

Calendar No. 458

114TH CONGRESS
2^D SESSION

S. 1915

[Report No. 114–251]

To direct the Secretary of Homeland Security to make anthrax vaccines and antimicrobials available to emergency response providers, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2015

Ms. AYOTTE (for herself, Mr. BOOKER, Mr. COONS, Mrs. FEINSTEIN, Mr. HOEVEN, Mr. WICKER, Mr. ROUNDS, Ms. BALDWIN, Mr. COCHRAN, Mrs. CAPITO, Mr. PETERS, Mr. CASEY, Mr. CARDIN, Mr. GARDNER, Mr. BARRASSO, Mr. DONNELLY, Mr. DAINES, and Mr. KIRK) introduced the following bill; which was read twice and referred to the Committee on Homeland Security and Governmental Affairs

MAY 9, 2016

Reported by Mr. JOHNSON, with an amendment and an amendment to the title

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

A BILL

To direct the Secretary of Homeland Security to make anthrax vaccines and antimicrobials available to emergency response providers, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “First Responder An-
3 thrax Preparedness Act”.

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

6 (a) ANTHRAX PREPAREDNESS.—

7 (1) IN GENERAL.—Title V of the Homeland Se-
8 curity Act of 2002 (6 U.S.C. 311 et seq.) is amend-
9 ed by adding at the end the following new section:

10 **“SEC. 526. ANTHRAX PREPAREDNESS.**

11 **“(a) PRE-EVENT ANTHRAX VACCINATION PROGRAM**
12 **FOR EMERGENCY RESPONSE PROVIDERS.—**For the pur-
13 pose of domestic preparedness for and collective response
14 to terrorism, the Secretary, in coordination with the Sec-
15 retary of Health and Human Services, shall—

16 “(1) establish a program to provide anthrax
17 vaccines from the strategic national stockpile under
18 section 319F-2(a) of the Public Health Service Act
19 (42 U.S.C. 247d-6b(a)) that will be nearing the end
20 of their labeled dates of use at the time such vac-
21 cines are to be administered to emergency response
22 providers who are at high risk of exposure to an-
23 thrax and who voluntarily consent to such adminis-
24 tration;

1 “(2) establish any necessary logistical and
2 tracking systems to facilitate making the vaccines
3 described in paragraph (1) so available;

4 “(3) distribute disclosures regarding associated
5 benefits and risks to end users; and

6 “(4) conduct outreach to educate emergency re-
7 sponse providers about the voluntary program.

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

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

12 “(2) leverage existing and emerging homeland
13 security intelligence capabilities and structures to
14 enhance prevention, protection, response, and recov-
15 ery efforts with respect to an anthrax terror attack;
16 and

17 “(3) share information and provide tailored an-
18 alytical support on threats posed by anthrax to
19 State, local, and tribal authorities, as well as other
20 national biosecurity and biodefense stakeholders.”.

21 “(2) CLERICAL AMENDMENT.—The table of con-
22 tents in section 1(b) of such Act is amended by in-
23 sserting at the end of the items relating to title V the
24 following new item:

“Sec. 526. Anthrax preparedness.”.

25 “(b) PILOT PROGRAM.—

1 (1) IN GENERAL.—In carrying out the pre-
2 event vaccination program authorized under section
3 526(a) of the Homeland Security Act of 2002, as
4 added by subsection (a), the Secretary of Homeland
5 Security, in coordination with the Secretary of
6 Health and Human Services, shall carry out a pilot
7 program to provide anthrax vaccines to emergency
8 response providers as so authorized. The duration of
9 the pilot program shall be 24 months from the date
10 the initial vaccines are administered to participants.

11 (2) PRELIMINARY REQUIREMENTS.—Prior to
12 implementing the pilot program under paragraph
13 (1), the Secretary of Homeland Security shall—

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

16 (B) establish education and training mod-
17 ules for the pilot program;

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

20 (D) create a logistical platform for the an-
21 thrax vaccine request process under the pilot
22 program.

