AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—112th Cong., 1st Sess.

S. 1855

To amend the Public Health Service Act to reauthorize various programs under the Pandemic and All-Hazards Preparedness Act.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Pandemic and All-Hazards Preparedness Act Reauthorization of 2011''.

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

TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND RESPONSE FOR PUBLIC HEALTH EMERGENCIES

SEC. 101. NATIONAL HEALTH SECURITY STRATEGY.

(a) IN GENERAL.—Section 2802 of the Public Health Service Act (42 U.S.C. 300hh–1) is amended—

(1) in subsection (a)(1), by striking ''2009'' and inserting ''2014''; and

(2) in subsection (b)—

(A) in paragraph (3)—

(i) in the matter preceding subparagraph (A)—

(I) by striking ''facilities), and trauma care'' and inserting ''facilities and which may include dental health facilities), and trauma care, critical care,''; and

(II) by inserting ''(including related availability, accessibility, and coordination)'' after ''public health emergencies'';

(ii) in subparagraph (A), by inserting ''and trauma'' after ''medical'';

(iii) in subparagraph (D), by inserting ''(which may include such dental health assets)'' after ''medical assets'';

(iv) by adding at the end the following:

''(F) Optimizing a coordinated and flexible approach to the medical surge capacity of hospitals, other healthcare facilities, and trauma care (which may include trauma centers) and emergency medical systems.'';

(B) in paragraph (4)—

(i) in subparagraph (A), by inserting '', including the unique needs and considerations of individuals with disabilities,''

after ''medical needs of at-risk individuals''; and

(ii) in subparagraph (B), by inserting ''the'' before ''purpose of this section''; and

(C) by adding at the end the following:

''(7) COUNTERMEASURES.—

''(A) Promoting strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, chemical, radiological, or nuclear agent or agents, whether naturally occurring, unintentional, or deliberate.

''(B) For purposes of this paragraph the term 'countermeasures' has the same meaning as the terms 'qualified countermeasures' under section 319F–1, 'qualified pandemic and epidemic products' under section 319F–3, and 'security countermeasures' under section 319F–2.

''(8) MEDICAL AND PUBLIC HEALTH COMMUNITY RESILIENCY.—Strengthening the ability of States, local communities, and tribal communities to prepare for, respond to, and be resilient in the event of public health emergencies, whether naturally occurring, unintentional, or deliberate by—

''(A) optimizing alignment and integration of medical and public health preparedness and response planning and capabilities with and into routine daily activities; and

''(B) promoting familiarity with local medical and public health systems.''.

(b) AT-RISK INDIVIDUALS.—Section 2814 of the Public Health Service Act (42 U.S.C. 300hh–16) is amended—

(1) by striking paragraphs (5), (7), and (8);

(2) by redesignating paragraphs (1) through (4) as paragraphs (2) through (5), respectively;

(3) by inserting before paragraph (2) (as so redesignated), the following:

''(1) monitor emerging issues and concerns as they relate to medical and public health preparedness and response for at-risk individuals in the event of a public health emergency declared by the Secretary under section 319;'';

(4) in paragraph (2) (as so redesignated), by striking ''National Preparedness goal'' and inserting ''preparedness goals, as described in section 2802(b),''; and

(5) by inserting after paragraph (6), the following:

''(7) disseminate and, as appropriate, update novel and best practices of outreach to and care of at-risk individuals before, during, and following public health emergencies in as timely a manner as is practicable, including from the time a public health threat is identified;

''(8) ensure that public health and medical information distributed by the Department of Health and Human Services during a public health emergency is delivered in a manner that takes into account the range of communication needs of the intended recipients, including at-risk individuals; and''.

SEC. 102. ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(1) in subsection (b)(4), by adding at the end the following:

''(D) POLICY COORDINATION AND STRATEGIC DIRECTION.—Provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for 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, before, during, and following public health emergencies.'';

(2) by striking subsection (c) and inserting the following:

''(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);

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

''(C) the Medical Reserve Corps pursuant to section 2813;

''(D) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 319I; and

''(E) administering grants and related authorities related to trauma care under parts A through C of title XII, such authority to be

transferred by the Secretary from the Administrator of the Health Resources and Services Administration to such Assistant Secretary;

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

''(A) the Public Health Emergency Preparedness Cooperative Agreement Program pursuant to section 319C–1;

''(B) the Strategic National Stockpile; and

''(C) the Cities Readiness Initiative;

''(3) align and coordinate medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this Act, to the extent possible, including program requirements, timelines, and measurable goals, and in coordination with the Secretary of Homeland Security, to—

''(A) optimize and streamline medical and public health preparedness capabilities and the ability of local communities to respond to public health emergencies;

''(B) minimize duplication of efforts with regard to medical and public health preparedness and response programs; and

''(C) gather and disseminate best practices among grant and cooperative agreement recipients, as appropriate;

''(4) carry out drills and operational exercises, in coordination with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies, as necessary and appropriate, to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness, including exercises based on—

''(A) identified threats for which countermeasures are available and for which no countermeasures are available; and

''(B) unknown threats for which no countermeasures are available; and

''(5) assume other duties as determined appropriate by the Secretary.''; and

(3) by adding at the end the following:

''(d) NATIONAL SECURITY PRIORITY.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall on a periodic basis conduct meetings, as applicable and appropriate, with the Assistant to the President for National Security Affairs to provide an update on, and discuss, medical and public health

preparedness and response activities pursuant to this Act and the Federal Food, Drug, and Cosmetic Act, including progress on the development, approval, clearance, and licensure of medical countermeasures.

"(e) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, and every other year thereafter, the Secretary, acting through the Assistant Secretary for Preparedness and Response and in consultation with the Director of the Biomedical Advanced Research and Development Authority, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration, shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. Such strategy and plan shall be known as the 'Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan'.

''(2) REQUIREMENTS.—The plan under paragraph (1) shall—

''(A) consider and reflect the full spectrum of medical countermeasure-related activities, including research, advanced research, development, procurement, stockpiling, deployment, and distribution;

''(B) identify and prioritize near-term, mid-term, and long-term priority qualified and security countermeasure (as defined in sections 319F–1 and 319F–2) needs and goals of the Federal Government according to chemical, biological, radiological, and nuclear threat or threats;

''(C) identify projected timelines, anticipated funding allocations, benchmarks, and milestones for each medical countermeasure priority under subparagraph (B), including projected needs with regard to replenishment of the Strategic National Stockpile;

''(D) be informed by the recommendations of the National Biodefense Science Board pursuant to section 319M;

''(E) report on advanced research and development awards and the date of the issuance

of contract awards, including awards made through the special reserve fund (as defined in section 319F–2(c)(10));

''(F) identify progress made in meeting the goals, benchmarks, and milestones identified under subparagraph (C) in plans submitted subsequent to the initial plan;

''(G) identify the progress made in meeting the medical countermeasure priorities for at-risk individuals, (as defined in 2802(b)(4)(B)), as applicable under subparagraph (B), including with regard to the projected needs for related stockpiling and replenishment of the Strategic National Stockpile; and

''(H) be made publicly available.

