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PANDEMIC AND ALL-HAZARDS PREPAREDNESS REAUTHORIZATION ACT OF 2011

NOVEMBER 16, 2011.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2405]

[Including cost estimate of the Congressional Budget Office]

The Committee on on Energy and Commerce, to whom was referred the bill (H.R. 2405) to reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

The amendment is as follows:

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 Reauthorization Act of 2011".

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

SEC. 2. REAUTHORIZATION OF CERTAIN PROVISIONS RELATING TO PUBLIC HEALTH PREPAREDNESS.

(a) VACCINE TRACKING AND DISTRIBUTION.—Subsection (e) of section 319A of the Public Health Service Act (42 U.S.C. 247d–1) 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".

(b) IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—Effective on October 1, 2011, section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended—

(1) in subsection (b)(2)(A)—

(A) in clause (iv), by striking "and" at the end;

(B) in clause (v), by adding "and" at the end; and

(C) by adding at the end the following:

"(vi) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers;";

(2) in subsection (f)—

(A) in paragraph (2), by inserting "and" at the end;

(B) in paragraph (3), by striking "; and" and inserting a period; and

(C) by striking paragraph (4);

(3) by striking subsection (h); and

(4) in subsection (i)—

(A) in paragraph (1)—

(i) by amending subparagraph (A) to read as follows:

"(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $632,900,000 for each of fiscal years 2012 through 2016."; and

(ii) by striking subparagraph (B); and

(B) in subparagraphs (C) and (D) of paragraph (3), by striking "(1)(A)(i)(I)" each place it appears and inserting "(1)(A)".

(c) 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—

(1) in subsection (a), by inserting ", including capacity and preparedness to address the needs of pediatric and other at-risk populations" before the period at the end;

(2) in subsection (i)—

(A) by striking "The requirements of" and inserting the following:

"(1) IN GENERAL.—The requirements of"; and

(B) by adding at the end the following:

"(2) MEETING GOALS OF NATIONAL HEALTH SECURITY STRATEGY.—The Secretary shall implement objective, evidence-based metrics to ensure that entities receiving awards under this section are meeting, to the extent practicable, the goals of the National Health Security Strategy under section 2802."; and

(3) by amending subsection (j)(1) to read as follows:

"(1) IN GENERAL.—For purposes of carrying out this section, there is authorized to be appropriated $378,000,000 for each of fiscal years 2012 through 2016.".

(d) CDC PROGRAMS FOR COMBATING PUBLIC HEALTH THREATS.—Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended—

(1) by striking subsection (c); and

(2) 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".

(e) DENTAL EMERGENCY RESPONDERS: PUBLIC HEALTH AND MEDICAL RESPONSE.—

(1) 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".

(2) NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(3) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting "and which may include dental health facilities" after "mental health facilities"; and

(B) in subparagraph (D), by inserting "(which may include dental health assets)" after "medical assets".

(f) PROCUREMENT OF COUNTERMEASURES.—

(1) CONTRACT TERMS.—Subclause (IX) of section 319F–2(c)(7)(C)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)(ii)) is amended to read as follows:

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

"(aa) 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

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

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

(A) in subsection (c)—

(i) by striking "special reserve fund under paragraph (10)" each place it appears and inserting "special reserve fund as defined in subsection (g)(5)"; and

(ii) by striking paragraphs (9) and (10); and

(B) by adding at the end the following:

"(g) SPECIAL RESERVE FUND.—

"(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

"(2) NOTICE OF INSUFFICIENT FUNDS.—Not later than 15 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 Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the amount of such funds available for procurement and the impact such funding will have—

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

"(B) on the annual Countermeasure Implementation Plan under section 2811(d).

"(3) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary may utilize not more than 30 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

"(4) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay—

"(A) costs other than payments made by the Secretary to a vendor for advanced development (under section 319L) or for procurement of a security countermeasure under subsection (c)(7); and

"(B) any administrative expenses, including salaries.

"(5) DEFINITION.—In this section, the term 'special reserve fund' means the 'Biodefense Countermeasures' appropriations account, any appropriation made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to paragraph (1) of this paragraph.".

(g) 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 "are authorized to be appropriated $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 "is authorized to be appropriated $5,900,000 for each of fiscal years 2012 through 2016".

(h) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) 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.".

(2) BIODEFENSE MEDICAL COUNTERMEASURE DEVELOPMENT FUND.—Paragraph (2) of section 319L(d) of the Public Health Service Act (42 U.S.C. 247d–7e(d)) 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, the amounts to remain available until expended.".

(3) 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 "the date that is 7 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act" and inserting "September 30, 2016".

(i) 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), by adding at the end the following:

"(D) ADMINISTRATION.—The Secretary may determine and pay claims for reimbursement for services under subparagraph (A) directly or by contract providing 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".

(j) NATIONAL HEALTH SECURITY STRATEGY TIMELINE.—Section 2802(a)(1) of the Public Health Service Act (42 U.S.C. 300hh–1(a)(1)) is amended by striking "2009" and inserting "2014".

(k) ENHANCING SURGE CAPACITY.—Section 2802(b) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(3)) is amended—

(1) in paragraph (1)(A), by inserting ", including drills and exercises to ensure medical surge capacity for events without notice" after "exercises"; and

(2) in paragraph (3)—

(A) in the matter preceding subparagraph (A), as amended by subsection (e)(2) of this section—

(i) by inserting "availability, coordination, accessibility," after "response capabilities,";

(ii) by striking "including mental health facilities" and inserting "including mental health and ambulatory care facilities"; and

(iii) by striking "trauma care and emergency medical service systems" and inserting "trauma care, critical care, and emergency medical service systems"; and

(B) in subparagraph (B), by striking "Medical evacuation and fatality management" and inserting "Fatality management, and coordinated medical triage and evacuation to the appropriate medical institution based on patient medical need as part of regional systems".

(l) VOLUNTEER MEDICAL RESERVE CORPS.—Section 2813(i) of the Public Health Service Act (42 U.S.C. 300hh–15(i)) is amended 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".

(m) EXTENSION OF LIMITED ANTITRUST EXEMPTION.—Section 405(b) of the Pandemic and All-Hazard Preparedness Act (42 U.S.C. 247d–6a note) is amended by striking "at the end of the 6-year period that begins on the date of enactment of this Act" and inserting "on September 30, 2016".

SEC. 3. TEMPORARY REDEPLOYMENT OF PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(e) TEMPORARY REDEPLOYMENT OF PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.—

"(1) EMERGENCY REDEPLOYMENT OF FEDERALLY FUNDED PERSONNEL.—Notwithstanding any other provision of law, and subject to paragraph (2), upon a request that is from a State, locality, territory, tribe, or the Freely Associated States and that includes such information and assurances as the Secretary may require, the Secretary may authorize the requesting entity to temporarily redeploy to immediately address a public health emergency non-Federal personnel funded in whole or in part through—

"(A) any program under this Act; or

"(B) at the discretion of the Secretary, any other program funded in whole or in part by the Department of Health and Human Services.

"(2) ACTIVATION OF EMERGENCY REDEPLOYMENT.—

"(A) PUBLIC HEALTH EMERGENCY.—The Secretary may exercise the authority vested by paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

"(B) CONSIDERATIONS.—In authorizing a temporary redeployment under paragraph (1), the Secretary shall consider each of the following:

"(i) The degree to which the emergency cannot be adequately and appropriately addressed by the public health workforce.

"(ii) The degree to which the emergency requires or would otherwise benefit from supplemental staffing from those funded through non-preparedness Federal programs.

"(iii) The degree to which such programs would be adversely affected by the redeployment.

"(iv) Such other factors as the Secretary may deem appropriate.

"(C) TERMINATION AND EXTENSION.—

"(i) TERMINATION.—The authority to authorize a temporary redeployment of personnel under paragraph (1) shall terminate upon the earlier of the following:

"(I) The Secretary's determination that the public health emergency no longer exists.

"(II) Subject to clause (ii), 30 days after the activation of the Secretary's authority pursuant to subparagraph (A).

"(ii) EXTENSION AUTHORITY.—The Secretary may extend the authority to authorize a temporary redeployment of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists, but only if—

"(I) the extension is requested by the entity that requested authority to authorize a temporary redeployment; and

"(II) the Secretary gives notice to the Congress in conjunction with the extension.".

SEC. 4. COORDINATION BY ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

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

(1) in subsection (b)(3)—

(A) by inserting "stockpiling, distribution," before "and procurement"; and

(B) by inserting ", security measures (as defined in section 319F–2," after "qualified countermeasures (as defined in section 319F–1)";

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

"(D) IDENTIFICATION OF INEFFICIENCIES.—Identify gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles.

"(E) DEVELOPMENT OF COUNTERMEASURE IMPLEMENTATION PLAN.—Lead the development of a coordinated Countermeasure Implementation Plan under subsection (d).

"(F) COUNTERMEASURES BUDGET ANALYSIS.—Oversee the development of a comprehensive, cross-cutting 5-year budget analysis with respect to activities described in paragraph (3)—

"(i) to inform prioritization of resources; and

"(ii) to ensure that challenges to such activities are adequately addressed.

"(G) GRANT PROGRAMS FOR MEDICAL AND PUBLIC HEALTH PREPAREDNESS CAPABILITIES.—Coordinate, in consultation with the Secretary of Homeland Security, grant programs of the Department of Health and Human Services

relating to medical and public health preparedness capabilities and the activities of local communities to respond to public health emergencies, including the—

"(i) coordination of relevant program requirements, timelines, and measurable goals of such grant programs; and

"(ii) establishment of a system for gathering and disseminating best practices among grant recipients.";

(3) by amending subsection (c) to read as follows:

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

"(1) have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy and coordination;

"(2) 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 Biomedical Advanced Research and Development Authority under section 319L; and

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

"(3) provide policy coordination and oversight of—

"(A) the Strategic National Stockpile under section 319F–2;

"(B) the Cities Readiness Initiative; and

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

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

(4) by adding at the end the following:

"(d) COUNTERMEASURE IMPLEMENTATION PLAN.—Not later than 6 months after the date of enactment of this subsection, and annually thereafter, the Assistant Secretary for Preparedness and Response shall submit through the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a Countermeasure Implementation Plan that—

"(1) describes the chemical, biological, radiological, and nuclear threats facing the Nation and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), or qualified pandemic or epidemic products (as defined in section 319F–3) for each threat;

"(2) evaluates the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, and utilization;

"(3) identifies and prioritizes near-, mid-, and long-term needs with respect to such countermeasures or products to address chemical, biological, radiological, and nuclear threats;

"(4) identifies, with respect to each category of threat, a summary of all advanced development and procurement awards, including—

"(A) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination);

"(B) projected timelines for development and procurement of such countermeasures or products;

"(C) clearly defined goals, benchmarks, and milestones for each such countermeasure or product, including information on the number of doses required, the intended use of the countermeasure or product, and the required countermeasure or product characteristics; and

"(D) projected needs with regard to the replenishment of the Strategic National Stockpile;

"(5) evaluates progress made in meeting the goals, benchmarks, and milestones identified under paragraph (4)(C);

"(6) reports on the amount of funds available for procurement in the special reserve fund as defined in section 319F–2(g)(5) and the impact this funding will have on meeting the requirements under section 319F–2;

"(7) incorporates input from Federal, State, local, and tribal stakeholders; and

"(8) addresses the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile and includes—

"(A) a list of such countermeasures and products necessary to address the needs of pediatric populations;

"(B) a description of measures taken to coordinate with Office of Pediatric Therapeutics of the Food and Drug Administration to maximize the label-

ing, dosages, and formulations of such countermeasures and products for pediatric populations;

"(C) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

"(D) an evaluation of the progress made in addressing gaps identified pursuant to subparagraph (C).

