

109TH CONGRESS
1ST SESSION

H. R. 4062

To amend the Public Health Service Act with respect to preparation for an influenza pandemic, including an avian influenza pandemic, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 17, 2005

Mrs. LOWEY (for herself, Mr. EMANUEL, Mr. CASE, Mr. CONYERS, Mrs. MALONEY, Mr. JACKSON of Illinois, Mrs. CHRISTENSEN, Mr. OWENS, Mr. KILDEE, Mr. McNULTY, Mr. PAYNE, Mr. PRICE of North Carolina, Mr. REYES, Mr. HOYER, Mr. VAN HOLLEN, Mr. PALLONE, Mr. DEFazio, Mr. INSLEE, Mr. MCGOVERN, Mr. GUTIERREZ, Ms. BEAN, Ms. JACKSON-LEE of Texas, Mr. NADLER, Mr. SCHIFF, Mr. SKELTON, Mr. SANDERS, Ms. BORDALLO, Mr. MORAN of Virginia, Mr. MARKEY, Mr. WEXLER, Mr. ACKERMAN, and Mr. ALLEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act with respect to preparation for an influenza pandemic, including an avian influenza pandemic, 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 “Pandemic Prepared-
5 ness and Response Act”.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) The Department of Health and Human
4 Services reports that an influenza pandemic has a
5 greater potential to cause rapid increases in death
6 and illness than virtually any other natural health
7 threat.

8 (2) Three pandemics occurred during the 20th
9 century: the Spanish flu pandemic in 1918, the
10 Asian flu pandemic in 1957, and the Hong Kong flu
11 pandemic in 1968. The Spanish flu pandemic was
12 the most severe, causing an estimated 500,000
13 deaths in the United States and more than
14 20,000,000 deaths worldwide.

15 (3) The Centers for Disease Control and Pre-
16 vention has estimated conservatively that up to
17 207,000 Americans would die, and up to 10 million
18 would be hospitalized, during the next pandemic.
19 The costs of the pandemic, including the total direct
20 costs associated with medical care and indirect costs
21 of lost productivity and death, are estimated at be-
22 tween \$71,000,000,000 and \$166,500,000,000.
23 These costs do not include the economic effects of
24 pandemic on commerce and society.

25 (4) Recent studies suggest that avian influenza
26 strains, which are endemic in wild birds and poultry

1 populations in some countries, are becoming increas-
2 ingly capable of causing severe disease in humans
3 and are likely to cause the next pandemic flu.

4 (5) In 2004, 8 nations—Thailand, Vietnam, In-
5 donesia, Japan, Laos, China, Cambodia, and the Re-
6 public of Korea—experienced outbreaks of avian flu
7 (H5N1) among poultry flocks. Cases of human in-
8 fections were confirmed in Thailand, Cambodia, In-
9 donesia, and Vietnam (including a possible human-
10 to-human infection in Thailand).

11 (6) As of September 29, 2005, 116 confirmed
12 human cases of avian influenza (H5N1) have been
13 reported, 60 of which resulted in death. Of these
14 cases, 91 were in Vietnam, 17 in Thailand, 4 in
15 Cambodia, and 4 in Indonesia.

16 (7) On February 21, 2005, Dr. Julie
17 Gerberding, Director of the Centers for Disease
18 Control and Prevention, stated that “this is a very
19 ominous situation for the globe . . . the most impor-
20 tant threat we are facing right now.”

21 (8) On February 23, 2005, Dr. Shigeru Omi,
22 Asia regional director of the World Health Organiza-
23 tion (WHO), stated with respect to the avian flu,
24 “We at WHO believe that the world is now in the
25 gravest possible danger of a pandemic.”

1 (9) The best defense against influenza
2 pandemics is a heightened global surveillance sys-
3 tem. In many of the nations where avian flu (H5N1)
4 has become endemic the early detection capabilities
5 are severely lacking, as is the transparency in the
6 health systems.

7 (10) In addition to surveillance, pandemic pre-
8 paredness requires domestic and international co-
9 ordination and cooperation to ensure an adequate
10 medical response, including communication and in-
11 formation networks, public health measures to pre-
12 vent spread, use of vaccination and antivirals, provi-
13 sion of health outpatient and inpatient services, and
14 maintenance of core public functions.

15 **SEC. 3. AMENDMENTS TO THE PUBLIC HEALTH SERVICE**

16 **ACT.**

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

20 **“Subtitle 3—Pandemic Influenza**
21 **Preparedness**

22 **“SEC. 2141. DEFINITION.**

23 “For purposes of this subtitle, the term ‘State’ shall
24 have the meaning given such term in section 2(f) and shall
25 include Indian tribes and tribal organizations (as defined

1 in section 4(b) and 4(c) of the Indian Self-Determination
2 and Education Assistance Act).

3 **“SEC. 2142. NATIONAL DIRECTOR OF PANDEMIC PRE-**
4 **PAREDNESS AND RESPONSE.**

5 “(a) APPOINTMENT.—The President shall appoint an
6 individual to serve as the National Director of Pandemic
7 Preparedness and Response (referred to in this section as
8 the ‘Director’) within the Executive Office of the Presi-
9 dent.

10 “(b) RESPONSIBILITIES.—The Director shall—

11 “(1) serve as the chairperson of the Pandemic
12 Influenza Preparedness Policy Coordinating Com-
13 mittee (as described in section 2143);

14 “(2) coordinate the Federal interagency prepa-
15 ration for a pandemic;

16 “(3) coordinate the Federal interagency re-
17 sponse to a pandemic;

18 “(4) oversee approval of State pandemic plans
19 to ensure nationwide preparedness standards and re-
20 gional coordination as provided for under section
21 2144(b)(3);

22 “(5) ensure coordination between the govern-
23 mental and non-governmental economic and finance
24 infrastructure as it relates to pandemic preparedness
25 and response;

1 “(6) as soon as practicable, finalize a National
2 Pandemic Influenza Preparedness Plan that de-
3 scribes programs and activities to decrease the bur-
4 den of disease, minimize social disruption, and re-
5 duce economic impact from an influenza pandemic;

6 “(7) implement the National Pandemic Influenza
7 Preparedness Plan;

8 “(8) make the National Pandemic Influenza
9 Preparedness Plan available to Congress, and the
10 public as appropriate;

11 “(9) submit to Congress an annual budget re-
12 quest related to the National Pandemic Influenza
13 Preparedness Plan;

14 “(10) report to Congress on a biannual basis
15 progress regarding the implementation of the Na-
16 tional Pandemic Influenza Preparedness Plan;

17 “(11) address any deficiencies in the National
18 Pandemic Influenza Preparedness Plan as deter-
19 mined by the Government Accountability Office re-
20 port under subsection (c);

21 “(12) coordinate the provision of technical as-
22 sistance related to pandemic preparedness across
23 Federal agencies, States, and local governments;

1 “(13) ensure outreach and education campaigns
2 are conducted related to preparedness for busi-
3 nesses, health care providers, and the public;

4 “(14) address supply chain issues related to a
5 pandemic;

6 “(15) ensure that the National Pandemic Influenza Preparedness Plan includes a specific focus on
7 traditionally underserved populations, including low-
8 income, racial and ethnic minorities, immigrants,
9 and uninsured populations; and
10 and uninsured populations; and

11 “(16) hire staff, request information, assist-
12 ance, or detailees from other Federal agencies, and
13 carry out other activities related to staffing and ad-
14 ministration.

