

Calendar No. 458

114TH CONGRESS }
2d Session }

SENATE

{ REPORT
114-251

FIRST RESPONDER ANTHRAX
PREPAREDNESS ACT

R E P O R T

OF THE

COMMITTEE ON HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

TO ACCOMPANY

S. 1915

TO DIRECT THE SECRETARY OF HOMELAND SECURITY TO MAKE
ANTHRAX VACCINES AND ANTIMICROBIALS AVAILABLE TO
EMERGENCY RESPONSE PROVIDERS, AND FOR OTHER PURPOSES



MAY 9, 2016.—Ordered to be printed

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FIRST RESPONDER ANTHRAX PREPAREDNESS ACT

MAY 9, 2016.—Ordered to be printed

Mr. JOHNSON, from the Committee on Homeland Security and Governmental Affairs, submitted the following

R E P O R T

[To accompany S. 1915]

The Committee on Homeland Security and Governmental Affairs, to which was referred the bill (S. 1915) 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, reports favorably thereon with an amendment and an amendment to the title and recommends that the bill, as amended, do pass.

CONTENTS

	Page
I. Purpose and Summary	1
II. Background and Need for the Legislation	2
III. Legislative History	4
IV. Section-by-Section Analysis	4
V. Evaluation of Regulatory Impact	5
VI. Congressional Budget Office Cost Estimate	6
VII. Changes in Existing Law Made by the Bill, as Reported	7

I. PURPOSE AND SUMMARY

The purpose of S. 1915, the First Responder Anthrax Preparedness Act, as reported by the Committee, is to require the Secretary of the Department of Homeland Security (“DHS” or “the Department”) to establish a pilot program to make available anthrax vaccines that are in the Strategic National Stockpile (SNS) and reaching the end of their labeled dates of use to emergency response providers. The program will be coordinated with the Secretary of the Department of Health and Human Services (HHS).

II. BACKGROUND AND THE NEED FOR LEGISLATION

HHS procures and stores medical countermeasures in the SNS to ensure the nation is prepared for public health emergencies, such as an intentional release of *Bacillus anthracis* or other high-risk pathogens.¹

Anthrax has been labeled by DHS as a material threat to national security since 2004.² Since 2005, HHS has procured BioThrax, a vaccine used for prevention of anthrax disease, for the SNS.³ In 2011, HHS contracted to purchase up to 44.75 million doses of BioThrax to be delivered to the stockpile over five years.⁴ The total cost of the contract was reported to be worth up to \$1.25 billion.⁵

BioThrax is the only vaccine currently approved by the Food and Drug Administration (FDA) for pre-exposure prophylaxis of anthrax disease in individuals who are at high-risk of exposure.⁶ The vaccine is also approved for post-exposure prophylaxis of anthrax disease, when combined with the recommended course of antimicrobial therapy in persons 18 through 65 years of age.⁷ The dosing schedule for pre-exposure prophylaxis requires five doses over 18 months, with a booster shot every 12 months thereafter to maintain efficacy of the immunization.⁸ The post-exposure dosing schedule is three shots over the course of four weeks, combined with antimicrobial therapy.⁹

As with other vaccines and medical countermeasures, purchased lots of BioThrax cannot be held in the SNS indefinitely. BioThrax has an FDA-approved shelf life of four years.¹⁰ The vaccine cannot be legally administered after the labeled date has lapsed, without a special extension from the FDA.¹¹ Vaccines in the SNS are generally destroyed after reaching the end of their labeled dates of use.¹²

¹ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, STRATEGIC NATIONAL STOCKPILE, available at <http://www.cdc.gov/phpr/stockpile/stockpile.htm>; see also GOV'T ACCOUNTABILITY OFFICE, GAO-14-690, NATIONAL PREPAREDNESS: HHS IS MONITORING THE PROGRESS OF ITS MEDICAL COUNTERMEASURE EFFORTS BUT HAS NOT PROVIDED PREVIOUSLY RECOMMENDED SPENDING ESTIMATES 2 (2014), available at <http://gao.gov/assets/660/659949.pdf>.

² Memorandum from Michael Chertoff, U.S. Sec'y of Homeland Security, to Michael O. Leavitt, U.S. Sec'y of Health and Human Services (Sept. 23, 2008), available at http://www.dhs.gov/xlibrary/assets/ofsec_signed_determination092308.pdf.

³ U.S. DEP'T OF HEALTH AND HUMAN SERVICES, OFFICE OF THE ASSISTANT SEC'Y FOR PREPAREDNESS AND RESPONSE, PROJECT BIOSHIELD ANNUAL REPORT TO CONGRESS: JANUARY 2011–DECEMBER 2011 4 (undated), available at https://www.medicalcountermeasures.gov/media/10061/pbs_report_2011_final_9-6-2012.pdf.

