S. 3678

One Hundred Ninth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and six

An Act

To amend the Public Health Service Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Pandemic and All-Hazards Preparedness Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—NATIONAL PREPAREDNESS AND RESPONSE, LEADERSHIP, ORGANIZATION, AND PLANNING

Sec. 101. Public health and medical preparedness and response functions of the Secretary of Health and Human Services.
Sec. 102. Assistant Secretary for Preparedness and Response.
Sec. 103. National Health Security Strategy.

TITLE II—PUBLIC HEALTH SECURITY PREPAREDNESS

Sec. 201. Improving State and local public health security.
Sec. 202. Using information technology to improve situational awareness in public health emergencies.
Sec. 203. Public health workforce enhancements.
Sec. 204. Vaccine tracking and distribution.
Sec. 205. National Science Advisory Board for Biosecurity.
Sec. 206. Revitalization of Commissioned Corps.

TITLE III—ALL-HAZARDS MEDICAL SURGE CAPACITY

Sec. 301. National disaster medical system.
Sec. 302. Enhancing medical surge capacity.
Sec. 303. Encouraging health professional volunteers.
Sec. 304. Core education and training.
Sec. 305. Partnerships for State and regional hospital preparedness to improve surge capacity.
Sec. 306. Enhancing the role of the Department of Veterans Affairs.

TITLE IV—PANDEMIC AND BIODEFENSE VACCINE AND DRUG DEVELOPMENT

Sec. 401. Biomedical Advanced Research and Development Authority.
Sec. 402. National Biodefense Science Board.
Sec. 403. Clarification of countermeasures covered by Project BioShield.
Sec. 404. Technical assistance.
Sec. 405. Collaboration and coordination.
Sec. 406. Procurement.

TITLE I—NATIONAL PREPAREDNESS AND RESPONSE, LEADERSHIP, ORGANIZATION, AND PLANNING

SEC. 101. PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE FUNCTIONS OF THE SECRETARY OF HEALTH AND HUMAN SERVICES.

Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–11 et seq.) is amended—

(1) by striking the title heading and inserting the following:

"TITLE XXVIII—NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES";

and

(2) by amending subtitle A to read as follows:

"Subtitle A—National All-Hazards Preparedness and Response Planning, Coordinating, and Reporting

"SEC. 2801. PUBLIC HEALTH AND MEDICAL PREPAREDNESS AND RESPONSE FUNCTIONS.

"(a) IN GENERAL.—The Secretary of Health and Human Services shall lead all Federal public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan.

"(b) INTERAGENCY AGREEMENT.—The Secretary, in collaboration with the Secretary of Veterans Affairs, the Secretary of Transportation, the Secretary of Defense, the Secretary of Homeland Security, and the head of any other relevant Federal agency, shall establish an interagency agreement, consistent with the National Response Plan or any successor plan, under which agreement the Secretary of Health and Human Services shall assume operational control of emergency public health and medical response assets, as necessary, in the event of a public health emergency, except that members of the armed forces under the authority of the Secretary of Defense shall remain under the command and control of the Secretary of Defense, as shall any associated assets of the Department of Defense.".

SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

(a) ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.—Subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–11 et seq.) is amended—

(1) in the subtitle heading, by inserting "All-Hazards" before "Emergency Preparedness";

(2) by redesignating section 2811 as section 2812;

(3) by inserting after the subtitle heading the following new section:

"SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.

"(a) IN GENERAL.—There is established within the Department of Health and Human Services the position of the Assistant Secretary for Preparedness and Response. The President, with the advice and consent of the Senate, shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

"(b) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Preparedness and Response shall carry out the following functions:

"(1) LEADERSHIP.—Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.

"(2) PERSONNEL.—Register, credential, organize, train, equip, and have the authority to deploy Federal public health and medical personnel under the authority of the Secretary, including the National Disaster Medical System, and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals.

"(3) COUNTERMEASURES.—Oversee advanced research, development, and procurement of qualified countermeasures (as defined in section 319F–1) and qualified pandemic or epidemic products (as defined in section 319F–3).

"(4) COORDINATION.—

"(A) FEDERAL INTEGRATION.—Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.

"(B) STATE, LOCAL, AND TRIBAL INTEGRATION.—Coordinate with State, local, and tribal public health officials, the Emergency Management Assistance Compact, health care systems, and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.

"(C) EMERGENCY MEDICAL SERVICES.—Promote improved emergency medical services medical direction, system integration, research, and uniformity of data collection, treatment protocols, and policies with regard to public health emergencies.

"(5) LOGISTICS.—In coordination with the Secretary of Veterans Affairs, the Secretary of Homeland Security, the General Services Administration, and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies.

"(6) LEADERSHIP.—Provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.

"(c) FUNCTIONS.—The Assistant Secretary for Preparedness and Response shall—

"(1) have authority over and responsibility for—

"(A) the National Disaster Medical System (in accordance with section 301 of the Pandemic and All-Hazards Preparedness Act); and

"(B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 319C–2;

"(2) exercise the responsibilities and authorities of the Secretary with respect to the coordination of—

"(A) the Medical Reserve Corps pursuant to section 2813;

"(B) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 319I;

"(C) the Strategic National Stockpile; and

"(D) the Cities Readiness Initiative; and

"(3) assume other duties as determined appropriate by the Secretary."; and

(4) by striking "Assistant Secretary for Public Health Emergency Preparedness" each place it appears and inserting "Assistant Secretary for Preparedness and Response".

(b) TRANSFER OF FUNCTIONS; REFERENCES.—

(1) TRANSFER OF FUNCTIONS.—There shall be transferred to the Office of the Assistant Secretary for Preparedness and Response the functions, personnel, assets, and liabilities of the Assistant Secretary for Public Health Emergency Preparedness as in effect on the day before the date of enactment of this Act.

(2) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Assistant Secretary for Public Health Emergency Preparedness as in effect the day before the date of enactment of this Act, shall be deemed to be a reference to the Assistant Secretary for Preparedness and Response.

(c) STOCKPILE.—Section 319F–2(a)(1) of the Public Health Service Act (42 U.S.C. 247d–6b(a)(1)) is amended by—

(1) inserting "in collaboration with the Director of the Centers for Disease Control and Prevention, and" after "Secretary,"; and

(2) inserting at the end the following: "The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review.".

(d) AT-RISK INDIVIDUALS.—Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.), as amended by section 303 of this Act, is amended by inserting after section 2813 the following:

"SEC. 2814. AT-RISK INDIVIDUALS.

"The Secretary, acting through such employee of the Department of Health and Human Services as determined by the Secretary and designated publicly (which may, at the discretion of the Secretary, involve the appointment or designation of an individual as the Director of At-Risk Individuals), shall—

"(1) oversee the implementation of the National Preparedness goal of taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency, as described in section 2802(b)(4);

"(2) assist other Federal agencies responsible for planning for, responding to, and recovering from public health emergencies in addressing the needs of at-risk individuals;

"(3) provide guidance to and ensure that recipients of State and local public health grants include preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency, as described in section 319C–1(b)(2)(A)(iii);

"(4) ensure that the contents of the strategic national stockpile take into account at-risk populations as described in section 2811(b)(3)(B);

"(5) oversee the progress of the Advisory Committee on At-Risk Individuals and Public Health Emergencies established under section 319F(b)(2) and make recommendations with a focus on opportunities for action based on the work of the Committee;

"(6) oversee curriculum development for the public health and medical response training program on medical management of casualties, as it concerns at-risk individuals as described in subparagraphs (A) through (C) of section 319F(a)(2);

"(7) disseminate novel and best practices of outreach to and care of at-risk individuals before, during, and following public health emergencies; and

"(8) not later than one year after the date of enactment of the Pandemic and All-Hazards Preparedness Act, prepare and submit to Congress a report describing the progress made on implementing the duties described in this section.".

SEC. 103. NATIONAL HEALTH SECURITY STRATEGY.

Title XXVIII of the Public Health Service Act (300hh–11 et seq.), as amended by section 101, is amended by inserting after section 2801 the following:

"SEC. 2802. NATIONAL HEALTH SECURITY STRATEGY.

"(a) IN GENERAL.—

"(1) PREPAREDNESS AND RESPONSE REGARDING PUBLIC HEALTH EMERGENCIES.—Beginning in 2009 and every four years thereafter, the Secretary shall prepare and submit to the relevant committees of Congress a coordinated strategy (to be known as the National Health Security Strategy) and any revisions thereof, and an accompanying implementation plan for public health emergency preparedness and response. Such National Health Security Strategy shall identify the process for achieving the preparedness goals described in subsection (b) and shall be consistent with the National Preparedness Goal, the National Incident Management System, and the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan.

"(2) EVALUATION OF PROGRESS.—The National Health Security Strategy shall include an evaluation of the progress made by Federal, State, local, and tribal entities, based on the evidence-based benchmarks and objective standards that measure levels of preparedness established pursuant to section 319C–1(g). Such evaluation shall include aggregate and State-specific breakdowns of obligated funding spent by major category (as defined by the Secretary) for activities funded through awards pursuant to sections 319C–1 and 319C–2.

"(3) PUBLIC HEALTH WORKFORCE.—In 2009, the National Health Security Strategy shall include a national strategy for establishing an effective and prepared public health workforce, including defining the functions, capabilities, and gaps in such workforce, and identifying strategies to recruit, retain, and protect such workforce from workplace exposures during public health emergencies.

"(b) PREPAREDNESS GOALS.—The National Health Security Strategy shall include provisions in furtherance of the following:

"(1) INTEGRATION.—Integrating public health and public and private medical capabilities with other first responder systems, including through—

"(A) the periodic evaluation of Federal, State, local, and tribal preparedness and response capabilities through drills and exercises; and

"(B) integrating public and private sector public health and medical donations and volunteers.

"(2) PUBLIC HEALTH.—Developing and sustaining Federal, State, local, and tribal essential public health security capabilities, including the following:

"(A) Disease situational awareness domestically and abroad, including detection, identification, and investigation.

"(B) Disease containment including capabilities for isolation, quarantine, social distancing, and decontamination.

"(C) Risk communication and public preparedness.

"(D) Rapid distribution and administration of medical countermeasures.

"(3) MEDICAL.—Increasing the preparedness, response capabilities, and surge capacity of hospitals, other health care facilities (including mental health facilities), and trauma care and emergency medical service systems, with respect to public health emergencies, which shall include developing plans for the following:

"(A) Strengthening public health emergency medical management and treatment capabilities.

"(B) Medical evacuation and fatality management.

"(C) Rapid distribution and administration of medical countermeasures.

"(D) Effective utilization of any available public and private mobile medical assets and integration of other Federal assets.

