to the court in which
20 it was instituted if it appears that the
21 court lacks subject matter jurisdiction;

22 “(ii) the United States shall not be
23 liable based on the acts or omissions of
24 such person; and

1 “(iii) the Attorney General shall not
2 be obligated to defend such action.

3 “(6) RECOURSE AGAINST COVERED PERSONS IN
4 CASE OF GROSS MISCONDUCT OR MATERIAL BREACH
5 OF CONTRACT.—

6 “(A) IN GENERAL.—If payment is made by
7 the United States to any claimant bringing a
8 claim against a covered person under this sub-
9 section, either by way of administrative deter-
10 mination, settlement, or court judgment, the
11 United States shall have, notwithstanding any
12 provision of State law, the right to recover for
13 that portion of the damages so awarded or paid,
14 as well as interest and any costs of litigation,
15 resulting from—

16 “(i) such covered person’s intentional
17 breach of a procurement contract, so long
18 as such breach was materially related to
19 the injury that is the subject of the claim,
20 or

21 “(ii) any grossly negligent or reckless
22 conduct, or willful misconduct, on the part
23 of such covered person, so long as such
24 conduct or misconduct was materially re-

1 lated to the injury that is the subject to
2 the claim.

3 “(B) ACTION BY THE UNITED STATES.—
4 The United States may maintain an action
5 under this paragraph against a covered person
6 described in subparagraph (A) in the district
7 court of the United States in which such person
8 resides or has its principal place of business.”.

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