⁴ *Emergent BioSolutions Receives Award to Supply 44.75 Million Doses of BioThrax to U.S. Government over Five Years*, Emergent BioSolutions, Inc. (Oct. 3, 2011), available at <http://investors.emergentbiosolutions.com/phoenix.zhtml?c=202582&p=irol-newsArticle&ID=1612431>.

⁵ *Id.*
⁶ U.S. Food and Drug Admin., *Complete List of Vaccines Licensed for Immunization and Distribution in the U.S.* (last updated Dec. 3, 2015), available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>; see also U.S. Food and Drug Admin., *BioThrax* (last updated Dec. 1, 2015), available at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm133822.htm>.

⁷ *Id.*
⁸ U.S. FOOD AND DRUG ADMIN., PACKAGE INSERT AND INFORMATION FOR PATIENTS—BIOTHRAX 1 (Nov. 2015), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/UCM074923.pdf>.

⁹ *Id.*
¹⁰ *Emergent BioSolutions Receives FDA Approval Extending Shelf Life of BioThrax (Anthrax Vaccine Adsorbed) to 4 Years*, Emergent BioSolutions, Inc. (Jun. 10, 2009), available at <http://investors.emergentbiosolutions.com/phoenix.zhtml?c=202582&p=irol-newsArticle&ID=1298056>.

¹¹ 21 C.F.R. 610.53 (2011).
¹² GOV'T ACCOUNTABILITY OFFICE, GAO-14-690, PROJECT BIOSHIELD: ACTIONS NEEDED TO AVOID REPEATING PAST PROBLEMS WITH PROCURING NEW ANTHRAX VACCINE AND MANAGING

Rather than dispose of these doses, the Federal Government could identify stockpiled anthrax vaccine doses that are close to being cycled out and offer them to emergency responders across the nation who are at high-risk of exposure to anthrax. Since 2011, DHS has been developing a pilot program to test the feasibility of this use for BioThrax held in the SNS.¹³

Having a cadre of emergency responders who are immunized against anthrax may enable a quicker and more effective response to an anthrax attack. Immunized responders may be more willing to render their service, knowing they are protected from infection.

It is unclear, however, whether creating a permanent Federal program to distribute such a vaccine on a voluntary basis would be effective in increasing pre-exposure prophylaxis among emergency responders. BioThrax is already commercially available to emergency responders and emergency response agencies, with valid prescriptions.

A pilot program will enable DHS to work with emergency responders in a limited number of states to assess the potential opportunities and interest in increasing the use of the vaccine among emergency responders, and to promote improved preparedness for a release of anthrax. This bill will provide statutory authority for such a pilot program and strengthen accountability in this ongoing effort. The Department will be required to provide an annual report to several Congressional committees on the costs resulting from the program, associated staff resources, and data about the number of participants. In a final report after the program ends, DHS will provide analysis on the costs and benefits of whether the program should be continued.

Implementing the pilot program in close coordination with HHS will be essential to its success. HHS is the lead department tasked with planning and overseeing the Federal response to a public health emergency. Utilizing this experience will be vital to the pilot program. DHS and HHS also need to collaborate to ensure the resources of the SNS are adequately maintained and planned for through the duration of the pilot program.

Because resources to operate the pilot program are limited, the Secretary of DHS should focus the efforts of the pilot program on regions and emergency response jurisdictions that are at highest risk of a terrorist attack utilizing anthrax. Efforts to vaccinate first responders in each state or jurisdiction should be part of a holistic response strategy that incorporates the risks and benefits for communities and first responders themselves.

The Secretary of DHS should work closely with participating state and local governments and entities, whose emergency response providers may be eligible for the program, to ensure the pilot program is optimally utilized to improve any potential response to a release of anthrax. For example, a community may benefit the most when efforts are focused on vaccinating a cadre of responders who will likely be the primary responders in the event of a release.

THE STOCKPILE OF LICENSED VACCINE 27 (2007), available at <http://www.gao.gov/assets/270/268295.pdf>.

¹³*Taking Measure of Countermeasures (Part 3): Protecting the Protectors: Hearing Before the Subcomm. on Emergency Preparedness, Response, and Communications of the H. Comm. on Homeland Security*, 112th Cong. (2012) (statement of Dr. James Polk, Principal Deputy Assistant Secretary and Deputy Chief Medical Officer, Department of Homeland Security).

This pilot program, or any similar program, should not impact what kinds and quantities of medical countermeasures are procured for the SNS. At any point in the future, the type and amount of anthrax vaccine in the stockpile may change, potentially limiting the ability of the Federal Government to distribute excess vaccines. Procurement decisions for the stockpile are solely made on the basis of the threats and risks posed by high-risk pathogens and other chemical, radiological, or nuclear agents.

III. LEGISLATIVE HISTORY

Representative Peter King introduced H.R. 1300, the First Responder Anthrax Preparedness Act, on March 4, 2015, which was referred to the House Committee on Homeland Security, and House Committee on Energy and Commerce. The House of Representatives passed the act on July 29, 2015. It was received in the Senate, read twice, and referred to the Committee on Homeland Security and Governmental Affairs.