15 “(c) GAO REPORT.—

16 “(1) IN GENERAL.—Not later than 60 days
17 after the Director has finalized the National Pan-
18 demic Influenza Preparedness Plan under subsection
19 (b)(5), the Government Accountability Office shall
20 submit to the Director and Congress a report con-
21 cerning the National Pandemic Influenza Prepared-
22 ness Plan.

23 “(2) REQUIREMENTS.—At a minimum, the re-
24 port under paragraph (1) shall evaluate the ability

1 of the National Pandemic Influenza Preparedness
2 Plan to—

3 “(A) address the organizational structure
4 and chain of command, both in the Federal
5 government and at the State level;

6 “(B) ensure adequate laboratory surveil-
7 lance of influenza, including the ability to iso-
8 late and subtype influenza viruses year round;

9 “(C) improve vaccine research, develop-
10 ment, and production;

11 “(D) procure adequate doses of antivirals
12 for treatment.

13 “(E) develop systems for tracking and dis-
14 tributing antiviral medication and vaccines;

15 “(F) prioritize who would receive antivirals
16 and vaccines based on limited supplies;

17 “(G) stockpile medical and safety equip-
18 ment for health care workers and first respond-
19 ers;

20 “(H) assure surge capacity capabilities for
21 health care providers and institutions;

22 “(I) secure a backup health care workforce
23 in the event of a pandemic;

24 “(J) ensure the availability of food, water,
25 and other essential items during a pandemic;

1 “(K) provide guidance on needed State and
2 local authority to implement public health
3 measures such as isolation or quarantine;

4 “(L) maintain core public functions, in-
5 cluding public utilities, refuse disposal, mor-
6 tuary services, transportation, police and fire-
7 fighter services, and other critical services;

8 “(M) establish networks that provide alerts
9 and other information for health care providers;

10 “(N) communicate with the public with re-
11 spect to prevention and obtaining care during a
12 pandemic; and

13 “(O) provide security for first responders
14 and other medical personnel and volunteers,
15 hospitals, treatment centers, isolation and quar-
16 antine areas, and transportation and delivery of
17 resources.

18 **“SEC. 2143. POLICY COORDINATING COMMITTEE ON PAN-**

19 **DEMIC INFLUENZA PREPAREDNESS.**

20 “(a) IN GENERAL.—There is established the Pan-
21 demic Influenza Preparedness Policy Coordinating Com-
22 mittee (referred to in this section as the ‘Committee’).

23 “(b) MEMBERSHIP.—

24 “(1) IN GENERAL.—The Committee shall be
25 composed of—

1 “(A) the Secretary;

2 “(B) the Secretary of Homeland Security;

3 “(C) the Secretary of Agriculture;

4 “(D) the Secretary of State;

5 “(E) the Secretary of Defense;

6 “(F) the Secretary of Commerce;

7 “(G) the Administrator of the Environ-
8 mental Protection Agency;

9 “(H) the Secretary of Transportation;

10 “(I) the Secretary of Veterans Affairs; and

11 “(J) other representatives as determined
12 appropriate by the Chair of the Committee.

13 “(2) CHAIR.—The Director of Pandemic Pre-
14 paredness and Response shall serve as the Chair of
15 the Committee.

16 “(3) TERM.—The members of the Committee
17 shall serve for the life of the Committee.

18 “(c) MEETINGS.—

19 “(1) IN GENERAL.—The Committee shall meet
20 not less often than 2 times per year at the call of
21 the Chair or as determined necessary by the Presi-
22 dent.

23 “(2) REPRESENTATION.—A member of the
24 Committee under subsection (b) may designate a
25 representative to participate in Committee meetings,

1 but such representative shall hold the position of at
2 least an assistant secretary or equivalent position.

3 “(d) DUTIES OF THE COMMITTEE.—

4 “(1) PREPAREDNESS PLANS.—Each member of
5 the Committee shall submit to the Committee a pan-
6 demic influenza preparedness plan for the agency in-
7 volved that describes—

8 “(A) initiatives and proposals by such
9 member to address pandemic influenza (includ-
10 ing avian influenza) preparedness; and

11 “(B) any activities and coordination with
12 international entities related to such initiatives
13 and proposals.

14 “(2) INTERAGENCY PLAN AND RECOMMENDA-
15 TIONS.—

16 “(A) IN GENERAL.—

17 “(i) PREPAREDNESS PLAN.—Based on
18 the preparedness plans described under
19 paragraph (1), and not later than 90 days
20 after the date of enactment of this subtitle,
21 the Committee shall develop an Inter-
22 agency Preparedness Plan that integrates
23 and coordinates such preparedness plans.

1 “(ii) CONTENT OF PLAN.—The Inter-
2 agency Preparedness Plan under clause (i)
3 shall include a description of—

4 “(I) departmental or agency re-
5 sponsibility and accountability for
6 each component of such plan;

7 “(II) funding requirements and
8 sources;

9 “(III) international collaboration
10 and coordination efforts; and

11 “(IV) recommendations and a
12 timeline for implementation of such
13 plan.

14 “(B) REPORT.—

15 “(i) IN GENERAL.—The Committee
16 shall submit to the President and Con-
17 gress, and make available to the public as
18 appropriate, a report that includes the
19 Interagency Preparedness Plan.

20 “(ii) UPDATED REPORT.—The Com-
21 mittee shall submit to the President and
22 Congress, and make available to the public
23 as appropriate, on a biannual basis, an up-
24 date of the report that includes a descrip-
25 tion of—

1 “(I) progress made toward plan
2 implementation, as described under
3 clause (i); and

4 “(II) progress of the domestic
5 preparedness programs under section
6 2144 and of the international assist-
7 ance programs under section 2145.

8 “(C) CONSULTATION WITH INTER-
9 NATIONAL ENTITIES.—In developing the pre-
10 paredness plans described under subparagraph
11 (A) and the report under subparagraph (B), the
12 Committee should consult with representatives
13 from the World Health Organization, the World
14 Organization for Animal Health, and other
15 international bodies, as appropriate.

16 “(e) APPLICATION OF FACA.—Notwithstanding the
17 Federal Advisory Committee Act, non-government individ-
18 uals and entities may participate in the activities of the
19 Committee.

