

# Calendar No. 388

114TH CONGRESS  
2D SESSION

# S. 2055

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

SEPTEMBER 17, 2015

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

MARCH 14, 2016

Reported by Mr. ALEXANDER, with an amendment

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

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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”.

1 **SEC. 2. MEDICAL COUNTERMEASURE GUIDELINES.**

2 (a) STRATEGIC NATIONAL STOCKPILE AND SECUR-  
3 RITY COUNTERMEASURE PROCUREMENTS.—Section  
4 319F–2 of the Public Health Service Act (42 U.S.C.  
5 247d–6b) is amended—

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

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

16 (2) in subsection (g)—

17 (A) by amending paragraph (4) to read as  
18 follows:

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

1 Committee on Appropriations and the Committee on  
2 Energy and Commerce of the House of Representa-  
3 tives a report detailing the amount of such funds  
4 available for procurement and the impact such  
5 amount of funding will have—

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

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

12 **SEC. 3. CLARIFICATION ON BARDA CONTRACTING AUTHOR-**  
13 **ITY.**

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

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

1       operative agreements pursuant to this section and  
2       section 319L.”.

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

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

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

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

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

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

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

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

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

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

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

1 such guidance, for why the Secretary has failed to  
 2 finalize the guidance as required by this sub-  
 3 section.”.

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

6 Section ~~319F-2(c)~~ of the Public Health Service Act  
 7 (~~42 U.S.C. 247d-6b(c)~~) is amended—

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

15 (2) in paragraph (6)—

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

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

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

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

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

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

19 (3) in paragraph (7)—

20 (A) by striking subparagraph (A);

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

23 “(A) PAYMENTS FROM SPECIAL RESERVE  
24 FUND.—The special reserve fund as defined in  
25 subsection (h) shall be available for payments

1           made by the Secretary to a vendor for procure-  
 2           ment of a security countermeasure in accord-  
 3           ance with the provisions of this paragraph.”;

4           and

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

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

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

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

16          “(a) **DEFINITIONS.**—In this section:

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



1 Food and Drug Administration Safety and Innova-  
2 tion Act.

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

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

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

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

23 “(ii) to mitigate, prevent, or treat  
24 harm from a condition that may result in  
25 adverse health consequences or death and

1           may be caused by administering a drug, or  
2           biological product against such agent;

3           “(B) the Secretary deems eligible for pri-  
4           ority review;

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

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

13        “(b) PRIORITY REVIEW VOUCHER.—

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

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

1 submitted after the date of the approval of the mate-  
2 rial threat medical countermeasure application.  
3 There is no limit on the number of times a priority  
4 review voucher may be transferred before such  
5 voucher is used.

6 “(3) NOTIFICATION.—

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

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

1 “(c) PRIORITY REVIEW USER FEE.—

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

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

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

20 “(4) PAYMENT.—

21 “(A) IN GENERAL.—The priority review  
22 user fee required by this subsection shall be due  
23 upon the submission of a human drug applica-  
24 tion under section 505(b)(1) or section 351 of

1 the Public Health Service Act for which the pri-  
2 ority review voucher is used.

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

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

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

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

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

1       “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-  
2 PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary  
3 shall publish a notice in the Federal Register and on the  
4 Internet Website of the Food and Drug Administration  
5 not later than 30 calendar days after the occurrence of  
6 each of the following:

7           “(1) The Secretary issues a priority review  
8 voucher under this section.

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

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

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

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Medical Countermeasure*  
3 *Innovation Act of 2016”.*

4 **SEC. 2. MEDICAL COUNTERMEASURE GUIDELINES.**

5 *(a) STRATEGIC NATIONAL STOCKPILE AND SECURITY*  
6 *COUNTERMEASURE PROCUREMENTS.—Section 319F–2 of*  
7 *the Public Health Service Act (42 U.S.C. 247d–6b) is*  
8 *amended—*

9 *(1) in subsection (a), by adding at the end the*  
10 *following:*

11 *“(3) UTILIZATION GUIDELINES.—The Secretary*  
12 *shall ensure timely and accurate recommended utili-*  
13 *zation guidelines for qualified countermeasures (as*  
14 *defined in section 319F–1), qualified pandemic and*  
15 *epidemic products (as defined in section 319F–3),*  
16 *and security countermeasures (as defined in sub-*  
17 *section (c)), including for such products in the stock-*  
18 *pile.”; and*