Notwithstanding any other provision of this subsection, the Plan shall not include any confidential commercial information, proprietary information, or information that could reveal vulnerabilities of the Nation in the preparation for or ability to respond to chemical, biological, radiological, or nuclear threats.".

(b) CONSULTATION IN AUTHORIZING MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Subsection (c) of section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended by striking "consultation with the Director of the National Institutes of Health" and inserting "consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health,".

(c) BIOSURVEILLANCE PLAN.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a plan to improve information sharing, coordination, and communications among disparate biosurveillance systems supported by the Department of Health and Human Services.

SEC. 5. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD REPORTS.

Section 5 of the Project Bioshield Act of 2004 (42 U.S.C. 247d–6c) is repealed.

SEC. 6. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

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 "DECLARATION OF EMERGENCY" and inserting "DECLARATION SUPPORTING EMERGENCY USE AUTHORIZATION";

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "an emergency justifying" and inserting "that circumstances exist justifying";

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

(iii) in subparagraph (B), by striking "specified"; and

(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, involving a heightened risk to national security or the health and security of United States citizens abroad, and involving a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents.";

(C) in paragraph (2)—

(i) by amending subparagraph (A) to read as follows:

"(A) IN GENERAL.—A declaration under this subsection shall terminate upon a determination by the Secretary, in consultation with, as appropriate, the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist.";

(ii) by striking subparagraph (B); and

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

(D) in paragraph (4), by striking "advance notice of termination, and renewal" and inserting "and advance notice of termination";

(3) in subsection (c)(1), by striking "specified in" and insert "covered by";

(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)(B), by amending clause (iii) to read as follows:

"(iii) Appropriate conditions with respect to the collection and analysis of information concerning the safety and effectiveness of the product with respect to the actual use of such product pursuant to an authorization under this section.";

(B) in paragraph (2)—

(i) in subparagraph (A)—

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

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

(ii) in subparagraph (B)(i), by inserting ", with the exception of extensions of a product's expiration date authorized under section 564A(b)" before the period at the end; 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 a product, the Secretary shall not impose conditions that would restrict distribution or administration of the product that is solely for the approved uses.";

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

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

"(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 501 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)."; and

(D) by adding at the end the following:

"(5) EXISTING AUTHORITIES.—Nothing in this section restricts any authority vested in the Secretary by any other provision of this Act or the Public Health Service Act for establishing conditions of authorization for a product."; and

(6) in subsection (g)—

(A) in the heading, by striking "REVOCATION OF AUTHORIZATION" and inserting "REVIEW, MODIFICATION, AND REVOCATION OF AUTHORIZATION";

(B) in paragraph (1), by striking "periodically review" and inserting "review not less than every three years"; and

(C) by adding at the end the following:

"(3) MODIFICATION.—The Secretary may modify an authorization under this section or the conditions of such an authorization, at any time, based on a review of the authorization or new information that is otherwise obtained, including information obtained during an emergency.".

SEC. 7. ADDITIONAL PROVISIONS RELATED TO MEDICAL PRODUCTS FOR EMERGENCY USE.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 564 (21 U.S.C. 360bbb–3) the following:

"SEC. 564A. ADDITIONAL PROVISIONS RELATED TO MEDICAL PRODUCTS FOR EMERGENCY USE.

"(a) DEFINITIONS.—For purposes of this section:

"(1) The term 'product' means a drug, device, or biological product.

"(2) The term 'eligible product' means a product that is—

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

"(B) intended to be used to diagnose, prevent, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents during—

"(i) a domestic emergency or military emergency involving heightened risk of attack with such an agent or agents; or

"(ii) a public health emergency affecting national security or the health and security of United States citizens abroad.

"(b) EXPIRATION DATING.—

"(1) IN GENERAL.—The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if—

"(A) the eligible product is intended to be held for use for a domestic, military, or public health emergency described in subsection (a)(2)(B);

"(B) the expiration date extension is intended to support the United States' ability to protect—

"(i) the public health; or

"(ii) military preparedness and effectiveness; and

"(C) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

"(2) REQUIREMENTS AND CONDITIONS.—Any extension of an expiration date under paragraph (1) shall, as part of the extension, identify—

"(A) each specific lot, batch, or other unit of the product for which extended expiration is authorized;

"(B) the duration of the extension; and

"(C) any other requirements or conditions as the Secretary may deem appropriate for the protection of the public health, which may include requirements for, or conditions on, product sampling, storage, packaging or repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing or retesting, or product disposition.

"(3) EFFECT.—Notwithstanding any other provision of this Act or the Public Health Service Act, an eligible product shall not be considered an unapproved product (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because, with respect to such product, the Secretary has, under paragraph (1), extended the expiration date and authorized the introduction or delivery for introduction into interstate commerce of such product after the expiration date provided by the manufacturer.

"(c) CURRENT GOOD MANUFACTURING PRACTICES.—

"(1) IN GENERAL.—The Secretary may, when the circumstances of a domestic, military, or public health emergency described in subsection (a)(2)(B) 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 (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

"(d) MASS DISPENSING.—The requirements of section 503(b) and 520(e) shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because it is dispensed without an individual prescription, if—

"(1) the product is dispensed during an actual emergency described in subsection (a)(2)(B); and

"(2) such dispensing without an individual prescription occurs—

"(A) as permitted under the law of the State in which the product is dispensed; or

"(B) in accordance with an order issued by the Secretary.

"(e) 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 (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because of—

"(A) the issuance of emergency use instructions under paragraph (1) with respect to such product; or

"(B) the introduction or delivery for introduction of such product into interstate commerce accompanied by such instructions during an emergency response to an actual emergency described in subsection (a)(2)(B).".

(b) 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, an actual or potential domestic emergency or military emergency involving heightened risk of attack with a biological, chemical, radiological, or nuclear agent, or an actual or potential public health emergency affecting national security or the health and security of United States citizens abroad.".

SEC. 8. 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 section 7, 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. 9. ACCELERATE COUNTERMEASURE DEVELOPMENT BY STRENGTHENING FDA'S ROLE IN REVIEWING PRODUCTS FOR NATIONAL SECURITY PRIORITIES.

(a) IN GENERAL.—Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended to read as follows:

"SEC. 565. COUNTERMEASURE DEVELOPMENT AND REVIEW.

"(a) COUNTERMEASURES AND PRODUCTS.—The countermeasures and products referred to in this subsection are—

"(1) qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act);

"(2) security countermeasures (as defined in section 319F–2 of such Act); and

"(3) qualified pandemic or epidemic products (as defined in section 319F–3 of such Act) that the Secretary determines to be a priority.

"(b) IN GENERAL.—

"(1) INVOLVEMENT OF FDA PERSONNEL IN INTERAGENCY ACTIVITIES.—For the purpose of accelerating the development, stockpiling, approval, clearance, and licensure of countermeasures and products referred to in subsection (a), the Secretary shall expand the involvement of Food and Drug Administration personnel in interagency activities with the Assistant Secretary for Preparedness and Response (including the Biomedical Advanced Research and Development Authority), the Centers for Disease Control and Prevention, the National Institutes of Health, and the Department of Defense.

"(2) TECHNICAL ASSISTANCE.—The Secretary shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practices) to provide both off-site and on-site technical assistance to the manufacturers of countermeasures and products referred to in subsection (a). On-site technical assistance shall be provided upon the request of the manufacturer and at the discretion of the Secretary if the Secretary determines that the provision of such assistance would accelerate the development, manufacturing, or approval, clearance, or licensure of countermeasures and products referred to in subsection (a).

"(c) AGENCY INTERACTION WITH SECURITY COUNTERMEASURE SPONSORS.—

"(1) IN GENERAL.—For security countermeasures (as defined in section 319F–2 of the Public Health Service Act) that are procured under such section 319F–2—

"(A) the Secretary shall establish a process for frequent scientific feedback and interactions between the Food and Drug Administration and the security countermeasure sponsor (referred to in this subsection as the 'sponsor'), designed to facilitate the approval, clearance, and licensure of the security countermeasures;

"(B) such feedback and interactions shall include meetings and, in accordance with subsection (b)(2), on-site technical assistance; and

"(C) at the request of the Secretary, the process under this paragraph shall include participation by the Food and Drug Administration in meetings between the Biomedical Advanced Research and Development Authority and sponsors on the development of such countermeasures.

"(2) REGULATORY MANAGEMENT PLAN.—

"(A) IN GENERAL.—The process established under paragraph (1) shall allow for the development of a written regulatory management plan (in this paragraph referred to as the 'plan') for a security countermeasure (as defined in paragraph (1)) in accordance with this paragraph.

"(B) PROPOSAL AND FINALIZATION OF PLAN.—In carrying out the process under paragraph (1), the Secretary shall direct the Food and Drug Administration, upon submission of a written request by the sponsor that includes a proposed plan and relevant data and future planning detail to support such a plan, to work with the sponsor to agree on a final plan within a reasonable time not to exceed 90 days. The basis for this agreement shall be the proposed plan submitted by the sponsor. Notwithstanding the preceding sentence, the Secretary shall retain full discretion to determine the contents of the final plan or to determine that no such plan can be agreed upon. If the Secretary determines that no final plan can be agreed upon, the Secretary shall provide to the sponsor, in writing, the scientific or regulatory rationale why such agreement cannot be reached. If a final plan is agreed upon, it shall be shared with the sponsor in writing.

"(C) CONTENTS.—The plan shall include an agreement on the nature of, and timelines for, feedback and interactions between the sponsor and the Food and Drug Administration, shall provide reasonable flexibility in implementing and adjusting the agreement under this paragraph as warranted during the countermeasure development process, and shall identify—

"(i) the current regulatory status of the countermeasure, an assessment of known scientific gaps relevant to approval, clearance, or licensure of the countermeasure, and a proposed pathway to approval, clearance, or licensure of the countermeasure;

"(ii) developmental milestones whose completion will result in meetings to be scheduled within a reasonable time between the applicable review division of the Food and Drug Administration and the sponsor;

"(iii) sponsor submissions that will result in written feedback from the review division within a reasonable time;

"(iv) feedback by the Food and Drug Administration regarding the data required to support delivery of the countermeasure to the Strategic National Stockpile under section 319F–2 of the Public Health Service Act;

"(v) feedback by the Food and Drug Administration regarding data required to support submission of a proposed agreement on the design and size of clinical trials for review under section 505(b)(5)(B); and

"(vi) other issues that have the potential to delay approval, clearance, or licensure.

"(D) CHANGES.—Changes to the plan shall be made by subsequent agreement between the Secretary and the sponsor. If after reasonable attempts to negotiate changes to the plan the Secretary and the sponsor are unable to finalize such changes, the Secretary shall provide to the sponsor, in writing, the scientific or regulatory rationale why such changes are required or cannot be included in the plan.

"(3) APPLICABILITY TO CERTAIN QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS.—The Secretary may, with respect to qualified pandemic or epidemic products (as defined in section 319F–3 of the Public Health Service Act) for which a contract for advanced research and development is entered into under section 319L of such Act, choose to apply the provisions of paragraphs (1) and (2) to the same extent and in the same manner as such provisions apply with respect to security countermeasures.

"(d) FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL MODELS.—

"(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011, the Secretary shall provide final guidance to industry regarding the development of animal models to support approval, clearance, or licensure of countermeasures and products referred to in subsection (a) when human efficacy studies are not ethical or feasible.

"(2) AUTHORITY TO EXTEND DEADLINE.—The Secretary may extend the deadline for providing final guidance under paragraph (1) by not more than 6 months upon submission by the Secretary of a report on the status of such guidance to the Committee on Energy and Commerce of the House of Representa-

tives and the Committee on Health, Education, Labor, and Pensions of the Senate.

"(e) BIENNIAL REPORT.—Not later than January 1, 2013, and every 2 years thereafter, the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, that, with respect to the preceding 2 fiscal years, includes—

"(1) the number of full-time equivalent employees of the Food and Drug Administration who directly support the review of countermeasures and products referred to in subsection (a);

"(2) estimates of funds obligated by the Food and Drug Administration for review of such countermeasures and products;

"(3) the number of regulatory teams at the Food and Drug Administration specific to such countermeasures and products and, for each such team, the assigned products, classes of products, or technologies;

"(4) the length of time between each request by the sponsor of such a countermeasure or product for information and the provision of such information by the Food and Drug Administration;

"(5) the number, type, and frequency of official interactions between the Food and Drug Administration and—

"(A) sponsors of a countermeasure or product referred to in subsection (a); or

"(B) another agency engaged in development or management of portfolios for such countermeasures or products, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense;

"(6) a description of other measures that, as determined by the Secretary, are appropriate to determine the efficiency of the regulatory teams described in paragraph (3); and

"(7) the regulatory science priorities that relate to countermeasures or products referred to in subsection (a) and which the Food and Drug Administration is addressing and the progress made on these priorities.".

(b) SPECIAL PROTOCOL ASSESSMENT.—Subparagraph (B) of section 505(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)) is amended to read as follows:

"(B)(i) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of—

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

"(II) animal efficacy trials and any associated clinical trials that in combination are intended to form the primary basis of an effectiveness claim for a countermeasure or product referred to in section 565(a) when human efficacy studies are not ethical or feasible.

"(ii) The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.".

PURPOSE AND SUMMARY

H.R. 2405, the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011," was introduced on June 28, 2011, by Representative Mike Rogers (R–MI) and referred to the Committee on Energy and Commerce.

The legislation would facilitate the development of chemical, biological, radioactive, and nuclear (CBRN) medical countermeasures (MCMs) and bolster the nation's public health preparedness infrastructure so the Nation can better respond to public health emergencies and disasters, including those caused by CBRN attack.

BACKGROUND AND NEED FOR LEGISLATION

In the wake of the September 11th terrorist attacks, Congress took important steps to build the Nation's health infrastructure and foster the development of CBRN MCMs to enable the Nation to better respond to CBRN attacks. As part of these steps, Congress enacted two key pieces of legislation, the "Project BioShield Act of 2004" (Project BioShield) (P.L. 108–276) and the "Pandemic and All-Hazards Preparedness Act of 2006" (PAHPA) (P.L. 109–417), and they have dramatically improved our nation's ability to respond to public health emergencies and disasters, including those caused by terrorism. As described in this report, the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011" would reauthorize and improve certain provisions of Project BioShield and PAHPA in order to increase certainty and predictability, clarify the role of the Assistant Secretary for Preparedness and Response (ASPR) as the leader of preparedness and response, and strengthen our nation's preparedness infrastructure.

The 108th Congress passed Project BioShield to encourage the private sector to develop MCMs against CBRN agents that would not otherwise have a commercial market and bring certainty and predictability to the MCM development space. Project BioShield included provisions that, among other things, authorized funds for the purchase of MCMs through the Special Reserve Fund (SRF) and enabled the Secretary of the Department of Health and Human Services (HHS) to authorize the emergency use of medical products. The SRF was intended to be a secure funding source for the procurement of critical MCMs; it is critical because it clearly demonstrates the Federal government's commitment to MCM procurement. By increasing certainty and predictability, which this legislation seeks to do through the reauthorization of the Special Reserve Fund and the Biodefense Advanced Research and Development Authority (BARDA) as well as the establishment of the Regulatory Management Plan process, among other provisions, H.R. 2405 would build on the provisions of Project BioShield to encourage investment, research, and development and increase the likelihood of securing the MCMs necessary to protect our citizens during health emergencies and disasters, including those caused by terrorism.

Shortly after the enactment of Project BioShield, the 109th Congress passed PAHPA, which reauthorized a number of expiring preparedness and response programs in the Public Health Service Act and established several new authorities. For instance, PAHPA established BARDA, a new authority within HHS, to foster advanced MCM development and facilitate interactions between HHS and MCM developers. PAHPA also established a crucial new position at HHS, the Assistant Secretary for Preparedness and Response, to lead the Federal government's efforts and coordination for CBRN preparedness and response. H.R. 2405 includes provisions to clarify that the ASPR has lead responsibility within HHS for emergency preparedness and response policy and coordination. Finally, PAHPA included provisions to build the nation's public health infrastructure. The provisions of H.R. 2405 would reauthorize many of these PAHPA provisions to continue the effort to strengthen our Nation's preparedness infrastructure.

HEARINGS

On July 21, 2011, the Subcommittee on Health held a hearing entitled "Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues." H.R. 2405, the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011," was one of three bills considered at this hearing. The Subcommittee received testimony from: Representative Charlie Dent (PA–15); Nicole Lurie, M.D., M.S.P.H, Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services; and Howard K. Koh, M.D., M.P.H, Assistant Secretary for Health, U.S. Department of Health and Human Services.

COMMITTEE CONSIDERATION

H.R. 2405, the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011," was introduced on June 28, 2011, by Representative Mike Rogers (R–MI) and referred to the Committee on Energy and Commerce.

The Subcommittee on Health held a legislative hearing on July 21, 2011, entitled, "Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues," during which it considered H.R. 2405. On July 26, 2011, the Subcommittee met in open markup session to consider H.R. 2405. The Subcommittee favorably reported an Amendment in the Nature of a Substitute, which included technical changes recommended by the Administration and the reauthorization of two programs from the original PAHPA law passed in 2006: the Medical Reserve Corps and the Emergency System for Advance Registration of Health Professional Volunteers. Thereafter, the Subcommittee ordered that H.R. 2405 be favorably forwarded to the full Committee for consideration.

On July 28, 2011, the Committee on Energy and Commerce met in open markup session to consider H.R. 2405, as approved by the Subcommittee on Health. The Committee considered an Amendment in the Nature of a Substitute, which included provisions to improve the accountability of the Hospital Preparedness Cooperative Agreement Program, enhance surge capacity as part of the National Health Security Strategy, allow the temporary reassignment of federally funded personnel at the request of states or localities, and enhance reporting on biosurveillance efforts. It also further clarified that the ASPR would lead emergency response efforts across the various HHS agencies and among federal interagency partners. The Committee also considered an amendment to the Amendment in the Nature of a Substitute. In addition to a number of technical and conforming changes, the amendment to the Amendment in the Nature of a Substitute included provisions that would provide increased clarity and flexibility to enhance our nation's ability to pre-position and deploy medical countermeasures. In addition, it included provisions that would enable the federal government to extend the shelf-life of current countermeasures in the Strategic National Stockpile and to dispense medical countermeasures requiring prescriptions on a mass-level during emergencies.

The full Committee approved both the amendment to the Amendment in the Nature of a Substitute and the Amendment in the Na-

ture of a Substitute by voice vote, and ordered that H.R. 2405 be favorably reported to the House by voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. There were no recorded votes taken in connection with ordering H.R. 2405 reported. A motion to order H.R. 2405 be reported to the House, as amended, was agreed to by voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report, including the finding that the nation must facilitate development of CBRN MCMs and bolster our public health preparedness infrastructure so the nation can better respond to public health emergencies and disasters, including those caused by CBRN attack.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal that the nation facilitate the development of CBRN MCMs and bolster our public health preparedness infrastructure so the nation can better respond to public health emergencies and disasters, including those caused by CBRN attack.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2405, the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011," would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2405, the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011," contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by

the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 26, 2011.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2405, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Andrea Noda.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 2405—Pandemic and All-Hazards Preparedness Reauthorization Act of 2011

Summary: H.R. 2405 would amend the Public Health Service Act to authorize funding for certain activities carried out by various agencies and offices within the Department of Health and Human Services (HHS) that would support the readiness of the public health system to address public health and medical emergencies. Those activities are conducted by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and several offices within the HHS Office of the Secretary.

CBO estimates that implementing the bill would cost $395 million in 2012 and $7.9 billion over the 2012–2016 period, assuming the appropriation of the authorized amounts. The funding authorized by H.R. 2405 is similar to the appropriation amounts enacted in recent years for the same activities. Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

H.R. 2405 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 2405 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2012	2013	2014	2015	2016	2012–2016
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Centers for Disease Control and Prevention:						
State and Local Public Health Security:						
Authorization Level	633	633	633	633	633	3,165
Estimated Outlays	130	440	540	600	615	2,325
Public Health Threats:						
Authorization Level	160	160	160	160	160	800
Estimated Outlays	55	120	145	150	155	625
Vaccine Tracking and Distribution:						
Authorization Level	31	31	31	31	31	155
Estimated Outlays	15	25	30	30	30	130
Food and Drug Administration:						
Estimated Authorization	15	30	35	40	40	160

	By fiscal year, in millions of dollars—					
	2012	2013	2014	2015	2016	2012–2016
Estimated Outlays	15	25	35	35	40	150
Office of the Assistant Secretary for Health:						
Authorization Level	12	12	12	12	12	60
Estimated Outlays	5	10	10	10	10	45
Office of the Assistant Secretary for Preparedness and Response:						
Procurement of Countermeasures:						
Authorization Level	2,800	0	0	0	0	2,800
Estimated Outlays	0	0	365	665	330	1,360
Advance Development of Countermeasures:						
Authorization Level	415	415	415	415	415	2,075
Estimated Outlays	85	315	380	405	415	1,600
Hospital Preparedness:						
Authorization Level	378	378	378	378	378	1,890
Estimated Outlays	75	265	320	360	365	1,385
National Disaster Medical System:						
Authorization Level	56	56	56	56	56	280
Estimated Outlays	10	45	50	55	55	215
Emergency Volunteer Registration:						
Authorization Level	6	6	6	6	6	30
Estimated Outlays	5	5	5	5	5	25
Total Changes:						
Authorization Level	4,506	1,721	1,726	1,731	1,731	11,415
Estimated Outlays	395	1,250	1,880	2,315	2,020	7,860

Basis of estimate: For this estimate, CBO assumes that H.R. 2405 will be enacted near the start of fiscal year 2012 and that the authorized amounts will be appropriated for each year.

The bill contains provisions that would authorize funding for activities administered by CDC, FDA, the Office of the Assistant Secretary of Health (ASH), and the Office of the Assistant Secretary for Preparedness and Response (ASPR) to improve the coordination of preparedness activities and to increase medical system capacity in the event of a public health emergency.