On August 3, 2015, Senators Kelly Ayotte, Cory Booker, and Christopher Coons introduced S. 1915, an identical companion to H.R. 1300, which was referred to the Committee on Homeland Security and Governmental Affairs.

The Committee considered S. 1915 at a business meeting on December 9, 2015. A modified substitute amendment was offered by Senator Ayotte and Senator Ron Johnson that removed the permanent authorization for the program, bolstered reporting requirements, required stronger coordination between DHS and HHS, and added a five-year sunset to the pilot program. The amendment also increased the duration of the pilot program from 24 to 36 months, and required information about the anthrax vaccine, published by the Centers for Disease Control and Prevention (CDC), to be distributed to program participants, rather than similar information published by the FDA.

The Committee approved the Ayotte-Johnson modified substitute amendment, and ordered the bill, as amended, be reported favorably by voice vote. Senators present for both the vote on the amendment and the vote on final passage were: Johnson, Portman, Lankford, Ayotte, Ernst, Carper, Tester, Baldwin, and Booker.

IV. SECTION-BY-SECTION ANALYSIS OF THE BILL, AS REPORTED

Section 1. Short title

This section provides the bill's short title, the "First Responder Anthrax Preparedness Act."

Section 2. Voluntary pre-event anthrax vaccination pilot program for emergency response providers

Subsection (a) requires the Secretary of DHS, in coordination with the Secretary of HHS, to carry out a pilot program to provide anthrax vaccines reaching the end of their labeled dates of use from the SNS to emergency response providers. Participation in the pilot program is voluntary for first responders. The duration of the pilot program is set at 36 months from the date on which the initial vaccines are administered.

This subsection also requires the Secretary of DHS, before implementing the pilot program, to develop communication, education

and training tools, as well as a system to manage requests for vaccine under the pilot program. The Secretary of DHS is also required to develop a comprehensive economic analysis of expected costs and benefits prior to implementation of the pilot program, as well as establish goals and desired outcomes for the pilot.

The Secretary of DHS must select emergency response providers in no less than two states, but not more than five states, for participation in the pilot program. The Secretary of DHS, in coordination with the Secretary of HHS, is required to provide guidance to states and units of local governments to aid them in determining which emergency response providers are at high risk of exposure to anthrax.

Participating emergency responders are to receive information published by the CDC about anthrax vaccines and a notice that the Federal Government is not obligated to continue providing doses of the vaccine to participants after the pilot program ends.

This subsection also requires the Secretary of DHS to enter into a memorandum of understanding with the Secretary of HHS to define roles and responsibilities for the pilot program, and to establish other performance metrics and policies as appropriate.

This subsection also establishes reporting requirements for the pilot program. The Secretary of DHS, in coordination with the Secretary of HHS, is required to submit an annual report to relevant Congressional committees providing detailed tabulations of the costs of the program, data on participation and the number of vaccine doses administered, and recommendations for improving participation. The final report shall include an analysis of the costs and benefits of continuing the program, an explanation of the benefits of administering vaccines through the pilot program rather than post-event treatment, and a plan under which the program could be continued.

Subsection (b) requires the Secretary of DHS to implement the program not later than one year after the date of enactment of this Act.

Subsection (c) terminates the statutory authority to operate the pilot program five years after the enactment of S. 1915. This sunset provides a clear deadline for Congress and DHS to examine the merits of whether the program should be modified and continued.

V. EVALUATION OF REGULATORY IMPACT

Pursuant to the requirements of paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee has considered the regulatory impact of this bill and determined that the bill will have no regulatory impact within the meaning of the rules. The Committee agrees with the Congressional Budget Office's statement that the bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

VI. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

JANUARY 15, 2016.

Hon. RON JOHNSON, *Chairman,*
Committee on Homeland Security and Governmental Affairs,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1915, 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 Mark Grabowicz and Rebecca Yip.

Sincerely,

KEITH HALL.

Enclosure.

S. 1915—First Responder Anthrax Preparedness Act

S. 1915 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 S. 1915 would cost about \$4 million over the 2016–2020 period, assuming appropriation of the necessary amounts.

Enacting S. 1915 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. CBO estimates that enacting S. 1915 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2026.

S. 1915 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.

On June 24, 2015, CBO transmitted a cost estimate for H.R. 1300, the First Responder Anthrax Preparedness Act, as ordered reported by the House Committee on Homeland Security on May 20, 2015. CBO's estimate of the budgetary effects of implementing both pieces of legislation is the same.

The CBO staff contacts for this estimate are Mark Grabowicz (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.

VII. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

Because S. 1915 would not repeal or amend any provision of current law, it would make no changes in existing law within the meaning of clauses (a) and (b) of paragraph 12 of rule XXVI of the Standing Rules of the Senate.