''(3) GAO REPORT.—

''(A) IN GENERAL.—Not later than 1 year after the date on which a Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection is issued by the Secretary, the Government Accountability Office shall conduct an independent evaluation and submit to the appropriate committees of Congress a report concerning such strategy and implementation plan.

"(B) CONTENT.—The report described in subparagraph (A) shall review and assess—

"(i) the near-term, mid-term, and long-term medical countermeasure needs and identified priorities of the Federal Government pursuant to subparagraphs (A) and (B) of paragraph (2);

"(ii) the activities of the Department of Health and Human Services with respect to advanced research and development pursuant to section 319L; and

"(iii) the progress made toward meeting the goals, benchmarks, and milestones identified in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection.

"(f) INTERNAL MULTIYEAR PLANNING PROCESS.—The Secretary shall develop, and update on an annual basis, a coordinated 5-year budget plan based on the medical countermeasure priorities and goals described in subsection (e). Each such plan shall—

"(1) include consideration of the entire medical countermeasures enterprise, including—

''(A) basic research, advanced research and development;

''(B) approval, clearance, licensure, and authorized uses of products; and

''(C) procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile;

''(2) include measurable outputs and outcomes to allow for the tracking of the progress made toward identified goals;

''(3) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 319F–2; and

''(4) be made available to the appropriate committees of Congress upon request.

''(g) INTERAGENCY COORDINATION PLAN.—Not later than one year after the date of enactment of this subsection, the Secretary, in coordination with the Secretary of Defense, shall submit to the appropriate committees of Congress a report concerning the manner in which the Department of Health and Human Services is coordinating with the Department of Defense regarding countermeasure activities to address chemical, biological, radio-

logical, and nuclear threats. Such report shall include information with respect to—

''(1) the research, advanced research, development, procurement, stockpiling, and distribution of countermeasures to meet identified needs; and

''(2) the coordination of efforts between the Department of Health and Human Services and the Department of Defense to address countermeasure needs for various segments of the population.

''(h) PROTECTION OF NATIONAL SECURITY.—In carrying out subsections (e), (f), and (g), the Secretary shall ensure that information and items that could compromise national security are not disclosed.''.

SEC. 103. MODERNIZATION OF THE NATIONAL DISASTER MEDICAL SYSTEM.

Section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11) is amended—

(1) in subsection (a)(3)—

(A) in subparagraph (A), in clause (i) by inserting '', including at-risk individuals as applicable'' after ''victims of a public health emergency'';

(B) by redesignating subparagraph (C) as subparagraph (E); and

(C) by inserting after subparagraph (B), the following:

''(C) CONSIDERATIONS FOR AT-RISK POPULATIONS.—The Secretary shall take steps to ensure that an appropriate specialized and focused range of public health and medical capabilities are represented in the National Disaster Medical System, which take into account the needs of at-risk individuals, in the event of a public health emergency.''.

''(D) ADMINISTRATION.—The Secretary may determine and pay claims for reimbursement for services under subparagraph (A) directly or through contracts that provide for payment in advance or by way of reimbursement.''; and

(2) in subsection (g), by striking ''such sums as may be necessary for each of the fiscal years 2007 through 2011'' and inserting ''$56,000,000 for each of fiscal years 2012 through 2016''.

SEC. 104. CONTINUING THE ROLE OF THE DEPARTMENT OF VETERANS AFFAIRS.

Section 8117(g) of title 38, United States Code, is amended by striking ''such sums as may be necessary to carry out this section for each of fiscal years 2007 through

2011'' and inserting ''$156,500,000 for each of fiscal years 2012 through 2016 to carry out this section''.

TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS PREPAREDNESS AND RESPONSE

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

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

(1) in subsection (b)(2)—

(A) in subparagraph (A)—

(i) by striking clauses (i) and (ii) and inserting the following:

''(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 2802, including with respect to chemical, biological, radiological, or nuclear threats, whether naturally occurring, unintentional, or deliberate;

''(ii) a description of the activities such entity will carry out with respect to pandemic influenza, as a component of the

activities carried out under clause (i), and consistent with the requirements of paragraphs (2) and (5) of subsection (g);'';

(ii) in clause (iv), by striking ''and'' at the end; and

(iii) by adding at the end the following:

''(vi) a description of how, as appropriate, the entity may partner with relevant public and private stakeholders in public health emergency preparedness and response;

''(vii) a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State educational agencies (as defined in section 9101(41) of the Elementary and Secondary Education Act of 1965) and State child care lead agencies (as defined in section 658D of the Child Care and Development Block Grant Act); and

''(viii) in the case of entities that operate on the United States-Mexico border

or the United States-Canada border, a description of the activities such entity will carry out under the agreement that are specific to the border area including disease detection, identification, and investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks whether naturally-occurring or due to bioterrorism, consistent with the requirements of this section;''; and

(B) in subparagraph (C), by inserting '', including addressing the needs of at-risk individuals,'' after ''capabilities of such entity'';

(2) in subsection (g)—

(A) in paragraph (1), by striking subparagraph (A) and inserting the following:

''(A) include outcome goals representing operational achievements of the National Preparedness Goals developed under section 2802(b) with respect to all-hazards, including chemical, biological, radiological, or nuclear threats; and''; and

(B) in paragraph (2)(A), by adding at the end the following: ''The Secretary shall periodi-

cally update, as necessary and appropriate, such pandemic influenza plan criteria and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1).'';

(3) in subsection (i)—

(A) in paragraph (1)(A)—

(i) by striking ''$824,000,000 for fiscal year 2007'' and inserting ''$632,900,000 for fiscal year 2012''; and

(ii) by striking ''such sums as may be necessary for each of fiscal years 2008 through 2011'' and inserting ''$632,900,000 for each of fiscal years 2013 through 2016''; and

(B) by adding at the end the following:

''(7) AVAILABILITY OF COOPERATIVE AGREEMENT FUNDS.—

''(A) IN GENERAL.—Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

"(B) FUNDS CONTINGENT ON ACHIEVING BENCHMARKS.—The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as described in subsection (g)."; and

(4) in subsection (j), by striking paragraph (3).