19 *(2) in subsection (g)—*

20 *(A) by amending paragraph (4) to read as*  
21 *follows:*

22 *“(4) REPORT ON SECURITY COUNTERMEASURE*  
23 *PROCUREMENT.—Not later than March 1 of each year*  
24 *in which the Secretary determines that the amount of*  
25 *funds available for procurement of security counter-*  
26 *measures is less than \$1,500,000,000, the Secretary*

1 shall submit to the Committee on Appropriations and  
 2 the Committee on Health, Education, Labor, and  
 3 Pensions of the Senate and the Committee on Approp-  
 4 riations and the Committee on Energy and Com-  
 5 merce of the House of Representatives a report detail-  
 6 ing the amount of such funds available for procure-  
 7 ment and the impact such amount of funding will  
 8 have—

9 “(A) in meeting the security countermeasure  
 10 needs identified under this section; and

11 “(B) on the annual Public Health Emer-  
 12 gency Medical Countermeasures Enterprise and  
 13 Strategy Implementation Plan (pursuant to sec-  
 14 tion 2811(d)).”; and

15 **SEC. 3. CLARIFICATION ON BARDA CONTRACTING AUTHOR-**  
 16 **ITY.**

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

20 “(5) *CLARIFICATION ON CONTRACTING AUTHOR-*  
 21 *ITY.*—The Secretary, acting through the Director of  
 22 the Biomedical Advanced Research and Development  
 23 Authority, shall carry out the programs funded by the  
 24 special reserve fund (for the procurement of security  
 25 countermeasures under subsection (c) and for car-



1        *rying out section 319L), including the execution of*  
 2        *procurement contracts, grants, and cooperative agree-*  
 3        *ments pursuant to this section and section 319L.”.*

4        *(b) BARDA CONTRACTING AUTHORITY.—Section*  
 5        *319L(c)(3) of the Public Health Service Act (42 U.S.C.*  
 6        *247d-7c) is amended by inserting “, including the execution*  
 7        *of procurement contracts, grants, and cooperative agree-*  
 8        *ments pursuant to this section” before the period.*

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

10        *Section 2811(b)(7) of the Public Health Service Act*  
 11        *(42 U.S.C. 300hh-10(b)(7)) is amended—*

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

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

3           (3) *in subparagraph (D), by striking “to the ap-*  
4 *propriate committees of Congress upon request.” and*  
5 *inserting “, not later than March 15 of each year, to*  
6 *the Committee on Appropriations and the Committee*  
7 *on Health, Education, Labor, and Pensions of the*  
8 *Senate and the Committee on Appropriations and the*  
9 *Committee on Energy and Commerce of the House of*  
10 *Representatives; and”;* and

11           (4) *by adding at the end the following:*

12                   “(E) *not later than March 15 of each year,*  
13 *be made publicly available in a manner that*  
14 *does not compromise national security.”.*

15 **SEC. 5. MEDICAL COUNTERMEASURES INNOVATION.**

16           *Section 319L(c)(4) of the Public Health Service Act*  
17 *(42 U.S.C. 247d–7e(c)(4)) is amended by adding at the end*  
18 *the following:*

19                   “(E) *MEDICAL COUNTERMEASURES INNOVA-*  
20 *TION PARTNER.—*

21                           “(i) *IN GENERAL.—To support the*  
22 *purposes described in paragraph (2), the*  
23 *Secretary, acting through the Director of*  
24 *BARDA, may enter into an agreement (in-*  
25 *cluding through the use of grants, contracts,*

1            *cooperative agreements, or other trans-*  
2            *actions as described in paragraph (5)) with*  
3            *an independent, non-profit entity to—*

4                    *“(I) foster and accelerate the de-*  
5                    *velopment and innovation of medical*  
6                    *countermeasures and technologies that*  
7                    *may assist advanced research and de-*  
8                    *velopment of qualified countermeasures*  
9                    *and qualified pandemic or epidemic*  
10                   *products, including through the use of*  
11                   *strategic venture capital practices and*  
12                   *methods;*