20 **“SEC. 2144. DOMESTIC PANDEMIC INFLUENZA PREPARED-**
21 **NESS ACTIVITIES.**

22 “(a) PANDEMIC PREPAREDNESS ACTIVITIES.—The
23 Director of Pandemic Preparedness and Response shall
24 strengthen, expand, and coordinate domestic pandemic in-
25 fluenza preparedness activities.

1 “(b) STATE PREPAREDNESS PLAN.—

2 “(1) IN GENERAL.—As a condition of receiving
3 funds from the Centers for Disease Control and Pre-
4 vention or the Health Resources and Services Ad-
5 ministration related to bioterrorism, a State shall—

6 “(A) designate an official or office as re-
7 sponsible for pandemic influenza preparedness;

8 “(B) submit to the Director of the Centers
9 for Disease Control and Prevention a Pandemic
10 Influenza Preparedness Plan described under
11 paragraph (2); and

12 “(C) have such Preparedness Plan ap-
13 proved in accordance with this subsection.

14 “(2) PREPAREDNESS PLAN.—

15 “(A) IN GENERAL.—The Pandemic Influenza
16 Preparedness Plan required under para-
17 graph (1) shall address—

18 “(i) human and animal surveillance
19 activities, including capacity for epidemio-
20 logical analysis, isolation and subtyping of
21 influenza viruses year-round, including for
22 avian influenza among domestic poultry,
23 and reporting of information across human
24 and veterinary sectors;

1 “(ii) methods to ensure surge capacity
2 in hospitals, laboratories, outpatient
3 healthcare provider offices, medical sup-
4 pliers, and communication networks;

5 “(iii) assisting the recruitment and
6 coordination of national and State volun-
7 teer banks of healthcare professionals;

8 “(iv) distribution of vaccines,
9 antivirals, and other treatments to priority
10 groups, and monitor effectiveness and ad-
11 verse events;

12 “(v) networks that provide alerts and
13 other information for healthcare providers
14 and organizations at the National, State,
15 and regional level;

16 “(vi) communication with the public
17 with respect to prevention and obtaining
18 care during pandemic influenza;

19 “(vii) maintenance of core public
20 functions, including public utilities, refuse
21 disposal, mortuary services, transportation,
22 police and firefighter services, and other
23 critical services;

24 “(viii) provision of security for—

1 “(I) first responders and other
2 medical personnel and volunteers;

3 “(II) hospitals, treatment cen-
4 ters, and isolation and quarantine
5 areas;

6 “(III) transport and delivery of
7 resources, including vaccines, medica-
8 tions and other supplies; and

9 “(IV) other persons or functions
10 as determined appropriate by the Sec-
11 retary;

12 “(ix) the acquisition of necessary legal
13 authority for pandemic activities;

14 “(x) integration with existing na-
15 tional, State, and regional bioterrorism
16 preparedness activities or infrastructure;

17 “(xi) coordination among public and
18 private health sectors with respect to
19 healthcare delivery, including mass vac-
20 cination and treatment systems, during
21 pandemic influenza; and

22 “(xii) coordination with Federal pan-
23 demic influenza preparedness activities.

24 “(B) UNDERSERVED POPULATIONS.—The
25 Pandemic Influenza Preparedness Plan required

1 under paragraph (1) shall include a specific
2 focus on surveillance, prevention, and medical
3 care for traditionally underserved populations,
4 including low-income, racial and ethnic minor-
5 ity, immigrant, and uninsured populations.

6 “(3) APPROVAL OF STATE PLAN.—

7 “(A) IN GENERAL.—The Director of Pan-
8 demic Preparedness and Response, in collabora-
9 tion with the Pandemic Influenza Preparedness
10 Policy Coordinating Committee, shall develop
11 criteria to rate State Pandemic Influenza Pre-
12 paredness Plans required under paragraph (1)
13 and determine the minimum rating needed for
14 approval.

15 “(B) TIMING OF APPROVAL.—Not later
16 than 90 days after a State submits a State
17 Pandemic Influenza Preparedness Plan as re-
18 quired under paragraph (1), the Director of
19 Pandemic Preparedness and Response shall
20 make a determination regarding approval of
21 such Plan.

22 “(4) REPORTING OF STATE PLAN.—All Pan-
23 demic Influenza Preparedness Plans submitted and
24 approved under this section shall be made available

1 to Congress, State officials, and the public as deter-
2 mined appropriate by the Director.

3 “(5) ASSISTANCE TO STATES.—The Centers for
4 Disease Control and Prevention and the Health Re-
5 sources and Services Administration may provide as-
6 sistance to States in carrying out this subsection, or
7 implementing an approved State Pandemic Influenza
8 Preparedness Plan, which may include the detail of
9 an officer to approved domestic pandemic sites or
10 the purchase of equipment and supplies.

11 “(6) WAIVER.—The Director of Pandemic Pre-
12 paredness and Response may grant a temporary
13 waiver of 1 or more of the requirements under this
14 subsection.

15 “(c) DOMESTIC SURVEILLANCE.—

16 “(1) IN GENERAL.—The Secretary, in coordina-
17 tion with the Secretary of Agriculture, shall establish
18 minimum thresholds for States with respect to ade-
19 quate surveillance for pandemic influenza, including
20 possible pandemic avian influenza.

21 “(2) ASSISTANCE TO STATES.—

22 “(A) IN GENERAL.—The Secretary, in co-
23 ordination with the Secretary of Agriculture,
24 shall provide assistance to States and regions to

1 meet the minimum thresholds established under
2 paragraph (1).

3 “(B) TYPES OF ASSISTANCE.—Assistance
4 provided to States under subparagraph (A) may
5 include—

6 “(i) the establishment or expansion of
7 State surveillance and alert systems, in-
8 cluding the Sentinel Physician Surveillance
9 System and 122 Cities Mortalities Report
10 System;

11 “(ii) the provision of equipment and
12 supplies;

13 “(iii) support for epidemiological anal-
14 ysis and investigation of novel strains;

15 “(iv) the sharing of biological speci-
16 mens and epidemiological and clinical data
17 within and across States; and

18 “(v) other activities determined appro-
19 priate by the Secretary.

20 “(3) DETAIL OF OFFICERS.—The Secretary
21 may detail officers to States for technical assistance
22 as needed to carry out this subsection.

23 “(d) PRIVATE SECTOR INVOLVEMENT.—

24 “(1) IN GENERAL.—The Secretary, acting
25 through the Director of the Centers for Disease

1 Control and Prevention and the Administrator of the
2 Health Resources and Services Administration, and
3 in coordination with private sector entities, shall in-
4 tegrate and coordinate public and private influenza
5 surveillance activities, as appropriate.