(b) VACCINE TRACKING AND DISTRIBUTION.—Section 319A(e) of the Public Health Service Act (42 U.S.C. 247d–1(e)) is amended by striking "such sums for each of fiscal years 2007 through 2011" and inserting "$30,800,000 for each of fiscal years 2012 through 2016".

(c) GAO REPORT.—Section 319C-1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended by adding at the end the following:

"(l) GAO REPORT.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011, the Government Accountability Office shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning Federal programs at the Department of Health and

Human Services that support medical and public health preparedness and response programs at the State and local levels.

''(2) CONTENT.—The report described in paragraph (1) shall review and assess—

''(A) the extent to which grant and cooperative agreement requirements and goals have been met by recipients;

''(B) the extent to which such grants and cooperative agreements have supported medical and public health preparedness and response goals pursuant to section 2802(b), as appropriate and applicable;

''(C) whether recipients or the Department of Health and Human Services have identified any factors that may impede a recipient's ability to achieve programmatic goals and requirements; and

''(D) instances in which funds may not have been used appropriately, in accordance with grant and cooperative agreement requirements, and actions taken to address inappropriate expenditures.''.

SEC. 202. HOSPITAL PREPAREDNESS AND MEDICAL SURGE CAPACITY.

(a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—Section 319F(a)(5)(B) of the Public Health Service Act (42 U.S.C. 247d–6(a)(5)(B)) is amended by striking ''public health or medical'' and inserting ''public health, medical, or dental''.

(b) ENCOURAGING HEALTH PROFESSIONAL VOLUNTEERS.—

(1) EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF VOLUNTEER HEALTH PROFESSIONALS.—Section 319I(k) of the Public Health Service Act (42 U.S.C. 247d–7b(k)) is amended by striking ''$2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011'' and inserting ''$5,900,000 for each of fiscal years 2012 through 2016''.

(2) VOLUNTEERS.—Section 2813 of the Public Health Service Act (42 U.S.C. 300hh–15) is amended—

(A) in subsection (d)(2), by adding at the end the following: ''Such training exercises shall, as appropriate and applicable, incorporate

the needs of at-risk individuals in the event of a public health emergency.''; and

(B) in subsection (i), by striking ''$22,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011'' and inserting ''$11,900,000 for each of fiscal years 2012 through 2016''.

(c) PARTNERSHIPS FOR STATE AND REGIONAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—Section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) is amended—

(1) in subsection (b)(1)(A)(ii), by striking ''centers, primary'' and inserting ''centers, community health centers, primary'';

(2) by striking subsection (c) and inserting the following:

''(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) with respect to all-hazards, including chemical, biological, radiological, or nuclear threats.'';

(3) by striking subsection (g) and inserting the following:

''(g) COORDINATION.—

''(1) 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 local Cities Readiness Initiative, and local emergency plans.

''(2) NATIONAL COLLABORATION.—Partnerships consisting of one or more eligible entities under this section may, to the extent practicable, collaborate with other partnerships consisting of one or more eligible entities under this section for purposes of national coordination and collaboration with respect to activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 2802(b).''; and

(4) in subsection (j)—

(A) in paragraph (1), by striking ''$474,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011'' and inserting ''$378,000,000 for each of fiscal years 2012 through 2016''; and

(B) by adding at the end the following:

''(4) AVAILABILITY OF COOPERATIVE AGREEMENT FUNDS.—

''(A) IN GENERAL.—Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

''(B) FUNDS CONTINGENT ON ACHIEVING BENCHMARKS.—The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as required under subsection (i).''.

SEC. 203. ENHANCING SITUATIONAL AWARENESS AND BIOSURVEILLANCE.

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

(1) in subsection (b)—

(A) in paragraph (1)(B), by inserting ''poison control centers,'' after ''hospitals,'';

(B) in paragraph (2), by inserting before the period the following: '', allowing for coordi-

nation to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort''; and

(C) in paragraph (3), by inserting before the period the following: ''and update such standards as necessary'';

(2) in subsection (d)—

(A) in the subsection heading, by striking ''PUBLIC HEALTH SITUATIONAL AWARENESS'' and inserting ''MODERNIZING PUBLIC HEALTH SITUATIONAL AWARENESS AND BIOSURVEILLANCE'';

(B) in paragraph (1)—

(i) by striking ''Pandemic and All-Hazards Preparedness Act'' and inserting ''Pandemic and All-Hazards Preparedness Act Reauthorization of 2011''; and

(ii) by inserting '', novel emerging threats,'' after ''disease outbreaks'';

(C) by striking paragraph (2) and inserting the following:

''(2) STRATEGY AND IMPLEMENTATION PLAN.—Not later than 180 days after the date of enactment of the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011, the Sec-

retary shall submit to the appropriate committees of Congress, a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measurable steps the Secretary will carry out to—

''(A) develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3); and

''(B) modernize and enhance biosurveillance activities.'';

(D) in paragraph (3)(D), by inserting ''community health centers, health centers'' after ''poison control,'';

(E) in paragraph (5), by striking subparagraph (A) and inserting the following:

''(A) utilize applicable interoperability standards as determined by the Secretary, and in consultation with the Office of the National Coordinator for Health Information Technology, through a joint public and private sector process;''; and

(F) by adding at the end the following:

''(6) CONSULTATION WITH THE NATIONAL BIODEFENSE SCIENCE BOARD.—In carrying out this section consistent with section 319M, the National

Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Humans Services to ensure comprehensive, real-time all-hazards biosurveillance capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

"(A) identify the steps necessary to achieve a national biosurveillance system for human health, with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers;

"(B) identify any duplicative surveillance programs under the authority of the Secretary, or changes that are necessary to existing programs, in order to enhance and modernize such activities, minimize duplication, strengthen and streamline such activities under the authority of the Secretary, and achieve real-time and appro-

priate data that relate to disease activity, both human and zoonotic; and

''(C) coordinate with applicable existing advisory committees of the Director of the Centers for Disease Control and Prevention, including such advisory committees consisting of representatives from State, local, and tribal public health authorities and appropriate public and private sector health care entities and academic institutions, in order to provide guidance on public health surveillance activities.'';

(3) in subsection (e)(5), by striking ''4 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act'' and inserting ''3 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act Reauthorization of 2011'';

(4) in subsection (g), by striking ''such sums as may be necessary in each of fiscal years 2007 through 2011'' and inserting ''$160,121,000 for each of fiscal years 2012 through 2016''; and

(5) by adding at the end the following:

''(h) DEFINITION.—For purposes of this section the term 'biosurveillance' means the process of gathering near real-time, biological data that relates to disease activity

and threats to human or zoonotic health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing tracking of health events, and overall situational awareness of disease activity.''.

