PANDEMIC AND ALL-HAZARDS PREPAREDNESS REAUTHORIZATION ACT OF 2011

Mr. PITTS. Mr. Speaker, I move to suspend the rules and pass 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, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2405

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. 1. Short title; table of contents.
Sec. 2. Reauthorization of certain provisions relating to public health preparedness and countermeasure development.
Sec. 3. Temporary redeployment of personnel during a public health emergency.
Sec. 4. Coordination by Assistant Secretary for Preparedness and Response.
Sec. 5. Eliminating duplicative Project BioShield reports.
Sec. 6. Authorization for medical products for use in emergencies.
Sec. 7. Additional provisions related to medical products for emergency use.
Sec. 8. Products held for emergency use.
Sec. 9. Accelerate countermeasure development by strengthening FDA’s role in reviewing products for national security priorities.

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 2012” and inserting “$39,000,000 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 (j)—
(A) by striking “‘the requirements of’” and inserting “‘The requirements of’”;
(B) by adding at the end the following:
(1) IN GENERAL.—For purposes of carrying out this section, there is authorized to be appropriated $374,000,000 for each of fiscal years 2012 through 2016.
(2) MEETING GOALS OF NATIONAL SECURITY STRATEGY.—The Secretary shall implement objectives to ensure that entities receiving awards under this section are meeting, to the extent practicable, the goals of the National Security Strategy under section 2802.

(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 (b), by striking “(A)” and inserting “(A)(i)” each place it appears and inserting “(A)(ii)”.

(d) CDC PROGRAMS FOR COMBATING PUBLIC HEALTH TERRORISM OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 247d–4) is amended—

(1) by striking subsection (c); and
(2) in subsection (d), by striking “such sums as may be necessary for each of fiscal years 2007 through 2011” and inserting “$650,121,000 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) of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by striking “‘public health or medical’ and inserting “‘public health, medical, or dental’.

(2) NATIONAL SECURITY STRATEGY.—Section 2802(b)(3) of the Public Health Service Act (42 U.S.C. 2090h–1(3)(3)) is amended.

(f) 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) for special reserve fund purposes (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L shall not be otherwise authorized to be appropriated to carry out such section.

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

(1) costs other than payments made by the Secretary to a vendor for procurement of security countermeasures under section 319L or for procurement of a security countermeasure under subsection (c)(7); and
(2) any administrative expenses, including salaries.

(h) 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, any appropriation made available pursuant to paragraph (1) of this paragraph, or any appropriation made available pursuant to paragraph (1) of the Homeland Security Act of 2002.

(i) DENTAL EMERGENCY RESPONDERS: MEDICAL AND DENTAL—

(4) in subsection (i)—
(A) by striking “(I)” and inserting “(I)”; and
(B) by adding at the end the following:
(1) IN GENERAL.—The requirements of this section (g)(5)”;
(2) FUNDING.—To carry out the purposes of this section, there is authorized to be appropriated $374,000,000 for each of fiscal years 2012 through 2016.

(j) 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) for special reserve fund purposes (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L shall not be otherwise authorized to be appropriated to carry out such section.

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

(1) costs other than payments made by the Secretary to a vendor for procurement of security countermeasures under section 319L or for procurement of a security countermeasure under subsection (c)(7); and
(2) any administrative expenses, including salaries.

(l) 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, any appropriation made available pursuant to paragraph (1) of this paragraph, or any appropriation made available pursuant to paragraph (1) of the Homeland Security Act of 2002.

(m) DENTAL EMERGENCY RESPONDERS: MEDICAL AND DENTAL—

(5) in subsection (i)—
(A) by striking “such sums as” and inserting “such sums as may be necessary for each of fiscal years 2007 through 2011”;
(B) by striking “such sums as may be necessary for each of fiscal years 2012 through 2016” and inserting “$650,121,000 for each of fiscal years 2012 through 2016.”

(n) DENTAL EMERGENCY RESPONDERS: MEDICAL AND DENTAL—

(6) amounts in the special reserve fund shall not be used to pay—

(1) costs other than payments made by the Secretary to a vendor for procurement of security countermeasures under section 319L or for procurement of a security countermeasure under subsection (c)(7); and
(2) any administrative expenses, including salaries.

(o) 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, any appropriation made available pursuant to paragraph (1) of this paragraph, or any appropriation made available pursuant to paragraph (1) of the Homeland Security Act of 2002.

(p) DENTAL EMERGENCY RESPONDERS: MEDICAL AND DENTAL—

(7) amounts in the special reserve fund shall not be used to pay—

(1) costs other than payments made by the Secretary to a vendor for procurement of security countermeasures under section 319L or for procurement of a security countermeasure under subsection (c)(7); and
(2) any administrative expenses, including salaries.

(q) 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, any appropriation made available pursuant to paragraph (1) of this paragraph, or any appropriation made available pursuant to paragraph (1) of the Homeland Security Act of 2002.

(r) DENTAL EMERGENCY RESPONDERS: MEDICAL AND DENTAL—

(8) amounts in the special reserve fund shall not be used to pay—

(1) costs other than payments made by the Secretary to a vendor for procurement of security countermeasures under section 319L or for procurement of a security countermeasure under subsection (c)(7); and
(2) any administrative expenses, including salaries.

(s) 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, any appropriation made available pursuant to paragraph (1) of this paragraph, or any appropriation made available pursuant to paragraph (1) of the Homeland Security Act of 2002.

(t) DENTAL EMERGENCY RESPONDERS: MEDICAL AND DENTAL—

(9) amounts in the special reserve fund shall not be used to pay—

(1) costs other than payments made by the Secretary to a vendor for procurement of security countermeasures under section 319L or for procurement of a security countermeasure under subsection (c)(7); and
(2) any administrative expenses, including salaries.
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, 2015.’’

(n) NATIONAL DISASTER MEDICAL SYSTEM.—Section 3012 of the Public Health Service Act (42 U.S.C. 300hh–11) is amended—

(1) by deleting subsection (d)(3), by adding, at the end the following:

(2) 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) NATIONAL HEALTH SECURITY STRATEGY TIMELINE.—Section 2002(a)(1) of the Public Health Service Act (42 U.S.C. 247d–7a(1)(A)) is amended by striking ‘‘2009’’ and inserting ‘‘2014’’;

(k) ENHANCING SURFACE CAPACITY.—Section 2002(b) of the Public Health Service Act (42 U.S.C. 247d–7a(1)) is amended—

(1) by adding (A) at the end, after ‘‘(1)’’, inserting ‘‘including exercises to ensure medical surveillance capacity for events without notice’’ after ‘‘emergency planning’’;

(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’’;

(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 management systems, inserting ‘‘Fatality management, and coordinated medical triage and evacuation to the appropriate medical institution based on patient medical need’’

(l) VOLUNTEER MEDICAL RESERVE CORPS.—Section 2313(i) of the Public Health Service Act (42 U.S.C. 300h–15(i)) is amended by striking ‘‘2002’’ and inserting ‘‘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) EXTENDED ANTI-TRUST EXEMPTION.—Section 405(b) of the Pandemic and All-Hazard Preparedness Act (42 U.S.C. 247d–4a note) is amended by striking ‘‘at the end of the 6-year period beginning on the date of enactment of this Act’’ and inserting ‘‘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. 2813(i)) 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), the Secretary of Health and Human Services may authorize the temporary redeployment of personnel from federal programs to any other program funded by the federal government in order to perform functions necessary to address a public health emergency.

(2) AUTHORIZATION OF TEMPORARY REDEPLOYMENT.—The Secretary may, after consultation with the appropriate congressional committees, temporarily redeploy personnel to any other program funded by the federal government in order to perform functions necessary to address a public health emergency. Such authorization shall be made only after consultation with the appropriate congressional committees and shall include—

(i) a list of such programs and the functions that such programs are expected to perform;

(ii) the degree to which such programs would be adversely affected by the redeployment;

and

(iii) such other factors as the Secretary may deem appropriate.

((f) TERMINATION.—The Secretary shall rescind the temporary redeployment of personnel upon the earlier of the following:

(1) the Secretary’s determination that the public health emergency no longer exists;

(2) Subject to clause (i), 30 days after the activation of the Secretary’s authority pursuant to subparagraph (A);

(3) 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) if the public health emergency still exists; but only if the Secretary determines that requested authority to authorize a temporary redeployment is necessary for the continuity of operations in conjunction with the extension.