6 “(2) GRANT PROGRAM.—

7 “(A) IN GENERAL.—In carrying out the
8 activities under paragraph (1), the Secretary
9 may establish a grant program, or expand exist-
10 ing grant programs, to provide funding to eligi-
11 ble entities to coordinate or integrate as appro-
12 priate, pandemic preparedness surveillance ac-
13 tivities between States and private health sector
14 entities, including hospitals, health plans, and
15 other health systems.

16 “(B) ELIGIBILITY.—To be eligible to re-
17 ceive a grant under subparagraph (A), an entity
18 shall submit an application at such time, in
19 such manner, and containing such information
20 as the Secretary may require.

21 “(C) USE OF FUNDS.—Funds under a
22 grant under subparagraph (A) may be used
23 to—

1 “(i) develop and implement surveil-
2 lance protocols for patients in outpatient
3 and hospital settings;

4 “(ii) establish a communication alert
5 plan for patients for reportable signs and
6 symptoms that may suggest influenza;

7 “(iii) plan for the vaccination of popu-
8 lations and, if appropriate, dissemination
9 of antiviral drugs;

10 “(iv) purchase necessary equipment
11 and supplies;

12 “(v) increase laboratory testing and
13 networking capacity;

14 “(vi) conduct epidemiological and
15 other analyses; or

16 “(vii) report and disseminate data.

17 “(D) DETAIL OF OFFICERS.—The Sec-
18 retary may detail officers to grantees under
19 subparagraph (A) for technical assistance.

20 “(E) REQUIREMENT.—As a condition of
21 receiving a grant under subparagraph (A), a
22 State shall have a plan to meet minimum
23 thresholds for State influenza surveillance es-
24 tablished by the Director of the Centers for
25 Disease Control and Prevention in coordination

1 with the Secretary of Agriculture under sub-
2 section (b).

3 “(e) PROCUREMENT OF ANTIVIRALS FOR THE STRA-
4 TEGIC NATIONAL STOCKPILE.—The Secretary shall take
5 immediate action to procure for the Strategic National
6 Stockpile described under section 319F-2 antivirals need-
7 ed to prevent or treat infection during a pandemic influ-
8 enza, including possible pandemic avian influenza, for at
9 least 50 percent of the population.

10 “(f) PROCUREMENT OF VACCINES FOR THE STRA-
11 TEGIC NATIONAL STOCKPILE.—Subject to development
12 and testing of potential vaccines for pandemic influenza,
13 including possible pandemic avian influenza, the Secretary
14 shall determine the minimum number of doses of vaccines
15 needed to prevent infection during at least the first wave
16 of pandemic influenza for health professionals (including
17 doctors, nurses, mental health professionals, pharmacists,
18 laboratory personnel, epidemiologists, virologists, and pub-
19 lic health practitioners), core public utility employees, and
20 those persons expected to be at high risk for serious mor-
21 bidity and mortality from pandemic influenza, and take
22 immediate steps to procure this minimum number of doses
23 for the Strategic National Stockpile described under sec-
24 tion 319F-2.

1 “(g) PROCUREMENT OF ESSENTIAL MEDICATIONS.—

2 The Secretary shall, as soon as is practicable, take action
3 to procure for the Strategic National Stockpile essential
4 medications and other supplies that may be needed in the
5 event of a pandemic.

6 “(h) NATIONAL TRACKING AND DISTRIBUTION SYS-
7 TEM FOR VACCINES AND ANTIVIRALS.—

8 “(1) IN GENERAL.—The Secretary shall develop
9 and implement a national system for the tracking
10 and distribution of antiviral medications and vac-
11 cines in order to prepare and respond to pandemic
12 influenza.

13 “(2) SYSTEM.—The system developed under
14 paragraph (1) shall—

15 “(A) allow for the electronic tracking of all
16 domestically available antiviral medication and
17 vaccines for pandemic influenza;

18 “(B) anticipate shortages, and alert offi-
19 cials if shortages are expected in such medica-
20 tions and vaccines;

21 “(C) target distribution to high-risk
22 groups, including health professionals and relief
23 personnel and other individuals determined to
24 be most susceptible to disease or death from
25 pandemic flu;

1 “(3) application process by which a country
2 may apply to receive assistance from such Fund;

3 “(4) factors used to make a determination re-
4 garding a submitted application, which may in-
5 clude—

6 “(A) the gross domestic product of the ap-
7 plicant country;

8 “(B) the burden of need, as determined by
9 estimated human morbidity and mortality and
10 economic impact related to pandemic influenza
11 and the existing capacity and resources of the
12 applicant country to control the spread of the
13 disease; and

14 “(C) the willingness of the country to co-
15 operate with other countries with respect to
16 preventing and controlling the spread of the
17 pandemic influenza; and

18 “(5) any other information the Secretary deter-
19 mines necessary.

20 “(c) USE OF FUNDS.—Funds from any Pandemic
21 Fund established as provided for in this section shall be
22 used to complement and augment ongoing bilateral pro-
23 grams and activities from the United States and other
24 donor nations, or establish new programs as needed.

1 **“SEC. 2146. INTERNATIONAL DIPLOMATIC AND DEVELOP-**
2 **MENT STRATEGY.**

3 “(a) **POLICY.**—It is the policy of the United States
4 to develop and implement a comprehensive diplomatic
5 strategy targeted at (but not limited to) nations in South-
6 east and East Asia that are most at risk for an outbreak
7 of the avian influenza, including Cambodia, China, Laos,
8 Thailand, Indonesia, and Vietnam, in order to strengthen
9 international public health structures to detect, prevent,
10 and effectively respond to an outbreak of the avian flu.

11 “(b) **STRATEGY.**—The strategy developed and imple-
12 mented under subsection (a) shall include—

13 “(1) supporting information sharing and
14 strengthening surveillance, and rapid response ca-
15 pacities in key nations, including the development of
16 pandemic preparedness and response plans;

17 “(2) issuing demarches to key nations in the re-
18 gion urging additional cooperation and coordination
19 with the United States, regional governments, and
20 international organizations;

21 “(3) provide for regular visits by cabinet-level
22 officials of the United States Government, including
23 the Secretary of State, Secretary of Health and
24 Human Services, Secretary of Agriculture, Secretary
25 of Homeland Security, and Secretary of Defense, to

1 key nations in Southeast and East Asia in order to
2 enhance cooperation;

3 “(4) expanding ongoing technical assistance
4 programs, including training of personnel, procuring
5 laboratory equipment, logistics support, bio-safety
6 procedures, quality control, and case detection inves-
7 tigation techniques;

8 “(5) exchanges of scientists and medical per-
9 sonnel engaged in significant work on issues related
10 to avian flu;

11 “(6) encouraging regional governments to im-
12 plement viable compensation schemes to encourage
13 reporting by poultry farmers of cases of avian influ-
14 enza in commercial flocks;

15 “(7) forward deployment of additional United
16 States Government science and medical personnel to
17 embassies and consulates in the region;

18 “(8) public awareness campaigns in the region,
19 including increased involvement of the Broadcasting
20 Board of Governors and Voice of America, to ensure
21 timely and accurate dissemination of information;

22 “(9) using the voice and vote of the United
23 States at meeting of appropriate international orga-
24 nizations to support the aforementioned efforts; and

1 “(10) integrating the private sector, especially
2 those entities with a strong presence in the region,
3 into this effort.