Centers for Disease Control and Prevention

H.R. 2405 would authorize funding through 2016 for activities related to preparing for a public health emergency at levels similar to the appropriations for recent years.

State and Local Public Health Security. H.R. 2405 would allow CDC to continue to administer cooperative agreements with state and local governments to help prepare for public health emergencies. Entities receiving funding through those cooperative agreements must submit plans for responding to an outbreak of pandemic influenza and contribute matching funds. This bill would authorize the appropriation of $633 million each fiscal year for 2012 through 2016 for CDC to administer those cooperative agreements. Based on historical spending patterns of similar programs, CBO estimates that implementing that provision would cost $130 million in 2012 and $2.3 billion over the 2012–2016 period, assuming appropriation of the authorized amounts.

Public Health Threats. H.R. 2405 would authorize funding for the Secretary to continue to expand, enhance, and improve the capacity for CDC to respond effectively to bioterrorism and other public health emergencies. H.R. 2405 would also authorize funding to establish and maintain surveillance programs and networks that enhance coordinated efforts in response to outbreaks of infectious

diseases and public health emergencies. The bill would authorize the appropriation of $160 million a year for fiscal years 2012 through 2016. Based on historical spending patterns for similar programs, CBO estimates that implementing that provision would cost $55 million in 2012 and $625 million over the 2012–2016 period, assuming appropriation of the authorized amounts.

Vaccine Tracking and Distribution. CDC collaborates with officials in state, local, and tribal governments as well as private entities, such as vaccine manufacturers, wholesalers, and distributors, to track the distribution of vaccines for pandemic flu and to promote effective distribution of vaccines for the seasonal flu. H.R. 2405 would authorize the Secretary to continue those activities and would authorize the appropriation $31 million for each fiscal year over the 2012–2016 period. Assuming appropriation of authorized amounts, CBO estimates that implementing that provision would cost $15 million in 2012 and $130 million over the 2012–2016 period, based on historical spending patterns for similar programs.

Food and Drug Administration

H.R. 2405 would expand the role of FDA personnel in supporting the development, stockpiling, approval and licensure of medical countermeasures (such as diagnostic tests, drugs, vaccines and other treatments for response to chemical, biological, radiological and nuclear threats) as well as medical responses to pandemics and epidemics. The bill would require the formation of a team of experts on manufacturing and regulatory activities within the FDA to provide both off-site and on-site technical assistance to manufacturers of those products. CBO estimates that the FDA would require the appropriation of an additional $15 million in 2012 and $160 million for the 2012–2016 period for such activities. Assuming the appropriation of those amounts, CBO estimates those provisions would cost $150 million over the 2012–2016 period.

Office of the Assistant Secretary of Health

The Medical Reserve Corps (MRC) is a community-based program that coordinates medical and public health volunteers to support public health activities, including emergency preparedness and response efforts. The bill would authorize funding for the MRC, which is operated by the HHS Office of the Surgeon General within the ASH. The MRC received an appropriation of just under $12 million for fiscal year 2011. The bill would authorize the same amount for each fiscal year over the 2012–2016 period. Based on historical spending patterns for similar programs, CBO estimates that implementing that provision would cost $5 million in 2012 and $45 million over the 2012–2016 period, assuming appropriation of authorized amounts.

Office of the Assistant Secretary for Preparedness and Response

H.R. 2405 would authorize funding for the following activities administered by ASPR related to medical system capacity and countermeasure development and procurement.

Procurement of Countermeasures. Project Bioshield, a special reserve fund established for the procurement of biodefense countermeasures, is funded by an appropriation of approximately $5.6 billion for fiscal years 2004–2013. H.R. 2405 would authorize an addi-

tional appropriation of $2.8 billion for fiscal years 2014–2018 to the fund for continuing those activities. H.R. 2405 would allow up to 30 percent of the $2.8 billion to be used for advance research and development of countermeasures. Based on historical spending patterns, CBO estimates that implementing the provision would cost $1.4 billion over the 2012–2016 period, assuming appropriation of the authorized amount.

Advance Development of Countermeasures. The Biomedical Advance Research and Development Authority (BARDA) office within ASPR supports the advance development of medical countermeasures to respond to bioterrorism and other public health emergencies. BARDA is funded by the Biodefense Medical Countermeasure Development Fund. H.R. 2405 would authorize $415 million for the fund in each year for fiscal years 2012 through 2016. Based on historical spending patterns, CBO estimates that implementing that provision would cost $85 million in 2012 and $1.6 billion over the 2012–2016 period, assuming appropriation of the authorized amounts.

Hospital Preparedness. The bill would authorize a grant program that provides funding to entities such as states, localities, or health care facilities to enhance hospital capacity to handle a surge of patients in the event of a public health emergency. The grant program received an appropriation of $378 million in fiscal year 2011. The bill would authorize the same amount in each fiscal year over the 2012–2016 period. Assuming appropriation of authorized amounts, CBO estimates that implementing that provision would cost $75 million in 2012 and $1.4 billion over the 2012–2016 period, based on historical spending patterns of similar programs.

National Disaster Medical System (NDMS). The bill would authorize funding for the NDMS, which is a partnership between HHS, the Departments of Defense, Homeland Security, and Veterans Affairs. It provides for medical assistance to states and localities when responding to a large-scale public health emergency. In fiscal year 2011, the NDMS received an appropriation of $56 million. The bill would authorize the same amount in each fiscal year over the 2012–2016 period. Based on historical spending patterns of similar programs, CBO estimates that implementing that provision would cost $215 million over the 2012–2016 period, assuming appropriation of authorized amounts.

Emergency Volunteer Registration. The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR–VHP) is a national database that links state credential verification systems in order to streamline the pre-registration of volunteer health professionals who are willing to respond in the event of a public health emergency. The ESAR–VHP received an appropriation of about $6 million in fiscal year 2011. The bill would authorize the same amount in each fiscal year over the 2012–2016 period. Assuming appropriation of authorized amounts, CBO estimates that implementing that provision would cost $25 million over the 2012–2016 period, based on historical spending patterns of similar programs.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 2405 contains no intergovernmental or private-sector mandates as defined in UMRA. Programs and activities authorized in the bill would benefit

state, local, and tribal agencies that prepare for and respond to public health emergencies.

Estimate prepared by: Federal costs: Stephanie Cameron, Andrea Noda, Ellen Werble; Impact on state, local, and tribal governments: Lisa Ramirez-Branum; Impact on the private sector: Jimmy Jin.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1—Short title and table of contents

This section includes the name of the bill: "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011."

Section 2—Reauthorization of certain provisions relating to public health preparedness

This section includes the following provisions:

- *Section 2(a)—Vaccine tracking and distribution.* This provision would reauthorize the vaccine tracking and distribution program used during an influenza pandemic. The bill would authorize the program at $30.8 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level.
- *Section 2(b)—Public health preparedness grants.* This provision would reauthorize the Public Health Emergency Preparedness Cooperative Agreement (PHEP) administered by the Centers for Disease Control and Prevention (CDC). These grants to state and local health departments have greatly improved the Nation's ability to respond to many public health hazards. The bill would require those applying for the grants to describe any activities they will use to analyze clinical specimens, including any utilization of poison control centers, which the Committee believes are vital components to our nation's preparedness infrastructure and therefore should be utilized. Poison Control Centers possess the capacity and expertise to assist in responding to a public health emergency. The bill would authorize the program at $632.9 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level.

• *Section 2(c)—Health system preparedness grants.* This provision would reauthorize the Hospital Preparedness Program Cooperative Agreement administered by the ASPR. These grants to states and hospitals have greatly improved our Nation's preparedness for disasters that would result in a surge in the need for medical care. The bill includes language that would require the awards to take into account the needs of pediatric and other at-risk populations. The bill also would require the HHS Secretary to implement evidence-based metrics to ensure that those receiving awards meet the goals of the National Health Security Strategy. The bill would authorize the program at $378 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level.

• *Section 2(d)—CDC surveillance and capacity.* The provision would reauthorize the Federal, state, and local surveillance and situational awareness capacity program. The bill would authorize the program at $160.1 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level.

• *Section 2(e)—Dental emergency responders.* This provision would incorporate dentists by name into Federal and state disaster response frameworks, allowing dentists to be deployed during a natural or man-made disaster. This provision is based on H.R. 570, the "Dental Emergency Responder Act of 2011", which was introduced by Rep. Michael Burgess (R–TX) on February 9, 2011, and reported favorably by the Committee earlier this Congress. Recent disasters have made clear the critical need for a prepared, robust national medical response framework. Currently, dentists, allied dental personnel, and dental facilities are not part of that framework. These individuals and offices are both eager and willing to participate and otherwise assist in supporting medical and public health responses to disasters. The legislation would allow but not require these health care professionals to assist in public health emergencies.

• *Section 2(f)—BioShield Special Reserve Fund.* This provision would reauthorize the Project BioShield Special Reserve Fund, originally created in 2004. The SRF was intended to be used solely for procuring medical countermeasures in response to chemical, biological, radiological, or nuclear threats against the nation. Since 2004, the SRF has successfully procured medical countermeasures for the Strategic National Stockpile, protecting against threats such as anthrax and smallpox.

The Committee believes stable funding for MCM development and procurement is vital to create producer interest in and willingness to enter this space. The SRF is intended to be a secure funding source for the procurement of critical MCMs; it is critical because it clearly demonstrates the Federal government's commitment to MCM procurement. As such, the Committee believes these funds for development and procurement of MCMs should go to these specific activities and not be diverted. Because substantial funds have, in fact, been diverted to non-MCM activities, causing significant fear that there are or will soon be insufficient funds to support MCM development and procurement, H.R. 2405 would prohibit SRF funds from being used for anything other than MCM de-

velopment and procurement, as defined under sections 319L and 319F–2 of the Public Health Service Act.

This legislation would reauthorize the SRF at $2.8 billion over five years (FY 2014–2018). This level of funding is consistent with the SRF's original, 10-year appropriation of $5.6 billion for FY 2004–2013. In addition to reauthorizing the SRF, the provision also would:

- Require the Federal government to clearly define the purpose of a particular contract as it relates to the medical countermeasure being procured.
- Require the HHS Secretary to provide a report to Congress when funds available in the SRF go below $1.5 billion. The report would detail how the level of funding in the SRF would affect our nation's ability to develop medical countermeasures for public health threats.
- Allow the HHS Secretary to use up to 30 percent of funds available in the SRF for advanced research and development of medical countermeasures at BARDA. These funds would supplement, not supplant, BARDA's funding through the annual appropriations process.

• *Section 2(g)—Emergency System for Advance Registration of Health Professions Volunteers (ESAR–VHP).* This provision would reauthorize the ESAR–VHP program, which supports state and territories in establishing standardized volunteer registration programs for disasters and public health and medical emergencies. The program is funded at $5.9 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level.

• *Section 2(h)—Biomedical Advanced Research and Development Authority.* This provision would reauthorize BARDA, which was created in 2006 to help bridge the "valley of death" between medical countermeasure development and procurement. BARDA has been successful in getting many early-stage medical countermeasures through the expensive, time consuming development process so that these products can be procured for the Strategic National Stockpile. The bill would reauthorize BARDA at $415 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level. The bill also would extend the requirement that the HHS Secretary withhold from FOIA disclosure specific technical data or scientific information created during the advanced research and development of a medical countermeasure that would reveal vulnerabilities of existing medical or public health defenses against CBRN threats. Finally, the bill would require the Federal government to clearly define the purpose of a particular advanced research and development contract as it relates to the medical countermeasure under contract.