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

(a) IN GENERAL.—Section 2011 of the Public Health Service Act (42 U.S.C. 300h–10) is amended—

(1) in subsection (b)(3), by inserting ‘‘stockpiling, distribution,’’ before ‘‘and procurement’’;

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

((D) IDENTIFICATION OF INEFFECTIVENESS.—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-section budget analysis with respect to activities described in paragraph (3)—

(i) to inform prioritization of resources; and

(ii) to ensure that efficiencies 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 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.

(b) Effect of amendments.—With regard to the implementation of the amendments made by this section, the Secretary shall—

(1) functionally reorganize the Department of Health and Human Services to coordinate such efforts.

(2) authorize the temporary redeployment of personnel under this Act or any other provision of law, and subject to paragraph (1), the Secretary shall consider each of the following:

(i) the degree to which such programs would be adversely affected by the redeployment;

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

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

(1) have lead responsibility within the Department of Health and Human Services for 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; and

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

(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 2011;

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

(5) 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 an 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

(5) evaluates progress made in meeting the goals, benchmarks, and milestones identified under paragraph (4) in terms of—

(A) 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 3019F–2;

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

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

(i) 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 Homeland Security and 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 develop a biosurveillance coordination, and communications among disparate bio-surveillance systems supported by the Department of Homeland Security.

SEC. 5. ELIMINATING DUPLICATE PROJECT BIO-SHIELD REPORTS.

Section 5 of the Project BioShield Act of 2004 (42 U.S.C. 9995d–6) is amended—

(1) in subsection (a), by striking “sections 351, 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 sections 351, 510(k), and 515 of this Act”;

(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 inserting “specified”; and

(iv) in subparagraph (C), by striking “as defined in” and inserting “as defined in”;

(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 and the Secretary of Health and Human Services, that the circumstances described in paragraph (1) have ceased to exist:—

(ii) by striking subparagraph (B), and

(iii) by striking 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 inserting “covered by”;

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

(5) in subsection (e)(2), by amending clause (ii) to read as follows:

“(ii) Appropriate conditions with respect to the collection of information, or information that could reveal 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) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 564(a)(2)(A) the following:

“SEC. 644. ADDITIONAL PROVISIONS RELATED TO MEDICAL PRODUCTS FOR EMERGENCY USE.

“(a) IN GENERAL.—The term ‘product’ means a drug, device, or biological product.

“(b) The term ‘eligible product’ means a product that is—

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

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

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

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

“(c) EXTENSION OF EXPANSION DATE.

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

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

“(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, manufacturing, testing, storage, packaging or repackaging, transit, 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 of such product 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 practices required by this Act or any other requirement or condition 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)) 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) if—

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

(b) such dispensing without an individual prescription occurs—

‘‘(A) as permitted under the laws 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 providers or individuals 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)) and shall not be deemed adulterated or misbranded under this Act because—

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

‘‘(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); or

‘‘(C) the waiver of an application for an investigational new drug under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355e) is amended—

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

(2) by adding at the end the following:

‘‘(8) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement with respect to an qualified countermeasure (as defined in section 319F–2(a)(2) of the Public Health Service Act) to which a requirement under this section has been applied and 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. 331 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 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 510(k) of this Act; or

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

SEC. 9. ACCELERATE COUNTERMEASURE DEVELOPMENT AND REVIEW.

(a) IN GENERAL.—The Secretary of the Department of Health and Human Services, the Secretary of the Department of Homeland Security, the Secretary of the Department of Defense, the Secretary of Agriculture, the Secretary of Health and Human Services, and the Secretary of the Treasury may, acting through an appropriate official within the Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, the Department of Agriculture, or the Department of Health and Human Services, in accordance with subsection (b), conduct meetings and, in accordance with subsection (c), develop and adopt, in consultation with the appropriate entities, guidelines and protocols for the development, testing, and evaluation of countermeasures and products referred to in this subsection.

(b) MEETINGS.—The Secretary shall conduct meetings to—

(1) discuss the status and progress of development of countermeasures and products referred to in subsection (a), with appropriate officials of the Departments of Health and Human Services, Homeland Security, Defense, and Agriculture, and the National Institutes of Health and the Food and Drug Administration, to allow discussion of the current status and need for any additional actions to be taken;

(2) coordinate, with the appropriate federal agencies, the criteria and process for determining the eligibility of countermeasures and products referred to in subsection (a) when human efficacy studies and animal studies are not required for approval, clearance, or licensure of such countermeasures and products referred to in subsection (a); and

(c) GUIDELINES.—The Secretary shall develop guidelines for—

(1) the criteria and process for determining the eligibility of countermeasures and products referred to in subsection (a) for approval, clearance, or licensure of the countermeasures and products referred to in subsection (a); and

(2) the underlying regulations, requirements, and criteria for—

(i) the approval, clearance, or licensure of the countermeasures and products referred to in subsection (a); and

(ii) the approval, clearance, or licensure of additional studies or clinical trials necessary to support the approval, clearance, or licensure of the countermeasures and products referred to in subsection (a).
The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania? The Speaker: The question is taken. Mr. PITTS. Mr. Speaker, I yield myself such time as I may consume. H.R. 2405, introduced by my colleague MIKE ROGERS from Michigan, would reauthorize certain provisions of the Project BioShield Act of 2004 and the Pandemic and All-Hazards Preparedness Act of 2006. These two laws help protect the United States against attacks from chemical, biological, radiological, and nuclear weapons.

Project BioShield authorized funds for the purchase of medical countermeasures through the Special Reserve Fund and enabled the Secretary of Health and Human Services to authorize the emergency use of medical products. PAHPA created the Biodefense Advanced Research and Development Authority within HHS to help with the development of medical countermeasures and to ensure the communication between HHS and the developers of the medical countermeasures. PAHPA also created a position at HHS to lead the government’s efforts on the chemical, biological, radiological, and nuclear weapons preparedness and response, the Assistant Secretary for Preparedness and Response.

Some of these key provisions expired at the end of FY 2011. Since the terrorist attacks of 9/11, we have become more aware of the dangers our country faces and of the lengths to which some may go to inflict harm on us. These provisions must be reauthorized, so I would urge all Members to support this critical piece of legislation. I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume. I am pleased to rise in support of H.R. 2405, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011. This bill is an opportunity to build a more prepared and resilient public health infrastructure. We all know very well that our Nation continues to face threats that require an ongoing commitment to public health and emergency preparedness, which is why, over the past 10 years, this Congress has placed a high priority on bio-defense.

In 2004, with tremendous bipartisan support, we passed the Project BioShield Act. Democrats and Republicans worked together to establish a process that would help our Nation respond to bioterrorism threats and attacks. We then identified some shortfalls and, in 2006, worked to amend the program by passing the Pandemic and All-Hazards Preparedness Act, also known as PAHPA. Specifically, PAHPA provided the Department of Health and Human Services with the additional authorities and resources necessary to rapidly develop drugs and vaccines to protect citizens from various medical incidents, whether accidental, such as H1N1 outbreaks, or those that are deliberate, such as anthrax attacks.

The programs and activities first established in both the 2004 Project BioShield Act and the 2006 PAHPA codified the Federal Government’s support for public health preparedness. As a result of these bills and the investments that followed, our Nation is better equipped to respond to bioterrorism threats and attacks. H.R. 2405 will not only help to fund that progress. The bill further facilitates the development of medical countermeasures, and it bolsters the Nation’s public health preparedness infrastructure. It strengthens and clarifies the position of Assistant Secretary for Preparedness and Response, who has led the Federal Government’s efforts and attempts to improve coordination and accountability.

I was especially supportive of the bipartisan effort to address the special needs of pediatric populations in emergency situations. It was clear that there were some gaps in our Nation’s public health emergency strategy for children, and I’m confident we took an appropriate approach for filling in these gaps.

So I really want to thank Representative MIKE ROGERS and Representative GENE GREEN and their staffs, who authored the base bill and have continued to work to strengthen its provisions. I would also like to thank the staff of the Energy and Commerce Committee and, of course, my chairman, Mr. PITTS, who collaborated in a bipartisan manner to further enhance the bill. They have worked hard to accomplish the goals of our Members, as well as stakeholders, and to strengthen its provisions. It’s been a good bipartisan process and one that I think should be emulated in our subcommittee and full committee in the future.

I would urge all Members to support H.R. 2405.

I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume. I’m a strong supporter of the gentleman from Pennsylvania, Mr. PITTS.

The SPEAKER pro tempore. The gentleman from Pennsylvania, Mr. PITTS, will control 20 minutes.

The Chair recognizes the gentleman from Pennsylvania.