23 (3) LOCATION.—In carrying out the pilot pro-
24 gram under this subsection, the Secretary of Home-
25 land Security shall select emergency response pro-

1 viders based in not less than 2 States for participa-
2 tion in the pilot program.

3 (4) DISTRIBUTION OF INFORMATION.—The
4 Secretary of Homeland Security shall provide to
5 each emergency response provider who participates
6 in the pilot program under this subsection disclo-
7 sures and educational materials regarding the asso-
8 ciated benefits and risks of any vaccine provided
9 under the pilot program and of exposure to anthrax.

10 (5) REPORT.—

11 (A) IN GENERAL.—Not later than 1 year
12 after the date of enactment of this Act, and an-
13 nually thereafter until 1 year after the comple-
14 tion of the pilot program, the Secretary of
15 Homeland Security shall submit to the Com-
16 mittee on Homeland Security and the Com-
17 mittee on Energy and Commerce of the House
18 of Representatives and the Committee on
19 Homeland Security and Governmental Affairs
20 of the Senate a report on the progress and re-
21 sults of the pilot program, including—

22 (i) the percentage of eligible emer-
23 gency response providers, as determined by
24 each pilot location, that volunteer to par-
25 ticipate;

1 (ii) the degree to which participants
2 obtain necessary vaccinations, as appro-
3 priate; and

4 (iii) recommendations to improve ini-
5 tial and recurrent participation in the pilot
6 program.

7 (B) **REQUIRED PLAN.**—The report re-
8 quired under subparagraph (A) shall include a
9 plan under which the Secretary plans to con-
10 tinue the program to provide vaccines to emer-
11 gency response providers under section 526(a)
12 of the Homeland Security Act of 2002, as
13 added by subsection (a).

14 (6) **DEADLINE FOR IMPLEMENTATION.**—Not
15 later than 1 year after the date of enactment of this
16 Act, the Secretary of Homeland Security shall begin
17 implementing the pilot program under this sub-
18 section.

19 **SECTION 1. SHORT TITLE.**

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

22 **SEC. 2. VOLUNTARY PRE-EVENT ANTHRAX VACCINATION**
23 **PILOT PROGRAM FOR EMERGENCY RESPONSE**
24 **PROVIDERS.**

25 (a) **PILOT PROGRAM.**—

1 (1) *ESTABLISHMENT.*—*The Secretary of Home-*
2 *land Security, in coordination with the Secretary of*
3 *Health and Human Services, shall carry out a pilot*
4 *program to provide anthrax vaccines from the stra-*
5 *tegic national stockpile under section 319F–2(a) of*
6 *the Public Health Service Act (42 U.S.C. 247d–6b(a))*
7 *that will be nearing the end of their labeled dates of*
8 *use at the time such vaccines are to be administered*
9 *to emergency response providers who are at high risk*
10 *of exposure to anthrax and who voluntarily consent*
11 *to such administration.*

12 (2) *DURATION.*—*The duration of the pilot pro-*
13 *gram required under paragraph (1) shall be 36*
14 *months beginning on the date on which the initial*
15 *vaccines are administered.*

16 (3) *PRELIMINARY REQUIREMENTS.*—*Before im-*
17 *plementing the pilot program under paragraph (1),*
18 *the Secretary of Homeland Security, in coordination*
19 *with the Secretary of Health and Human Services,*
20 *shall—*

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

23 (B) *develop and deliver education and*
24 *training for the pilot program;*

1 (C) conduct an economic analysis of the
2 pilot program, including a preliminary estimate
3 of total costs and expected benefits;

4 (D) create a logistical platform for the an-
5 thrax vaccine request process under the pilot pro-
6 gram; and

7 (E) establish goals and desired outcomes for
8 the pilot program.

9 (4) LOCATION.—In carrying out the pilot pro-
10 gram under this subsection, the Secretary of Home-
11 land Security shall select emergency response pro-
12 viders based in not less than 2 nor more than 5
13 States for participation in the pilot program.