4 **“SEC. 2147. INTERNATIONAL PANDEMIC INFLUENZA AS-**
5 **SISTANCE.**

6 “(a) IN GENERAL.—The Secretary shall assist other
7 countries in preparation for, and response to, pandemic
8 influenza, including possible pandemic avian influenza.

9 “(b) INTERNATIONAL SURVEILLANCE.—

10 “(1) IN GENERAL.—The Secretary, acting
11 through the Director of the Centers for Disease
12 Control and Prevention, and in collaboration with
13 the Secretary of Agriculture, in consultation with the
14 World Health Organization and the World Organiza-
15 tion for Animal Health, shall establish minimum
16 standards for surveillance capacity for all countries
17 with respect to viral strains with pandemic potential,
18 including avian influenza.

19 “(2) ASSISTANCE.—The Secretary and the Sec-
20 retary of Agriculture shall assist other countries to
21 meet the standards established in paragraph (1)
22 through—

23 “(A) the detail of officers to foreign coun-
24 tries for the provision of technical assistance or
25 training;

1 “(B) laboratory testing, including testing
2 of specimens for viral isolation or subtype anal-
3 ysis;

4 “(C) epidemiological analysis and inves-
5 tigation of novel strains;

6 “(D) provision of equipment or supplies;

7 “(E) coordination of surveillance activities
8 within and among countries;

9 “(F) the establishment and maintenance of
10 an Internet database that is accessible to health
11 officials domestically and internationally, for
12 the purpose of reporting new cases or clusters
13 of influenza and other information that may
14 help avert the pandemic spread of influenza;
15 and

16 “(G) other activities as determined nec-
17 essary by the Secretary.

18 “(c) INCREASED INTERNATIONAL MEDICAL CAPAC-
19 ITY DURING PANDEMIC INFLUENZA.—Notwithstanding
20 any other provision of law, the Secretary, in consultation
21 with the Secretary of State, may provide vaccines,
22 antiviral medications, and supplies to foreign countries
23 from the Strategic National Stockpile described under sec-
24 tion 319F–2.

1 “(d) ASSISTANCE TO FOREIGN COUNTRIES.—The
 2 Centers for Disease Control and Prevention and the
 3 Health Resources and Services Administration may pro-
 4 vide assistance to foreign countries in carrying out this
 5 section, which may include the detail of an officer to ap-
 6 proved international pandemic sites or the purchase of
 7 equipment and supplies.

8 **“SEC. 2148. PUBLIC EDUCATION AND AWARENESS CAM-**
 9 **PAIGN.**

10 “(a) IN GENERAL.—The Director of the Centers for
 11 Disease Control and Prevention, in consultation with the
 12 United States Agency for International Development, the
 13 World Health Organization, the World Organization for
 14 Animal Health, and foreign countries, shall develop an
 15 outreach campaign with respect to public education and
 16 awareness of influenza and influenza preparedness.

17 “(b) DETAILS OF CAMPAIGN.—The campaign estab-
 18 lished under subsection (a) shall—

19 “(1) be culturally and linguistically appropriate
 20 for domestic populations;

21 “(2) be adaptable for use in foreign countries;

22 “(3) target high-risk populations (those most
 23 likely to contract, transmit, and die from influenza);

1 “(4) promote personal influenza precautionary
2 measures and knowledge, and the need for general
3 vaccination, as appropriate; and

4 “(5) describe precautions at the State and local
5 level that could be implemented during pandemic in-
6 fluenza, including quarantine and other measures.

7 **“SEC. 2149. HEALTH PROFESSIONAL TRAINING.**

8 “The Secretary, directly or through contract, and in
9 consultation with professional health and medical soci-
10 eties, shall develop and disseminate pandemic influenza
11 training curricula—

12 “(1) to educate and train health professionals,
13 including physicians, nurses, public health practi-
14 tioners, virologists and epidemiologists, veterinar-
15 ians, mental health providers, allied health profes-
16 sionals, and paramedics and other first responders;

17 “(2) to educate and train volunteer, non-med-
18 ical personnel whose assistance may be required dur-
19 ing a pandemic influenza outbreak; and

20 “(3) that address prevention, including use of
21 quarantine and other isolation precautions, pan-
22 demic influenza diagnosis, medical guidelines for use
23 of antivirals and vaccines, and professional require-
24 ments and responsibilities, as appropriate.

1 **“SEC. 2150. RESEARCH AT THE NATIONAL INSTITUTES OF**
2 **HEALTH.**

3 “The Director of the National Institutes of Health
4 (referred to in this section as the ‘Director of NIH’), in
5 collaboration with the Director of the Centers for Disease
6 Control and Prevention, and other relevant agencies, shall
7 expand and intensify human and animal research, with re-
8 spect to influenza, on—

9 “(1) vaccine development and manufacture, in-
10 cluding strategies to increase immunological re-
11 sponse;

12 “(2) effectiveness of inducing heterosubtypic
13 immunity;

14 “(3) antigen-sparing studies;

15 “(4) antivirals, including minimal dose or
16 course of treatment and timing to achieve prophylactic or therapeutic effect;

17 “(5) side effects and drug safety of vaccines
18 and antivirals in subpopulations;

19 “(6) alternative routes of delivery of vaccines,
20 antivirals, and other medications as appropriate;

21 “(7) more efficient methods for testing and de-
22 termining virus subtype;

23 “(8) protective measures;

24 “(9) modes of influenza transmission;

1 “(10) effectiveness of masks, hand-washing,
2 and other non-pharmaceutical measures in pre-
3 venting transmission;

4 “(11) improved diagnostic tools for influenza;
5 and

6 “(12) other areas determined appropriate by
7 the Director of NIH.

8 **“SEC. 2151. RESEARCH AT THE CENTERS FOR DISEASE CON-**
9 **TROL AND PREVENTION.**

10 “The Director of the Centers for Disease Control and
11 Prevention, in collaboration with other relevant agencies,
12 shall expand and intensify research, with respect to influ-
13 enza, on—

14 “(1) historical research on prior pandemics to
15 better understand pandemic epidemiology, trans-
16 mission, protective measures, high-risk groups, and
17 other lessons that may be applicable to future pan-
18 demic;

19 “(2) communication strategies for the public
20 during pandemic influenza, taking into consideration
21 age, racial and ethnic background, health literacy,
22 and risk status;

23 “(3) changing and influencing human behavior
24 as it relates to vaccination;

1 “(4) development and implementation of a pub-
2 lic, non-commercial and non-competitive broadcast
3 system and person-to-person networks;

4 “(5) population-based surveillance methods to
5 estimate influenza infection rates and rates of out-
6 patient illness;

7 “(6) vaccine effectiveness;

8 “(7) systems to monitor vaccination coverage
9 levels and adverse events from vaccination; and

10 “(8) other areas determined appropriate by the
11 Director of the Centers for Disease Control and Pre-
12 vention.