13                   *“(II) promote the development of*  
14                   *new and promising technologies that*  
15                   *address urgent medical countermeasure*  
16                   *needs, as identified by the Secretary;*

17                   *“(III) address unmet public*  
18                   *health needs that are directly related to*  
19                   *medical countermeasure requirements,*  
20                   *such as novel antimicrobials for*  
21                   *multidrug resistant organisms and*  
22                   *multiuse platform technologies for*  
23                   *diagnostics, prophylaxis, vaccines, and*  
24                   *therapeutics; and*

1           “(IV) provide expert consultation  
2           and advice to foster viable medical  
3           countermeasure innovators, including  
4           helping qualified countermeasure  
5           innovators navigate unique industry  
6           challenges with respect to developing  
7           chemical, biological, radiological, and  
8           nuclear countermeasure products.

9           “(ii) *ELIGIBILITY.*—

10           “(I) *IN GENERAL.*—To be eligible  
11           to enter into an agreement under  
12           clause (i) an entity shall—

13                   “(aa) be an independent,  
14                   non-profit entity;

15                   “(bb) have a demonstrated  
16                   record of being able to create link-  
17                   ages between innovators and in-  
18                   vestors and leverage such partner-  
19                   ships and resources for the pur-  
20                   pose of addressing identified stra-  
21                   tegic needs of the Federal Govern-  
22                   ment;

23                   “(cc) have experience in pro-  
24                   moting novel technology innova-  
25                   tion;

1           “(dd) be problem driven and  
2           solution focused based on the  
3           needs, requirements, and problems  
4           identified by the Secretary under  
5           clause (iv);

6           “(ee) demonstrate the ability,  
7           or the potential ability, to pro-  
8           mote the development of medical  
9           countermeasure products;

10           “(ff) demonstrate expertise,  
11           or the capacity to develop or ac-  
12           quire expertise, related to tech-  
13           nical and regulatory consider-  
14           ations with respect to medical  
15           countermeasures; and

16           “(gg) not be within the De-  
17           partment of Health and Human  
18           Services.

19           “(II) PARTNERING EXPERI-  
20           ENCE.—In selecting an entity with  
21           which to enter into an agreement  
22           under clause (i), the Secretary shall  
23           place a high value on the demonstrated  
24           experience of the entity in partnering

1                   *with the Federal Government to meet*  
2                   *identified strategic needs.*

3                   “(iii) *NOT AGENCY.*—*An entity that*  
4                   *enters into an agreement under clause (i)*  
5                   *shall not be deemed to be a Federal agency*  
6                   *for any purpose, including for any purpose*  
7                   *under title 5, United States Code.*

8                   “(iv) *DIRECTION.*—*Pursuant to an*  
9                   *agreement entered into under this subpara-*  
10                  *graph, the Secretary, acting through the Di-*  
11                  *rector of BARDA, shall provide direction to*  
12                  *the entity that enters into an agreement*  
13                  *under clause (i). As part of this agreement*  
14                  *the Director of BARDA shall—*

15                  “(I) *communicate the medical*  
16                  *countermeasure needs, requirements,*  
17                  *and problems to be addressed by the*  
18                  *entity under the agreement;*

19                  “(II) *develop a description of*  
20                  *work to be performed by the entity*  
21                  *under the agreement;*

22                  “(III) *provide technical feedback*  
23                  *and appropriate oversight over work*  
24                  *carried out by the entity under the*  
25                  *agreement, including subsequent devel-*

1                    *opment and partnerships consistent*  
2                    *with the needs and requirements set*  
3                    *forth in this subparagraph;*

4                    *“(IV) ensure fair consideration of*  
5                    *products developed under the agree-*  
6                    *ment in order to maintain competition*  
7                    *to the maximum practical extent, as*  
8                    *applicable and appropriate under ap-*  
9                    *plicable provisions of this section; and*

10                   *“(V) ensure, as a condition of the*  
11                   *agreement—*

12                   *“(aa) a comprehensive set of*  
13                   *policies that demonstrate a com-*  
14                   *mitment to transparency and ac-*  
15                   *countability;*

16                   *“(bb) protection against con-*  
17                   *licts of interest through a com-*  
18                   *prehensive set of policies that ad-*  
19                   *dress potential conflicts of inter-*  
20                   *est, ethics, disclosure, and report-*  
21                   *ing requirements;*

22                   *“(cc) that the entity provides*  
23                   *monthly accounting on the use of*  
24                   *funds provided under such agree-*  
25                   *ment; and*

1                   “(dd) that the entity provides  
2                   on a quarterly basis, reports re-  
3                   garding the progress made toward  
4                   meeting the identified needs set  
5                   forth in the agreement.

6                   “(v) SUPPLEMENT NOT SUPPLANT.—  
7                   Activities carried out under this subpara-  
8                   graph shall supplement, and not supplant,  
9                   other activities carried out under this sec-  
10                  tion.

11                  “(vi) NO ESTABLISHMENT OF ENTI-  
12                  TY.—To prevent unnecessary duplication  
13                  and target resources effectively, nothing in  
14                  this subparagraph shall be construed to au-  
15                  thorize the Secretary to establish within the  
16                  Department of Health and Human Services  
17                  an entity for the purposes of carrying out  
18                  this subparagraph.

19                  “(vii) TRANSPARENCY AND OVER-  
20                  SIGHT.—Upon request, the Secretary shall  
21                  provide to Congress the information pro-  
22                  vided to the Secretary under clause  
23                  (iv)(V)(dd).

24                  “(viii) INDEPENDENT EVALUATION.—  
25                  Not later than 4 years after the date of en-



1            *actment of this subparagraph, the Govern-*  
2            *ment Accountability Office shall conduct an*  
3            *independent evaluation, and submit to the*  
4            *Secretary and the appropriate committees*  
5            *of Congress a report, concerning the activi-*  
6            *ties conducted under this subparagraph.*  
7            *Such report shall include recommendations*  
8            *with respect to any agreement or activities*  
9            *carried out pursuant to this subparagraph.*

10            *“(ix) SUNSET.—This subparagraph*  
11            *shall have no force or effect after September*  
12            *30, 2022.”.*

13    **SEC. 6. STREAMLINING THE PROJECT BIOSHIELD PRO-**  
14            **CUREMENT PROCESS.**

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

17            *(1) in paragraph (4)(A)(ii), by striking “make a*  
18            *recommendation under paragraph (6) that the special*  
19            *reserve fund as defined in subsection (h) be made*  
20            *available for the procurement of such countermeasure”*  
21            *and inserting “and subject to the availability of ap-*  
22            *propriations, make available the special reserve fund*  
23            *as defined in subsection (h) for procurement of such*  
24            *countermeasure, as applicable”;*

25            *(2) in paragraph (6)—*

1           (A) by striking subparagraphs (A), (B), and  
2           (E);

3           (B) by redesignating subparagraphs (C)  
4           and (D) as subparagraphs (A) and (B), respec-  
5           tively;

6           (C) by amending subparagraph (A), as so  
7           redesignated, to read as follows:

8           “(A) NOTICE TO APPROPRIATE CONGRES-  
9           SIONAL COMMITTEES.—The Secretary shall no-  
10          tify the Committee on Appropriations and the  
11          Committee on Health, Education, Labor, and  
12          Pensions of the Senate and the Committee on  
13          Appropriations and the Committee on Energy  
14          and Commerce of the House of Representatives of  
15          each decision to make available the special re-  
16          serve fund as defined in subsection (h) for pro-  
17          curement of a security countermeasure, includ-  
18          ing, where available, the number of, the nature  
19          of, and other information concerning potential  
20          suppliers of such countermeasure, and whether  
21          other potential suppliers of the same or similar  
22          countermeasures were considered and rejected for  
23          procurement under this section and the reasons  
24          therefore.”; and

1           (D) *in the heading, by striking “REC-*  
2           *COMMENDATION FOR PRESIDENT’S APPROVAL”*  
3           *and inserting “RECOMMENDATIONS FOR PRO-*  
4           *CUREMENT”*; and

5           (3) *in paragraph (7)—*

6                 (A) *by striking subparagraph (A)*;

7                 (B) *by striking subparagraph (B) and in-*  
8           *serting the following:*