Mr. PITTS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials into the RECORD.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania? The Speaker: The question is taken.

Mr. PITTS. Mr. Speaker, I yield myself such time as I may consume.

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I would urge all Members to support H.R. 2405.

I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

These revisions are a significant step forward on a framework for FDA to develop better policies and guidance in emergency situations.

In addition, I was appreciative of the bipartisan effort to address the special needs of pediatric populations in emergency situations. It was clear that there were some gaps in our Nation’s public health emergency strategy for children, and I’m confident we took an appropriate approach for filling in these gaps.

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I would urge all Members to support H.R. 2405.

I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.
It’s been more than 10 years since 9/11 and the anthrax attacks that followed. And while we haven’t had a successful terrorist attack on U.S. soil, our enemies are still working every day to kill innocent Americans. Today the threat of bioterrorism remains very real.

Earlier this year, the bipartisan Graham-Talent Commission warned that the United States is still “vulnerable to a large-scale biological attack.”

Thankfully, we have spent the last decade preparing for chemical, biological, radiological, and nuclear threats by developing and stockpiling numerous medical countermeasures to protect American citizens in case of such an attack. Because of these efforts, we now have numerous vaccines and treatments in the Strategic National Stockpile that will save lives, and thousands of lives, in the event of such an attack.

But we have more work to do to be prepared. H.R. 2405 is a bipartisan, fiscally responsible bill that will authorize successful biodefense programs at the Department of Health and Human Services while also making some key changes to our Nation’s biodefense strategy.

In 2004 Congress passed Project BioShield, which created a market guarantee that prompted the private sector to develop countermeasures for the Federal Government. Because the government is the only purchaser of these countermeasures, it was important to show the private sector we were committed to developing and eventually purchasing these products for stockpile.

Project BioShield Special Reserve Fund has been a critical tool to protect our country against an attack, and this legislation will reauthorize the fund for 5 additional years to continue the Federal Government's commitment to procurement of medical countermeasures. Importantly, this legislation reaffirms the Federal Government's commitment to protecting American citizens in case of such an attack.

In 2006, Congress created a Bipartisan Advanced Research and Development Organization, called BARDA, which helped bridge what many termed the “valley of death” that had prevented many countermeasures developers from being successful. BARDA was created because we recognize that most of the CBRN countermeasures do not yet exist and medical development countermeasure is a risky, expensive and lengthy process.

BARDA bridges the funding gap between early-stage research and the ultimate procurement of products from the SRF fund from the national stockpile. H.R. 2405 reauthorizes BARDA for 5 years.

In 2006, we also created a unique set of public health programs to assist hospitals, local public health departments, and first responders in their preparedness efforts. Under H.R. 2405, these programs have been reauthorized for an additional 5 years so that we can continue to strengthen our preparedness infrastructure so critical for prevention and dealing with any possible attack.

H.R. 2405 also strengthens the role of the HHS Assistant Secretary of Preparedness and Response. We need to have one leader at HHS that coordinates and manages stockpiling across all agencies. This bill does that.

Finally, this bill includes important reforms to the Food and Drug Administration, the FDA. The bill strengthens FDA's role in reviewing medical products for national security priorities.

I believe that we’ve identified biological threats and spent millions in taxpayers' funds to develop countermeasures, Mr. Speaker; but we cannot rely on the public will be protected from an attack.

While we can use many of these products without FDA approval through an emergency-use authorization, the FDA’s role in reviewing medical products without FDA approval through an emergency-use approval is hugely important and sends an important signal to developers of these new hopeful technologies and immunizations working on next-generation medical countermeasures.

Simply put, medical countermeasures for national security priorities cannot continue to be treated the same way as the next Viagra or Lipitor. FDA must accelerate their review and approval.

It’s important for Members to know that this legislation, again, is fiscally responsible. H.R. 2405 does not create any new Federal programs or increase spending in any existing programs. I am pleased CBO has confirmed this in their score. H.R. 2405 creates a 5-year reauthorization of the biodefense programs we know are working while making critical policy changes at HHS to strengthen countermeasure development and oversight.

I would like to thank my colleagues on the Energy and Commerce Committee for their hard work on this bipartisan legislation. Mr. Upton, Mr. Pitts, Mr. Waxman, Mr. Pallone, and their staffs have spent several months helping us develop a bipartisan bill that can be signed into law. I want to especially thank my friends, Gene Green, Sue Myrick, and Anna Eshoo for their work to advance this legislation, and I appreciate their work and counsel along the way, Mr. Green.