TITLE III—ENHANCING MEDICAL COUNTERMEASURE REVIEW

SEC. 301. SPECIAL PROTOCOL ASSESSMENT.

Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by striking ''size of clinical trials intended'' and all that follows through ''. The sponsor or applicant'' and inserting the following: ''size—

''(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

''(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

''(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant''.

SEC. 302. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by striking ''sections 505, 510(k), and 515 of this Act'' and inserting ''any provision of this Act'';

(B) in paragraph (2)(A), by striking ''under a provision of law referred to in such paragraph'' and inserting ''under a provision of law in section 505, 510(k), or 515 of this Act or section 351 of the Public Health Service Act''; and

(C) in paragraph (3), by striking ''a provision of law referred to in such paragraph'' and inserting ''a provision of law referred to in paragraph (2)(A)'';

(2) in subsection (b)—

(A) in the subsection heading, by striking ''EMERGENCY'' and inserting ''EMERGENCY OR THREAT JUSTIFYING EMERGENCY AUTHORIZED USE'';

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''may declare an emergency'' and inserting ''may make a declaration that the circumstances exist'';

(ii) in subparagraph (A), by striking ''specified'';

(iii) in subparagraph (B)—

(I) by striking ''specified''; and

(II) by striking ''; or'' and inserting a semicolon;

(iv) by amending subparagraph (C) to read as follows:

''(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or''; and

(v) by adding at the end the following:

''(D) the identification of a material threat pursuant to section 319F–2 of the Public

Health Service Act sufficient to affect national security or the health and security of United States citizens living abroad.'';

(C) in paragraph (2)(A)—

(i) by amending clause (ii) to read as follows:

''(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.'';

(ii) by striking subparagraph (B); and

(iii) by redesignating subparagraph (C) as subparagraph (B);

(D) in paragraph (4), by striking ''advance notice of termination, and renewal under this subsection.'' and inserting '', and advance notice of termination under this subsection. The Secretary shall make any renewal under this subsection available on the Internet Web site of the Food and Drug Administration.''; and

(E) by adding at the end the following:

''(5) EXPLANATION BY SECRETARY.—If an authorization under this section with respect to an unapproved product has been in effect for more than 1 year, the Secretary shall provide in writing to

sponsor of such product, an explanation of the scientific, regulatory, or other obstacles to approval, licensure, or clearance of such product, including specific actions to be taken by the Secretary and the sponsor to overcome such obstacles.'';

(3) in subsection (c)—

(A) in the matter preceding paragraph (1)—

(i) by inserting ''the Assistant Secretary for Preparedness and Response,'' after ''consultation with'';

(ii) by striking ''Health and'' and inserting ''Health, and''; and

(iii) by striking ''circumstances of the emergency involved'' and inserting ''applicable circumstances described in subsection (b)(1)'';

(B) in paragraph (1), by striking ''specified'' and inserting ''referred to''; and

(C) in paragraph (2)(B), by inserting '', taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable'' after ''risks of the product'';

(4) in subsection (d)(3), by inserting ", to the extent practicable given the circumstances of the emergency," after "including";

(5) in subsection (e)—

(A) in paragraph (1)(A), by striking "circumstances of the emergency" and inserting "applicable circumstances described in subsection (b)(1)";

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) by striking "manufacturer of the product" and inserting "person";

(II) by striking "circumstances of the emergency" and inserting "applicable circumstances described in subsection (b)(1)"; and

(III) by inserting at the end before the period "or in paragraph (1)(B)";

(ii) in subparagraph (B)(i), by inserting before the period at the end ", except as provided in section 564A with respect to authorized changes to the product expiration date"; and

(iii) by amending subparagraph (C) to read as follows:

''(C) In establishing conditions under this paragraph with respect to the distribution and administration of the product for the unapproved use, the Secretary shall not impose conditions that would restrict distribution or administration of the product when done solely for the approved use.''; and

(C) by amending paragraph (3) to read as follows:

''(3) GOOD MANUFACTURING PRACTICE; PRESCRIPTION.—With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the applicable circumstances described in subsection (b)(1)—

''(A) requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established under section 510 or 520(f)(1), and including

relevant conditions prescribed with respect to the product by an order under section 520(f)(2);

''(B) requirements established under section 503(b); and

''(C) requirements established under section 520(e).'';

(6) in subsection (g)—

(A) in the subsection heading, by inserting ''REVIEW AND'' before ''REVOCATION'';

(B) in paragraph (1), by inserting after the period at the end the following: ''As part of such review, the Secretary shall regularly review the progress made with respect to the approval, licensure, or clearance of—

''(A) an unapproved product for which an authorization was issued under this section; or

''(B) an unapproved use of an approved product for which an authorization was issued under this section.''; and

(C) by amending paragraph (2) to read as follows:

''(2) REVISION AND REVOCATION.—The Secretary may revise or revoke an authorization under this section if—

''(A) the circumstances described under subsection (b)(1) no longer exist;

''(B) the criteria under subsection (c) for issuance of such authorization are no longer met; or

''(C) other circumstances make such revision or revocation appropriate to protect the public health or safety.'';

(7) in subsection (h)(1), by adding after the period at the end the following: ''The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration.''; and

(8) by adding at the end of subsection (j) the following:

''(4) Nothing in this section shall be construed as authorizing a delay in the review or other consideration by the Food and Drug Administration of any application pending before the Administration for a countermeasure or product referred to in subsection (a).''.

(b) EMERGENCY USE OF MEDICAL PRODUCTS.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 564 the following:

"SEC. 564A. EMERGENCY USE OF MEDICAL PRODUCTS.

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE PRODUCT.—The term 'eligible product' means a product that—

"(A) is approved or cleared under this chapter or licensed under section 351 of the Public Health Service Act;

"(B)(i) is intended for use to prevent, diagnose, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents, including a product intended to be used to prevent or treat pandemic influenza; or

"(ii) is intended for use to prevent, diagnose, or treat a serious or life-threatening disease or condition caused by a product described in clause (i); and

"(C) is intended for use during the circumstances under which—

"(i) a determination described in subparagraph (A), (B), or (C) of section 564(b)(1) has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

"(ii) the identification of a material threat described in subparagraph (D) of

section 564(b)(1) has been made pursuant to section 319F–2 of the Public Health Service Act.

