

114TH CONGRESS
1ST SESSION

S. 2055

To amend the Public Health Service Act and the Federal Food, Drug,
and Cosmetic Act with respect to national health security.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 17, 2015

Mr. BURR (for himself and Mr. CASEY) introduced the following bill; which
was read twice and referred to the Committee on Health, Education,
Labor, and Pensions

A BILL

To amend the Public Health Service Act and the Federal
Food, Drug, and Cosmetic Act with respect to national
health security.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Counter-
5 measure Innovation Act of 2015”.

6 **SEC. 2. MEDICAL COUNTERMEASURE GUIDELINES.**

7 (a) STRATEGIC NATIONAL STOCKPILE AND SECUR-
8 RITY COUNTERMEASURE PROCUREMENTS.—Section

1 319F–2 of the Public Health Service Act (42 U.S.C.
2 247d–6b) is amended—

3 (1) in subsection (a), by adding at the end the
4 following:

5 “(3) UTILIZATION GUIDELINES.—The Secretary
6 shall ensure timely and accurate recommended utili-
7 zation guidelines for qualified countermeasures (as
8 defined in section 319F–1), qualified pandemic and
9 epidemic products (as defined in section 319F–3),
10 and security countermeasures (as defined in sub-
11 section (c)), including for such products in the
12 stockpile.”; and

13 (2) in subsection (g)—

14 (A) by amending paragraph (4) to read as
15 follows:

16 “(4) REPORT ON SECURITY COUNTERMEASURE
17 PROCUREMENT.—Not later than March 1 of each
18 year in which the Secretary determines that the
19 amount of funds available for procurement of secu-
20 rity countermeasures is less than \$1,500,000,000,
21 the Secretary shall submit to the Committee on Ap-
22 propriations and the Committee on Health, Edu-
23 cation, Labor, and Pensions of the Senate and the
24 Committee on Appropriations and the Committee on
25 Energy and Commerce of the House of Representa-

1 tives a report detailing the amount of such funds
2 available for procurement and the impact such
3 amount of funding will have—

4 “(A) in meeting the security counter-
5 measure needs identified under this section; and

6 “(B) on the annual Public Health Emer-
7 gency Medical Countermeasures Enterprise and
8 Strategy Implementation Plan (pursuant to sec-
9 tion 2811(d)).”.

10 **SEC. 3. CLARIFICATION ON BARDA CONTRACTING AUTHOR-**
11 **ITY.**

12 (a) IN GENERAL.—Section 319F–2(g) of the Public
13 Health Service Act (42 U.S.C. 247d–6b(g)) is amended
14 by adding at the end the following:

15 “(5) CLARIFICATION ON CONTRACTING AU-
16 THORITY.—The Secretary, acting through the Direc-
17 tor of the Biomedical Advanced Research and Devel-
18 opment Authority, shall carry out the programs
19 funded by the special reserve fund (for the procure-
20 ment of security countermeasures under subsection
21 (c) and for carrying out section 319L), including the
22 execution of procurement contracts, grants, and co-
23 operative agreements pursuant to this section and
24 section 319L.”.

1 (b) BARDA CONTRACTING AUTHORITY.—Section
2 319L(c)(3) of the Public Health Service Act (42 U.S.C.
3 247d–7c) is amended by inserting “, including the execu-
4 tion of procurement contracts, grants, and cooperative
5 agreements pursuant to this section” before the period.

6 **SEC. 4. COUNTERMEASURES BUDGET PLAN.**

7 Section 2811(b)(7) of the Public Health Service Act
8 (42 U.S.C. 300hh–10(b)(7)) is amended—

9 (1) by striking the first sentence and inserting
10 “Develop, and update not later than March 1 of
11 each year, a coordinated 5-year budget plan based
12 on the medical countermeasure priorities described
13 in subsection (d), including with respect to chemical,
14 biological, radiological, and nuclear agent or agents
15 that may present a threat to the Nation, including
16 such agents that are novel or emerging infectious
17 diseases, and the corresponding efforts to develop
18 qualified countermeasures (as defined in section
19 319F–1), security countermeasures (as defined in
20 section 319F–2), and qualified pandemic or epidemic
21 products (as defined in section 319F–3) for each
22 such threat.”;

23 (2) in subparagraph (C), by striking “; and”
24 and inserting a semicolon;

1 (3) in subparagraph (D), by striking “to the
2 appropriate committees of Congress upon request.”
3 and inserting “, not later than March 15 of each
4 year, to the Committee on Appropriations and the
5 Committee on Health, Education, Labor, and Pen-
6 sions of the Senate and the Committee on Appro-
7 priations and the Committee on Energy and Com-
8 merce of the House of Representatives; and”;

9 (4) by adding at the end the following:

10 “(E) not later than March 15 of each year,
11 be made publicly available.”.