"(E) Protecting health care workers and health care first responders from workplace exposures during a public health emergency.

"(4) AT-RISK INDIVIDUALS.—

"(A) Taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency.

"(B) For purpose of this section and sections 319C–1, 319F, and 319L, the term 'at-risk individuals' means children, pregnant women, senior citizens and other individuals who have special needs in the event of a public health emergency, as determined by the Secretary.

"(5) COORDINATION.—Minimizing duplication of, and ensuring coordination between, Federal, State, local, and tribal planning, preparedness, and response activities (including the

State Emergency Management Assistance Compact). Such planning shall be consistent with the National Response Plan, or any successor plan, and National Incident Management System and the National Preparedness Goal.

"(6) CONTINUITY OF OPERATIONS.—Maintaining vital public health and medical services to allow for optimal Federal, State, local, and tribal operations in the event of a public health emergency.".

TITLE II—PUBLIC HEALTH SECURITY PREPAREDNESS

SEC. 201. IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.

Section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended—

(1) by amending the heading to read as follows: "**IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.**";

(2) by striking subsections (a) through (i) and inserting the following:

"(a) IN GENERAL.—To enhance the security of the United States with respect to public health emergencies, the Secretary shall award cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

"(b) ELIGIBLE ENTITIES.—To be eligible to receive an award under subsection (a), an entity shall—

"(1)(A) be a State;

"(B) be a political subdivision determined by the Secretary to be eligible for an award under this section (based on criteria described in subsection (i)(4)); or

"(C) be a consortium of entities described in subparagraph (A); and

"(2) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including—

"(A) an All-Hazards Public Health Emergency Preparedness and Response Plan which shall include—

"(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 2802;

"(ii) a pandemic influenza plan consistent with the requirements of paragraphs (2) and (5) of subsection (g);

"(iii) preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency;

"(iv) a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact or other mutual aid agreements for medical and public health mutual aid; and

"(v) a description of how the entity will include the State Unit on Aging in public health emergency preparedness;

"(B) an assurance that the entity will report to the Secretary on an annual basis (or more frequently as determined by the Secretary) on the evidence-based benchmarks

and objective standards established by the Secretary to evaluate the preparedness and response capabilities of such entity under subsection (g);

"(C) an assurance that the entity will conduct, on at least an annual basis, an exercise or drill that meets any criteria established by the Secretary to test the preparedness and response capabilities of such entity, and that the entity will report back to the Secretary within the application of the following year on the strengths and weaknesses identified through such exercise or drill, and corrective actions taken to address material weaknesses;

"(D) an assurance that the entity will provide to the Secretary the data described under section 319D(d)(3) as determined feasible by the Secretary;

"(E) an assurance that the entity will conduct activities to inform and educate the hospitals within the jurisdiction of such entity on the role of such hospitals in the plan required under subparagraph (A);

"(F) an assurance that the entity, with respect to the plan described under subparagraph (A), has developed and will implement an accountability system to ensure that such entity make satisfactory annual improvement and describe such system in the plan under subparagraph (A);

"(G) a description of the means by which to obtain public comment and input on the plan described in subparagraph (A) and on the implementation of such plan, that shall include an advisory committee or other similar mechanism for obtaining comment from the public and from other State, local, and tribal stakeholders; and

"(H) as relevant, a description of the process used by the entity to consult with local departments of public health to reach consensus, approval, or concurrence on the relative distribution of amounts received under this section.

"(c) LIMITATION.—Beginning in fiscal year 2009, the Secretary may not award a cooperative agreement to a State unless such State is a participant in the Emergency System for Advance Registration of Volunteer Health Professionals described in section 319I.

"(d) USE OF FUNDS.—

"(1) IN GENERAL.—An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (2), (4), (5), and (6) of section 2802(b).

"(2) EFFECT OF SECTION.—Nothing in this subsection may be construed as establishing new regulatory authority or as modifying any existing regulatory authority.

"(e) COORDINATION WITH LOCAL RESPONSE CAPABILITIES.—An entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant Metropolitan Medical Response Systems, local public health departments, the Cities Readiness Initiative, and local emergency plans.

"(f) CONSULTATION WITH HOMELAND SECURITY.—In making awards under subsection (a), the Secretary shall consult with the Secretary of Homeland Security to—

"(1) ensure maximum coordination of public health and medical preparedness and response activities with the Metropolitan Medical Response System, and other relevant activities;

"(2) minimize duplicative funding of programs and activities;

"(3) analyze activities, including exercises and drills, conducted under this section to develop recommendations and guidance on best practices for such activities; and

"(4) disseminate such recommendations and guidance, including through expanding existing lessons learned information systems to create a single Internet-based point of access for sharing and distributing medical and public health best practices and lessons learned from drills, exercises, disasters, and other emergencies.

"(g) ACHIEVEMENT OF MEASURABLE EVIDENCE-BASED BENCHMARKS AND OBJECTIVE STANDARDS.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop or where appropriate adopt, and require the application of, measurable evidence-based benchmarks and objective standards that measure levels of preparedness with respect to the activities described in this section and with respect to activities described in section 319C–2. In developing such benchmarks and standards, the Secretary shall consult with and seek comments from State, local, and tribal officials and private entities, as appropriate. Where appropriate, the Secretary shall incorporate existing objective standards. Such benchmarks and standards shall—

"(A) include outcome goals representing operational achievement of the National Preparedness Goals developed under section 2802(b); and

"(B) at a minimum, require entities to—

"(i) measure progress toward achieving the outcome goals; and

"(ii) at least annually, test, exercise, and rigorously evaluate the public health and medical emergency preparedness and response capabilities of the entity, and report to the Secretary on such measured and tested capabilities and measured and tested progress toward achieving outcome goals, based on criteria established by the Secretary.

"(2) CRITERIA FOR PANDEMIC INFLUENZA PLANS.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and disseminate to the chief executive officer of each State criteria for an effective State plan for responding to pandemic influenza.

"(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the duplication of Federal efforts with respect to the development of criteria or standards, without regard to whether such efforts were carried out prior to or after the date of enactment of this section.

"(3) TECHNICAL ASSISTANCE.—The Secretary shall, as determined appropriate by the Secretary, provide to a State, upon request, technical assistance in meeting the requirements of this section, including the provision of advice by experts in

the development of high-quality assessments, the setting of State objectives and assessment methods, the development of measures of satisfactory annual improvement that are valid and reliable, and other relevant areas.

"(4) NOTIFICATION OF FAILURES.—The Secretary shall develop and implement a process to notify entities that are determined by the Secretary to have failed to meet the requirements of paragraph (1) or (2). Such process shall provide such entities with the opportunity to correct such noncompliance. An entity that fails to correct such noncompliance shall be subject to paragraph (5).

"(5) WITHHOLDING OF AMOUNTS FROM ENTITIES THAT FAIL TO ACHIEVE BENCHMARKS OR SUBMIT INFLUENZA PLAN.—Beginning with fiscal year 2009, and in each succeeding fiscal year, the Secretary shall—

"(A) withhold from each entity that has failed substantially to meet the benchmarks and performance measures described in paragraph (1) for the immediately preceding fiscal year (beginning with fiscal year 2008), pursuant to the process developed under paragraph (4), the amount described in paragraph (6); and

"(B) withhold from each entity that has failed to submit to the Secretary a plan for responding to pandemic influenza that meets the criteria developed under paragraph (2), the amount described in paragraph (6).

"(6) AMOUNTS DESCRIBED.—

"(A) IN GENERAL.—The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in section 319C–1 or 319C–2:

"(i) For the fiscal year immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5) by the entity, an amount equal to 10 percent of the amount the entity was eligible to receive for such fiscal year.

"(ii) For the fiscal year immediately following two consecutive fiscal years in which an entity experienced such a failure, an amount equal to 15 percent of the amount the entity was eligible to receive for such fiscal year, taking into account the withholding of funds for the immediately preceding fiscal year under clause (i).

"(iii) For the fiscal year immediately following three consecutive fiscal years in which an entity experienced such a failure, an amount equal to 20 percent of the amount the entity was eligible to receive for such fiscal year, taking into account the withholding of funds for the immediately preceding fiscal years under clauses (i) and (ii).

"(iv) For the fiscal year immediately following four consecutive fiscal years in which an entity experienced such a failure, an amount equal to 25 percent of the amount the entity was eligible to receive for such a fiscal year, taking into account the withholding of funds for the immediately preceding fiscal years under clauses (i), (ii), and (iii).

"(B) SEPARATE ACCOUNTING.—Each failure described in subparagraph (A) or (B) of paragraph (5) shall be treated as a separate failure for purposes of calculating amounts withheld under subparagraph (A).

"(7) REALLOCATION OF AMOUNTS WITHHELD.—

"(A) IN GENERAL.—The Secretary shall make amounts withheld under paragraph (6) available for making awards under section 319C–2 to entities described in subsection (b)(1) of such section.

"(B) PREFERENCE IN REALLOCATION.—In making awards under section 319C–2 with amounts described in subparagraph (A), the Secretary shall give preference to eligible entities (as described in section 319C–2(b)(1)) that are located in whole or in part in States from which amounts have been withheld under paragraph (6).

"(8) WAIVE OR REDUCE WITHHOLDING.—The Secretary may waive or reduce the withholding described in paragraph (6), for a single entity or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction.

"(h) GRANTS FOR REAL-TIME DISEASE DETECTION IMPROVEMENT.—

"(1) IN GENERAL.—The Secretary may award grants to eligible entities to carry out projects described under paragraph (4).

"(2) ELIGIBLE ENTITY.—For purposes of this section, the term 'eligible entity' means an entity that is—

"(A)(i) a hospital, clinical laboratory, university; or

"(ii) a poison control center or professional organization in the field of poison control; and

"(B) a participant in the network established under subsection 319D(d).

"(3) APPLICATION.—Each eligible entity desiring a grant under this subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(4) USE OF FUNDS.—

"(A) IN GENERAL.—An eligible entity described in paragraph (2)(A)(i) that receives a grant under this subsection shall use the funds awarded pursuant to such grant to carry out a pilot demonstration project to purchase and implement the use of advanced diagnostic medical equipment to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance and report any results from such project to State, local, and tribal public health entities and the network established under section 319D(d).