''(2) PRODUCT.—The term 'product' means a drug, device, or biological product.

''(b) EXTENSION OF EXPIRATION DATE.—

''(1) AUTHORITY TO EXTEND EXPIRATION DATE.—The Secretary may extend the expiration date of a eligible product in accordance with this subsection.

''(2) EXPIRATION DATE.—For purposes of this subsection, the term 'expiration date' means the date established through appropriate stability testing required by the regulations issued by the Secretary to ensure that the product meets applicable standards of identity, strength, quality, and purity at the time of use.

''(3) EFFECT OF EXTENSION.—Notwithstanding any other provision of this Act or the Public Health Service Act, if the expiration date of an eligible product is extended in accordance with this section, the introduction or delivery for introduction into interstate commerce of such product after the expiration date provided by the manufacturer and

within the duration of such extension shall not be deemed to render the product—

"(A) an unapproved product; or

"(B) adulterated or misbranded under this Act.

"(4) DETERMINATIONS BY SECRETARY.—Before extending the expiration date of an eligible product under this subsection, the Secretary shall determine—

"(A) that extension of the expiration date will help protect public health;

"(B) that any extension of expiration is supported by scientific evaluation that is conducted or accepted by the Secretary;

"(C) what changes to the product labeling, if any, are required or permitted, including whether and how any additional labeling communicating the extension of the expiration date may alter or obscure the labeling provided by the manufacturer; and

"(D) that any other conditions that the Secretary deems appropriate have been met.

"(5) SCOPE OF EXTENSION.—With respect to each extension of an expiration date granted under this subsection, the Secretary shall determine—

''(A) the batch, lot, or unit to which such extension shall apply;

''(B) the duration of such extension; and

''(C) any conditions to effectuate such extension that are necessary and appropriate to protect public health or safety.

''(c) CURRENT GOOD MANUFACTURING PRACTICE.—

''(1) IN GENERAL.—The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including requirements under section 501 or 520(f)(1) or applicable conditions prescribed with respect to the eligible product by an order under section 520(f)(2).

''(2) EFFECT.—Notwithstanding any other provision of this Act or the Public Health Service Act, an eligible product shall not be considered an unapproved product and shall not be deemed adulterated or misbranded under this Act because, with respect to such product, the Secretary has authorized devi-

ations from current good manufacturing practices under paragraph (1).

''(d) EMERGENCY USE INSTRUCTIONS.—

''(1) IN GENERAL.—The Secretary, acting through an appropriate official within the Department of Health and Human Services, may create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning such product's approved, licensed, or cleared conditions of use.

''(2) EFFECT.—Notwithstanding any other provisions of this Act or the Public Health Service Act, a product shall not be considered an unapproved product and shall not be deemed adulterated or misbranded under this Act because of the issuance of emergency use instructions under paragraph (1) with respect to such product or the introduction or delivery for introduction of such product into interstate commerce accompanied by such instructions—

''(A) during an emergency response to an actual emergency that is the basis for a determination described in subsection (a)(1)(C)(i); or

''(B) by a government entity (including a Federal, State, local, and tribal government en-

tity), or a person acting on behalf of such a government entity, in preparation for an emergency response.''.

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), is amended—

(1) in subsection (f), by striking paragraph (7); and

(2) by adding at the end the following:

''(k) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this section with respect to a qualified countermeasure (as defined in section 319F–1(a)(2) of the Public Health Service Act) to which a requirement under this section has been applied, if the Secretary determines that such waiver is required to mitigate the effects of, or reduce the severity of, the circumstances under which—

''(1) a determination described in subparagraph (A), (B), or (C) of section 564(b)(1) has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

''(2) the identification of a material threat described in subparagraph (D) of section 564(b)(1) has been made pursuant to section 319F–2 of the Public Health Service Act.''.

(d) PRODUCTS HELD FOR EMERGENCY USE.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by inserting after section 564A, as added by subsection (b), the following:

"SEC. 564B. PRODUCTS HELD FOR EMERGENCY USE.

"It is not a violation of any section of this Act or of the Public Health Service Act for a government entity (including a Federal, State, local, and tribal government entity), or a person acting on behalf of such a government entity, to introduce into interstate commerce a product (as defined in section 564(a)(4)) intended for emergency use, if that product—

"(1) is intended to be held and not used; and

"(2) is held and not used, unless and until that product—

"(A) is approved, cleared, or licensed under section 505, 510(k), or 515 of this Act or section 351 of the Public Health Service Act;

"(B) is authorized for investigational use under section 505 or 520 of this Act or section 351 of the Public Health Service Act; or

"(C) is authorized for use under section 564.".

SEC. 303. DEFINITIONS.

Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended by striking ''The Secretary, in consultation'' and inserting the following:

''(a) DEFINITIONS.—In this section—

''(1) the term 'countermeasure' means a qualified countermeasure, a security countermeasure, and a qualified pandemic or epidemic product;

''(2) the term 'qualified countermeasure' has the meaning given such term in section 319F–1 of the Public Health Service Act;

''(3) the term 'security countermeasure' has the meaning given such term in section 319F–2 of such Act; and

''(4) the term 'qualified pandemic or epidemic product' means a product that meets the definition given such term in section 319F–3 of the Public Health Service Act and—

''(A) that has been identified by the Department of Health and Human Services or the Department of Defense as receiving funding directly related to addressing chemical, biological, radiological or nuclear threats, including pandemic influenza; or

''(B) is included under this paragraph pursuant to a determination by the Secretary.

''(b) GENERAL DUTIES.—The Secretary, in consultation''.

SEC. 304. ENHANCING MEDICAL COUNTERMEASURE ACTIVITIES.

Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as amended by section 303, is further amended—

(1) in the section heading, by striking ''**TECHNICAL ASSISTANCE**'' and inserting ''**COUNTERMEASURE DEVELOPMENT, REVIEW, AND TECHNICAL ASSISTANCE**'';

(2) in subsection (b), by striking the subsection heading and all that follows through ''shall establish'' and inserting the following:

''(b) GENERAL DUTIES.—In order to accelerate the development, stockpiling, approval, licensure, and clearance of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products, the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, shall—

''(1) ensure the appropriate involvement of Food and Drug Administration personnel in interagency activities related to countermeasure advanced research and development, consistent with sections

319F, 319F–1, 319F–2, 319F–3, and 319L of the Public Health Service Act;

''(2) ensure the appropriate involvement and consultation of Food and Drug Administration personnel in any flexible manufacturing activities carried out under section 319L of the Public Health Service Act, including with respect to meeting regulatory requirements set forth in this Act;

''(3) promote countermeasure expertise within the Food and Drug Administration by—

''(A) ensuring that Food and Drug Administration personnel involved in reviewing countermeasures for approval, licensure, or clearance are informed by the Assistant Secretary for Preparedness and Response on the material threat assessment conducted under section 319F–2 of the Public Health Service Act for the agent or agents for which the countermeasure under review is intended;

''(B) training Food and Drug Administration personnel regarding review of countermeasures for approval, licensure, or clearance;

''(C) holding public meetings at least twice annually to encourage the exchange of scientific ideas; and

''(D) establishing protocols to ensure that countermeasure reviewers have sufficient training or experience with countermeasures;

''(4) maintain teams, composed of Food and Drug Administration personnel with expertise on countermeasures, including specific countermeasures, populations with special clinical needs (including children and pregnant women that may use countermeasures, as applicable and appropriate), classes or groups of countermeasures, or other countermeasure-related technologies and capabilities, that shall—

''(A) consult with countermeasure experts, including countermeasure sponsors and applicants, to identify and help resolve scientific issues related to the approval, licensure, or clearance of countermeasures, through workshops or public meetings;

''(B) improve and advance the science relating to the development of new tools, standards, and approaches to assessing and evaluating countermeasures—

''(i) in order to inform the process for countermeasure approval, clearance, and licensure; and

"(ii) with respect to the development of countermeasures for populations with special clinical needs, including children and pregnant women, in order to meet the needs of such populations, as necessary and appropriate; and

"(5) establish"; and

(3) by adding at the end the following:

"(c) DEVELOPMENT AND ANIMAL MODELING PROCEDURES.—

"(1) AVAILABILITY OF ANIMAL MODEL MEETINGS.—To facilitate the timely development of animal models and support the development, stockpiling, licensure, approval, and clearance of countermeasures, the Secretary shall, not later than 180 days after the enactment of this subsection, establish a procedure by which a sponsor or applicant that is developing a countermeasure for which human efficacy studies are not ethical or practicable, and that has an approved investigational new drug application or investigational device exemption, may request and receive—

"(A) a meeting to discuss proposed animal model development activities; and

"(B) a meeting prior to initiating pivotal animal studies.

"(2) PEDIATRIC MODELS.—To facilitate the development and selection of animal models that could translate to pediatric studies, any meeting conducted under paragraph (1) shall include discussion of animal models for pediatric populations, as appropriate.

"(d) REVIEW AND APPROVAL OF COUNTERMEASURES.—

"(1) MATERIAL THREAT.—When evaluating an application or submission for approval, licensure, or clearance of a countermeasure, the Secretary shall take into account the material threat posed by the chemical, biological, radiological, or nuclear agent or agents identified under section 319F–2 of the Public Health Service Act for which the countermeasure under review is intended.

"(2) REVIEW EXPERTISE.—When practicable and appropriate, teams of Food and Drug Administration personnel reviewing applications or submissions described under paragraph (1) shall include a reviewer with sufficient training or experience with countermeasures pursuant to the protocols established under subsection (b)(3)(D).".

SEC. 305. REGULATORY MANAGEMENT PLANS.

Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as amended by section 304, is further amended by adding at the end the following:

''(e) REGULATORY MANAGEMENT PLAN.—

''(1) DEFINITION.—In this subsection, the term 'eligible countermeasure' means—

''(A) a security countermeasure; or

''(B) a countermeasure with respect to which the Biomedical Advanced Research and Development Authority has provided funding under section 319L of the Public Health Service Act for advanced research and development.

''(2) REGULATORY MANAGEMENT PLAN PROCESS.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority, shall establish a formal process for obtaining scientific feedback and interactions regarding the development and regulatory review of eligible countermeasures by facilitating the development of written regulatory management plans in accordance with this subsection.

''(3) SUBMISSION OF REQUEST AND PROPOSED PLAN BY SPONSOR OR APPLICANT.—

"(A) IN GENERAL.—A sponsor or applicant of an eligible countermeasure may initiate the process described under paragraph (2) upon submission of written request to the Secretary. Such request shall include a proposed regulatory management plan.

"(B) TIMING OF SUBMISSION.—A sponsor or applicant may submit a written request under subparagraph (A) after the eligible countermeasure has an investigational new drug or investigational device exemption in effect.

"(C) RESPONSE BY SECRETARY.—The Secretary shall direct the Food and Drug Administration, upon submission of a written request by a sponsor or applicant under subparagraph (A), to work with the sponsor or applicant to agree on a regulatory management plan within a reasonable time not to exceed 90 days. If the Secretary determines that no plan can be agreed upon, the Secretary shall provide to the sponsor or applicant, in writing, the scientific or regulatory rationale why such agreement cannot be reached.

"(4) PLAN.—The content of a regulatory management plan agreed to by the Secretary and a sponsor or applicant shall include—

"(A) an agreement between the Secretary and the sponsor or applicant regarding developmental milestones that will trigger responses by the Secretary as described in subparagraph (B);

"(B) performance targets and goals for timely and appropriate responses by the Secretary to the triggers described under subparagraph (A), including meetings between the Secretary and the sponsor or applicant, written feedback, decisions by the Secretary, and other activities carried out as part of the development and review process; and

"(C) an agreement on how the plan shall be modified, if needed.

"(5) MILESTONES AND PERFORMANCE TARGETS.—The developmental milestones described in paragraph (4)(A) and the performance targets and goals described in paragraph (4)(B) shall include—

"(A) feedback from the Secretary regarding the data required to support the approval, clearance, or licensure of the eligible countermeasure involved;

"(B) feedback from the Secretary regarding the data necessary to inform any authorization under section 564;

"(C) feedback from the Secretary regarding the data necessary to support the positioning and delivery of the eligible countermeasure, including to the Strategic National Stockpile;

"(D) feedback from the Secretary regarding the data necessary to support the submission of protocols for review under section 505(b)(5)(B);

"(E) feedback from the Secretary regarding any gaps in scientific knowledge that will need resolution prior to approval, licensure, or clearance of the eligible countermeasure, and plans for conducting the necessary scientific research;

"(F) identification of the population for which the countermeasure sponsor or applicant seeks approval, licensure, or clearance, and the population for which desired labeling would not be appropriate, if known; and

"(G) as necessary and appropriate, and to the extent practicable, a plan for demonstrating

safety and effectiveness in pediatric populations, and for developing pediatric dosing, formulation, and administration with respect to the eligible countermeasure, provided that such plan would not delay authorization under section 564, approval, licensure, or clearance for adults.

''(6) PRIORITIZATION.—If the Commissioner of Food and Drugs determines that resources are not available to establish regulatory management plans under this section for all eligible countermeasures for which a request is submitted under paragraph (3)(A), the Director of the Biomedical Advanced Research and Development Authority, in consultation with the Commissioner of Food and Drugs, shall prioritize which eligible countermeasures may receive regulatory managements plans, and in doing so shall give priority to eligible countermeasures that are security countermeasures.''.

SEC. 306. REPORT.

Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as amended by section 305, is further amended by adding at the end the following:

''(f) ANNUAL REPORT.—Not later than 180 days after the date of enactment of this subsection, and annu-

ally thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that details the countermeasure development and review activities of the Food and Drug Administration, including—

"(1) with respect to the development of new tools, standards, and approaches to assess and evaluate countermeasures—

"(A) the identification of the priorities of the Food and Drug Administration and the progress made on such priorities; and

"(B) the identification of scientific gaps that impede the development or approval, licensure, or clearance of countermeasures for populations with special clinical needs, including children and pregnant women, and the progress made on resolving these challenges;

"(2) with respect to countermeasures for which a regulatory management plan has been agreed upon under subsection (e), the extent to which the performance targets and goals set forth in subsection (e)(4)(B) and the regulatory management plan has been met, including, for each such countermeasure—

''(A) whether the regulatory management plan was completed within the required timeframe, and the length of time taken to complete such plan;

''(B) whether the Secretary adhered to the timely and appropriate response times set forth in such plan; and

''(C) explanations for any failure to meet such performance targets and goals;

''(3) the number of regulatory teams established pursuant to subsection (b)(4), the number of products, classes of products, or technologies assigned to each such team, and the number of, type of, and any progress made as a result of consultations carried out under subsection (b)(4)(A);

''(4) an estimate of resources obligated to countermeasure development and regulatory assessment, including Center specific objectives and accomplishments;

''(5) the number of countermeasure applications submitted, the number of countermeasures approved, licensed, or cleared, the status of remaining submitted applications, and the number of each type of authorization issued pursuant to section 564; and

''(6) the number of written requests for a regulatory management plan submitted under subsection (e)(3)(A), the number of regulatory management plans developed, and the number of such plans developed for security countermeasures.''.

SEC. 307. PEDIATRIC MEDICAL COUNTERMEASURES.

(a) PEDIATRIC STUDIES OF DRUGS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

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

''(5) CONSULTATION.—With respect to a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act), a security countermeasure (as defined in section 319F–2 of the Public Health Service Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act), the Secretary shall solicit input from the Assistant Secretary for Preparedness and Response regarding the need for and, from the Director of the Biomedical Advanced Research and Development Authority regarding the conduct of, pediatric studies under this section.''; and

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

"(C) For a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act), a security countermeasure (as defined in section 319F–2 of the Public Health Service Act), or a qualified pandemic or epidemic product (as defined in section 319F–3 of such Act), in addition to any action with respect to such drug under subparagraph (A) or (B), the Secretary shall notify the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority of all pediatric studies in the written request issued by the Commissioner of Food and Drugs.".

(b) ADDITION TO PRIORITY LIST CONSIDERATIONS.—Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) by striking subsection (a)(2) and inserting the following:

"(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary—

''(A) shall consider—

''(i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

''(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

''(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

''(B) may consider the availability of qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) to address the needs of pediatric populations, in consultation with the Assistant Secretary for

Preparedness and Response, consistent with the purposes of this section.''; and

(2) in subsection (b), by striking ''subsection (a)'' and inserting ''paragraphs (1) and (2)(A) of subsection (a)''.

(c) ADVICE AND RECOMMENDATIONS OF THE PEDIATRIC ADVISORY COMMITTEE REGARDING COUNTERMEASURES FOR PEDIATRIC POPULATIONS.—Subsection (b)(2) of section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subparagraph (C), by striking the period and inserting ''; and''; and

(2) by adding at the end the following:

''(D) the development of countermeasures (as defined in section 565(a) of the Federal Food, Drug, and Cosmetic Act) for pediatric populations.''.

TITLE IV—ACCELERATING MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

SEC. 401. BIOSHIELD.

(a) REAUTHORIZATION OF THE SPECIAL RESERVE FUND.—Section 319F–2(c) of the Public Health Service

Act (42 U.S.C. 247d-6b(c)) is amended by adding at the end the following:

"(11) REAUTHORIZATION OF THE SPECIAL RESERVE FUND.—In addition to amounts otherwise appropriated, there are authorized to be appropriated for the special reserve fund, $2,800,000,000 for the fiscal years 2014 through 2018.

"(12) REPORT.—Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the biennial Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).".

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

(1) in paragraph (1)(B)(i)(III)(bb), by striking ''eight years'' and inserting ''10 years'';

(2) in paragraph (5)(B)(ii), by striking ''eight years'' and inserting ''10 years'';

(3) in paragraph (7)(C)—

(A) in clause (i)(I), by inserting ''including advanced research and development,'' after ''as may reasonably be required,'';

(B) in clause (ii)—

(i) in subclause (III), by striking ''eight years'' and inserting ''10 years''; and

(ii) by striking subclause (IX) and inserting the following:

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

''(aa) may specify—

''(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

''(BB) the amount of funding that will be dedicated by the Secretary for

advanced research, development, and procurement of the countermeasure; and

''(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

''(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).''; and

(C) by adding at the end the following:

''(viii) FLEXIBILITY.—In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.'';

(4) in paragraph (9)(B), by inserting before the period the following: ", except that this subparagraph shall not be construed to prohibit the use of such amounts as otherwise authorized in this title"; and

(5) in paragraph (10), by adding at the end the following:

"(C) ADVANCED RESEARCH AND DEVELOPMENT.—For purposes of this paragraph, the term 'advanced research and development' shall have the meaning given such term in section 319L(a).".

SEC. 402. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

(a) DUTIES.—Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(4)) is amended—

(1) in subparagraph (B)(iii), by inserting "(which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act)" after "development"; and

(2) in subparagraph (D)(iii), by striking "and vaccine manufacturing technologies" and inserting "vaccine manufacturing technologies, dose sparing

technologies, efficacy increasing technologies, and platform technologies''.