12 **SEC. 5. PRIORITIZING THE ANIMAL RULE GUIDANCE.**

13 Section 565(c) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 360bbb–4(c)) is amended by adding
15 at the end the following:

16 “(3) WRITTEN EXPLANATION.—The Secretary
17 shall provide to the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate and the
19 Committee on Energy and Commerce of the House
20 of Representatives a written explanation, not later
21 than the last day of each month after the date of en-
22 actment of the Medical Countermeasure Innovation
23 Act of 2015 in which the Secretary fails to finalize
24 such guidance, for why the Secretary has failed to

1 finalize the guidance as required by this sub-
2 section.”.

3 **SEC. 6. STREAMLINING THE PROJECT BIOSHIELD PRO-**
4 **CUREMENT PROCESS.**

5 Section 319F–2(c) of the Public Health Service Act
6 (42 U.S.C. 247d–6b(c)) is amended—

7 (1) in paragraph (4)(A)(ii), by striking “make
8 a recommendation under paragraph (6) that the spe-
9 cial reserve fund as defined in subsection (h) be
10 made available for the procurement of such counter-
11 measure” and inserting “make available the special
12 reserve fund as defined in subsection (h) for pro-
13 curement of such countermeasure, as applicable”;

14 (2) in paragraph (6)—

15 (A) by striking subparagraphs (A), (B),
16 and (E);

17 (B) by redesignating subparagraphs (C)
18 and (D) as subparagraphs (A) and (B), respec-
19 tively;

20 (C) by amending subparagraph (A), as so
21 redesignated, to read as follows:

22 “(A) NOTICE TO APPROPRIATE CONGRES-
23 SIONAL COMMITTEES.—The Secretary shall no-
24 tify the Committee on Appropriations and the
25 Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Committee on
2 Appropriations and the Committee on Energy
3 and Commerce of the House of Representatives
4 of each decision to make available the special
5 reserve fund as defined in subsection (h) for
6 procurement of a security countermeasure, in-
7 cluding, where available, the number of, the na-
8 ture of, and other information concerning po-
9 tential suppliers of such countermeasure, and
10 whether other potential suppliers of the same or
11 similar countermeasures were considered and
12 rejected for procurement under this section and
13 the reasons therefore.”; and

14 (D) in the heading, by striking “REC-
15 OMMENDATION FOR PRESIDENT’S APPROVAL”
16 and inserting “RECOMMENDATIONS FOR PRO-
17 CUREMENT”; and

18 (3) in paragraph (7)—

19 (A) by striking subparagraph (A);

20 (B) by striking subparagraph (B) and in-
21 serting the following:

22 “(A) PAYMENTS FROM SPECIAL RESERVE
23 FUND.—The special reserve fund as defined in
24 subsection (h) shall be available for payments
25 made by the Secretary to a vendor for procure-

1 ment of a security countermeasure in accord-
2 ance with the provisions of this paragraph.”;
3 and

4 (C) by redesignating subparagraph (C) as
5 subparagraph (B).

6 **SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**
7 **FOR AGENTS THAT PRESENT NATIONAL SE-**
8 **CURITY THREATS.**

9 Subchapter E of chapter V of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
11 amended by inserting after section 565 the following:

12 **“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREAT-**
13 **MENTS FOR AGENTS THAT PRESENT NA-**
14 **TIONAL SECURITY THREATS.**

15 “(a) DEFINITIONS.—In this section:

16 “(1) The term ‘priority review’ with respect to
17 a human drug application as defined in section
18 735(1), means review and action by the Secretary on
19 such application not later than 6 months after re-
20 ceipt by the Secretary of such application, as de-
21 scribed in the Manual of Policies and Procedures in
22 the Food and Drug Administration and goals identi-
23 fied in the letters described in section 101(b) of the
24 Food and Drug Administration Safety and Innova-
25 tion Act.

1 “(2) PRIORITY REVIEW VOUCHER.—The term
2 ‘priority review voucher’ means a voucher issued by
3 the Secretary to the sponsor of a material threat
4 medical countermeasure application that entitles the
5 holder of such voucher to priority review of a single
6 human drug application submitted under section
7 505(b)(1) or section 351 of the Public Health Serv-
8 ice Act after the date of approval of the material
9 threat medical countermeasure application.

10 “(3) MATERIAL THREAT MEDICAL COUNTER-
11 MEASURE APPLICATION.—The term ‘material threat
12 medical countermeasure application’ means an appli-
13 cation that—

14 “(A) is a human drug application as de-
15 fined in section 735(1)—

16 “(i) to prevent, or treat harm from a
17 biological, chemical, radiological, or nuclear
18 agent identified as a material threat under
19 section 319F–2(e)(2)(A)(ii) of the Public
20 Health Service Act, or

21 “(ii) to mitigate, prevent, or treat
22 harm from a condition that may result in
23 adverse health consequences or death and
24 may be caused by administering a drug, or
25 biological product against such agent;

1 “(B) the Secretary deems eligible for pri-
2 ority review;

3 “(C) is approved after the date of enact-
4 ment of the Medical Countermeasure Innova-
5 tion Act of 2015; and

6 “(D) is for a human drug, no active ingre-
7 dient (including any ester or salt of the active
8 ingredient) of which has been approved in any
9 other application under section 505(b)(1) or
10 section 351 of the Public Health Service Act.