"(B) OTHER ENTITIES.—An eligible entity described in paragraph (2)(A)(ii) that receives a grant under this section shall use the funds awarded pursuant to such grant to—

"(i) improve the early detection, surveillance, and investigative capabilities of poison control centers for chemical, biological, radiological, and nuclear events by training poison information personnel to improve

the accuracy of surveillance data, improving the definitions used by the poison control centers for surveillance, and enhancing timely and efficient investigation of data anomalies;

"(ii) improve the capabilities of poison control centers to provide information to health care providers and the public with regard to chemical, biological, radiological, or nuclear threats or exposures, in consultation with the appropriate State, local, and tribal public health entities; or

"(iii) provide surge capacity in the event of a chemical, biological, radiological, or nuclear event through the establishment of alternative poison control center worksites and the training of nontraditional personnel.";

(3) by redesignating subsection (j) as subsection (i);

(4) in subsection (i), as so redesignated—

(A) by striking paragraphs (1) through (3)(A) and inserting the following:

"(1) AUTHORIZATION OF APPROPRIATIONS.—

"(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $824,000,000 for fiscal year 2007, of which $35,000,000 shall be used to carry out subsection (h), for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)), and such sums as may be necessary for each of fiscal years 2008 through 2011.

"(B) COORDINATION.—There are authorized to be appropriated, $10,000,000 for fiscal year 2007 to carry out subsection (f)(4) of this section and section 2814.

"(C) REQUIREMENT FOR STATE MATCHING FUNDS.—Beginning in fiscal year 2009, in the case of any State or consortium of two or more States, the Secretary may not award a cooperative agreement under this section unless the State or consortium of States agree that, with respect to the amount of the cooperative agreement awarded by the Secretary, the State or consortium of States will make available (directly or through donations from public or private entities) non-Federal contributions in an amount equal to—

"(i) for the first fiscal year of the cooperative agreement, not less than 5 percent of such costs ($1 for each $20 of Federal funds provided in the cooperative agreement); and

"(ii) for any second fiscal year of the cooperative agreement, and for any subsequent fiscal year of such cooperative agreement, not less than 10 percent of such costs ($1 for each $10 of Federal funds provided in the cooperative agreement).

"(D) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTIONS.—As determined by the Secretary, non-Federal contributions required in subparagraph (C) may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided

by the Federal government, or services assisted or subsidized to any significant extent by the Federal government, may not be included in determining the amount of such non-Federal contributions.

"(2) MAINTAINING STATE FUNDING.—

"(A) IN GENERAL.—An entity that receives an award under this section shall maintain expenditures for public health security at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

"(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal public health agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

"(3) DETERMINATION OF AMOUNT.—

"(A) IN GENERAL.—The Secretary shall award cooperative agreements under subsection (a) to each State or consortium of 2 or more States that submits to the Secretary an application that meets the criteria of the Secretary for the receipt of such an award and that meets other implementation conditions established by the Secretary for such awards.";

(B) in paragraph (4)(A)—

(i) by striking "2003" and inserting "2007"; and

(ii) by striking "(A)(i)(I)";

(C) in paragraph (4)(D), by striking "2002" and inserting "2006";

(D) in paragraph (5)—

(i) by striking "2003" and inserting "2007"; and

(ii) by striking "(A)(i)(I)"; and

(E) by striking paragraph (6) and inserting the following:

"(6) FUNDING OF LOCAL ENTITIES.—The Secretary shall, in making awards under this section, ensure that with respect to the cooperative agreement awarded, the entity make available appropriate portions of such award to political subdivisions and local departments of public health through a process involving the consensus, approval or concurrence with such local entities."; and

(5) by adding at the end the following:

"(j) ADMINISTRATIVE AND FISCAL RESPONSIBILITY.—

"(1) ANNUAL REPORTING REQUIREMENTS.—Each entity shall prepare and submit to the Secretary annual reports on its activities under this section and section 319C–2. Each such report shall be prepared by, or in consultation with, the health department. In order to properly evaluate and compare the performance of different entities assisted under this section and section 319C–2 and to assure the proper expenditure of funds under this section and section 319C–2, such reports shall be in such standardized form and contain such information as the Secretary determines and describes within 180 days of the date of enactment of the Pandemic and All-Hazards

Preparedness Act (after consultation with the States) to be necessary to—

"(A) secure an accurate description of those activities;

"(B) secure a complete record of the purposes for which funds were spent, and of the recipients of such funds;

"(C) describe the extent to which the entity has met the goals and objectives it set forth under this section or section 319C–2;

"(D) determine the extent to which funds were expended consistent with the entity's application transmitted under this section or section 319C–2; and

"(E) publish such information on a Federal Internet website consistent with subsection (k).

"(2) AUDITS; IMPLEMENTATION.—

"(A) IN GENERAL.—Each entity receiving funds under this section or section 319C–2 shall, not less often than once every 2 years, audit its expenditures from amounts received under this section or section 319C–2. Such audits shall be conducted by an entity independent of the agency administering a program funded under this section or section 319C–2 in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions and generally accepted auditing standards. Within 30 days following the completion of each audit report, the entity shall submit a copy of that audit report to the Secretary.

"(B) REPAYMENT.—Each entity shall repay to the United States amounts found by the Secretary, after notice and opportunity for a hearing to the entity, not to have been expended in accordance with this section or section 319C–2 and, if such repayment is not made, the Secretary may offset such amounts against the amount of any allotment to which the entity is or may become entitled under this section or section 319C–2 or may otherwise recover such amounts.

"(C) WITHHOLDING OF PAYMENT.—The Secretary may, after notice and opportunity for a hearing, withhold payment of funds to any entity which is not using its allotment under this section or section 319C–2 in accordance with such section. The Secretary may withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

"(3) MAXIMUM CARRYOVER AMOUNT.—

"(A) IN GENERAL.—For each fiscal year, the Secretary, in consultation with the States and political subdivisions, shall determine the maximum percentage amount of an award under this section that an entity may carryover to the succeeding fiscal year.

"(B) AMOUNT EXCEEDED.—For each fiscal year, if the percentage amount of an award under this section unexpended by an entity exceeds the maximum percentage permitted by the Secretary under subparagraph (A), the entity shall return to the Secretary the portion of the unexpended amount that exceeds the maximum amount permitted to be carried over by the Secretary.

"(C) ACTION BY SECRETARY.—The Secretary shall make amounts returned to the Secretary under subparagraph (B) available for awards under section 319C–2(b)(1). In making awards under section 319C–2(b)(1) with amounts collected under this paragraph the Secretary shall give preference to entities that are located in whole or in part in States from which amounts have been returned under subparagraph (B).

"(D) WAIVER.—An entity may apply to the Secretary for a waiver of the maximum percentage amount under subparagraph (A). Such an application for a waiver shall include an explanation why such requirement should not apply to the entity and the steps taken by such entity to ensure that all funds under an award under this section will be expended appropriately.

"(E) WAIVE OR REDUCE WITHHOLDING.—The Secretary may waive the application of subparagraph (B), or reduce the amount determined under such subparagraph, for a single entity pursuant to subparagraph (D) or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction.

"(k) COMPILATION AND AVAILABILITY OF DATA.—The Secretary shall compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet website in a format that is useful to the public and to other entities and that provides information on what activities are best contributing to the achievement of the outcome goals described in subsection (g).".

SEC. 202. USING INFORMATION TECHNOLOGY TO IMPROVE SITUATIONAL AWARENESS IN PUBLIC HEALTH EMERGENCIES.

Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended—

(1) in subsection (a)(1), by inserting "domestically and abroad" after "public health threats"; and

(2) by adding at the end the following:

"(d) PUBLIC HEALTH SITUATIONAL AWARENESS.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary, in collaboration with State, local, and tribal public health officials, shall establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of rapid response to, and management of, potentially catastrophic infectious disease outbreaks and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such connectivity.

"(2) STRATEGIC PLAN.—Not later than 180 days after the date of enactment the Pandemic and All-Hazards Preparedness Act, the Secretary shall submit to the appropriate committees of Congress, a strategic plan that demonstrates the steps the Secretary will undertake to develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3).

"(3) ELEMENTS.—The network described in paragraph (1) shall include data and information transmitted in a standardized format from—

"(A) State, local, and tribal public health entities, including public health laboratories;

"(B) Federal health agencies;

"(C) zoonotic disease monitoring systems;

"(D) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, and clinical laboratories, to the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and tribal public health agencies; and

"(E) such other sources as the Secretary may deem appropriate.

"(4) RULE OF CONSTRUCTION.—Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.

"(5) REQUIRED ACTIVITIES.—In establishing and operating the network described in paragraph (1), the Secretary shall—

"(A) utilize applicable interoperability standards as determined by the Secretary through a joint public and private sector process;

"(B) define minimal data elements for such network;

"(C) in collaboration with State, local, and tribal public health officials, integrate and build upon existing State, local, and tribal capabilities, ensuring simultaneous sharing of data, information, and analyses from the network described in paragraph (1) with State, local, and tribal public health agencies; and

"(D) in collaboration with State, local, and tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1).

"(e) STATE AND REGIONAL SYSTEMS TO ENHANCE SITUATIONAL AWARENESS IN PUBLIC HEALTH EMERGENCIES.—

"(1) IN GENERAL.—To implement the network described in subsection (d), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, other health care organizations, and animal health organizations within such States.

"(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

"(A) reports of such data, information, and metrics as the Secretary may require;

"(B) a report on the effectiveness of the systems funded under the grant; and

"(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies.

"(3) USE OF FUNDS.—A State or consortium of States that receives an award under this subsection—

"(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

"(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

"(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

"(4) LIMITATION.—Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

"(A) interoperability and other technological standards, as determined by the Secretary; and

"(B) data collection and reporting requirements for the network described in subsection (d).

"(5) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report concerning the activities conducted under this subsection and subsection (d).

"(f) TELEHEALTH ENHANCEMENTS FOR EMERGENCY RESPONSE.—

"(1) EVALUATION.—The Secretary, in consultation with the Federal Communications Commission and other relevant Federal agencies, shall—

"(A) conduct an inventory of telehealth initiatives in existence on the date of enactment of the Pandemic and All-Hazards Preparedness Act, including—

"(i) the specific location of network components;

"(ii) the medical, technological, and communications capabilities of such components;

"(iii) the functionality of such components; and

"(iv) the capacity and ability of such components to handle increased volume during the response to a public health emergency;

"(B) identify methods to expand and interconnect the regional health information networks funded by the Secretary, the State and regional broadband networks funded through the rural health care support mechanism pilot program funded by the Federal Communications Commission, and other telehealth networks;

"(C) evaluate ways to prepare for, monitor, respond rapidly to, or manage the events of, a public health emergency through the enhanced use of telehealth technologies, including mechanisms for payment or reimbursement for use of such technologies and personnel during public health emergencies;

"(D) identify methods for reducing legal barriers that deter health care professionals from providing telemedicine services, such as by utilizing State emergency health care professional credentialing verification systems, encouraging States to establish and implement mechanisms to improve interstate medical licensure cooperation, facilitating the exchange of information among States regarding investigations and adverse actions, and encouraging States to waive the application of licensing requirements during a public health emergency;

"(E) evaluate ways to integrate the practice of telemedicine within the National Disaster Medical System; and

"(F) promote greater coordination among existing Federal interagency telemedicine and health information technology initiatives.