(b) STRATEGIC PUBLIC-PRIVATE PARTNERSHIP.—Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d-7e(c)(4)) is amended by adding at the end the following:

''(E) STRATEGIC INVESTOR.—

''(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions consistent with paragraph (5)) with an independent, non-profit entity to—

''(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products, including strategic investment through the use of venture capital practices and methods;

"(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

"(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

"(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

"(ii) ELIGIBILITY.—

"(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

"(aa) be an independent, non-profit entity not otherwise affiliated with the Department of Health and Human Services;

"(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

"(cc) have experience in promoting novel technology innovation;

"(dd) be problem driven and solution focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

"(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products; and

"(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures.

"(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

"(iii) NOT AGENCY.—An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

"(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agree-

ment under clause (i). As part of this agreement the Director of BARDA shall—

"(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

"(II) develop a description of work to be performed by the entity under the agreement;

"(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

"(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

"(V) ensure, as a condition of the agreement—

"(aa) a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

"(bb) protection against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

"(cc) that the entity provides monthly accounting on the use of funds provided under such agreement; and

"(dd) that the entity provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

"(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

"(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services a strategic investor entity.

"(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

"(viii) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of this subparagraph, 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 subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

"(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2016.".

(c) TRANSACTION AUTHORITIES.—Section 319L(c)(5) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5)) is amended by adding at the end the following:

"(G) GOVERNMENT PURPOSE.—In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.".

(d) FUND.—Paragraph (2) of section 319L(d) of the Public Health Service Act (42 U.S.C. 247d–7e(d)(2)) is amended to read as follows:

"(2) FUNDING.—To carry out the purposes of this section, there is authorized to be appropriated to the Fund $415,000,000 for each of fiscal years 2012 through 2016, such amounts to remain available until expended.".

(e) CONTINUED INAPPLICABILITY OF CERTAIN PROVISIONS.—Section 319L(e)(1)(C) of the Public Health

Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is amended by striking ''7 years'' and inserting ''10 years''.

(f) EXTENSION OF LIMITED ANTITRUST EXEMPTION.—Section 405(b) of the Pandemic and All-Hazards Preparedness Act (42 U.S.C. 247d–6a note) is amended by striking ''6-year'' and inserting ''10-year''.

(g) INDEPENDENT EVALUATION.—Section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended by adding at the end the following:

''(f) INDEPENDENT EVALUATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, the Government Accountability Office shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

''(2) REPORT.—Not later than 1 year after the date of enactment of this subsection, the Government Accountability Office shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

''(A) the extent to which flexible manufacturing capacity under this section is dedicated

to chemical, biological, radiological, and nuclear threats;

''(B) the activities supported by flexible manufacturing initiatives; and

''(C) the ability of flexible manufacturing activities carried out under this section to—

''(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

''(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological and nuclear agents.''.

(h) DEFINITIONS.—

(1) QUALIFIED COUNTERMEASURE.—Section 319F–1(a)(2)(A) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2)(A)) is amended—

(A) in the matter preceding clause (i), by striking ''to—'' and inserting ''—'';

(B) in clause (i)—

(i) by striking ''diagnose'' and inserting ''to diagnose''; and

(ii) by striking ''; or'' and inserting a semicolon;

(C) in clause (ii)—

(i) by striking ''diagnose'' and inserting ''to diagnose''; and

(ii) by striking the period at the end and inserting ''; or''; and

(D) by adding at the end the following:

''(iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).''.

(2) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—Section 319F–3(i)(7)(A) of the Public Health Service Act (42 U.S.C. 247d–6d(i)(7)(A)) is amended—

(A) in clause (i)(II), by striking ''; or'' and inserting '';'';

(B) in clause (ii), by striking ''; and'' and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and''.

(3) TECHNICAL AMENDMENTS.—Section 319F–3(i) of the Public Health Service Act (42 U.S.C. 247d–6d(i)) is amended—

(A) in paragraph (1)(C), by inserting ", 564A, or 564B" after "564"; and

(B) in paragraph (7)(B)(iii), by inserting ", 564A, or 564B" after "564".

SEC. 403. STRATEGIC NATIONAL STOCKPILE.

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

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by inserting "consistent with section 2811" before "by the Secretary to be appropriate"; and

(ii) by inserting before the period at the end the following: "and shall submit such review annually to the appropriate Congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security"; and

(B) in paragraph (2)—

(i) by redesignating subparagraphs (E) through (H) as subparagraphs (F) through (I), respectively; and

(ii) by inserting after subparagraph (D), the following:

''(E) identify and address the potential depletion and ensure appropriate replenishment of medical countermeasures, including those currently in the stockpile;''; and

(2) in subsection (f)(1), by striking ''$640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006'' and inserting ''$522,486,000 for each of fiscal years 2012 through 2016''.

(b) REPORT ON POTASSIUM IODIDE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate Committees of Congress a report regarding the stockpiling of potassium iodide. Such report shall include—

(1) an assessment of the availability of potassium iodide at Federal, State, and local levels; and

(2) a description of the extent to which such activities and policies provide public health protection

in the event of a nuclear incident, whether unintentional or deliberate, including an act of terrorism.

SEC. 404. NATIONAL BIODEFENSE SCIENCE BOARD.

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

(1) in paragraph (2)—

(A) in subparagraph (D)—

(i) in the matter preceding clause (i), by striking ''five'' and inserting ''six'';

(ii) in clause (i), by striking ''and'' at the end;

(iii) in clause (ii), by striking the period and inserting a semicolon; and

(iv) by adding at the end the following:

''(iii) one such member shall be an individual with pediatric subject matter expertise; and

''(iv) one such member shall be a State, tribal, territorial, or local public health official.''; and

(B) by adding at the end the following flush sentence:

''Nothing in this paragraph shall preclude a member of the Board from satisfying two or more of the requirements described in subparagraph (D).'';

(2) in paragraph (5)—

(A) in subparagraph (B), by striking ''and'' at the end;

(B) in subparagraph (C), by striking the period and inserting ''; and''; and

(C) by adding at the end the following:

''(D) provide any recommendation, finding, or report provided to the Secretary under this paragraph to the appropriate committees of Congress.''; and

(3) in paragraph (8), by adding at the end the following: ''Such chairperson shall serve as the deciding vote in the event that a deciding vote is necessary with respect to voting by members of the Board.''.