• *Section 2(i)—National Disaster Medical System (NDMS).* The bill would reauthorize the NDMS, which assists in managing the Federal government's medical response to major emergencies and disasters. The bill would reauthorize the program at $56 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level. Under this provision, the HHS Secretary could pay third party vendors to assist in the Federal response to emergencies and disasters.

• *Section 2(j)—National Health Security Strategy Timeline.* This provision would change the submission date of the National Health Security Strategy to 2014.

• *Section 2(k)—Enhancing Surge Capacity.* This provision would modify the goals in the National Health Security Strategy to ensure that periodic evaluation of Federal, State, local, and tribal preparedness will include drills and exercises to ensure medical surge capacity, particularly for events without notice. The goals for medical preparedness capacity would be expanded to include availability, coordination, and accessibility of resources. The provision also would change the definition of the components of medical preparedness under the strategy to include both ambulatory care and critical care. Finally, the provision would ensure that medical evacuation goals include triage and evacuation to the appropriate medical institution based on the medical needs of the patient, as part of regional systems.

• *Section 2(l)—Volunteer Medical Reserve Corps.* This provision would reauthorize the Medical Reserve Corps, which engages local volunteers to strengthen public health, emergency response and community resiliency. The bill would reauthorize the program at $11.9 million each year for five years (FY 2012–2016). This level of funding is equal to the program's FY 2011 appropriated level.

• *Section 2(m)—Extension of anti-trust exemptions.* This provision would extend limited anti-trust exemptions for meetings regarding medical countermeasure development that include national security information.

Section 3—Temporary redeployment of personnel during a public health emergency

The section would allow the HHS Secretary to redeploy non-Federal personnel (funded through the Public Health Service Act or programs funded through HHS) to assist in public health emergencies and disasters, but only at the request of the state or locality.

Section 4—Improving coordination by the Assistant Secretary for Preparedness and Response

The ASPR serves as the principal advisor to the HHS Secretary on all matters related to bioterrorism and other public health emergencies. Additionally, the ASPR plays a vital role in coordinating emergency response efforts across the various HHS agencies and among HHS; other Federal departments, agencies, and offices; and state and local officials. The Committee believes that it is clear that the successful execution of the ASPR's mission, which, according to the ASPR, is to "lead the nation in preventing, responding to and recovering from the adverse health effects of public health emergencies and disasters," is vital to ensuring that our Nation is prepared to effectively respond to a CBRN threat or emergency.[1] While centralizing significant coordination authority with the ASPR is necessary, the Federal response to recent emergencies has not always clearly demonstrated which office or agency leads our nation's efforts on preparedness and response.

[1] http://www.hhs.gov/open/contacts/aspr.html.

The section would amend Section 2811 of the Public Health Service Act to clarify that the ASPR has lead responsibility within HHS for emergency preparedness and response policy and coordination. The Committee believes this clarification is essential, not only to better coordinate our nation's preparedness efforts, but also to ensure that, if there is a public health emergency or disaster, the public, and those involved in responding to such an emergency or disaster, understand the division of responsibilities. To this end, the bill includes the following provisions that would require the ASPR to:

- Streamline and better coordinate HHS preparedness grants in order to avoid duplication, as well as to disseminate best practices.
- Conduct a comprehensive five-year budget analysis of the entire medical countermeasure enterprise to ensure prioritization of limited resources.
- Identify gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles.
- Conduct a Countermeasure Implementation Plan (CIP) in order to improve transparency, accountability, and success of the entire medical countermeasure enterprise. The CIP would require ASPR to identify threats against the nation, create measurable goals to address these threats, report on progress of meeting these goals, identify budget and funding needs, and identify specific timelines for medical countermeasure development. The CIP would be presented to Congress 6 months after the date of enactment of H.R. 2405 and annually thereafter.

  In the CIP, the Committee believes that the ASPR would have to address the needs of pediatric populations with respect to countermeasures and products in the Strategic National Stockpile, as there have been a number of concerns raised in this area. Specifically, the ASPR would have to include a list of qualified countermeasures and products necessary to address the needs of pediatric populations and a plan for addressing these needs. Through this process, the ASPR should remedy gaps in the pediatric countermeasure enterprise in addition to ensuring that countermeasures developed and approved in the future have pediatric labeling, dosages, and formulations, where feasible. Finally, with respect to pediatric populations, the ASPR would be required to advise the HHS Secretary on issues pertaining to pediatric qualified countermeasures and products.
- Be consulted when the HHS Secretary authorizes medical products for use during emergencies.
- Submit a plan on improving coordination of the biosurveillance systems of HHS.

The Committee underscores that it is not its intent to move the day-to-day operations of the Cities Readiness Initiative (CRI), the Medical Reserve Corps or the SNS. Rather, the legislation is designed to ensure that the ASPR has policy oversight and coordination authority over these preparedness programs.

Section 5—Eliminating duplicative Project Bioshield reports

This section would repeal a report included under Project Bioshield that is duplicative of parts of the new Countermeasure Implementation Plan created in Section 4.

Section 6—Authorization for medical products for use in emergencies

This section would amend FDA's current Emergency Use Authority (EUA) authority to enable FDA to authorize the distribution, stockpiling, and use of products before an actual emergency. Specifically, the provisions would:

- Enable the HHS Secretary to make a threat determination of a significant potential for a public health emergency (as opposed to an actual emergency) justifying issuance of an EUA and thus allowing FDA to take important, life-saving steps before the emergency actually occurs.
- Permit FDA to collect and analyze information about safety and effectiveness beyond the effective period of the EUA, but only for products actually used in an emergency.
- Allow FDA to issue an EUA for products or uses that otherwise may violate provisions of Federal Food, Drug, and Cosmetic Act (i.e. adulteration and misbranding provisions), but are important to protecting Americans.

The Committee notes that it intends the provisions applying to emergency use authority to include countermeasures and products for pediatric populations.

Section 7—Additional provisions related to medical products for emergency use

This section would provide added flexibility for emergency dispensing and use of eligible, FDA-approved medical countermeasure products. Specifically, the provisions would:

- Enable FDA to extend the expiration date for medical countermeasures intended to be used for emergency responses.
- Allow waivers of current Good Manufacturing Practices (cGMP) without rendering a product adulterated or misbranded.
- Authorize mass dispensing of medical countermeasures during an actual emergency without an individual prescription if permitted under state law or permitted by an order of the HHS Secretary.
- Authorize the HHS Secretary to create and issue emergency use instructions concerning a product's conditions of use.
- Authorize the HHS Secretary to waive a Risk Evaluation and Mitigation Strategy if the Secretary determines that a waiver is required to mitigate the effects or reduce the severity of emergencies.

Section 8—Product held for emergency use

This section would authorize pre-positioning of medical countermeasure by federal, state or local governments in anticipation of emergencies, allowing faster response during an actual emergency.

Section 9—Accelerating medical countermeasure development by strengthening FDA's role in reviewing products for national security priorities

Transparency, certainty, and predictability are particularly important in the context of MCM research and development because the stakes are so high for MCM sponsors and the American public. Because in some instances sponsors can rely only on the Federal government to purchase their MCM products, risk associated with investing the time and resources necessary to enter the countermeasure space is significant. By increasing transparency, accountability, and predictability in this area, which this legislation seeks to do, the Committee believes the bill will encourage investment, research, and development in the space and increase the likelihood of securing the MCMs necessary for public health emergencies and disasters, including those caused by terrorism.

This section includes provisions aimed at providing greater transparency, predictability, and certainty for medical countermeasure sponsors by increasing FDA's interaction with sponsors and requiring FDA to provide additional clarity around the requirements of the approval, clearance, and licensure processes. Specifically, the section would:

- Increase the involvement of FDA personnel in interagency, countermeasure-related activities.
- Permit FDA to provide on-site and off-site technical assistance to countermeasure manufacturers.
- Require FDA to establish a process for frequent scientific feedback and interaction with those sponsors whose countermeasures have been procured under Project BioShield, in order to facilitate the approval, clearance, and licensure of the countermeasures. As part of this process, the bill would allow for the development of regulatory management plans (RMPs) through which eligible sponsors can create an agreement with the FDA to have scientific exchanges throughout the product development process. The Committee believes the use of RMPs will reduce the uncertainty and risk experienced by countermeasure sponsors. Under the bill, these plans would be developed by the sponsors and include information on the following: current regulatory status of the countermeasure; proposed pathway to approval, clearance or licensure of the countermeasure including the data, clinical trials and any other information required for such approval, clearance or licensure; developmental milestones which will result in meetings between the sponsor and FDA; sponsor submissions which will result in written feedback and any other information; or issues that would facilitate or delay approval. FDA, upon receipt of a proposal with relevant data from a sponsor, would have 90 days to work with the sponsor to agree on a Regulatory Management Plan. FDA retains full discretion to determine the contents of the final plan, or to determine that no final plan can be agreed upon. In the latter case, FDA will provide the sponsor with the scientific or regulatory rationale why such agreement cannot be reached. Under the bill, the HHS would have the authority to apply this process to other qualified pandemic or epidemic products.

- Set forth a timeline for FDA's issuance of a final guidance on development of animal models. FDA would have one year to provide the final guidance, but the deadline could be extended by six months if the HHS Secretary submits a report to Congress on the status of the guidance.
- Expand the use of Special Protocol Assessments to the use of animal trials and any associated clinical trials necessary to support licensure of countermeasures referenced in Section 565(a) of the Federal Food, Drug, and Cosmetic Act when human efficacy studies are not ethical or feasible.
- Require FDA to report on countermeasure development and review activities on a biennial basis, starting on January 1, 2013.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * * * *

SEC. 319. PUBLIC HEALTH EMERGENCIES.

(a) * * *

* * * * * * *

(e) TEMPORARY REDEPLOYMENT OF PERSONNEL DURING A PUBLIC HEALTH EMERGENCY.—

(1) EMERGENCY REDEPLOYMENT OF FEDERALLY FUNDED PERSONNEL.—Notwithstanding any other provision of law, and subject to paragraph (2), upon a request that is from a State, locality, territory, tribe, or the Freely Associated States and that includes such information and assurances as the Secretary may require, the Secretary may authorize the requesting entity to temporarily redeploy to immediately address a public health emergency non-Federal personnel funded in whole or in part through—

(A) any program under this Act; or

(B) at the discretion of the Secretary, any other program funded in whole or in part by the Department of Health and Human Services.

(2) ACTIVATION OF EMERGENCY REDEPLOYMENT.—

(A) PUBLIC HEALTH EMERGENCY.—The Secretary may exercise the authority vested by paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) CONSIDERATIONS.—In authorizing a temporary redeployment under paragraph (1), the Secretary shall consider each of the following:

(i) The degree to which the emergency cannot be adequately and appropriately addressed by the public health workforce.

(ii) The degree to which the emergency requires or would otherwise benefit from supplemental staffing from those funded through nonpreparedness Federal programs.

(iii) The degree to which such programs would be adversely affected by the redeployment.

(iv) Such other factors as the Secretary may deem appropriate.