"(2) REPORT.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the findings and recommendations pursuant to subparagraphs (A) through (F) of paragraph (1).

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary in each of fiscal years 2007 through 2011.".

SEC. 203. PUBLIC HEALTH WORKFORCE ENHANCEMENTS.

(a) DEMONSTRATION PROJECT.—Subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254l) is amended by adding at the end the following:

"SEC. 338M. PUBLIC HEALTH DEPARTMENTS.

"(a) IN GENERAL.—To the extent that funds are appropriated under subsection (e), the Secretary shall establish a demonstration project to provide for the participation of individuals who are eligible for the Loan Repayment Program described in section 338B and who agree to complete their service obligation in a State health department that provides a significant amount of service to health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary, or in a local or tribal

health department that serves a health professional shortage area or an area at risk of a public health emergency.

"(b) PROCEDURE.—To be eligible to receive assistance under subsection (a), with respect to the program described in section 338B, an individual shall—

"(1) comply with all rules and requirements described in such section (other than section 338B(f)(1)(B)(iv)); and

"(2) agree to serve for a time period equal to 2 years, or such longer period as the individual may agree to, in a State, local, or tribal health department, described in subsection (a).

"(c) DESIGNATIONS.—The demonstration project described in subsection (a), and any healthcare providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of health professional shortage areas under section 332 during fiscal years 2007 through 2010.

"(d) REPORT.—Not later than 3 years after the date of enactment of this section, the Secretary shall submit a report to the relevant committees of Congress that evaluates the participation of individuals in the demonstration project under subsection (a), the impact of such participation on State, local, and tribal health departments, and the benefit and feasibility of permanently allowing such placements in the Loan Repayment Program.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2007 through 2010.".

(b) GRANTS FOR LOAN REPAYMENT PROGRAM.—Section 338I of the Public Health Service Act (42 U.S.C. 254q–1) is amended by adding at the end the following:

"(j) PUBLIC HEALTH LOAN REPAYMENT.—

"(1) IN GENERAL.—The Secretary may award grants to States for the purpose of assisting such States in operating loan repayment programs under which such States enter into contracts to repay all or part of the eligible loans borrowed by, or on behalf of, individuals who agree to serve in State, local, or tribal health departments that serve health professional shortage areas or other areas at risk of a public health emergency, as designated by the Secretary.

"(2) LOANS ELIGIBLE FOR REPAYMENT.—To be eligible for repayment under this subsection, a loan shall be a loan made, insured, or guaranteed by the Federal Government that is borrowed by, or on behalf of, an individual to pay the cost of attendance for a program of education leading to a degree appropriate for serving in a State, local, or tribal health department as determined by the Secretary and the chief executive officer of the State in which the grant is administered, at an institution of higher education (as defined in section 102 of the Higher Education Act of 1965), including principal, interest, and related expenses on such loan.

"(3) APPLICABILITY OF EXISTING REQUIREMENTS.—With respect to awards made under paragraph (1)—

"(A) the requirements of subsections (b), (f), and (g) shall apply to such awards; and

"(B) the requirements of subsection (c) shall apply to such awards except that with respect to paragraph (1) of such subsection, the State involved may assign an individual only to public and nonprofit private entities that

serve health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary.

"(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2007 through 2010.".

SEC. 204. VACCINE TRACKING AND DISTRIBUTION.

(a) IN GENERAL.—Section 319A of the Public Health Service Act (42 U.S.C. 247d–1) is amended to read as follows:

"SEC. 319A. VACCINE TRACKING AND DISTRIBUTION.

"(a) TRACKING.—The Secretary, together with relevant manufacturers, wholesalers, and distributors as may agree to cooperate, may track the initial distribution of federally purchased influenza vaccine in an influenza pandemic. Such tracking information shall be used to inform Federal, State, local, and tribal decision makers during an influenza pandemic.

"(b) DISTRIBUTION.—The Secretary shall promote communication between State, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate, regarding the effective distribution of seasonal influenza vaccine. Such communication shall include estimates of high priority populations, as determined by the Secretary, in State, local, and tribal jurisdictions in order to inform Federal, State, local, and tribal decision makers during vaccine shortages and supply disruptions.

"(c) CONFIDENTIALITY.—The information submitted to the Secretary or its contractors, if any, under this section or under any other section of this Act related to vaccine distribution information shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, United States Code, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18, United States Code, relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage.

"(d) GUIDELINES.—The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to provide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines for subsections (a) and (b).

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums for each of fiscal years 2007 through 2011.

"(f) REPORT TO CONGRESS.—As part of the National Health Security Strategy described in section 2802, the Secretary shall provide an update on the implementation of subsections (a) through (d).".

(b) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by striking sections 319B and 319C.

(2) TECHNICAL AMENDMENT.—Section 319D(a)(3) of the Public Health Service Act (42 U.S.C. 247d–4(a)(3)) is amended by striking ", taking into account evaluations under section 319B(a),".

SEC. 205. NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY.

The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to relevant Federal departments and agencies, advice, guidance, or recommendations concerning—

(1) a core curriculum and training requirements for workers in maximum containment biological laboratories; and

(2) periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity.

SEC. 206. REVITALIZATION OF COMMISSIONED CORPS.

(a) PURPOSE.—It is the purpose of this section to improve the force management and readiness of the Commissioned Corps to accomplish the following objectives:

(1) To ensure the Corps is ready to respond rapidly to urgent or emergency public health care needs and challenges.

(2) To ensure the availability of the Corps for assignments that address clinical and public health needs in isolated, hardship, and hazardous duty positions, and, when required, to address needs related to the well-being, security, and defense of the United States.

(3) To establish the Corps as a resource available to Federal and State Government agencies for assistance in meeting public health leadership and service roles.

(b) COMMISSIONED CORPS READINESS.—Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by inserting after section 203 the following:

"SEC. 203A. DEPLOYMENT READINESS.

"(a) READINESS REQUIREMENTS FOR COMMISSIONED CORPS OFFICERS.—

"(1) IN GENERAL.—The Secretary, with respect to members of the following Corps components, shall establish requirements, including training and medical examinations, to ensure the readiness of such components to respond to urgent or emergency public health care needs that cannot otherwise be met at the Federal, State, and local levels:

"(A) Active duty Regular Corps.

"(B) Active Reserves.

"(2) ANNUAL ASSESSMENT OF MEMBERS.—The Secretary shall annually determine whether each member of the Corps

meets the applicable readiness requirements established under paragraph (1).

"(3) FAILURE TO MEET REQUIREMENTS.—A member of the Corps who fails to meet or maintain the readiness requirements established under paragraph (1) or who fails to comply with orders to respond to an urgent or emergency public health care need shall, except as provided in paragraph (4), in accordance with procedures established by the Secretary, be subject to disciplinary action as prescribed by the Secretary.

"(4) WAIVER OF REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary may waive one or more of the requirements established under paragraph (1) for an individual who is not able to meet such requirements because of—

"(i) a disability;

"(ii) a temporary medical condition; or

"(iii) any other extraordinary limitation as determined by the Secretary.

"(B) REGULATIONS.—The Secretary shall promulgate regulations under which a waiver described in subparagraph (A) may be granted.

"(5) URGENT OR EMERGENCY PUBLIC HEALTH CARE NEED.—For purposes of this section and section 214, the term 'urgent or emergency public health care need' means a health care need, as determined by the Secretary, arising as the result of—

"(A) a national emergency declared by the President under the National Emergencies Act (50 U.S.C. 1601 et seq.);

"(B) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.);

"(C) a public health emergency declared by the Secretary under section 319 of this Act; or

"(D) any emergency that, in the judgment of the Secretary, is appropriate for the deployment of members of the Corps.

"(b) CORPS MANAGEMENT FOR DEPLOYMENT.—The Secretary shall—

"(1) organize members of the Corps into units for rapid deployment by the Secretary to respond to urgent or emergency public health care needs;

"(2) establish appropriate procedures for the command and control of units or individual members of the Corps that are deployed at the direction of the President or the Secretary in response to an urgent or emergency public health care need of national, State or local significance;

"(3) ensure that members of the Corps are trained, equipped and otherwise prepared to fulfill their public health and emergency response roles; and

"(4) ensure that deployment planning takes into account—

"(A) any deployment exemptions that may be granted by the Secretary based on the unique requirements of an agency and an individual's functional role in such agency; and

"(B) the nature of the urgent or emergency public health care need.

"(c) DEPLOYMENT OF DETAILED OR ASSIGNED OFFICERS.—For purposes of pay, allowances, and benefits of a Commissioned Corps officer who is detailed or assigned to a Federal entity, the deployment of such officer by the Secretary in response to an urgent or emergency public health care need shall be deemed to be an authorized activity of the Federal entity to which the officer is detailed or assigned.".

(c) PERSONNEL DEPLOYMENT AUTHORITY.—

(1) PERSONNEL DETAILED.—Section 214 of the Public Health Service Act (42 U.S.C. 215) is amended by adding at the end the following:

"(e) Except with respect to the United States Coast Guard and the Department of Defense, and except as provided in agreements negotiated with officials at agencies where officers of the Commissioned Corps may be assigned, the Secretary shall have the sole authority to deploy any Commissioned Corps officer assigned under this section to an entity outside of the Department of Health and Human Services for service under the Secretary's direction in response to an urgent or emergency public health care need (as defined in section 203A(a)(5)).".

(2) NATIONAL HEALTH SERVICE CORPS.—Section 331(f) of the Public Health Service Act (42 U.S.C. 254d(f)(1)) is amended by inserting before the period the following: ", except when such members are Commissioned Corps officers who entered into a contract with Secretary under section 338A or 338B after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 214 or 216 with respect to any such officer to would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services".

TITLE III—ALL-HAZARDS MEDICAL SURGE CAPACITY

SEC. 301. NATIONAL DISASTER MEDICAL SYSTEM.