13 **“SEC. 2152. INSTITUTE OF MEDICINE STUDY ON THE LEGAL,**
14 **ETHICAL, AND SOCIAL IMPLICATIONS OF**
15 **PANDEMIC INFLUENZA.**

16 “(a) IN GENERAL.—The Secretary shall contract
17 with the Institute of Medicine to—

18 “(1) study the legal, ethical, and social implica-
19 tions of, with respect to pandemic influenza—

20 “(A) animal/human interchange;

21 “(B) global surveillance;

22 “(C) case contact investigations;

23 “(D) vaccination and medical treatment;

24 “(E) community hygiene;

25 “(F) travel and border controls;

1 “(G) decreased social mixing and increased
2 social distance;

3 “(H) civil confinement; and

4 “(I) other topics as determined appropriate
5 by the Secretary; and

6 “(2) not later than 1 year after the date of en-
7 actment of the Pandemic Preparedness and Re-
8 sponse Act, submit to the Secretary a report that
9 describes recommendations based on the study con-
10 ducted under paragraph (1).

11 “(b) IMPLEMENTATION OF RECOMMENDATIONS.—

12 Not later than 90 days after the submission of the report
13 of under subsection (a)(2), the Secretary shall address the
14 recommendations of the Institute of Medicine regarding
15 the domestic and international allocation and distribution
16 of pandemic influenza vaccine and antivirals.

17 **“SEC. 2153. NATIONAL PANDEMIC INFLUENZA ECONOMICS**
18 **ADVISORY COMMITTEE.**

19 “(a) IN GENERAL.—There is established the National
20 Pandemic Influenza Economics Advisory Committee (re-
21 ferred to in this section as the ‘Committee’).

22 “(b) MEMBERSHIP.—

23 “(1) IN GENERAL.—The members of the Com-
24 mittee shall be appointed by the Comptroller General
25 of the United States and shall include domestic and

1 international experts on pandemic influenza, public
2 health, veterinary science, commerce, economics, fi-
3 nance, and international diplomacy.

4 “(2) CHAIR.—The Comptroller General of the
5 United States shall select a Chair from among the
6 members of the Committee.

7 “(c) DUTIES.—The Committee shall study and make
8 recommendations to Congress and the Secretary on the
9 financial and economic impact of pandemic influenza and
10 possible financial structures for domestic and inter-
11 national pandemic response, relating to—

12 “(1) the development, storage, and distribution
13 of vaccines;

14 “(2) the development, storage, and distribution
15 of antiviral and other medications and supplies;

16 “(3) increased surveillance activities;

17 “(4) provision of preventive and medical care
18 during pandemic;

19 “(5) reimbursement for health providers and
20 other core public function employees;

21 “(6) reasonable compensation for farmers and
22 other workers that bear direct or disproportionate
23 loss of revenue; and

24 “(7) other issues determined appropriate by the
25 Chair.

1 “(d) COMPENSATION.—

2 “(1) IN GENERAL.—Each member of the Com-
3 mittee who is not an officer or employee of the Fed-
4 eral Government shall be compensated at a rate
5 equal to the daily equivalent of the annual rate of
6 basic pay prescribed for level IV of the Executive
7 Schedule under section 5315 of title 5, United
8 States Code, for each day (including travel time)
9 during which such member is engaged in the per-
10 formance of the duties of the Committee. All mem-
11 bers who are officers or employees of the United
12 States shall serve without compensation in addition
13 to that received for their services as officers or em-
14 ployees of the United States.

15 “(2) TRAVEL EXPENSES.—A member of the
16 Committee shall be allowed travel expenses, includ-
17 ing per diem in lieu of subsistence, at rates author-
18 ized for an employee of an agency under subchapter
19 I of chapter 57 of title 5, United States Code, while
20 away from the home or regular place of business of
21 the member in the performance of the duties of the
22 Committee.

23 “(e) STAFF.—

24 “(1) IN GENERAL.—The Chair of the Com-
25 mittee shall provide the Committee with such profes-

1 sional and clerical staff, such information, and the
2 services of such consultants as may be necessary to
3 assist the Committee in carrying out the functions
4 under this section.

5 “(2) DETAIL OF FEDERAL GOVERNMENT EM-
6 PLOYEES.—

7 “(A) IN GENERAL.—An employee of the
8 Federal Government may be detailed to the
9 Committee without reimbursement.

10 “(B) CIVIL SERVICE STATUS.—The detail
11 of the employee shall be without interruption or
12 loss of civil service status or privilege.

13 “(3) PROCUREMENT OF TEMPORARY AND
14 INTERMITTENT SERVICES.—The Chair of the Com-
15 mittee may procure temporary and intermittent serv-
16 ices in accordance with section 3109(b) of title 5,
17 United States Code, at rates for individuals that do
18 not exceed the daily equivalent of the annual rate of
19 basic pay prescribed for level V of the Executive
20 Schedule under section 5316 of that title.

21 **“SEC. 2154. PANDEMIC INFLUENZA AND ANIMAL HEALTH.**

22 “(a) IN GENERAL.—The Secretary of Agriculture
23 shall expand and intensify efforts to prevent pandemic in-
24 fluenza, including possible pandemic avian influenza.

1 “(b) REPORT.—Not later than 180 days after the
2 date of enactment this Act, the Secretary of Agriculture
3 shall submit to Congress a report that describes the antici-
4 pated impact of pandemic influenza on the United States.

5 “(c) ASSISTANCE.—The Secretary of Agriculture, in
6 consultation with the Secretary of Health and Human
7 Services, the World Health Organization, and the World
8 Organization for Animal Health, shall provide domestic
9 and international assistance with respect to pandemic in-
10 fluenza preparedness to—

11 “(1) support the eradication of infectious ani-
12 mal diseases and zoonosis;

13 “(2) increase transparency in animal disease
14 states;

15 “(3) collect, analyze, and disseminate veterinary
16 data;

17 “(4) strengthen international coordination and
18 cooperation in the control of animal diseases; and

19 “(5) promote the safety of world trade in ani-
20 mals and animal products.

21 “(d) ELECTRONIC DATABASE.—The Secretary of Ag-
22 riculture, in conjunction with the Secretary of Health and
23 Human Services, shall establish an electronic disease sur-
24 veillance database in order to trace the incidence of avian

1 influenza in both animals and humans in the United
2 States.