11 “(b) PRIORITY REVIEW VOUCHER.—

12 “(1) IN GENERAL.—The Secretary shall award
13 a priority review voucher to the sponsor of a mate-
14 rial threat medical countermeasure application upon
15 approval by the Secretary of such material threat
16 medical countermeasure application.

17 “(2) TRANSFERABILITY.—The sponsor of a ma-
18 terial threat medical countermeasure application
19 that receives a priority review voucher under this
20 section may transfer (including by sale) the entitle-
21 ment to such voucher to a sponsor of a human drug
22 for which an application under section 505(b)(1) or
23 section 351 of the Public Health Service Act will be
24 submitted after the date of the approval of the mate-
25 rial threat medical countermeasure application.

1 There is no limit on the number of times a priority
2 review voucher may be transferred before such
3 voucher is used.

4 “(3) NOTIFICATION.—

5 “(A) IN GENERAL.—The sponsor of a
6 human drug application shall notify the Sec-
7 retary not later than 90 calendar days prior to
8 submission of the human drug application that
9 is the subject of a priority review voucher of an
10 intent to submit the human drug application,
11 including the date on which the sponsor intends
12 to submit the application. Such notification
13 shall be a legally binding commitment to pay
14 for the user fee to be assessed in accordance
15 with this section.

16 “(B) TRANSFER AFTER NOTICE.—The
17 sponsor of a human drug application that pro-
18 vides notification of the intent of such sponsor
19 to use the voucher for the human drug applica-
20 tion under subparagraph (A) may transfer the
21 voucher after such notification is provided, if
22 such sponsor has not yet submitted the human
23 drug application described in the notification.

24 “(c) PRIORITY REVIEW USER FEE.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a user fee program under which a sponsor of a
3 human drug application that is the subject of a pri-
4 ority review voucher shall pay to the Secretary a fee
5 determined under paragraph (2). Such fee shall be
6 in addition to any fee required to be submitted by
7 the sponsor under chapter VII.

8 “(2) FEE AMOUNT.—The amount of the pri-
9 ority review user fee shall be determined each fiscal
10 year by the Secretary and based on the average cost
11 incurred by the agency in the review of a human
12 drug application subject to priority review in the
13 previous fiscal year.

14 “(3) ANNUAL FEE SETTING.—The Secretary
15 shall establish, before the beginning of each fiscal
16 year beginning after September 30, 2015, for that
17 fiscal year, the amount of the priority review user
18 fee.

19 “(4) PAYMENT.—

20 “(A) IN GENERAL.—The priority review
21 user fee required by this subsection shall be due
22 upon the submission of a human drug applica-
23 tion under section 505(b)(1) or section 351 of
24 the Public Health Service Act for which the pri-
25 ority review voucher is used.

1 “(B) COMPLETE APPLICATION.—An appli-
2 cation described under subparagraph (A) for
3 which the sponsor requests the use of a priority
4 review voucher shall be considered incomplete if
5 the fee required by this subsection and all other
6 applicable user fees are not paid in accordance
7 with the Secretary’s procedures for paying such
8 fees.

9 “(C) NO WAIVERS, EXEMPTIONS, REDUC-
10 TIONS, OR REFUNDS.—The Secretary may not
11 grant a waiver, exemption, reduction, or refund
12 of any fees due and payable under this section.

13 “(5) OFFSETTING COLLECTIONS.—Fees col-
14 lected pursuant to this subsection for any fiscal
15 year—

16 “(A) shall be deposited and credited as off-
17 setting collections to the account providing ap-
18 propriations to the Food and Drug Administra-
19 tion; and

20 “(B) shall not be collected for any fiscal
21 year except to the extent provided in advance in
22 appropriation Acts.

23 “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-
24 PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary
25 shall publish a notice in the Federal Register and on the

1 Internet Website of the Food and Drug Administration
2 not later than 30 calendar days after the occurrence of
3 each of the following:

4 “(1) The Secretary issues a priority review
5 voucher under this section.

6 “(2) The Secretary approves a drug pursuant
7 to an application submitted under section 505(b) of
8 this Act or section 351(a) of the Public Health Serv-
9 ice Act for which the sponsor of the application used
10 a priority review voucher under this section.

11 “(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing
12 in this section precludes a sponsor who seeks a priority
13 review voucher under this section from participating in
14 any other incentive program, including under this Act, ex-
15 cept that no sponsor of a material threat medical counter-
16 measure application may receive more than one priority
17 review voucher with respect to such drug.

18 “(f) RELATION TO OTHER PROVISIONS.—The provi-
19 sions of this section shall supplement, not supplant, any
20 other provisions of this Act or the Public Health Service
21 Act that encourage the development of medical counter-
22 measures.”.

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