(a) NATIONAL DISASTER MEDICAL SYSTEM.—Section 2812 of subtitle B of title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–11 et seq.), as redesignated by section 102, is amended—

(1) by striking the section heading and inserting "**NATIONAL DISASTER MEDICAL SYSTEM**";

(2) by striking subsection (a);

(3) by redesignating subsections (b) through (h) as subsections (a) through (g);

(4) in subsection (a), as so redesignated—

(A) in paragraph (2)(B), by striking "Federal Emergency Management Agency" and inserting "Department of Homeland Security"; and

(B) in paragraph (3)(C), by striking "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" and inserting "Pandemic and All-Hazards Preparedness Act";

(5) in subsection (b), as so redesignated, by—

(A) striking the subsection heading and inserting "MODIFICATIONS";

(B) redesignating paragraph (2) as paragraph (3); and

(C) striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—Taking into account the findings from the joint review described under paragraph (2), the Secretary shall modify the policies of the National Disaster Medical System as necessary.

"(2) JOINT REVIEW AND MEDICAL SURGE CAPACITY STRATEGIC PLAN.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include an evaluation of medical surge capacity, as described by section 2803(a). As part of the National Health Security Strategy under section 2802, the Secretary shall update the findings from such review and further modify the policies of the National Disaster Medical System as necessary.";

(6) by striking "subsection (b)" each place it appears and inserting "subsection (a)";

(7) by striking "subsection (d)" each place it appears and inserting "subsection (c)"; and

(8) in subsection (g), as so redesignated, by striking "2002 through 2006" and inserting "2007 through 2011".

(b) TRANSFER OF NATIONAL DISASTER MEDICAL SYSTEM TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—There shall be transferred to the Secretary of Health and Human Services the functions, personnel, assets, and liabilities of the National Disaster Medical System of the Department of Homeland Security, including the functions of the Secretary of Homeland Security and the Under Secretary for Emergency Preparedness and Response relating thereto.

(c) CONFORMING AMENDMENTS TO THE HOMELAND SECURITY ACT OF 2002.—The Homeland Security Act of 2002 (6 U.S.C. 312(3)(B), 313(5)) is amended—

(1) in section 502(3)(B), by striking ", the National Disaster Medical System,"; and

(2) in section 503(5), by striking ", the National Disaster Medical System".

(d) UPDATE OF CERTAIN PROVISION.—Section 319F(b)(2) of the Public Health Service Act (42 U.S.C. 247d–6(b)(2)) is amended—

(1) in the paragraph heading, by striking "CHILDREN AND TERRORISM" and inserting "AT-RISK INDIVIDUALS AND PUBLIC HEALTH EMERGENCIES";

(2) in subparagraph (A), by striking "Children and Terrorism" and inserting "At-Risk Individuals and Public Health Emergencies";

(3) in subparagraph (B)—

(A) in clause (i), by striking "bioterrorism as it relates to children" and inserting "public health emergencies as they relate to at-risk individuals";

(B) in clause (ii), by striking "children" and inserting "at-risk individuals"; and

(C) in clause (iii), by striking "children" and inserting "at-risk individuals";

(4) in subparagraph (C), by striking "children" and all that follows through the period and inserting "at-risk populations."; and

(5) in subparagraph (D), by striking "one year" and inserting "six years".

(e) CONFORMING AMENDMENT.—Section 319F(b)(3)(B) of the Public Health Service Act (42 U.S.C. 247d–6(b)(3)(B)) is amended by striking "and the working group under subsection (a)".

(f) EFFECTIVE DATE.—The amendments made by subsections (b) and (c) shall take effect on January 1, 2007.

SEC. 302. ENHANCING MEDICAL SURGE CAPACITY.

(a) IN GENERAL.—Title XXVIII of the Public Health Service Act (300hh–11 et seq.), as amended by section 103, is amended by inserting after section 2802 the following:

"SEC. 2803. ENHANCING MEDICAL SURGE CAPACITY.

"(a) STUDY OF ENHANCING MEDICAL SURGE CAPACITY.—As part of the joint review described in section 2812(b), the Secretary shall evaluate the benefits and feasibility of improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency. Such study shall include an assessment of the need for and feasibility of improving surge capacity through—

"(1) acquisition and operation of mobile medical assets by the Secretary to be deployed, on a contingency basis, to a community in the event of a public health emergency;

"(2) integrating the practice of telemedicine within the National Disaster Medical System; and

"(3) other strategies to improve such capacity as determined appropriate by the Secretary.

"(b) AUTHORITY TO ACQUIRE AND OPERATE MOBILE MEDICAL ASSETS.—In addition to any other authority to acquire, deploy, and operate mobile medical assets, the Secretary may acquire, deploy, and operate mobile medical assets if, taking into consideration the evaluation conducted under subsection (a), such acquisition, deployment, and operation is determined to be beneficial and feasible in improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency.

"(c) USING FEDERAL FACILITIES TO ENHANCE MEDICAL SURGE CAPACITY.—

"(1) ANALYSIS.—The Secretary shall conduct an analysis of whether there are Federal facilities which, in the event of a public health emergency, could practicably be used as facilities in which to provide health care.

"(2) MEMORANDA OF UNDERSTANDING.—If, based on the analysis conducted under paragraph (1), the Secretary determines that there are Federal facilities which, in the event of a public health emergency, could be used as facilities in which to provide health care, the Secretary shall, with respect to each such facility, seek to conclude a memorandum of understanding with the head of the Department or agency that operates such facility that permits the use of such facility to provide health care in the event of a public health emergency.".

(b) EMTALA.—

(1) IN GENERAL.—Section 1135(b) of the Social Security Act (42 U.S.C. 1320b–5(b)) is amended—

(A) in paragraph (3), by striking subparagraph (B) and inserting the following:

"(B) the direction or relocation of an individual to receive medical screening in an alternative location—

"(i) pursuant to an appropriate State emergency preparedness plan; or

"(ii) in the case of a public health emergency described in subsection (g)(1)(B) that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan or a plan referred to in clause (i), whichever is applicable in the State;";

(B) in the third sentence, by striking "and shall be limited to" and inserting "and, except in the case of a waiver or modification to which the fifth sentence of this subsection applies, shall be limited to"; and

(C) by adding at the end the following: "If a public health emergency described in subsection (g)(1)(B) involves a pandemic infectious disease (such as pandemic influenza), the duration of a waiver or modification under paragraph (3) shall be determined in accordance with subsection (e) as such subsection applies to public health emergencies.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect on the date of the enactment of this Act and shall apply to public health emergencies declared pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d) on or after such date.

SEC. 303. ENCOURAGING HEALTH PROFESSIONAL VOLUNTEERS.

(a) VOLUNTEER MEDICAL RESERVE CORPS.—Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh–11 et seq.), as amended by this Act, is amended by inserting after section 2812 the following:

"SEC. 2813. VOLUNTEER MEDICAL RESERVE CORPS.

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary, in collaboration with State, local, and tribal officials, shall build on State, local, and tribal programs in existence on the date of enactment of such Act to establish and maintain a Medical Reserve Corps (referred to in this section as the 'Corps') to provide for an adequate supply of volunteers in the case of a Federal, State, local, or tribal public health emergency. The Corps shall be headed by a Director who shall be appointed by the Secretary and shall oversee the activities of the Corps chapters that exist at the State, local, and tribal levels.

"(b) STATE, LOCAL, AND TRIBAL COORDINATION.—The Corps shall be established using existing State, local, and tribal teams and shall not alter such teams.

"(c) COMPOSITION.—The Corps shall be composed of individuals who—

"(1)(A) are health professionals who have appropriate professional training and expertise as determined appropriate by the Director of the Corps; or

"(B) are non-health professionals who have an interest in serving in an auxiliary or support capacity to facilitate access to health care services in a public health emergency;

"(2) are certified in accordance with the certification program developed under subsection (d);

"(3) are geographically diverse in residence;

"(4) have registered and carry out training exercises with a local chapter of the Medical Reserve Corps; and

"(5) indicate whether they are willing to be deployed outside the area in which they reside in the event of a public health emergency.

"(d) CERTIFICATION; DRILLS.—

"(1) CERTIFICATION.—The Director, in collaboration with State, local, and tribal officials, shall establish a process for the periodic certification of individuals who volunteer for the Corps, as determined by the Secretary, which shall include the completion by each individual of the core training programs developed under section 319F, as required by the Director. Such certification shall not supercede State licensing or credentialing requirements.

"(2) DRILLS.—In conjunction with the core training programs referred to in paragraph (1), and in order to facilitate the integration of trained volunteers into the health care system at the local level, Corps members shall engage in periodic training exercises to be carried out at the local level.

"(e) DEPLOYMENT.—During a public health emergency, the Secretary shall have the authority to activate and deploy willing members of the Corps to areas of need, taking into consideration the public health and medical expertise required, with the concurrence of the State, local, or tribal officials from the area where the members reside.

"(f) EXPENSES AND TRANSPORTATION.—While engaged in performing duties as a member of the Corps pursuant to an assignment by the Secretary (including periods of travel to facilitate such assignment), members of the Corps who are not otherwise employed by the Federal Government shall be allowed travel or transportation expenses, including per diem in lieu of subsistence.

"(g) IDENTIFICATION.—The Secretary, in cooperation and consultation with the States, shall develop a Medical Reserve Corps Identification Card that describes the licensure and certification information of Corps members, as well as other identifying information determined necessary by the Secretary.

"(h) INTERMITTENT DISASTER-RESPONSE PERSONNEL.—

"(1) IN GENERAL.—For the purpose of assisting the Corps in carrying out duties under this section, during a public health emergency, the Secretary may appoint selected individuals to serve as intermittent personnel of such Corps in accordance with applicable civil service laws and regulations. In all other cases, members of the Corps are subject to the laws of the State in which the activities of the Corps are undertaken.

"(2) APPLICABLE PROTECTIONS.—Subsections (c)(2), (d), and (e) of section 2812 shall apply to an individual appointed under paragraph (1) in the same manner as such subsections apply to an individual appointed under section 2812(c).

"(3) LIMITATION.—State, local, and tribal officials shall have no authority to designate a member of the Corps as Federal intermittent disaster-response personnel, but may request the services of such members.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $22,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011.".

(b) ENCOURAGING HEALTH PROFESSIONS VOLUNTEERS.—Section 319I of the Public Health Service Act (42 U.S.C. 247d–7b) is amended—

(1) by redesignating subsections (e) and (f) as subsections (j) and (k), respectively;

(2) by striking subsections (a) and (b) and inserting the following:

"(a) IN GENERAL.—Not later than 12 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall link existing State verification systems to maintain a single national interoperable network of systems, each system being maintained by a State or group of States, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency.

