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112TH CONGRESS
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H. R. 2405

[Report No. 112–286]

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.

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2011

Mr. ROGERS of Michigan (for himself, Mrs. MYRICK, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

NOVEMBER 16, 2011

Additional sponsors: Mr. BURGESS and Ms. ESHOO

NOVEMBER 16, 2011

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on June 28, 2011]

A BILL

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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

retary 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 in-

serting "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 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. 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 Sec-

retary 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 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.".

(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 re-

view 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 As-

sistant 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 para-

graph (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 para-

graph 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.".

(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.".

Union Calendar No. 189

112TH CONGRESS
1ST SESSION

H. R. 2405

[Report No. 112–286]

A BILL

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.

NOVEMBER 16, 2011

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed