

FIRST RESPONDER ANTHRAX PREPAREDNESS ACT

JULY 22, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. McCAUL, from the Committee on Homeland Security, submitted the following

R E P O R T

[To accompany H.R. 1300]

[Including cost estimate of the Congressional Budget Office]

The Committee on Homeland Security, to whom was referred the bill (H.R. 1300) to direct the Secretary of Homeland Security to make anthrax vaccines and antimicrobials available to emergency response providers, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “First Responder Anthrax Preparedness Act”.

SEC. 2. PRE-EVENT ANTHRAX VACCINATION PROGRAM FOR EMERGENCY RESPONSE PROVIDERS.

(a) ANTHRAX PREPAREDNESS.—

(1) IN GENERAL.—Title V of the Homeland Security Act of 2002 (Public Law 107–296; 6 U.S.C. 311 et seq.) is amended by adding at the end the following new section:

“SEC. 526. ANTHRAX PREPAREDNESS.

“(a) PRE-EVENT ANTHRAX VACCINATION PROGRAM FOR EMERGENCY RESPONSE PROVIDERS.—For the purpose of domestic preparedness for and collective response to terrorism, the Secretary, in consultation with the Secretary of Health and Human Services, shall establish a program to provide surplus anthrax vaccines from the strategic national stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) to emergency response providers for administration to such providers who voluntarily consent to such administration, and shall—

“(1) establish any necessary logistical and tracking systems to facilitate making such vaccines so available;

“(2) distribute disclosures regarding associated benefits and risks to end users; and

“(3) conduct outreach to educate emergency response providers about the voluntary program.

“(b) THREAT ASSESSMENT.—The Secretary shall—

“(1) support homeland security-focused risk analysis and risk assessments of the threats posed by anthrax from an act of terror;

“(2) leverage existing and emerging homeland security intelligence capabilities and structures to enhance prevention, protection, response, and recovery efforts with respect to an anthrax terror attack; and

“(3) share information and provide tailored analytical support on threats posed by anthrax to State, local, and tribal authorities, as well as other national biosecurity and biodefense stakeholders.”.

(2) CLERICAL AMENDMENT.—The table of contents in section 1(b) of such Act is amended by inserting at the end of the items relating to title V the following new item:

“Sec. 526. Anthrax preparedness.”.

(b) PILOT PROGRAM.—

(1) IN GENERAL.—In carrying out the pre-event vaccination program authorized in section 526(a) of the Homeland Security Act of 2002, as added by subsection (a), the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall carry out a pilot program to provide anthrax vaccines to emergency response providers as so authorized. The duration of the pilot program shall be at least 18 months.

(2) PRELIMINARY REQUIREMENTS.—By not later than one year after the date of the enactment of this Act, and prior to implementing the pilot program under paragraph (1), the Secretary of Homeland Security shall—

(A) establish a communication platform for the pilot program;

(B) establish education and training modules for the pilot program;

(C) conduct economic analysis of the pilot program; and

(D) create a logistical platform for the anthrax vaccine request process under the pilot program.

(3) LOCATION.—In carrying out the pilot program under this subsection, the Secretary of Homeland Security shall select emergency response providers based in at least two States for participation in the pilot program.

(4) DISTRIBUTION OF INFORMATION.—The Secretary of Homeland Security shall provide to each emergency response provider who participates in the pilot program under this subsection disclosures and educational materials regarding the associated benefits and risks of any vaccine provided under the pilot program and of exposure to anthrax.

(5) REPORT.—Not later than one year after the date of the enactment of this Act, and annually thereafter until the completion of the pilot program, the Secretary of Homeland Security shall submit to the Committee on Homeland Security of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate a report on the progress and results of the pilot program, including the percentage of eligible emergency response

providers, as determined by each pilot location, that volunteer to participate, the degree to which participants obtain necessary vaccinations, as appropriate, and recommendations to improve initial and recurrent participation in the pilot program. The report shall include a plan under which the Secretary plans to continue the program to provide vaccines to emergency response providers under section 526(a) of the Homeland Security Act of 2002, as added by subsection (a).

(6) DEADLINE FOR IMPLEMENTATION.—The Secretary of Homeland Security shall begin implementing the pilot program under this subsection by not later than the date that is one year after the date of the enactment of this Act.

PURPOSE AND SUMMARY

The purpose of H.R. 1300 is to direct the Secretary of Homeland Security to make anthrax vaccines and antimicrobials available to emergency response providers, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

An anthrax attack is a serious mass casualty threat. Our national response capability to a wide-area anthrax attack would be greatly enhanced by having pre-vaccinated responders, able to deploy immediately and confidently, knowing that they have been afforded as much protection as possible. Pre-event vaccination is a safe, effective way to protect these responders so they can respond in an anthrax attack without fear of contracting disease. In fact, the first responder community has been asking for this capability. The Committee has received letters of support for H.R. 1300 from the International Association of Fire Chiefs, the International Association of Emergency Medical Services Chiefs, and the Alliance for Biosecurity.

The Department of Homeland Security (DHS) Office of Health Affairs (OHA) has been working with the Centers for Disease Control and Prevention (CDC) on a pilot program to provide surplus pre-event anthrax vaccine from the Strategic National Stockpile (SNS) to emergency response providers on a voluntary basis and free of charge. This legislation authorizes that program.

HEARINGS

The Committee did not hold any hearings specifically on H.R. 1300. However, the Subcommittee on Emergency Preparedness, Response, and Communications has held a number of hearings relevant to the legislation in the 112th, 113th, and 114th Congresses.

112th Congress

In the 112th Congress, the Subcommittee held a series of hearing on medical countermeasures, including “Taking Measure of Countermeasures: Protecting the Protectors.” The Subcommittee received testimony from Dr. James D. Polk, Principal Deputy Assistant Secretary of the Department of Homeland Security’s Office of Health Affairs, Mr. Edward Gabriel, Principal Deputy Assistant Secretary for Preparedness and Response at the Department of Health and Human Services, Chief Al Gillespie, President and Chairman of the Board of the International Association of Fire Chiefs, Mr. Bruce Lockwood, Second Vice President of the International Association of Emergency Managers, Sheriff Chris Nocco of Pasco County, Florida, and Mr. Manual Peralta, the Director of

Safety and Health for the National Association of Letter Carriers. At that hearing, Chief Gillespie, stated that a “pilot program that rotates non-expired, potent, and safe vaccines and drugs from the SNS to voluntary emergency responder immunization programs would greatly improve preparedness levels and better utilize federal resources and tax dollars.”

113th Congress

In the 113th Congress, the Subcommittee held a hearing, “Bioterrorism: Assessing the Threat.” The Subcommittee received testimony from Dr. Robert Kadlec, former Special Assistant to the President for Biodefense, Dr. Tom Inglesby, CEO and Director of the UPMC Center for Health Security, and Dr. Leonard Cole, Director of Terror Medicine and Security at the Rutgers Medical School. This hearing provided an assessment of the bioterrorism threat from experts in the biodefense field and discussed the potential impact of an attack, particularly on first responders.

114th Congress

During a hearing on biological threats on April 22, 2015, “Strategic Perspectives on the Bioterrorism Threat,” the Subcommittee on Emergency Preparedness, Response, and Communications received testimony from the Honorable Jim Talent, former Senator and Co-Chair of the WMD Commission, Dr. Charles Cairns, Interim Dean of the University of Arizona Medical School, and Ms. Marisa Raphael, Deputy Commissioner of the New York City Department of Public Health and Mental Hygiene. At this hearing, Members discussed with the witnesses the benefits of having a program, such as the one authorized by H.R. 1300, in place to protect emergency response providers.

COMMITTEE CONSIDERATION

The Committee met on May 20, 2015, to consider H.R. 1300, and ordered the measure to be reported to the House with a favorable recommendation, amended, by voice vote. The Committee took the following actions:

The following amendments were offered:

An Amendment in the Nature of a Substitute offered by MR. KING of New York (#1); was AGREED TO by voice vote.

An Amendment by MS. JACKSON LEE to the Amendment in the Nature of a Substitute (#1A); was AGREED TO by voice vote.

Page 4, line 24, insert after “including” the following: “the percentage of eligible emergency response providers, as determined by each pilot location, that volunteer to participate.”

The Subcommittee on Emergency Preparedness, Response, and Communications met on May 14, 2015, to consider H.R. 1300, and ordered the measure to be reported to the Full Committee with a favorable recommendation, amended, by voice vote. The Committee took the following actions:

The following amendments were offered:

An Amendment in the Nature of a Substitute offered by MS. MCSALLY (#1); was AGREED TO, amended, by voice vote.

An Amendment by MRS. WATSON COLEMAN to the Amendment in the Nature of a Substitute (#1A); was AGREED TO by voice vote.

Page 2, line 7, strike “and”.

Page 2, line 9, strike the period and insert “; and”.

Page 2, after line 10, insert the following: “(3) conduct outreach to educate emergency response providers about the voluntary program.”

An Amendment by MR. PAYNE to the Amendment in the Nature of a Substitute (#1B); was AGREED TO by voice vote.

Page 4, line 19, before the period insert the following: “, including the degree to which participants obtain necessary vaccinations, as appropriate, and recommendations to improve initial and recurrent participation in the program”.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto.

No recorded votes were requested during consideration of H.R. 1300.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has held oversight hearings and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1300, the First Responder Anthrax Preparedness Act, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

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

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 24, 2015.

Hon. MICHAEL MCCAUL,
Chairman, Committee on Homeland Security, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1300, the First Responder Anthrax Preparedness Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Martin von Gnechten, and Rebecca Yip.

Sincerely,

KEITH HALL.

Enclosure.

H.R. 1300—First Responder Anthrax Preparedness Act

H.R. 1300 would direct the Department of Homeland Security (DHS), in consultation with the Department of Health and Human

Services (HHS), to provide anthrax vaccines from the Strategic National Stockpile to first responders who volunteer to receive them. Under the bill, DHS would establish a tracking system for the vaccine and would provide educational outreach for the program. The bill would direct DHS, in coordination with HHS, to establish a pilot program in at least two states to begin providing the vaccine.

Based on information provided by DHS and HHS, CBO estimates that implementing H.R. 1300 would cost about \$4 million over the 2016–2020 period, assuming appropriation of the necessary amounts. Enacting H.R. 1300 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 1300 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

The CBO staff contacts for this estimate are Martin von Gnechten (for the Department of Homeland Security) and Rebecca Yip (for the Department of Health and Human Services). The estimate was approved by H. Samuel Papenfuss, Deputy Assistant Director for Budget Analysis.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 1300 contains the following general performance goals and objectives, including outcome related goals and objectives authorized. H.R. 1300 directs the Secretary of DHS to carry out a pilot program with a duration of at least 18 months to provide, on a voluntary basis, anthrax vaccines to emergency response providers. Within one year of the enactment of this act, the Secretary of DHS must establish certain preliminary requirements prior to the implementation of the pilot program to include a communication platform, education and training modules, economic analysis, and a logistical platform for the anthrax vaccine request process.

H.R. 1300 also directs the Secretary of DHS to report within one year of enactment of H.R. 1300 on the progress and results of the pilot program, in addition to a plan to continue to make vaccines and antimicrobials available to emergency response providers.

DUPLICATIVE FEDERAL PROGRAMS

Pursuant to clause 3(c) of rule XIII, the Committee finds that H.R. 1300 does not contain any provision that establishes or reauthorizes a program known to be duplicative of another Federal program.

CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with rule XXI of the Rules of the House of Representatives, this bill, as reported, contains no congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of the rule XXI.

FEDERAL MANDATES STATEMENT

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

PREEMPTION CLARIFICATION

In compliance with section 423 of the Congressional Budget Act of 1974, requiring the report of any Committee on a bill or joint resolution to include a statement on the extent to which the bill or joint resolution is intended to preempt State, local, or Tribal law, the Committee finds that H.R. 1300 does not preempt any State, local, or Tribal law.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that H.R. 1300 would require no directed rule makings.

ADVISORY COMMITTEE STATEMENT

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

APPLICABILITY TO LEGISLATIVE BRANCH

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

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section provides that bill may be cited as the “First Responder Anthrax Preparedness Act.”

Section 2. Anthrax vaccination program for first responders

This section amends Title V of the Homeland Security Act of 2002 (Public Law 107–296; 6 U.S.C. 311 *et seq.*) by adding a new section at the end titled “Anthrax Preparedness” and establishes a voluntary anthrax vaccination program for emergency response providers.

This Section directs the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services, to establish a program to provide surplus vaccines from the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) to emergency response providers who voluntarily consent. It specifies that the program shall establish necessary logistical and tracking systems to facilitate making such vaccines available and shall distribute disclosures regarding associated benefits and risks to emergency response providers.

Threat assessment

This section directs the Secretary of DHS to support homeland security-focused risk analysis and risk assessments of the threats posed by anthrax from an act of terror; leverage existing and

emerging homeland security intelligence capabilities and structures to enhance prevention, protection, response, and recovery efforts with respect to an anthrax terror attack; and share information and provide analytical support on threats posed by anthrax to State, local, and tribal authorities, as well as national biosecurity and biodefense stakeholders.

Pilot program

This section directs the Secretary of DHS to carry out a pilot program to administer anthrax vaccines to emergency response providers, on a voluntary basis. The pilot program shall have a duration of at least 18 months and shall have participation of at least two states. This section delineates preliminary requirements for implementing the pilot program and requires the Secretary to provide information to pilot participants on benefits and risks of the anthrax vaccine and exposure to anthrax.