"(b) REQUIREMENTS.—The interoperable network of systems established under subsection (a) (referred to in this section as the 'verification network') shall include—

"(1) with respect to each volunteer health professional included in the verification network—

"(A) information necessary for the rapid identification of, and communication with, such professionals; and

"(B) the credentials, certifications, licenses, and relevant training of such individuals; and

"(2) the name of each member of the Medical Reserve Corps, the National Disaster Medical System, and any other relevant federally-sponsored or administered programs determined necessary by the Secretary.";

(3) in subsection (c), strike "system" and insert "network"; and

(4) by striking subsection (d) and inserting the following:

"(d) ACCESSIBILITY.—The Secretary shall ensure that the verification network is electronically accessible by State, local, and tribal health departments and can be linked with the identification cards under section 2813.

"(e) CONFIDENTIALITY.—The Secretary shall establish and require the application of and compliance with measures to ensure the effective security of, integrity of, and access to the data included in the verification network.

"(f) COORDINATION.—The Secretary shall coordinate with the Secretary of Veterans Affairs and the Secretary of Homeland Security to assess the feasibility of integrating the verification network under this section with the VetPro system of the Department of Veterans Affairs and the National Emergency Responder Credentialing System of the Department of Homeland Security. The Secretary shall, if feasible, integrate the verification network under this section with such VetPro system and the National Emergency Responder Credentialing System.

"(g) UPDATING OF INFORMATION.—The States that are participants in the verification network shall, on at least a quarterly basis, work with the Director to provide for the updating of the information contained in the verification network.

"(h) CLARIFICATION.—Inclusion of a health professional in the verification network shall not constitute appointment of such individual as a Federal employee for any purpose, either under section 2812(c) or otherwise. Such appointment may only be made under section 2812 or 2813.

"(i) HEALTH CARE PROVIDER LICENSES.—The Secretary shall encourage States to establish and implement mechanisms to waive

the application of licensing requirements applicable to health professionals, who are seeking to provide medical services (within their scope of practice), during a national, State, local, or tribal public health emergency upon verification that such health professionals are licensed and in good standing in another State and have not been disciplined by any State health licensing or disciplinary board."; and

(5) in subsection (k) (as so redesignated), by striking "2006" and inserting "2011".

SEC. 304. CORE EDUCATION AND TRAINING.

Section 319F of the Public Health Service Act (42 U.S.C. 247d–6) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—

"(1) IN GENERAL.—The Secretary, in collaboration with the Secretary of Defense, and in consultation with relevant public and private entities, shall develop core health and medical response curricula and trainings by adapting applicable existing curricula and training programs to improve responses to public health emergencies.

"(2) CURRICULUM.—The public health and medical response training program may include course work related to—

"(A) medical management of casualties, taking into account the needs of at-risk individuals;

"(B) public health aspects of public health emergencies;

"(C) mental health aspects of public health emergencies;

"(D) national incident management, including coordination among Federal, State, local, tribal, international agencies, and other entities; and

"(E) protecting health care workers and health care first responders from workplace exposures during a public health emergency.

"(3) PEER REVIEW.—On a periodic basis, products prepared as part of the program shall be rigorously tested and peer-reviewed by experts in the relevant fields.

"(4) CREDIT.—The Secretary and the Secretary of Defense shall—

"(A) take into account continuing professional education requirements of public health and healthcare professions; and

"(B) cooperate with State, local, and tribal accrediting agencies and with professional associations in arranging for students enrolled in the program to obtain continuing professional education credit for program courses.

"(5) DISSEMINATION AND TRAINING.—

"(A) IN GENERAL.—The Secretary may provide for the dissemination and teaching of the materials described in paragraphs (1) and (2) by appropriate means, as determined by the Secretary.

"(B) CERTAIN ENTITIES.—The education and training activities described in subparagraph (A) may be carried out by Federal public health or medical entities, appropriate educational entities, professional organizations and

societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

"(C) GRANTS AND CONTRACTS.—In carrying out this subsection, the Secretary may carry out activities directly or through the award of grants and contracts, and may enter into interagency agreements with other Federal agencies.".

(2) by striking subsections (c) through (g) and inserting the following:

"(c) EXPANSION OF EPIDEMIC INTELLIGENCE SERVICE PROGRAM.—The Secretary may establish 20 officer positions in the Epidemic Intelligence Service Program, in addition to the number of the officer positions offered under such Program in 2006, for individuals who agree to participate, for a period of not less than 2 years, in the Career Epidemiology Field Officer program in a State, local, or tribal health department that serves a health professional shortage area (as defined under section 332(a)), a medically underserved population (as defined under section 330(b)(3)), or a medically underserved area or area at high risk of a public health emergency as designated by the Secretary.

"(d) CENTERS FOR PUBLIC HEALTH PREPAREDNESS; CORE CURRICULA AND TRAINING.—

"(1) IN GENERAL.—The Secretary may establish at accredited schools of public health, Centers for Public Health Preparedness (hereafter referred to in this section as the 'Centers').

"(2) ELIGIBILITY.—To be eligible to receive an award under this subsection to establish a Center, an accredited school of public health shall agree to conduct activities consistent with the requirements of this subsection.

"(3) CORE CURRICULA.—The Secretary, in collaboration with the Centers and other public or private entities shall establish core curricula based on established competencies leading to a 4-year bachelor's degree, a graduate degree, a combined bachelor and master's degree, or a certificate program, for use by each Center. The Secretary shall disseminate such curricula to other accredited schools of public health and other health professions schools determined appropriate by the Secretary, for voluntary use by such schools.

"(4) CORE COMPETENCY-BASED TRAINING PROGRAM.—The Secretary, in collaboration with the Centers and other public or private entities shall facilitate the development of a competency-based training program to train public health practitioners. The Centers shall use such training program to train public health practitioners. The Secretary shall disseminate such training program to other accredited schools of public health, health professions schools, and other public or private entities as determined by the Secretary, for voluntary use by such entities.

"(5) CONTENT OF CORE CURRICULA AND TRAINING PROGRAM.—The Secretary shall ensure that the core curricula and training program established pursuant to this subsection respond to the needs of State, local, and tribal public health authorities and integrate and emphasize essential public health security capabilities consistent with section 2802(b)(2).

"(6) ACADEMIC-WORKFORCE COMMUNICATION.—As a condition of receiving funding from the Secretary under this subsection, a Center shall collaborate with a State, local, or tribal public health department to—

"(A) define the public health preparedness and response needs of the community involved;

"(B) assess the extent to which such needs are fulfilled by existing preparedness and response activities of such school or health department, and how such activities may be improved;

"(C) prior to developing new materials or trainings, evaluate and utilize relevant materials and trainings developed by others Centers; and

"(D) evaluate community impact and the effectiveness of any newly developed materials or trainings.

"(7) PUBLIC HEALTH SYSTEMS RESEARCH.—In consultation with relevant public and private entities, the Secretary shall define the existing knowledge base for public health preparedness and response systems, and establish a research agenda based on Federal, State, local, and tribal public health preparedness priorities. As a condition of receiving funding from the Secretary under this subsection, a Center shall conduct public health systems research that is consistent with the agenda described under this paragraph.";

(3) by redesignating subsection (h) as subsection (e);

(4) by inserting after subsection (e) (as so redesignated), the following:

"(f) AUTHORIZATION OF APPROPRIATIONS.—

"(1) FISCAL YEAR 2007.—There are authorized to be appropriated to carry out this section for fiscal year 2007—

"(A) to carry out subsection (a)—

"(i) $5,000,000 to carry out paragraphs (1) through (4); and

"(ii) $7,000,000 to carry out paragraph (5);

"(B) to carry out subsection (c), $3,000,000; and

"(C) to carry out subsection (d), $31,000,000, of which $5,000,000 shall be used to carry out paragraphs (3) through (5) of such subsection.

"(2) SUBSEQUENT FISCAL YEARS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2008 and each subsequent fiscal year."; and

(5) by striking subsections (i) and (j).

SEC. 305. PARTNERSHIPS FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.

Section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) is amended to read as follows:

"SEC. 319C–2. PARTNERSHIPS FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.

"(a) IN GENERAL.—The Secretary shall award competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies.

"(b) ELIGIBILITY.—To be eligible for an award under subsection (a), an entity shall—

"(1)(A) be a partnership consisting of—

"(i) one or more hospitals, at least one of which shall be a designated trauma center, consistent with section 1213(c);

"(ii) one or more other local health care facilities, including clinics, health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes; and

"(iii)(I) one or more political subdivisions;

"(II) one or more States; or

"(III) one or more States and one or more political subdivisions; and

"(B) prepare, in consultation with the Chief Executive Officer and the lead health officials of the State, District, or territory in which the hospital and health care facilities described in subparagraph (A) are located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require; or

"(2)(A) be an entity described in section 319C–1(b)(1); and

"(B) submit an application at such time, in such manner, and containing such information as the Secretary may require, including the information or assurances required under section 319C–1(b)(2) and an assurance that the State will adhere to any applicable guidelines established by the Secretary.

"(c) USE OF FUNDS.—An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 2802(b).

"(d) PREFERENCES.—

"(1) REGIONAL COORDINATION.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary—

"(A) will enhance coordination—

"(i) among the entities described in subsection (b)(1)(A)(i); and

"(ii) between such entities and the entities described in subsection (b)(1)(A)(ii); and

"(B) include, in the partnership described in subsection (b)(1)(A), a significant percentage of the hospitals and health care facilities within the geographic area served by such partnership.

"(2) OTHER PREFERENCES.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that, in the determination of the Secretary—

"(A) include one or more hospitals that are participants in the National Disaster Medical System;

"(B) are located in a geographic area that faces a high degree of risk, as determined by the Secretary in consultation with the Secretary of Homeland Security; or

"(C) have a significant need for funds to achieve the medical preparedness goals described in section 2802(b)(3).

"(e) CONSISTENCY OF PLANNED ACTIVITIES.—The Secretary may not award a cooperative agreement to an eligible entity described in subsection (b)(1) unless the application submitted by the entity is coordinated and consistent with an applicable State All-Hazards Public Health Emergency Preparedness and Response Plan and relevant local plans, as determined by the Secretary in consultation with relevant State health officials.

"(f) LIMITATION ON AWARDS.—A political subdivision shall not participate in more than one partnership described in subsection (b)(1).

"(g) COORDINATION WITH LOCAL RESPONSE CAPABILITIES.—An eligible entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant local Metropolitan Medical Response Systems, local Medical Reserve Corps, the Cities Readiness Initiative, and local emergency plans.

"(h) MAINTENANCE OF FUNDING.—

"(1) IN GENERAL.—An entity that receives an award under this section shall maintain expenditures for health care preparedness at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

"(i) PERFORMANCE AND ACCOUNTABILITY.—The requirements of section 319C–1(g), (j), and (k) shall apply to entities receiving awards under this section (regardless of whether such entities are described under subsection (b)(1)(A) or (b)(2)(A)) in the same manner as such requirements apply to entities under section 319C–1. An entity described in subsection (b)(1)(A) shall make such reports available to the lead health official of the State in which such partnership is located.