(C) TERMINATION AND EXTENSION.—

(i) TERMINATION.—The authority to authorize a temporary redeployment of personnel under paragraph (1) shall terminate upon the earlier of the following:

(I) The Secretary's determination that the public health emergency no longer exists.

(II) Subject to clause (ii), 30 days after the activation of the Secretary's authority pursuant to subparagraph (A).

(ii) EXTENSION AUTHORITY.—The Secretary may extend the authority to authorize a temporary redeployment of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists, but only if—

(I) the extension is requested by the entity that requested authority to authorize a temporary redeployment; and

(II) the Secretary gives notice to the Congress in conjunction with the extension.

SEC. 319A. VACCINE TRACKING AND DISTRIBUTION.

(a) * * *

* * * * * * *

(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⟧ *$30,800,000 for each of fiscal years 2012 through 2016*.

* * * * * * *

SEC. 319C–1. IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.

(a) * * *

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

(1) * * *

(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) * * *

* * * * * * *

(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; *and*

(vi) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers;

* * * * * * *

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

(1) * * *

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

(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.]

* * * * * * *

[(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.]

(i) FUNDING.—

(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.]

(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $632,900,000 for each of fiscal years 2012 through 2016.

* * * * * * *

(3) DETERMINATION OF AMOUNT.—

(A) * * *

* * * * * * *

(C) INCREASE ON BASIS OF POPULATION.—After determining the base amount for a State under subparagraph (B), the Secretary shall increase the base amount by an amount equal to the product of—

(i) the amount appropriated under paragraph [(1)(A)(i)(I)] *(1)(A)* for the fiscal year, less an amount equal to the sum of all base amounts determined for the States under subparagraph (B), and less the

amount, if any, reserved by the Secretary under paragraphs (4) and (5); and

* * * * * * *

(D) MINIMUM AMOUNT.—Subject to the amount appropriated under paragraph [(1)(A)(i)(I)] *(1)(A)*, an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

(I) * * *

(II) if the amount appropriated under paragraph [(1)(A)(i)(I)] *(1)(A)* is less than $667,000,000, an amount equal to 0.75 percent of the amount appropriated under such paragraph, less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); or

* * * * * * *

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*, including capacity and preparedness to address the needs of pediatric and other at-risk populations*.

* * * * * * *

(i) PERFORMANCE AND ACCOUNTABILITY.—[The requirements of]

(1) IN GENERAL.—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.

(2) MEETING GOALS OF NATIONAL HEALTH SECURITY STRATEGY.—The Secretary shall implement objective, evidence-based metrics to ensure that entities receiving awards under this section are meeting, to the extent practicable, the goals of the National Health Security Strategy under section 2802.

(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.]

(1) IN GENERAL.—For purposes of carrying out this section, there is authorized to be appropriated $378,000,000 for each of fiscal years 2012 through 2016.

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SEC. 319D. REVITALIZING THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

(a) * * *

* * * * * * *

[(c) AUTHORIZATION OF APPROPRIATIONS.—

[(1) FACILITIES; CAPACITIES.—

[(A) FACILITIES.—For the purpose of carrying out subsection (a)(2), there are authorized to be appropriated $300,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

[(B) MISSION; IMPROVING CAPACITIES.—For the purposes of achieving the mission of the Centers for Disease Control and Prevention described in subsection (a)(1), for carrying out subsection (a)(3), for better conducting the capacities described in section 319A, and for supporting public health activities, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

[(2) NATIONAL COMMUNICATIONS AND SURVEILLANCE NETWORKS.—For the purpose of carrying out subsection (b), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.]

* * * * * * *

(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] *$160,121,000 for each of fiscal years 2012 through 2016*.

* * * * * * *

SEC. 319F. PUBLIC HEALTH COUNTERMEASURES TO A BIOTERRORIST ATTACK.

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

(1) * * *

* * * * * * *

(5) DISSEMINATION AND TRAINING.—

(A) * * *

(B) CERTAIN ENTITIES.—The education and training activities described in subparagraph (A) may be carried out by Federal [public health or medical] *public health, medical, or dental* entities, appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

* * * * * * *

SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE AND SECURITY COUNTERMEASURE PROCUREMENTS.

(a) * * *

* * * * * * *

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)*.

* * * * * * *

(4) CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) * * *

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, make a recommendation under paragraph (6) that the [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* be made available for the procurement of such countermeasure.

* * * * * * *

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* (referred to in this subsection individually as a "procurement under this subsection").

* * * * * * *

(6) RECOMMENDATION FOR PRESIDENT'S APPROVAL.—

(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* be made available for the procurement of such countermeasure.

(B) PRESIDENTIAL APPROVAL.—The [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

(C) NOTICE TO DESIGNATED CONGRESSIONAL COMMITTEES.—The Secretary and the Homeland Security Secretary shall notify the designated congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor.

* * * * * * *

(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.

(7) PROCUREMENT.—

(A) * * *

(B) INTERAGENCY AGREEMENT; COST.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The [special reserve fund under paragraph (10)] *special reserve fund as defined in subsection (g)(5)* shall be available for payments made by the Secretary to a vendor for such procurement.

(C) PROCUREMENT.—

(i) * * *

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) * * *

* * * * * * *

(IV) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the [special reserve fund under paragraph (10)] *special reserve fund as defined in*

subsection (g)(5) shall be available for costs of shipping, handling, storage, and related costs for such product.

* * * * * * *

[(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.]

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

(aa) 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

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

* * * * * * *

[(9) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund as defined in subsection (g)(5) shall not be used to pay—

[(A) costs for the purchase of vaccines under procurement contracts entered into before the date of the enactment of the Project BioShield Act of 2004; or

[(B) costs other than payments made by the Secretary to a vendor for a procurement of a security countermeasure under paragraph (7).

[(10) DEFINITIONS.—

[(A) SPECIAL RESERVE FUND.—For purposes of this subsection, the term "special reserve fund" has the meaning given such term in section 510 of the Homeland Security Act of 2002.

[(B) DESIGNATED CONGRESSIONAL COMMITTEES.—For purposes of this section, the term "designated congressional committees" means the following committees of the Congress:

[(i) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

[(ii) In the Senate: the appropriate committees.]

* * * * * * *

(g) SPECIAL RESERVE FUND.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

(2) NOTICE OF INSUFFICIENT FUNDS.—Not later than 15 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 Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the amount of such funds available for procurement and the impact such funding will have—

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

(B) on the annual Countermeasure Implementation Plan under section 2811(d).

(3) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary may utilize not more than 30 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(4) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay—

(A) costs other than payments made by the Secretary to a vendor for advanced development (under section 319L) or for procurement of a security countermeasure under subsection (c)(7); and

(B) any administrative expenses, including salaries.

(5) DEFINITION.—In this section, the term "special reserve fund" means the "Biodefense Countermeasures" appropriations account, any appropriation made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to paragraph (1) of this paragraph.

* * * * * * *

SEC. 319I. EMERGENCY SYSTEM FOR ADVANCE REGISTRATION OF HEALTH PROFESSIONS VOLUNTEERS.

(a) * * *

* * * * * * *

(k) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there [are authorized to be appropriated $2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011] *is authorized to be appropriated $5,900,000 for each of fiscal years 2012 through 2016.*

* * * * * * *

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

(a) * * *

* * * * * * *

(c) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) * * *

* * * * * * *

(5) TRANSACTION AUTHORITIES.—

(A) * * *

* * * * * * *

(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.—

(1) * * *

[(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.]

(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, the amounts to remain available until expended.

(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

(1) DISCLOSURE.—

(A) * * *

* * * * * * *

(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] *September 30, 2016*.

* * * * * * *

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

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

* * * * * * *

SEC. 2802. NATIONAL HEALTH SECURITY STRATEGY.

(a) IN GENERAL.—

(1) PREPAREDNESS AND RESPONSE REGARDING PUBLIC HEALTH EMERGENCIES.—Beginning in [2009] *2014* 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.

* * * * * * *

(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*, including drills and exercises to ensure medical surge capacity for events without notice*; and

* * * * * * *

(3) MEDICAL.—Increasing the preparedness, response capabilities, *availability, coordination, accessibility,* and surge capacity of hospitals, other health care facilities ([including mental health facilities] *including mental health and ambulatory care facilities and which may include dental health facilities*), and [trauma care and emergency medical service systems] *trauma care, critical care, and emergency medical service systems*, with respect to public health emergencies, which shall include developing plans for the following:

(A) * * *

(B) [Medical evacuation and fatality management] *Fatality management, and coordinated medical triage and evacuation to the appropriate medical institution based on patient medical need as part of regional systems.*

* * * * * * *

(D) Effective utilization of any available public and private mobile medical assets *(which may include dental health assets)* and integration of other Federal assets.

* * * * * * *

Subtitle B—All-Hazards Emergency Preparedness and Response

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

(a) * * *

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

(1) * * *

* * * * * * *

(3) COUNTERMEASURES.—Oversee advanced research, development, *stockpiling, distribution,* and procurement of qualified countermeasures (as defined in section 319F–1*), security measures (as defined in section 319F–2),* and qualified pandemic or epidemic products (as defined in section 319F–3).

(4) COORDINATION.—

(A) * * *

* * * * * * *

(D) IDENTIFICATION OF INEFFICIENCIES.—Identify gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles.

(E) DEVELOPMENT OF COUNTERMEASURE IMPLEMENTATION PLAN.—Lead the development of a coordinated Countermeasure Implementation Plan under subsection (d).

(F) COUNTERMEASURES BUDGET ANALYSIS.—Oversee the development of a comprehensive, cross-cutting 5-year budget analysis with respect to activities described in paragraph (3)—

(i) to inform prioritization of resources; and

(ii) to ensure that challenges to such activities are adequately addressed.

(G) GRANT PROGRAMS FOR MEDICAL AND PUBLIC HEALTH PREPAREDNESS CAPABILITIES.—Coordinate, in consultation with the Secretary of Homeland Security, grant programs of the Department of Health and Human Services relating to medical and public health preparedness capabilities and the activities of local communities to respond to public health emergencies, including the—

(i) coordination of relevant program requirements, timelines, and measurable goals of such grant programs; and

(ii) establishment of a system for gathering and disseminating best practices among grant recipients.

* * * * * * *

[(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.]

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

(1) have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy and coordination;

(2) 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 Biomedical Advanced Research and Development Authority under section 319L; and

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

(3) provide policy coordination and oversight of—

(A) the Strategic National Stockpile under section 319F–2;

(B) the Cities Readiness Initiative; and

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

(4) assume other duties as determined appropriate by the Secretary.