Report

This section requires an annual report on progress of the pilot and future plans for the program.

The Committee understands that there will be data and information generated as the pilot program is implemented. Therefore the Committee directs that the report include information on the percentage of eligible responders in a pilot location who elect to participate in the voluntary vaccination program. Additionally, since the anthrax vaccine requires a number of immunizations over many months, the Committee requires OHA to report on the degree to which participants receive all necessary immunizations.

Deadline

This section requires that the Department begin implementation of the pilot program within one year of enactment of H.R. 1300.

The Committee is supportive of the pre-event anthrax vaccine program. The Committee is concerned that OHA has been working on this pilot effort since 2012 and there are still many milestones to achieve before the pilot program rolls out. However, the Committee is encouraged that DHS has hired dedicated personnel to support the effort.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

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

HOMELAND SECURITY ACT OF 2002

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Homeland Security Act of 2002”.

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

* * * * *

TITLE V—NATIONAL EMERGENCY MANAGEMENT

* * * * *
Sec. 526. Anthrax preparedness.
* * * * *

**TITLE V—NATIONAL EMERGENCY
MANAGEMENT**

* * * * *

SEC. 526. ANTHRAX PREPAREDNESS.

(a) PRE-EVENT ANTHRAX VACCINATION PROGRAM FOR EMERGENCY RESPONSE PROVIDERS.—For the purpose of domestic preparedness for and collective response to terrorism, the Secretary, in consultation with the Secretary of Health and Human Services, shall establish a program to provide surplus anthrax vaccines from the strategic national stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)) to emergency response providers for administration to such providers who voluntarily consent to such administration, and shall—

- (1) establish any necessary logistical and tracking systems to facilitate making such vaccines so available;*
- (2) distribute disclosures regarding associated benefits and risks to end users; and*
- (3) conduct outreach to educate emergency response providers about the voluntary program.*

(b) THREAT ASSESSMENT.—The Secretary shall—

- (1) support homeland security-focused risk analysis and risk assessments of the threats posed by anthrax from an act of terror;*
- (2) leverage existing and emerging homeland security intelligence capabilities and structures to enhance prevention, protection, response, and recovery efforts with respect to an anthrax terror attack; and*
- (3) share information and provide tailored analytical support on threats posed by anthrax to State, local, and tribal authorities, as well as other national biosecurity and biodefense stakeholders.*

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COMMITTEE CORRESPONDENCE

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, July 21, 2015.

Hon. MICHAEL T. MCCAUL,
*Chairman, Committee on Homeland Security,
Ford House Office Building, Washington, DC.*

DEAR CHAIRMAN MCCAUL: I write in regard to H.R. 1300, First Responder Anthrax Preparedness Act, which was ordered to be reported by the Committee on Homeland Security on May 20, 2015. As you are aware, the bill also was referred to the Committee on Energy and Commerce. I wanted to notify you that the Committee on Energy and Commerce will forgo action on H.R. 1300 so that it may proceed expeditiously to the House floor for consideration.

This is done with the understanding that the Committee on Energy and Commerce's jurisdictional interests over this and similar legislation are in no way diminished or altered. In addition, the Committee reserves the right to seek conferees on H.R. 1300 and requests your support when such a request is made.

I would appreciate your response confirming this understanding with respect to H.R. 1300 and ask that a copy of our exchange of letters on this matter be included in the Congressional Record during consideration of the bill on the House floor.

Sincerely,

FRED UPTON,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC, July 22, 2015.

Hon. FRED UPTON,
*Chairman, Committee on Energy and Commerce,
Rayburn House Office Building, Washington, DC.*

DEAR CHAIRMAN UPTON: Thank you for your letter regarding H.R. 1300, the "First Responder Anthrax Preparedness Act." I appreciate your support in bringing this legislation before the House of Representatives, and accordingly, understand that the Committee on Energy and Commerce will forego consideration of the bill.

The Committee on Homeland Security concurs with the mutual understanding that by foregoing consideration on this bill at this time, the Committee on Energy and Commerce does not waive any jurisdiction over the subject matter contained in this bill or similar legislation in the future. In addition, should a conference on this bill be necessary, I would support a request by the Committee on

Energy and Commerce for conferees on those provisions within your jurisdiction.

I will insert copies of this exchange in the Congressional Record during consideration of this bill on the House floor. I thank you for your cooperation in this matter.

Sincerely,

MICHAEL T. MCCAUL,
Chairman.

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