"(j) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $474,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011.

"(2) RESERVATION OF AMOUNTS FOR PARTNERSHIPS.—Prior to making awards described in paragraph (3), the Secretary may reserve from the amount appropriated under paragraph (1) for a fiscal year, an amount determined appropriate by the Secretary for making awards to entities described in subsection (b)(1)(A).

"(3) AWARDS TO STATES AND POLITICAL SUBDIVISIONS.—

"(A) IN GENERAL.—From amounts appropriated for a fiscal year under paragraph (1) and not reserved under paragraph (2), the Secretary shall make awards to entities described in subsection (b)(2)(A) that have completed an application as described in subsection (b)(2)(B).

"(B) AMOUNT.—The Secretary shall determine the amount of an award to each entity described in subparagraph (A) in the same manner as such amounts are determined under section 319C–1(h).".

SEC. 306. ENHANCING THE ROLE OF THE DEPARTMENT OF VETERANS AFFAIRS.

(a) IN GENERAL.—Section 8117 of title 38, United States Code, is amended—

(1) in subsection (a)—

(A) in paragraph (1), by—

(i) striking "chemical or biological attack" and inserting "a public health emergency (as defined in section 2801 of the Public Health Service Act)";

(ii) striking "an attack" and inserting "such an emergency"; and

(iii) striking "public health emergencies" and inserting "such emergencies"; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "; and" and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting a semicolon; and

(iii) by adding at the end the following:

"(C) organizing, training, and equipping the staff of such centers to support the activities carried out by the Secretary of Health and Human Services under section 2801 of the Public Health Service Act in the event of a public health emergency and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan; and

"(D) providing medical logistical support to the National Disaster Medical System and the Secretary of Health and Human Services as necessary, on a reimbursable basis, and in coordination with other designated Federal agencies.";

(2) in subsection (c), by striking "a chemical or biological attack or other terrorist attack." and inserting "a public health emergency. The Secretary shall, through existing medical procurement contracts, and on a reimbursable basis, make available as necessary, medical supplies, equipment, and pharmaceuticals in response to a public health emergency in support of the Secretary of Health and Human Services.";

(3) in subsection (d), by—

(A) striking "develop and";

(B) striking "biological, chemical, or radiological attacks" and inserting "public health emergencies"; and

(C) by inserting "consistent with section 319F(a) of the Public Health Service Act" before the period; and

(4) in subsection (e)—

(A) in paragraph (1), by striking "2811(b)" and inserting "2812"; and

(B) in paragraph (2)—

(i) by striking "bioterrorism and other"; and

(ii) by striking "319F(a)" and inserting "319F".

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 8117 of title 38, United States Code, is amended by adding at the end the following:

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal years 2007 through 2011.".

TITLE IV—PANDEMIC AND BIODEFENSE VACCINE AND DRUG DEVELOPMENT

SEC. 401. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 319K the following:

"SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

"(a) DEFINITIONS.—In this section:

"(1) BARDA.—The term 'BARDA' means the Biomedical Advanced Research and Development Authority.

"(2) FUND.—The term 'Fund' means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

"(3) OTHER TRANSACTIONS.—The term 'other transactions' means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code.

"(4) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' has the meaning given such term in section 319F–1.

"(5) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term 'qualified pandemic or epidemic product' has the meaning given the term in section 319F–3.

"(6) ADVANCED RESEARCH AND DEVELOPMENT.—

"(A) IN GENERAL.—The term 'advanced research and development' means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

"(i) are conducted after basic research and preclinical development of the product; and

"(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

"(B) ACTIVITIES INCLUDED.—The term under subparagraph (A) includes—

"(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

"(ii) design and development of tests or models, including animal models, for such testing;

"(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

"(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

"(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

"(7) SECURITY COUNTERMEASURE.—The term 'security countermeasure' has the meaning given such term in section 319F–2.

"(8) RESEARCH TOOL.—The term 'research tool' means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

"(9) PROGRAM MANAGER.—The term 'program manager' means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

"(10) PERSON.—The term 'person' includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

"(b) STRATEGIC PLAN FOR COUNTERMEASURE RESEARCH, DEVELOPMENT, AND PROCUREMENT.—

"(1) IN GENERAL.—Not later than 6 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 2802.

"(2) CONTENT.—The strategic plan under paragraph (1) shall guide—

"(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

"(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as 'countermeasure and product advanced research and development'); and

"(C) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

"(c) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

"(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

"(2) IN GENERAL.—Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by—

"(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

"(B) promoting countermeasure and product advanced research and development;

"(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and

"(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

"(3) DIRECTOR.—The BARDA shall be headed by a Director (referred to in this section as the 'Director') who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

"(4) DUTIES.—

"(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary shall—

"(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

"(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

"(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

"(ii) at least annually—

"(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

"(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

"(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

"(iii) carry out the activities described in section 405 of the Pandemic and All-Hazards Preparedness Act.

"(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose described in paragraph (2)(B), the Secretary shall—

"(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

"(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

"(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development and innovation in such areas as the Secretary may identify as priority unmet need areas; and

"(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

"(C) FACILITATING ADVICE.—To carry out the purpose described in paragraph (2)(C) the Secretary shall—

"(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

"(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure.

"(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

"(i) innovation in technologies that may assist countermeasure and product advanced research and development;

"(ii) research on and development of research tools and other devices and technologies; and

"(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, and vaccine manufacturing technologies.

"(5) TRANSACTION AUTHORITIES.—

"(A) OTHER TRANSACTIONS.—

"(i) IN GENERAL.—The Secretary shall have the authority to enter into other transactions under this subsection in the same manner as the Secretary of

Defense enters into such transactions under section 2371 of title 10, United States Code.

"(ii) LIMITATIONS ON AUTHORITY.—

"(I) IN GENERAL.—Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845.

"(II) WRITTEN DETERMINATIONS REQUIRED.—The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $20,000,000 only upon a written determination by the senior procurement executive for the Department (as designated for purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c))), that the use of such authority is essential to promoting the success of the project. The authority of the senior procurement executive under this subclause may not be delegated.

"(iii) GUIDELINES.—The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

"(B) EXPEDITED AUTHORITIES.—

"(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 319F–1.

"(ii) APPLICATION OF PROVISIONS.—Provisions in such section 319F–1 that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

"(iii) AUTHORITY TO LIMIT COMPETITION.—For purposes of applying section 319F–1(b)(1)(D) to this paragraph, the phrase 'BioShield Program under the Project BioShield Act of 2004' shall be deemed to mean the countermeasure and product advanced research and development program under this section.

"(iv) AVAILABILITY OF DATA.—The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an

ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

"(C) ADVANCE PAYMENTS; ADVERTISING.—The Secretary may waive the requirements of section 3324(a) of title 31, United States Code, or section 3709 of the Revised Statutes of the United States (41 U.S.C. 5) upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

"(D) MILESTONE-BASED PAYMENTS ALLOWED.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

"(E) FOREIGN NATIONALS ELIGIBLE.—The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

"(F) ESTABLISHMENT OF RESEARCH CENTERS.—The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)).

"(6) AT-RISK INDIVIDUALS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.

"(7) PERSONNEL AUTHORITIES.—

"(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—

"(i) IN GENERAL.—In addition to any other personnel authorities, the Secretary may—

"(I) without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

"(II) compensate them in the same manner and subject to the same terms and conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

"(ii) MANNER OF EXERCISE OF AUTHORITY.—The authority provided for in this subparagraph shall be exercised subject to the same limitations described in section 319F–1(e)(2).

"(iii) TERM OF APPOINTMENT.—The term limitations described in section 9903(c) of title 5, United States Code, shall apply to appointments under this subparagraph, except that the references to the 'Secretary' and to the 'Department of Defense's national security missions' shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

"(B) SPECIAL CONSULTANTS.—In carrying out this section, the Secretary may appoint special consultants pursuant to section 207(f).

"(C) LIMITATION.—

"(i) IN GENERAL.—The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

"(ii) REPORT.—The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

"(d) FUND.—

"(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

"(2) FUNDING.—To carry out the purposes of this section, there are authorized to be appropriated to the Fund—

"(A) $1,070,000,000 for fiscal years 2006 through 2008, the amounts to remain available until expended; and

"(B) such sums as may be necessary for subsequent fiscal years, the amounts to remain available until expended.

"(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

"(1) DISCLOSURE.—

"(A) IN GENERAL.—The Secretary shall withhold from disclosure under section 552 of title 5, United States Code, specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

"(B) REVIEW.—Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

"(C) SUNSET.—This paragraph shall cease to have force or effect on the date that is 7 years after the date of

enactment of the Pandemic and All-Hazards Preparedness Act.

"(2) REVIEW.—Notwithstanding section 14 of the Federal Advisory Committee Act, a working group of BARDA under this section and the National Biodefense Science Board under section 319M shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.".

SEC. 402. NATIONAL BIODEFENSE SCIENCE BOARD.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), as amended by section 401, is further amended by inserting after section 319L the following:

"SEC. 319M. NATIONAL BIODEFENSE SCIENCE BOARD AND WORKING GROUPS.

"(a) IN GENERAL.—

"(1) ESTABLISHMENT AND FUNCTION.—The Secretary shall establish the National Biodefense Science Board (referred to in this section as the 'Board') to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

"(2) MEMBERSHIP.—The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

"(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

"(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

"(C) four individuals representing academia; and

"(D) five other members as determined appropriate by the Secretary, of whom—

"(i) one such member shall be a practicing healthcare professional; and

"(ii) one such member shall be an individual from an organization representing healthcare consumers.

"(3) TERM OF APPOINTMENT.—A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

"(4) CONSECUTIVE APPOINTMENTS; MAXIMUM TERMS.—A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

"(5) DUTIES.—The Board shall—

"(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

"(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b); and

"(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities.

"(6) MEETINGS.—

"(A) INITIAL MEETING.—Not later than one year after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall hold the first meeting of the Board.

"(B) SUBSEQUENT MEETINGS.—The Board shall meet at the call of the Secretary, but in no case less than twice annually.

"(7) VACANCIES.—Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

"(8) CHAIRPERSON.—The Secretary shall appoint a chairperson from among the members of the Board.

