

114TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

Mr. BURR (for himself and Mr. CASEY) introduced the following bill; which  
was read twice and referred to the Committee on \_\_\_\_\_

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**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  
9 319F–2 of the Public Health Service Act (42 U.S.C.  
10 247d–6b) is amended—

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

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

11           (2) in subsection (g)—

12           (A) by amending paragraph (4) to read as  
13 follows:

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

1 available for procurement and the impact such  
2 amount of funding will have—

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

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

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

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

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

24 (b) BARDA CONTRACTING AUTHORITY.—Section  
25 319L(c)(3) of the Public Health Service Act (42 U.S.C.

1 247d-7c) is amended by inserting “, including the execu-  
2 tion of procurement contracts, grants, and cooperative  
3 agreements pursuant to this section” before the period.

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

5 Section 2811(b)(7) of the Public Health Service Act  
6 (42 U.S.C. 300hh-10(b)(7)) is amended—

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

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

23 (3) in subparagraph (D), by striking “to the  
24 appropriate committees of Congress upon request.”  
25 and inserting “, not later than March 15 of each

1 year, to the Committee on Appropriations and the  
2 Committee on Health, Education, Labor, and Pen-  
3 sions of the Senate and the Committee on Appro-  
4 priations and the Committee on Energy and Com-  
5 merce of the House of Representatives; and”;

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

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

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

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

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

1 **SEC. 6. STREAMLINING THE PROJECT BIOSHIELD PRO-**  
2 **CUREMENT PROCESS.**

3 Section 319F–2(c) of the Public Health Service Act  
4 (42 U.S.C. 247d–6b(c)) is amended—

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

12 (2) in paragraph (6)—

13 (A) by striking subparagraphs (A), (B),  
14 and (E);

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

18 (C) by amending subparagraph (A), as so  
19 redesignated, to read as follows:

20 “(A) NOTICE TO APPROPRIATE CONGRES-  
21 SIONAL COMMITTEES.—The Secretary shall no-  
22 tify the Committee on Appropriations and the  
23 Committee on Health, Education, Labor, and  
24 Pensions of the Senate and the Committee on  
25 Appropriations and the Committee on Energy  
26 and Commerce of the House of Representatives

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

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

15 (3) in paragraph (7)—

16 (A) by striking subparagraph (A);

17 (B) by striking subparagraph (B) and in-  
18 serting the following:

19 “(A) PAYMENTS FROM SPECIAL RESERVE  
20 FUND.—The special reserve fund as defined in  
21 subsection (h) shall be available for payments  
22 made by the Secretary to a vendor for procure-  
23 ment of a security countermeasure in accord-  
24 ance with the provisions of this paragraph.”;  
25 and

1 (C) by redesignating subparagraph (C) as  
2 subparagraph (B).

3 **SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**  
4 **FOR AGENTS THAT PRESENT NATIONAL SE-**  
5 **CURITY THREATS.**

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

9 **“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREAT-**  
10 **MENTS FOR AGENTS THAT PRESENT NA-**  
11 **TIONAL SECURITY THREATS.**

12 “(a) DEFINITIONS.—In this section:

13 “(1) The term ‘priority review’ with respect to  
14 a human drug application as defined in section  
15 735(1), means review and action by the Secretary on  
16 such application not later than 6 months after re-  
17 ceipt by the Secretary of such application, as de-  
18 scribed in the Manual of Policies and Procedures in  
19 the Food and Drug Administration and goals identi-  
20 fied in the letters described in section 101(b) of the  
21 Food and Drug Administration Safety and Innova-  
22 tion Act.

23 “(2) PRIORITY REVIEW VOUCHER.—The term  
24 ‘priority review voucher’ means a voucher issued by  
25 the Secretary to the sponsor of a material threat

1 medical countermeasure application that entitles the  
2 holder of such voucher to priority review of a single  
3 human drug application submitted under section  
4 505(b)(1) or section 351 of the Public Health Serv-  
5 ice Act after the date of approval of the material  
6 threat medical countermeasure application.

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

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

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

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

23 “(B) the Secretary deems eligible for pri-  
24 ority review;

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

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

9           “(b) PRIORITY REVIEW VOUCHER.—

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

15           “(2) TRANSFERABILITY.—The sponsor of a ma-  
16           terial threat medical countermeasure application  
17           that receives a priority review voucher under this  
18           section may transfer (including by sale) the entitle-  
19           ment to such voucher to a sponsor of a human drug  
20           for which an application under section 505(b)(1) or  
21           section 351 of the Public Health Service Act will be  
22           submitted after the date of the approval of the mate-  
23           rial threat medical countermeasure application.  
24           There is no limit on the number of times a priority

1 review voucher may be transferred before such  
2 voucher is used.

3 “(3) NOTIFICATION.—

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

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

23 “(c) PRIORITY REVIEW USER FEE.—

24 “(1) IN GENERAL.—The Secretary shall estab-  
25 lish a user fee program under which a sponsor of a

1 human drug application that is the subject of a pri-  
2 ority review voucher shall pay to the Secretary a fee  
3 determined under paragraph (2). Such fee shall be  
4 in addition to any fee required to be submitted by  
5 the sponsor under chapter VII.

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

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

17 “(4) PAYMENT.—

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

24 “(B) COMPLETE APPLICATION.—An appli-  
25 cation described under subparagraph (A) for

1           which the sponsor requests the use of a priority  
2           review voucher shall be considered incomplete if  
3           the fee required by this subsection and all other  
4           applicable user fees are not paid in accordance  
5           with the Secretary's procedures for paying such  
6           fees.

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

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

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

18                 “(6) shall not be collected for any fiscal year  
19                 except to the extent provided in advance in appro-  
20                 priation Acts.

21          “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-  
22          PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary  
23          shall publish a notice in the Federal Register and on the  
24          Internet Website of the Food and Drug Administration

1 not later than 30 calendar days after the occurrence of  
2 each of the following:

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

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

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

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