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112TH CONGRESS
1ST SESSION

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.

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

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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 (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);

(2) by striking subsection (h); and

(3) 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.—Paragraph (1) of section 319C–2(j) of the Public Health Service Act (42 U.S.C. 247d–3b(j)) is amended 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 such dental health assets)'' after ''medical assets''.

(f) PROCUREMENT OF COUNTERMEASURES.—

(1) CONTRACT TERMS.—Clause (ii) of section 319F–2(c)(7)(C) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)) is amended by adding at the end the following:

"(X) GOVERNMENT PURPOSE.—The contract 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 relevant committees of Congress 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 Public Health Emergency Medical Countermeasure Enterprise Implementation Plan under section 319F–5(b).

"(3) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, 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 research and development or 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) 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 "7 years" and inserting "10 years".

(h) 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".

(i) 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 "6-year" and inserting "10-year".

SEC. 3. 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, in consultation with the Director of the Office of Management and Budget, 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 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 ability of local communities to respond to public health emergencies, including by—

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

"(ii) establishing 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 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;

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

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

"(F) the Strategic National Stockpile; and

"(G) the Cities Readiness Initiative; and

"(2) 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 to the Secretary and relevant congressional committees a Countermeasure Implementation Plan that—

"(1) describes the chemical, biological, radiological, and nuclear threats facing the Nation and the corresponding efforts to develop qualified coun-

termeasures (as defined in section 319F–1), secured 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 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), and including—

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

"(B) clearly defined goals, benchmarks, and milestones for each 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

"(C) 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);

"(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; and

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

(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,".

SEC. 4. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD REPORTS.

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

SEC. 5. 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).

"(b) IN GENERAL.—

"(1) INVOLVEMENT OF FDA PERSONNEL IN INTERAGENCY ACTIVITIES.—The Secretary shall accelerate the development, stockpiling, approval, and

licensure of countermeasures and products referred to in subsection (a) by expanding the involvement of Food and Drug Administration personnel in interagency activities with 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 Practice) to provide both off-site and on-site technical assistance to the manufacturers of countermeasures and products referred to in subsection (a).

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

"(1) COUNTERMEASURE DEVELOPMENT PROGRAM.—

"(A) IN GENERAL.—For each security countermeasure (as defined in section 319F–2 of the Public Health Service Act) that is procured under such section 319F–2, the Secretary shall initiate, in consultation with the security countermeasure sponsor (referred to in this sec-

tion as the 'countermeasure sponsor'), a program of frequent scientific feedback and interactions regarding the process of developing such countermeasure, including—

"(i) regular meetings between appropriate Food and Drug Administration personnel and the countermeasure sponsor during the process of developing the countermeasure, to be scheduled within 45 days after attainment of each milestone identified pursuant to subparagraph (B)(iv)(I) in the regulatory management plan for the countermeasure;

"(ii) written feedback from the Food and Drug Administration within 30 days after submission of a request for feedback pursuant to subparagraph (B)(iv)(II) in the regulatory management plan for the countermeasure;

"(iii) written feedback from the Food and Drug Administration within 30 days after submission by the countermeasure sponsor of a study report that is considered to be complete pursuant to subpara-

graph (B)(iv)(III) in the regulatory management plan for the countermeasure;

"(iv) at the request of the Director of the Biomedical Advanced Research and Development Authority, participation in meetings of such Authority on the development of the countermeasure; and

"(v) other meetings, including on-site meetings, as appropriate.

"(B) REGULATORY MANAGEMENT PLAN.—In carrying out the program under subparagraph (A), the Secretary shall, in consultation with the countermeasure sponsor, develop a written regulatory management plan for each security countermeasure (as defined in section 319F–2 of the Public Health Service Act) that is procured under such section 319F–2. The regulatory management plan shall be completed within 60 days of issuance of a contract for the countermeasure under such section 319F–2 or, for a countermeasure that was procured under such section 319F–2 before the date of the enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011, within 60 days after such date of enactment. The reg-

ulatory management plan for a security countermeasure shall include—

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

"(ii) guidance by the Food and Drug Administration regarding the data required to support delivery of the countermeasure to the Strategic National Stockpile;

"(iii) guidance 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

"(iv) an agreement between the Food and Drug Administration and the countermeasure sponsor to identify—

"(I) developmental milestones that will trigger meetings between the Administration and the sponsor;

"(II) the process for requesting and receiving written or oral feedback from the Administration; and

"(III) the type study reports that will be considered by the Administration to be complete.

"(C) 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 subparagraphs (A) and (B) 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.—Not later than 180 days 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 or licensure of countermeasures and products referred to in sub-

1 section (a) when human efficacy studies are not ethical
2 or feasible.

3 "(e) ANNUAL REPORT.—Not later than January 1,
4 2012, and every January 1 thereafter, the Secretary shall
5 submit a report to the Committee on Energy and Com-
6 merce of the House of Representatives and the Committee
7 on Health, Education, Labor, and Pensions of the Senate
8 that, with respect to the preceding fiscal year, includes—

9 "(1) the number of full-time equivalent employ-
10 ees of the Food and Drug Administration who di-
11 rectly support the review of countermeasures and
12 products referred to in subsection (a);

13 "(2) estimates of funds obligated by the Food
14 and Drug Administration for development of such
15 countermeasures and products;

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

21 "(4) the length of time between each request by
22 the sponsor of such a countermeasure or product for
23 information and the provision of such information by
24 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) any other measure to determine the efficiency of the regulatory teams described in paragraph (3); and

"(7) the regulatory science priorities which the Food and Drug Administration is addressing and the progress made on these priorities.".

(b) DISCUSSIONS BETWEEN FDA AND SPONSOR ON DESIGN AND SIZE OF ANIMAL AND CLINICAL TRIALS INTENDED TO FORM THE PRIMARY BASIS OF AN EFFECTIVENESS CLAIM WHEN HUMAN EFFICACY STUDIES ARE NOT ETHICAL OR FEASIBLE.—Subparagraph (B) of sec-

tion 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 and clinical trials intended to form the primary basis of an effectiveness claim 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.".

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