3 “(e) IMPROVEMENTS IN THE NATIONAL ANIMAL
4 HEALTH LABORATORY NETWORK.—The Secretary of Ag-
5 riculture shall evaluate the National Animal Health Lab-
6 oratory Network and make recommendations for improve-
7 ments to participating laboratories and other State animal
8 health laboratories to rapidly diagnose and research avian
9 influenza outbreaks.

10 “(f) COMMUNICATIONS LIAISONS.—

11 “(1) IN GENERAL.—The Secretary of Agri-
12 culture jointly with the Secretary of Homeland Secu-
13 rity shall designate a liaison in each State to facili-
14 tate and coordinate communications among and be-
15 tween States in the event of an agriculture emer-
16 gency.

17 “(2) FUNCTIONS.—Each liaison designated
18 under paragraph (1) shall—

19 “(A) be the central point of contact for
20 animal health in communications with the De-
21 partment of Agriculture and the Department of
22 Homeland Security;

23 “(B) communicate Federal preparedness
24 and response plans to State and local agri-
25 culture officials and veterinarians; and

1 “(C) communicate concerns from State
2 and local agriculture officials and veterinarians
3 to the Department of Agriculture and Depart-
4 ment of Homeland Security and the Depart-
5 ment of Health and Human Services.

6 **“Subtitle 4—Strengthening Public**
7 **Health Immunization Capacity**
8 **and Supply**

9 **“SEC. 2161. FINDINGS.**

10 “Congress finds that—

11 “(1) effective pandemic influenza preparedness
12 and response is dependent upon the existence of
13 solid public health infrastructure to combat seasonal
14 flu;

15 “(2) the domestic surveillance and vaccine pro-
16 duction and distribution capabilities needed in a
17 time of crisis should be well established and active
18 in a non-crisis capacity to enable a more efficient re-
19 sponse to pandemic influenza; and

20 “(3) each State receiving Federal funds should
21 have a State Immunization Program Coordinator,
22 who should be responsible for coordinating and im-
23 plementing activities related to influenza.

24 **“SEC. 2162. VACCINE SUPPLY.**

25 “(a) REQUESTS FOR MORE DOSES.—

1 “(1) IN GENERAL.—Not later than March 15 of
2 each year, the Secretary shall enter into contracts
3 with manufacturers to produce such additional doses
4 of the influenza vaccine as determined necessary by
5 the Secretary.

6 “(2) CONTENT OF CONTRACT.—A contract for
7 additional doses shall provide that the manufacturer
8 will be compensated by the Secretary at an equitable
9 rate negotiated by the Secretary and the manufac-
10 turer for any doses that—

11 “(A) were not sold by the manufacturer
12 through routine market mechanisms at the end
13 of the influenza season for that year; and

14 “(B) were requested by the Secretary to be
15 produced by such manufacturer.

16 “(3) WHEN SUCH VACCINE PURCHASES
17 SHOULD TAKE PLACE.—The Secretary may purchase
18 from the manufacturer the doses for which it has
19 contracted at any time after which it is determined
20 by the Secretary, in consultation with the manufac-
21 turer, that the doses will likely not be absorbed by
22 the private market.

23 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section
25 such sums as may be necessary.

1 **“SEC. 2163. DISCONTINUANCE OF INFLUENZA VACCINE.**

2 “(a) IN GENERAL.—

3 “(1) NOTICE TO SECRETARY.—A manufacturer
4 of the influenza vaccine shall notify the Secretary of
5 a discontinuance of the manufacture of the vaccine
6 at least 12 months prior to the date of the dis-
7 continuance.

8 “(2) DIRECTOR OF CENTERS FOR DISEASE
9 CONTROL AND PREVENTION.—Promptly after receiv-
10 ing a notice under paragraph (1), the Secretary shall
11 inform the Director of the Centers for Disease Con-
12 trol and Prevention of the notice. Promptly after de-
13 termining that a reduction under subsection (b) ap-
14 plies with respect to such a notice, the Secretary
15 shall inform such Director of the reduction.

16 “(3) RELATIONSHIP TO SEPARATE NOTICE PRO-
17 GRAM.—In the case of influenza vaccine that is ap-
18 proved by the Secretary and is a drug described in
19 section 506C(a), this section applies to the vaccine
20 in lieu of section 506C.

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

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

4 “(2) a biomaterials shortage prevents the con-
5 tinuation of the manufacturing for the 12-month pe-
6 riod;

7 “(3) continuation of the manufacturing for the
8 12-month period may cause substantial economic
9 hardship for the manufacturer;

10 “(4) the manufacturer has filed for bankruptcy
11 under chapter 7 or 11 of title 11, United States
12 Code; or

13 “(5) the manufacturer can continue the dis-
14 tribution of the vaccine involved for 12 months.

15 “(c) DISTRIBUTION.—To the maximum extent prac-
16 ticable, the Secretary shall distribute information on the
17 discontinuation of the manufacture of influenza vaccines
18 to appropriate physician and patient organizations.

19 **“SEC. 2164. SHORTAGE PREPAREDNESS AND RESPONSE.**

20 “(a) EMERGENCY RESPONSE PLANS REGARDING
21 SHORTAGES.—

22 “(1) NATIONAL EMERGENCY RESPONSE
23 PLAN.—The Secretary shall develop and maintain a
24 national plan for the response to potential shortages
25 in supplies of influenza vaccines that would con-

1 stitute public health emergencies. The plan shall in-
2 clude provisions with respect to communication
3 among relevant entities, distribution of available
4 supplies of the influenza vaccine involved, the des-
5 ignation of populations to be given priority for im-
6 munizations, interactions with State and local gov-
7 ernments, the use of the National Stockpile, and
8 special considerations for specific vaccines. The ini-
9 tial plan shall be completed not later than 12
10 months after the date of the enactment of this sec-
11 tion.

12 “(2) STATE EMERGENCY RESPONSE PLAN.—
13 Each State that receives funds under this Act shall,
14 not later than 6 months after the date on which the
15 National Plan is issued under paragraph (1), de-
16 velop, through the State Immunization Coordinator,
17 a State Emergency Response Plan that is modeled
18 on the National Plan.

19 **“SEC. 2165. PROVISIONS TO INCREASE VACCINE COVERAGE**
20 **RATES.**

21 “(a) IN GENERAL.—The Secretary shall develop a
22 plan for the distribution of seasonal flu vaccines to ensure
23 that uninsured and underinsured adults and children have
24 access to annual influenza vaccines and vaccines for condi-
25 tions potentially exacerbated by exposure to pandemic in-

1 fluenza. Immunizations should be available to such popu-
2 lations as well as children in the VFC program through
3 a wide variety of providers including both Federally quali-
4 fied health centers and State and local health depart-
5 ments.

6 “(b) REQUIREMENT.—The Secretary shall—

7 “(1) conduct an assessment to determine the
8 number of adults in need of vaccinations and the
9 barriers to vaccinating adults; and

10 “(2) develop and implement strategies to in-
11 crease the rate of immunizations in populations in
12 which a significant number of individuals have not
13 received immunizations with the federally rec-
14 ommended vaccines (as defined in section 317A(g))
15 for the populations.

16 “(c) DEFINITION.—For purposes of this section, the
17 term ‘adult’ means an individual who is not a child as de-
18 fined in section 1928 of the Social Security Act.

19 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated to carry out this section,
21 such sums as may be necessary.

22 **“SEC. 2166. OUTREACH, COMMUNICATION, EDUCATION.**

23 “(a) EDUCATION PROGRAM REGARDING ADULT IM-
24 MUNIZATIONS.—The Secretary, acting through the Direc-
25 tor of the Centers for Disease Control and Prevention (in

1 this section referred to as the ‘Director’), shall conduct
2 a public awareness campaign and education and outreach
3 efforts each year during the time period preceding the in-
4 fluenza season on each of the following:

5 “(1) The importance of receiving the influenza
6 vaccine.

7 “(2) Which populations the Director rec-
8 ommends to receive the influenza vaccine to prevent
9 health complications associated with influenza, in-
10 cluding health care workers and their household con-
11 tacts.

12 “(3) Professional medical education of physi-
13 cians, nurses, pharmacists, and other health care
14 providers and such providers’ associated organiza-
15 tions.

16 “(4) Information that emphasizes the safety
17 and benefit of recommended vaccines for the public
18 good.

19 “(b) OUTREACH TO MEDICARE RECIPIENTS.—

20 “(1) PROGRAM.—

21 “(A) IN GENERAL.—The Director, in con-
22 sultation with the Administrator of the Centers
23 for Medicare & Medicaid Services, shall, at the
24 earliest possible time in the influenza vaccine
25 planning and production process, reach out to

1 providers of medicare services, including man-
2 aged care providers, nursing homes, hospitals,
3 and physician offices to urge early and full
4 preordering of the influenza vaccine so that pro-
5 duction levels can accommodate the needs for
6 the influenza vaccine.

7 “(B) RATES OF IMMUNIZATION AMONG
8 MEDICARE RECIPIENTS.—The Director shall
9 work with the Administrator of the Centers for
10 Medicare & Medicaid Services to publish the
11 rates of influenza immunization among individ-
12 uals receiving assistance under the medicare
13 program under title XVIII of the Social Secu-
14 rity Act (42 U.S.C. 1395 et seq.).

15 “(2) STATE AND PUBLIC HEALTH ADULT IMMUN-
16 NIZATION ACTIVITIES.—The Director shall support
17 the development of State adult immunization pro-
18 grams that place emphasis on improving influenza
19 vaccine delivery to high-risk populations and the
20 general population, including the exploration of im-
21 proving access to the influenza vaccine.

22 “(3) EXISTING MODES OF COMMUNICATION.—
23 In carrying out the public awareness campaign and
24 education and outreach efforts under paragraph (1)

1 and (2), the Director may use existing websites or
2 structures for communication.

3 “(4) AUTHORIZATION OF APPROPRIATIONS.—
4 There are authorized to be appropriated to carry out
5 this subsection \$10,000,000 for each of fiscal years
6 2005 through 2009.

7 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there are authorized
9 to be appropriated such sums as may be necessary for
10 each of the fiscal years 2006 through 2010.”.

11 **SEC. 4. UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN**
12 **COMMERCE RELATED TO TREATMENTS FOR**
13 **PANDEMIC INFLUENZA.**

14 Part B of title III of the Public Health Service Act
15 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
16 tion 319K the following section:

17 **“SEC. 319L. UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN**
18 **COMMERCE RELATED TO TREATMENTS FOR**
19 **PANDEMIC INFLUENZA.**

20 “(a) SALES TO CONSUMERS AT UNCONSCIONABLE
21 PRICE.—

22 “(1) IN GENERAL.—During any public health
23 emergency declared by the Secretary under section
24 319 related to pandemic influenza, it shall be unlaw-
25 ful for any person to sell any drug (including an

1 anti-viral drug), device, or biologic for the prevention
2 or treatment of influenza in, or for use in, the area
3 to which that declaration applies at a price that—

4 “(A) is unconscionably excessive (as deter-
5 mined by the Secretary); or

6 “(B) indicates the seller is taking unfair
7 advantage of the circumstances to increase
8 prices unreasonably.

9 “(2) FACTORS TO BE CONSIDERED.—In deter-
10 mining whether a violation of paragraph (1) has oc-
11 curred, a court shall take into account, among other
12 factors, whether—

13 “(A) the amount charged represents a
14 gross disparity between the price of a drug, de-
15 vice, or biologic for the prevention or treatment
16 of influenza and the price at which the drug,
17 device, or biologic was offered for sale in the
18 usual course of the seller’s business immediately
19 prior to the public health emergency; or

20 “(B) the amount charged grossly exceeds
21 the price at which the same or similar drug, de-
22 vice, or biologic for the prevention or treatment
23 of influenza was readily obtainable by other
24 purchasers in the area in which the declaration
25 applies.

1 “(3) MITIGATING FACTORS.—In determining
2 whether a violation of paragraph (1) has occurred,
3 the court shall also take into account, among other
4 factors, the price that would reasonably equate sup-
5 ply and demand in a competitive and freely func-
6 tioning market and whether the price at which the
7 drug, device, or biologic for the prevention or treat-
8 ment of influenza was sold reasonably reflects addi-
9 tional costs, not within the control of the seller, that
10 were paid or incurred by the seller.

11 “(b) FALSE PRICING INFORMATION.—It shall be un-
12 lawful for any person to report information related to the
13 wholesale price of any drug, device, or biologic for the pre-
14 vention or treatment of influenza to the Secretary if—

15 “(1) that person knew, or reasonably should
16 have known, the information to be false or mis-
17 leading;

18 “(2) the information was required by law to be
19 reported; and

20 “(3) the person intended the false or misleading
21 data to affect data compiled by the department or
22 agency involved for statistical or analytical purposes
23 with respect to the market for drugs, devices, or bio-
24 logics for the prevention or treatment of influenza.

1 “(c) MARKET MANIPULATION.—It shall be unlawful
2 for any person, directly or indirectly, to use or employ,
3 in connection with the purchase or sale of drugs, devices,
4 or biologics for the prevention or treatment of influenza
5 at wholesale, any manipulative or deceptive device or con-
6 trivance, in contravention of such rules and regulations
7 as the Secretary may prescribe as necessary or appro-
8 priate in the public interest or for the protection of United
9 States citizens.”.

10 **SEC. 5. AUTHORIZATION OF APPROPRIATIONS.**

11 There are authorized to be appropriated such sums
12 as may be necessary to carry out this Act (and the amend-
13 ments made by this Act) for each of the fiscal years 2006
14 through 2010.

○