"(9) POWERS.—

"(A) HEARINGS.—The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

"(B) POSTAL SERVICES.—The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

"(10) PERSONNEL.—

"(A) EMPLOYEES OF THE FEDERAL GOVERNMENT.—A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

"(B) OTHER MEMBERS.—A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

"(C) TRAVEL EXPENSES.—Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

"(D) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Board with the approval for the contributing agency without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

"(b) OTHER WORKING GROUPS.—The Secretary may establish a working group of experts, or may use an existing working group or advisory committee, to—

"(1) identify innovative research with the potential to be developed as a qualified countermeasure or a qualified pandemic or epidemic product;

"(2) identify accepted animal models for particular diseases and conditions associated with any biological, chemical, radiological, or nuclear agent, any toxin, or any potential pandemic infectious disease, and identify strategies to accelerate animal model and research tool development and validation; and

"(3) obtain advice regarding supporting and facilitating advanced research and development related to qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, and other vulnerable populations, and other issues regarding activities under this section that affect such populations.

"(c) DEFINITIONS.—Any term that is defined in section 319L and that is used in this section shall have the same meaning in this section as such term is given in section 319L.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $1,000,000 to carry out this section for fiscal year 2007 and each fiscal year thereafter.".

SEC. 403. CLARIFICATION OF COUNTERMEASURES COVERED BY PROJECT BIOSHIELD.

(a) QUALIFIED COUNTERMEASURE.—Section 319F–1(a) of the Public Health Service Act (42 U.S.C. 247d–6a(a)) is amended by striking paragraph (2) and inserting the following:

"(2) DEFINITIONS.—In this section:

"(A) QUALIFIED COUNTERMEASURE.—The term 'qualified countermeasure' means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))), that the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to—

"(i) diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

"(ii) diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph.

"(B) INFECTIOUS DISEASE.—The term 'infectious disease' means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.".

(b) SECURITY COUNTERMEASURE.—Section 319F–2(c)(1)(B) is amended by striking "treat, identify, or prevent" each place it appears and inserting "diagnose, mitigate, prevent, or treat".

(c) LIMITATION ON USE OF FUNDS.—Section 510(a) of the Homeland Security Act of 2002 (6 U.S.C. 320(a)) is amended by adding at the end the following: "None of the funds made available under this subsection shall be used to procure countermeasures to

diagnose, mitigate, prevent, or treat harm resulting from any naturally occurring infectious disease or other public health threat that are not security countermeasures under section 319F–2(c)(1)(B).".

SEC. 404. TECHNICAL ASSISTANCE.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 565. TECHNICAL ASSISTANCE.

"The Secretary, in consultation with the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act), security countermeasures (as defined in section 319F–2 of such Act), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.".

SEC. 405. COLLABORATION AND COORDINATION.

(a) LIMITED ANTITRUST EXEMPTION.—

(1) MEETINGS AND CONSULTATIONS TO DISCUSS SECURITY COUNTERMEASURES, QUALIFIED COUNTERMEASURES, OR QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT DEVELOPMENT.—

(A) AUTHORITY TO CONDUCT MEETINGS AND CONSULTATIONS.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with persons engaged in the development of a security countermeasure (as defined in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)) (as amended by this Act), a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)) (as amended by this Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)) for the purpose of the development, manufacture, distribution, purchase, or storage of a countermeasure or product. The Secretary may convene such meeting or consultation at the request of the Secretary of Homeland Security, the Attorney General, the Chairman of the Federal Trade Commission (referred to in this section as the "Chairman"), or any interested person, or upon initiation by the Secretary. The Secretary shall give prior notice of any such meeting or consultation, and the topics to be discussed, to the Attorney General, the Chairman, and the Secretary of Homeland Security.

(B) MEETING AND CONSULTATION CONDITIONS.—A meeting or consultation conducted under subparagraph (A) shall—

(i) be chaired or, in the case of a consultation, facilitated by the Secretary;

(ii) be open to persons involved in the development, manufacture, distribution, purchase, or storage of a countermeasure or product, as determined by the Secretary;

(iii) be open to the Attorney General, the Secretary of Homeland Security, and the Chairman;

(iv) be limited to discussions involving covered activities; and

(v) be conducted in such manner as to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting or consultation.

(C) LIMITATION.—The Secretary may not require participants to disclose confidential commercial or proprietary information.

(D) TRANSCRIPT.—The Secretary shall maintain a complete verbatim transcript of each meeting or consultation conducted under this subsection. Such transcript (or a portion thereof) shall not be disclosed under section 552 of title 5, United States Code, to the extent that the Secretary, in consultation with the Attorney General and the Secretary of Homeland Security, determines that disclosure of such transcript (or portion thereof) would pose a threat to national security. The transcript (or portion thereof) with respect to which the Secretary has made such a determination shall be deemed to be information described in subsection (b)(3) of such section 552.

(E) EXEMPTION.—

(i) IN GENERAL.—Subject to clause (ii), it shall not be a violation of the antitrust laws for any person to participate in a meeting or consultation conducted in accordance with this paragraph.

(ii) LIMITATION.—Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that is not covered by an exemption granted under paragraph (4).

(2) SUBMISSION OF WRITTEN AGREEMENTS.—The Secretary shall submit each written agreement regarding covered activities that is made pursuant to meetings or consultations conducted under paragraph (1) to the Attorney General and the Chairman for consideration. In addition to the proposed agreement itself, any submission shall include—

(A) an explanation of the intended purpose of the agreement;

(B) a specific statement of the substance of the agreement;

(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

(D) an explanation of the necessity for a cooperative effort among the particular participating persons to achieve the objectives of the agreement; and

(E) any other relevant information determined necessary by the Attorney General, in consultation with the Chairman and the Secretary.

(3) EXEMPTION FOR CONDUCT UNDER APPROVED AGREEMENT.—It shall not be a violation of the antitrust laws for a person to engage in conduct in accordance with a written

agreement to the extent that such agreement has been granted an exemption under paragraph (4), during the period for which the exemption is in effect.

(4) ACTION ON WRITTEN AGREEMENTS.—

(A) IN GENERAL.—The Attorney General, in consultation with the Chairman, shall grant, deny, grant in part and deny in part, or propose modifications to an exemption request regarding a written agreement submitted under paragraph (2), in a written statement to the Secretary, within 15 business days of the receipt of such request. An exemption granted under this paragraph shall take effect immediately.

(B) EXTENSION.—The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to exceed 10 business days.

(C) DETERMINATION.—An exemption shall be granted regarding a written agreement submitted in accordance with paragraph (2) only to the extent that the Attorney General, in consultation with the Chairman and the Secretary, finds that the conduct that will be exempted will not have any substantial anticompetitive effect that is not reasonably necessary for ensuring the availability of the countermeasure or product involved.

(5) LIMITATION ON AND RENEWAL OF EXEMPTIONS.—An exemption granted under paragraph (4) shall be limited to covered activities, and such exemption shall be renewed (with modifications, as appropriate, consistent with the finding described in paragraph (4)(C)), on the date that is 3 years after the date on which the exemption is granted unless the Attorney General in consultation with the Chairman determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

(6) AUTHORITY TO OBTAIN INFORMATION.—Consideration by the Attorney General for granting or renewing an exemption submitted under this section shall be considered an antitrust investigation for purposes of the Antitrust Civil Process Act (15 U.S.C. 1311 et seq.).

(7) LIMITATION ON PARTIES.—The use of any information acquired under an agreement for which an exemption has been granted under paragraph (4), for any purpose other than specified in the exemption, shall be subject to the antitrust laws and any other applicable laws.

(8) REPORT.—Not later than one year after the date of enactment of this Act and biannually thereafter, the Attorney General and the Chairman shall report to Congress on the use of the exemption from the antitrust laws provided by this subsection.

(b) SUNSET.—The applicability of this section shall expire at the end of the 6-year period that begins on the date of enactment of this Act.

(c) DEFINITIONS.—In this section:

(1) ANTITRUST LAWS.—The term "antitrust laws"—

(A) has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal

Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition; and

(B) includes any State law similar to the laws referred to in subparagraph (A).

(2) COUNTERMEASURE OR PRODUCT.—The term "countermeasure or product" refers to a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product (as those terms are defined in subsection (a)(1)).

(3) COVERED ACTIVITIES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "covered activities" includes any activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure or product.

(B) EXCEPTION.—The term "covered activities" shall not include, with respect to a meeting or consultation conducted under subsection (a)(1) or an agreement for which an exemption has been granted under subsection (a)(4), the following activities involving 2 or more persons:

(i) Exchanging information among competitors relating to costs, profitability, or distribution of any product, process, or service if such information is not reasonably necessary to carry out covered activities—

(I) with respect to a countermeasure or product regarding which such meeting or consultation is being conducted; or

(II) that are described in the agreement as exempted.

(ii) Entering into any agreement or engaging in any other conduct—

(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

(II) to restrict or require participation, by any person participating in such covered activities, in other research and development activities, except as reasonably necessary to prevent the misappropriation of proprietary information contributed by any person participating in such covered activities or of the results of such covered activities.

(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws under subsection (a)(4).

(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to carry out such covered activities.

(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not expressly exempted from the antitrust laws under subsection (a)(4).

(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in

any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.

SEC. 406. PROCUREMENT.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in the section heading, by inserting "**AND SECURITY COUNTERMEASURE PROCUREMENTS**" before the period; and

(2) in subsection (c)—

(A) in the subsection heading, by striking "BIOMEDICAL";

(B) in paragraph (3)—

(i) by striking "COUNTERMEASURES.—The Secretary" and inserting the following: "COUNTERMEASURES.—

"(A) IN GENERAL.—The Secretary"; and

(ii) by adding at the end the following:

"(B) INFORMATION.—The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

"(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

"(ii) would otherwise be exempt from disclosure under section 552 of title 5, United States Code.";

(C) in paragraph (4)(A), by inserting "not developed or" after "currently";

(D) in paragraph (5)(B)(i), by striking "to meet the needs of the stockpile" and inserting "to meet the stockpile needs";

(E) in paragraph (7)(B)—

(i) by striking the subparagraph heading and all that follows through "Homeland Security Secretary" and inserting the following: "INTERAGENCY AGREEMENT; COST.—The Homeland Security Secretary"; and

(ii) by striking clause (ii);

(F) in paragraph (7)(C)(ii)—

(i) by amending subclause (I) to read as follows:

"(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the

contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government."; and

(ii) by adding at the end the following:

"(VII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

"(VIII) WARM BASED SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

"(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section, may specify—

"(aa) the dosing and administration requirements for countermeasures to be developed and procured;

"(bb) the amount of funding that will be dedicated by the Secretary for development and acquisition of the countermeasure; and

"(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section."; and

(G) in paragraph (8)(A), by adding at the end the following: "Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, United States Code, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.".

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.