I hope we never have to use these countermeasures, Mr. Speaker; but they are critical to the assurance that the public will be protected from an attack, an invasion of millions of lives, in the event of such an attack.

I would urge the strong support of H.R. 2405, Mr. Pallone, Mr. Speaker, I yield such time as he may consume to one of the authors of the bill, the gentleman from Texas (Mr. Gene Green).

Mr. GENE GREEN of Texas, Mr. Speaker, as a personal aside, this probably won’t be the headline on the 6 o’clock news tonight around the country because we’re actually agreeing on something, and I think I can associate myself with the remarks of my colleague, the prime sponsor of this bill, as well as he could associate with me, Mr. Pallone, and Mr. Pitts.

I strongly urge my colleagues to vote “yes.”

Mr. PITTS. I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I raise my time.

Mr. PITTS. I reserve the balance of my time.
Mrs. CAPPS. Mr. Speaker, I rise in support of H.R. 2105, the Pandemic and All-Hazards Preparedness Reauthorization Act. But I want to take this time to discuss a critical health issue that Congress must address before the year is out—fixing the sustainable growth rate issue.

Medicare physicians are facing steep reimbursement cuts of nearly 30 percent. And to let these cuts go into effect will harm not only them and their employees, but our seniors as well. That is why I have been a longtime supporter of efforts to postpone SGR cuts and continue to work on a permanent fix.

We here in the House passed legislation to do just that through our version of health care reform. And here we are again, just weeks from the next scheduled cut with an opportunity to craft a bipartisan solution to an issue that both sides of the aisle say they care about. But there is no workable plan in sight.

Instead, it is reported that any fix on the House side will come with indefensible strings attached, pitting doctors’ salaries against seniors’ benefits, Federal workers, and important cost-saving programs. To be clear, SGR must be fixed permanently, but the idea of stripping other critical health care funding to pay for it, ideas that will not see the light of day in the Senate, is like robbing Peter to pay Paul. It is disingenuous to our Nation’s doctors, and it is an indefensible action which will harm our seniors.

So I urge the majority to stop playing politics with the health and well-being of our seniors and to work together to achieve a meaningful and realistic fix.

Mr. PITTS. Mr. Speaker, I would tell the gentlewoman from Florida that I have no other speakers.

Mr. PALLONE. I have no additional speakers.

Mr. PALLONE. I am pleased that the measure before us takes important steps to ensure that our medical response systems are prepared to care for the critically ill and injured in the aftermath of a public health emergency.

As you can imagine, when we face a health emergency such as a flu pandemic, the critical care delivery system is an integral component of our nation’s medical response. Yet, up to this point, critical care medicine has been largely under-contemplated in our national health policy.

Earlier this year, I introduced the bipartisan Critical Care Assessment Act, H.R. 971, with my colleague from Minnesota, Ethan PAULSEN. This measure seeks to identify gaps in the current critical care delivery model and bolster our capabilities to meet future demands.

I am especially pleased to see that this bill takes important steps to ensure that our medical response systems are prepared to care for the critically ill and injured in the aftermath of a public health emergency.

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I am pleased that the measure before us today includes provisions from my bill to improve federal disaster preparedness efforts to care for the critically ill and injured.

Notably, the reauthorization bill adds critical care to the priorities within the nation’s medical preparedness goals. When a natural disaster strikes or a pandemic sweeps the nation, the demands on critical care increase exponentially, and I am pleased to see this language that recognizes the importance of treating the critically ill and injured in a public health emergency.

Additionally, the reauthorization bill improves efforts to ensure that the systems we have in place to address surge capacity will work effectively and efficiently during an emergency. Specifically, the bill includes language to provide for periodic evaluation and testing of the databases intended to ensure medical surge capacity.

As we learned during Hurricane Katrina and the 2009 H1N1 pandemic, having a system in place for the effective deployment of needed medical personnel and supplies is vital for the care of the critically ill and injured.

I would like to thank Chairman UPTON, Chairman PITTS, and my colleagues on both sides of the aisle for working with me to recognize the importance of critical care preparedness by including these important provisions. I look forward to continuing to work to ensure we have a robust critical care infrastructure.