(d) COUNTERMEASURE IMPLEMENTATION PLAN.—Not later than 6 months after the date of enactment of this subsection, and annually thereafter, the Assistant Secretary for Preparedness and Response shall submit through the Secretary to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a Countermeasure Implementation Plan that—

(1) describes the chemical, biological, radiological, and nuclear threats facing the Nation and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), or qualified pandemic or epidemic products (as defined in section 319F–3) for each threat;

(2) evaluates the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, and utilization;

(3) identifies and prioritizes near-, mid-, and long-term needs with respect to such countermeasures or products to address chemical, biological, radiological, and nuclear threats;

(4) identifies, with respect to each category of threat, a summary of all advanced development and procurement awards, including—

(A) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination);

(B) projected timelines for development and procurement of such countermeasures or products;

(C) clearly defined goals, benchmarks, and milestones for each such countermeasure or product, including information on the number of doses required, the intended use of the countermeasure or product, and the required countermeasure or product characteristics; and

(D) projected needs with regard to the replenishment of the Strategic National Stockpile;

(5) evaluates progress made in meeting the goals, benchmarks, and milestones identified under paragraph (4)(C);

(6) reports on the amount of funds available for procurement in the special reserve fund as defined in section 319F–2(g)(5) and the impact this funding will have on meeting the requirements under section 319F–2;

(7) incorporates input from Federal, State, local, and tribal stakeholders; and

(8) addresses the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile and includes—

(A) a list of such countermeasures and products necessary to address the needs of pediatric populations;

(B) a description of measures taken to coordinate with Office of Pediatric Therapeutics of the Food and Drug Administration to maximize the labeling, dosages, and formulations of such countermeasures and products for pediatric populations;

(C) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

(D) an evaluation of the progress made in addressing gaps identified pursuant to subparagraph (C).

Notwithstanding any other provision of this subsection, the Plan shall not include any confidential commercial information, proprietary information, or information that could reveal vulnerabilities of the Nation in the preparation for or ability to respond to chemical, biological, radiological, or nuclear threats.

SEC. 2812. NATIONAL DISASTER MEDICAL SYSTEM.

(a) NATIONAL DISASTER MEDICAL SYSTEM.—

(1) * * *

* * * * * * *

(3) PURPOSE OF SYSTEM.—

(A) * * *

* * * * * * *

(D) ADMINISTRATION.—The Secretary may determine and pay claims for reimbursement for services under subparagraph (A) directly or by contract providing for payment in advance or by way of reimbursement.

* * * * * * *

(g) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing for the Assistant Secretary for Preparedness and Response and the operations of the National Disaster Medical System, other than purposes for which amounts in the Public Health Emergency Fund under section 319 are available, there are authorized to be appropriated **[**such sums as may be necessary for each of the fiscal years 2007 through 2011**]** *$56,000,000 for each of fiscal years 2012 through 2016*.

SEC. 2813. VOLUNTEER MEDICAL RESERVE CORPS.

(a) * * *

* * * * * * *

(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**]** *$11,900,000 for each of fiscal years 2012 through 2016*.

* * * * * * *

SECTION 405 OF THE PANDEMIC AND ALL-HAZARD PREPAREDNESS ACT

SEC. 405. COLLABORATION AND COORDINATION.

(a) * * *

(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**]** *on September 30, 2016*.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * * * *

NEW DRUGS

SEC. 505. (a) * * *

(b)(1) * * *

* * * * * * *

(5)(A) * * *

[(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.]

(B)(i) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of—

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

(II) animal efficacy trials and any associated clinical trials that in combination are intended to form the primary basis of an effectiveness claim for a countermeasure or product referred to in section 565(a) when human efficacy studies are not ethical or feasible.

(ii) The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

* * * * * * *

SEC. 505–1. RISK EVALUATION AND MITIGATION STRATEGIES.

(a) * * *

* * * * * * *

(f) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

(1) * * *

* * * * * * *

[(7) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this subsection during the period described in section 319(a) of the Public Health Service Act with respect to a qualified countermeasure described under section 319F–1(a)(2) of such Act, to which a requirement under this subsection has been applied, if the Secretary has—

[(A) declared a public health emergency under such section 319; and

[(B) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.]

* * * * * * *

(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, an actual or potential domestic emergency or military emergency involving heightened risk of attack with a biological, chemical, radiological, or nuclear agent, or an actual or potential public health emergency affecting national security or the health and security of United States citizens abroad.

* * * * * * *

SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

* * * * * * *

SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—

(1) EMERGENCY USES.—Notwithstanding [sections 505, 510(k), and 515 of this Act] *any provision of this Act* and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution [under a provision of law referred to in such paragraph] *under a provision of law in section 505, 510(k), or 515 of this Act or section 351 of the Public Health Service Act* (referred to in this section as an "unapproved product"); or

* * * * * * *

(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under [a provision of law referred to in such paragraph] *a provision of law referred to in paragraph (2)(A)*.

* * * * * * *

(b) [DECLARATION OF EMERGENCY] *DECLARATION SUPPORTING EMERGENCY USE AUTHORIZATION.*—

(1) IN GENERAL.—The Secretary may declare [an emergency justifying] *that circumstances exist justifying* the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a [specified] biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a [specified] biological, chemical, radiological, or nuclear agent or agents; or

[(C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.]

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

(2) TERMINATION OF DECLARATION.—

[(A) IN GENERAL.—A declaration under this subsection shall terminate upon the earlier of—

[(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

[(ii) the expiration of the one-year period beginning on the date on which the declaration is made.

[(B) RENEWAL.—Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal.]

(A) IN GENERAL.—A declaration under this subsection shall terminate upon a determination by the Secretary, in consultation with, as appropriate, the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist.

[(C)] *(B)* DISPOSITION OF PRODUCT.—If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

* * * * * * *

(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, [advance notice of termination, and renewal] *and advance notice of termination* under this subsection.

(c) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after [consultation with the Director of the National Institutes of Health] *consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health,* and the Director of the Centers

for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes—

(1) that an agent [specified in] *covered by* a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

* * * * * * *

(d) SCOPE OF AUTHORIZATION.—An authorization of a product under this section shall state—

(1) * * *

* * * * * * *

(3) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including*, to the extent practicable given the circumstances of the emergency,* an assessment of the available scientific evidence.

(e) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) * * *

(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) * * *

* * * * * * *

[(iii) Appropriate conditions with respect to the collection and analysis of information, during the period when the authorization is in effect, concerning the safety and effectiveness of the product with respect to the emergency use of such product.]

(iii) Appropriate conditions with respect to the collection and analysis of information concerning the safety and effectiveness of the product with respect to the actual use of such product pursuant to an authorization under this section.

* * * * * * *

(2) UNAPPROVED USE.—With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) For a [manufacturer of the product] *person* who carries out any activity for which the authorization is issued, the Secretary shall, to the extent practicable given the circumstances of the emergency, establish conditions described in clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv) of such paragraph *or in paragraph (1)(B)*.

(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not au-

thorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer, *with the exception of extensions of a product's expiration date authorized under section 564A(b).*

* * * * * * *

[(C) The Secretary may establish with respect to the distribution and administration of the product for the unapproved use conditions no more restrictive than those established by the Secretary with respect to the distribution and administration of the product for the approved use.**]**

(C) In establishing conditions under this paragraph with respect to the distribution and administration of a product, the Secretary shall not impose conditions that would restrict distribution or administration of the product that is solely for the approved uses.

[(3) GOOD MANUFACTURING PRACTICE.—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 circumstances of the emergency, 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 501.**]**

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

(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 501 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).

* * * * * * *

(5) EXISTING AUTHORITIES.—Nothing in this section restricts any authority vested in the Secretary by any other provision of this Act or the Public Health Service Act for establishing conditions of authorization for a product.

* * * * * * *

(g) **[**REVOCATION OF AUTHORIZATION**]** *REVIEW, MODIFICATION, AND REVOCATION OF AUTHORIZATION.—*

(1) REVIEW.—The Secretary shall **[**periodically review**]** *review not less than every three years* the circumstances and the appropriateness of an authorization under this section.

* * * * * * *

(3) MODIFICATION.—The Secretary may modify an authorization under this section or the conditions of such an authorization, at any time, based on a review of the authorization or new information that is otherwise obtained, including information obtained during an emergency.

* * * * * * *

SEC. 564A. ADDITIONAL PROVISIONS RELATED TO MEDICAL PRODUCTS FOR EMERGENCY USE.

(a) DEFINITIONS.—For purposes of this section:

(1) The term "product" means a drug, device, or biological product.

(2) The term "eligible product" means a product that is—

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

(B) intended to be used to diagnose, prevent, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents during—

(i) a domestic emergency or military emergency involving heightened risk of attack with such an agent or agents; or

(ii) a public health emergency affecting national security or the health and security of United States citizens abroad.

(b) EXPIRATION DATING.—

(1) IN GENERAL.—The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if—

(A) the eligible product is intended to be held for use for a domestic, military, or public health emergency described in subsection (a)(2)(B);

(B) the expiration date extension is intended to support the United States' ability to protect—

(i) the public health; or

(ii) military preparedness and effectiveness; and

(C) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

(2) REQUIREMENTS AND CONDITIONS.—Any extension of an expiration date under paragraph (1) shall, as part of the extension, identify—

(A) each specific lot, batch, or other unit of the product for which extended expiration is authorized;

(B) the duration of the extension; and

(C) any other requirements or conditions as the Secretary may deem appropriate for the protection of the public health, which may include requirements for, or conditions on, product sampling, storage, packaging or repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing or retesting, or product disposition.

(3) EFFECT.—Notwithstanding any other provision of this Act or the Public Health Service Act, an eligible product shall not be considered an unapproved product (as defined in section

564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because, with respect to such product, the Secretary has, under paragraph (1), extended the expiration date and authorized the introduction or delivery for introduction into interstate commerce of such product after the expiration date provided by the manufacturer.

(c) CURRENT GOOD MANUFACTURING PRACTICES.—

(1) IN GENERAL.—The Secretary may, when the circumstances of a domestic, military, or public health emergency described in subsection (a)(2)(B) 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 (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

(d) MASS DISPENSING.—The requirements of section 503(b) and 520(e) shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because it is dispensed without an individual prescription, if—

(1) the product is dispensed during an actual emergency described in subsection (a)(2)(B); and

(2) such dispensing without an individual prescription occurs—

(A) as permitted under the law of the State in which the product is dispensed; or

(B) in accordance with an order issued by the Secretary.

(e) 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 (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this Act because of—

(A) the issuance of emergency use instructions under paragraph (1) with respect to such product; or

(B) the introduction or delivery for introduction of such product into interstate commerce accompanied by such instructions during an emergency response to an actual emergency described in subsection (a)(2)(B).

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. 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. 565. COUNTERMEASURE DEVELOPMENT AND REVIEW.

(a) COUNTERMEASURES AND PRODUCTS.—The countermeasures and products referred to in this subsection are—

(1) qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act);

(2) security countermeasures (as defined in section 319F–2 of such Act); and

(3) qualified pandemic or epidemic products (as defined in section 319F–3 of such Act) that the Secretary determines to be a priority.

(b) IN GENERAL.—

(1) INVOLVEMENT OF FDA PERSONNEL IN INTERAGENCY ACTIVITIES.—For the purpose of accelerating the development, stockpiling, approval, clearance, and licensure of countermeasures and products referred to in subsection (a), the Secretary shall expand the involvement of Food and Drug Administration personnel in interagency activities with the Assistant Secretary for Preparedness and Response (including the Biomedical Advanced Research and Development Authority), the Centers for Disease Control and Prevention, the National Institutes of Health, and the Department of Defense.

(2) TECHNICAL ASSISTANCE.—The Secretary shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance

with current Good Manufacturing Practices) to provide both off-site and on-site technical assistance to the manufacturers of countermeasures and products referred to in subsection (a). On-site technical assistance shall be provided upon the request of the manufacturer and at the discretion of the Secretary if the Secretary determines that the provision of such assistance would accelerate the development, manufacturing, or approval, clearance, or licensure of countermeasures and products referred to in subsection (a).

(c) AGENCY INTERACTION WITH SECURITY COUNTERMEASURE SPONSORS.—

(1) IN GENERAL.—For security countermeasures (as defined in section 319F–2 of the Public Health Service Act) that are procured under such section 319F–2—

(A) the Secretary shall establish a process for frequent scientific feedback and interactions between the Food and Drug Administration and the security countermeasure sponsor (referred to in this subsection as the "sponsor"), designed to facilitate the approval, clearance, and licensure of the security countermeasures;

(B) such feedback and interactions shall include meetings and, in accordance with subsection (b)(2), on-site technical assistance; and

(C) at the request of the Secretary, the process under this paragraph shall include participation by the Food and Drug Administration in meetings between the Biomedical Advanced Research and Development Authority and sponsors on the development of such countermeasures.

(2) REGULATORY MANAGEMENT PLAN.—

(A) IN GENERAL.—The process established under paragraph (1) shall allow for the development of a written regulatory management plan (in this paragraph referred to as the "plan") for a security countermeasure (as defined in paragraph (1)) in accordance with this paragraph.

(B) PROPOSAL AND FINALIZATION OF PLAN.—In carrying out the process under paragraph (1), the Secretary shall direct the Food and Drug Administration, upon submission of a written request by the sponsor that includes a proposed plan and relevant data and future planning detail to support such a plan, to work with the sponsor to agree on a final plan within a reasonable time not to exceed 90 days. The basis for this agreement shall be the proposed plan submitted by the sponsor. Notwithstanding the preceding sentence, the Secretary shall retain full discretion to determine the contents of the final plan or to determine that no such plan can be agreed upon. If the Secretary determines that no final plan can be agreed upon, the Secretary shall provide to the sponsor, in writing, the scientific or regulatory rationale why such agreement cannot be reached. If a final plan is agreed upon, it shall be shared with the sponsor in writing.

(C) CONTENTS.—The plan shall include an agreement on the nature of, and timelines for, feedback and interactions between the sponsor and the Food and Drug Administration, shall provide reasonable flexibility in implementing

and adjusting the agreement under this paragraph as warranted during the countermeasure development process, and shall identify—

(i) the current regulatory status of the countermeasure, an assessment of known scientific gaps relevant to approval, clearance, or licensure of the countermeasure, and a proposed pathway to approval, clearance, or licensure of the countermeasure;

(ii) developmental milestones whose completion will result in meetings to be scheduled within a reasonable time between the applicable review division of the Food and Drug Administration and the sponsor;

(iii) sponsor submissions that will result in written feedback from the review division within a reasonable time;

(iv) feedback by the Food and Drug Administration regarding the data required to support delivery of the countermeasure to the Strategic National Stockpile under section 319F–2 of the Public Health Service Act;

(v) feedback by the Food and Drug Administration regarding data required to support submission of a proposed agreement on the design and size of clinical trials for review under section 505(b)(5)(B); and

(vi) other issues that have the potential to delay approval, clearance, or licensure.

(D) CHANGES.—Changes to the plan shall be made by subsequent agreement between the Secretary and the sponsor. If after reasonable attempts to negotiate changes to the plan the Secretary and the sponsor are unable to finalize such changes, the Secretary shall provide to the sponsor, in writing, the scientific or regulatory rationale why such changes are required or cannot be included in the plan.

(3) APPLICABILITY TO CERTAIN QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS.—The Secretary may, with respect to qualified pandemic or epidemic products (as defined in section 319F–3 of the Public Health Service Act) for which a contract for advanced research and development is entered into under section 319L of such Act, choose to apply the provisions of paragraphs (1) and (2) to the same extent and in the same manner as such provisions apply with respect to security countermeasures.

(d) FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL MODELS.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011, the Secretary shall provide final guidance to industry regarding the development of animal models to support approval, clearance, or licensure of countermeasures and products referred to in subsection (a) when human efficacy studies are not ethical or feasible.

(2) AUTHORITY TO EXTEND DEADLINE.—The Secretary may extend the deadline for providing final guidance under paragraph (1) by not more than 6 months upon submission by the Secretary of a report on the status of such guidance to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(e) BIENNIAL REPORT.—Not later than January 1, 2013, and every 2 years thereafter, the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, that, with respect to the preceding 2 fiscal years, includes—

(1) the number of full-time equivalent employees of the Food and Drug Administration who directly support the review of countermeasures and products referred to in subsection (a);

(2) estimates of funds obligated by the Food and Drug Administration for review of such countermeasures and products;

(3) the number of regulatory teams at the Food and Drug Administration specific to such countermeasures and products and, for each such team, the assigned products, classes of products, or technologies;

(4) the length of time between each request by the sponsor of such a countermeasure or product for information and the provision of such information by the Food and Drug Administration;

(5) the number, type, and frequency of official interactions between the Food and Drug Administration and—

(A) sponsors of a countermeasure or product referred to in subsection (a); or

(B) another agency engaged in development or management of portfolios for such countermeasures or products, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense;

(6) a description of other measures that, as determined by the Secretary, are appropriate to determine the efficiency of the regulatory teams described in paragraph (3); and

(7) the regulatory science priorities that relate to countermeasures or products referred to in subsection (a) and which the Food and Drug Administration is addressing and the progress made on these priorities.

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PROJECT BIOSHIELD ACT OF 2004

[SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS ACT.

[(a) SECRETARY OF HEALTH AND HUMAN SERVICES.—

[(1) ANNUAL REPORTS ON PARTICULAR EXERCISES OF AUTHORITY.—

[(A) RELEVANT AUTHORITIES.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

[(i) With respect to section 319F–1 of the Public Health Service Act (as added by section 2 of this Act):

[(I) Subsection (b)(1) (relating to increased simplified acquisition threshold).

[(II) Subsection (b)(2) (relating to procedures other than full and open competition).

[(III) Subsection (c) (relating to expedited peer review procedures).

[(ii) With respect to section 319F–2 of the Public Health Service Act (as added by section 3 of this Act):

[(I) Subsection (c)(7)(C)(iii) (relating to simplified acquisition procedures).

[(II) Subsection (c)(7)(C)(iv) (relating to procedures other than full and open competition).

[(III) Subsection (c)(7)(C)(v) (relating to premium provision in multiple-award contracts).

[(iii) With respect to section 564 of the Federal Food, Drug, and Cosmetic Act (as added by section 4 of this Act):

[(I) Subsection (a)(1) (relating to emergency uses of certain drugs and devices).

[(II) Subsection (b)(1) (relating to a declaration of an emergency).

[(III) Subsection (e) (relating to conditions on authorization).

[(B) CONTENTS OF REPORTS.—The Secretary shall annually submit to the designated congressional committees a report that summarizes—

[(i) the particular actions that were taken under the authorities specified in subparagraph (A), including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

[(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

[(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and

[(iv) whether, with respect to each procurement that is approved by the President under section 319F–2(c)(6) of the Public Health Service Act (as added by section 3 of this Act), a contract was entered into within one year after such approval by the President.

[(2) ANNUAL SUMMARIES REGARDING CERTAIN ACTIVITY.—The Secretary shall annually submit to the designated congressional committees a report that summarizes the activity undertaken pursuant to the following authorities under section 319F–1 of the Public Health Service Act (as added by section 2 of this Act):

[(A) Subsection (b)(3) (relating to increased micropurchase threshold).

[(B) Subsection (d) (relating to authority for personal services contracts).

[(C) Subsection (e) (relating to streamlined personnel authority).

With respect to subparagraph (B), the report shall include a provision specifying, for the one-year period for which the report is submitted, the number of persons who were paid amounts greater than $100,000 and the number of persons who were paid amounts between $50,000 and $100,000.

[(3) REPORT ON ADDITIONAL BARRIERS TO PROCUREMENT OF SECURITY COUNTERMEASURES.—Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with the Secretary of Homeland Security, shall report to the designated congressional committees any potential barriers to the procurement of security countermeasures that have not been addressed by this Act.

[(b) GENERAL ACCOUNTING OFFICE REVIEW.—

[(1) IN GENERAL.—Four years after the date of the enactment of this Act, the Comptroller General of the United States shall initiate a study—

[(A)(i)to review the Secretary of Health and Human Services' utilization of the authorities granted under this Act with respect to simplified acquisition procedures, procedures other than full and open competition, increased micropurchase thresholds, personal services contracts, streamlined personnel authority, and the purchase of security countermeasures under the special reserve fund; and

[(ii) to make recommendations to improve the utilization or effectiveness of such authorities in the future;

[(B)(i)to review and assess the adequacy of the internal controls instituted by such Secretary with respect to such authorities, where required by this Act; and

[(ii) to make recommendations to improve the effectiveness of such controls;

[(C)(i)to review such Secretary's utilization of the authority granted under this Act to authorize an emergency use of a biomedical countermeasure, including the means by which the Secretary determines whether and under what conditions any such authorizations should be granted and the benefits and adverse impacts, if any, resulting from the use of such authority; and

[(ii) to make recommendations to improve the utilization or effectiveness of such authority and to enhance protection of the public health;

[(D) to identify any purchases or procurements that would not have been made or would have been significantly delayed except for the authorities described in subparagraph (A)(i); and

[(E)(i)to determine whether and to what extent activities undertaken pursuant to the biomedical countermeasure research and development authorities established in this Act have enhanced the development of biomedical countermeasures affecting national security; and

[(ii) to make recommendations to improve the ability of the Secretary to carry out these activities in the future.

[(2) ADDITIONAL PROVISIONS REGARDING DETERMINATION ON DEVELOPMENT OF BIOMEDICAL COUNTERMEASURES AFFECTING NATIONAL SECURITY.—In the report under paragraph (1), the determination under subparagraph (E) of such paragraph shall include—

[(A) the Comptroller General's assessment of the current availability of countermeasures to address threats identified by the Secretary of Homeland Security;

[(B) the Comptroller General's assessment of the extent to which programs and activities under this Act will reduce any gap between the threat and the availability of countermeasures to an acceptable level of risk; and

[(C)(i)the Comptroller General's assessment of threats to national security that are posed by technology that will enable, during the 10-year period beginning on the date of the enactment of this Act, the development of antibiotic resistant, mutated, or bioengineered strains of biological agents; and

[(ii) recommendations on short-term and long-term governmental strategies for addressing such threats, including recommendations for Federal policies regarding research priorities, the development of countermeasures, and investments in technology.

[(3) REPORT.—A report providing the results of the study under paragraph (1) shall be submitted to the designated congressional committees not later than five years after the date of the enactment of this Act.

[(c) REPORT REGARDING BIOCONTAINMENT FACILITIES.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Homeland Security and the Secretary of Health and Human Services shall jointly report to the designated congressional committees whether there is a lack of adequate large-scale biocontainment facilities necessary for the testing of security countermeasures in accordance with Food and Drug Administration requirements.

[(d) DESIGNATED CONGRESSIONAL COMMITTEES.—For purposes of this section, the term "designated congressional committees" means the following committees of the Congress:

[(1) In the House of Representatives: the Committee on Energy and Commerce, the Committee on Appropriations, the Committee on Government Reform, and the Select Committee on Homeland Security (or any successor to the Select Committee).

[(2) In the Senate: the appropriate committees.]

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