14 (5) GUIDANCE FOR SELECTION.—To ensure that
15 participation in the pilot program strategically in-
16 creases State and local response readiness for an an-
17 thrax release, the Secretary of Homeland Security, in
18 coordination with the Secretary of Health and
19 Human Services, shall provide guidance to partici-
20 pating States and units of local government on iden-
21 tifying emergency response providers who are at high
22 risk of exposure to anthrax.

23 (6) DISTRIBUTION OF INFORMATION.—The Sec-
24 retary of Homeland Security shall provide to each
25 emergency response provider who participates in the

1 *pilot program under this subsection disclosures and*
2 *educational materials regarding the associated bene-*
3 *fits and risks of any vaccine provided under the pilot*
4 *program, consistent with Centers for Disease Control*
5 *and Prevention clinical guidance, and of exposure to*
6 *anthrax, including notice that the Federal Govern-*
7 *ment is not obligated to continue providing anthrax*
8 *vaccines after the pilot program has ended.*

9 (7) *MEMORANDUM OF UNDERSTANDING.—Before*
10 *implementing the pilot program under this sub-*
11 *section, the Secretary of Homeland Security shall*
12 *enter into a memorandum of understanding with the*
13 *Secretary of Health and Human Services to—*

14 (A) *define the roles and responsibilities of*
15 *each Department for the pilot program; and*

16 (B) *establish other performance metrics or*
17 *policies, as appropriate.*

18 (8) *REPORT.—*

19 (A) *IN GENERAL.—Not later than 1 year*
20 *after the date on which the initial vaccines are*
21 *administered under this section, and annually*
22 *thereafter until 1 year after the completion of the*
23 *pilot program, the Secretary of Homeland Secu-*
24 *rity, in coordination with the Secretary of*
25 *Health and Human Services, shall submit to the*

1 *Committee on Homeland Security and the Com-*
2 *mittee on Energy and Commerce of the House of*
3 *Representatives and the Committee on Homeland*
4 *Security and Governmental Affairs and the*
5 *Committee on Health, Education, Labor, and*
6 *Pensions of the Senate a report on the progress*
7 *and results of the pilot program, including—*

8 *(i) a detailed tabulation of the costs to*
9 *administer the program, including—*

10 *(I) total costs for management*
11 *and administration;*

12 *(II) total costs to ship vaccines;*
13 *and*

14 *(III) the total number of full-time*
15 *equivalents allocated to the program;*

16 *(ii) the number and percentage of eligi-*
17 *ble emergency response providers, as deter-*
18 *mined by each pilot location, that volunteer*
19 *to participate;*

20 *(iii) the degree to which participants*
21 *obtain the necessary vaccinations;*

22 *(iv) the total number of doses of vac-*
23 *cine administered; and*

1 (v) *recommendations to improve initial*
2 *and recurrent participation in the pilot*
3 *program.*

4 (B) *FINAL REPORT.*—*The final report re-*
5 *quired under subparagraph (A) shall include an*
6 *analysis of the costs and benefits of continuing*
7 *the program to provide anthrax vaccines to*
8 *emergency response providers, an explanation of*
9 *the economic, health, and other benefits of ad-*
10 *ministering vaccines through the pilot program*
11 *rather than post-event treatment, and a plan*
12 *under which the program could be continued.*

13 (b) *DEADLINE FOR IMPLEMENTATION.*—*Not later than*
14 *1 year after the date of enactment of this Act, the Secretary*
15 *of Homeland Security shall begin implementing the pilot*
16 *program under this section.*

17 (c) *SUNSET.*—*The authority to carry out the pilot pro-*
18 *gram under this section shall expire on the date that is 5*
19 *years after the date of enactment of this Act.*

Amend the title so as to read: “A bill to direct the Secretary of Homeland Security to make anthrax vaccines available to emergency response providers, and for other purposes.”.

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