9                     “(A) *PAYMENTS FROM SPECIAL RESERVE*  
10           *FUND.—The special reserve fund as defined in*  
11           *subsection (h) shall be available for payments*  
12           *made by the Secretary to a vendor for procure-*  
13           *ment of a security countermeasure in accordance*  
14           *with the provisions of this paragraph.”*; and

15                 (C) *by redesignating subparagraph (C) as*  
16           *subparagraph (B).*

17   **SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**  
18                     **FOR AGENTS THAT PRESENT NATIONAL SE-**  
19                     **CURITY THREATS.**

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

1 **“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREAT-**  
2 **MENTS FOR AGENTS THAT PRESENT NA-**  
3 **TIONAL SECURITY THREATS.**

4 “(a) *DEFINITIONS.—In this section:*

5 “(1) *The term ‘priority review’ with respect to a*  
6 *human drug application as defined in section 735(1),*  
7 *means review and action by the Secretary on such*  
8 *application not later than 6 months after receipt by*  
9 *the Secretary of such application, as described in the*  
10 *Manual of Policies and Procedures in the Food and*  
11 *Drug Administration and goals identified in the let-*  
12 *ters described in section 101(b) of the Food and Drug*  
13 *Administration Safety and Innovation Act.*

14 “(2) *PRIORITY REVIEW VOUCHER.—The term*  
15 *‘priority review voucher’ means a voucher issued by*  
16 *the Secretary to the sponsor of a material threat med-*  
17 *ical countermeasure application that entitles the hold-*  
18 *er of such voucher to priority review of a single*  
19 *human drug application submitted under section*  
20 *505(b)(1) or section 351(a) of the Public Health Serv-*  
21 *ice Act after the date of approval of the material*  
22 *threat medical countermeasure application.*

23 “(3) *MATERIAL THREAT MEDICAL COUNTER-*  
24 *MEASURE APPLICATION.—The term ‘material threat*  
25 *medical countermeasure application’ means an appli-*  
26 *cation that—*

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

3           “(i) to prevent, or treat harm from a  
4           biological, chemical, radiological, or nuclear  
5           agent identified as a material threat under  
6           section 319F-2(c)(2)(A)(ii) of the Public  
7           Health Service Act, or

8           “(ii) to mitigate, prevent, or treat  
9           harm from a condition that may result in  
10          adverse health consequences or death and  
11          may be caused by administering a drug, or  
12          biological product against such agent; and

13          “(B) the Secretary deems eligible for pri-  
14          ority review;

15          “(C) is approved after the date of enactment  
16          of the Medical Countermeasure Innovation Act of  
17          2016; and

18          “(D) is for a human drug, no active ingre-  
19          dient (including any ester or salt of the active  
20          ingredient) of which has been approved in any  
21          other application under section 505(b)(1) or sec-  
22          tion 351(a) of the Public Health Service Act.

23          “(b) PRIORITY REVIEW VOUCHER.—

24                 “(1) IN GENERAL.—The Secretary shall award a  
25                 priority review voucher to the sponsor of a material

1       *threat medical countermeasure application upon ap-*  
2       *proval by the Secretary of such material threat med-*  
3       *ical countermeasure application.*

4               “(2) *TRANSFERABILITY.*—*The sponsor of a mate-*  
5       *rial threat medical countermeasure application that*  
6       *receives a priority review voucher under this section*  
7       *may transfer (including by sale) the entitlement to*  
8       *such voucher to a sponsor of a human drug for which*  
9       *an application under section 505(b)(1) or section*  
10       *351(a) of the Public Health Service Act will be sub-*  
11       *mitted after the date of the approval of the material*  
12       *threat medical countermeasure application. There is*  
13       *no limit on the number of times a priority review*  
14       *voucher may be transferred before such voucher is*  
15       *used.*

16               “(3) *NOTIFICATION.*—

17               “(A) *IN GENERAL.*—*The sponsor of a*  
18       *human drug application shall notify the Sec-*  
19       *retary not later than 90 calendar days prior to*  
20       *submission of the human drug application that*  
21       *is the subject of a priority review voucher of an*  
22       *intent to submit the human drug application,*  
23       *including the date on which the sponsor intends*  
24       *to submit the application. Such notification*  
25       *shall be a legally binding commitment to pay for*

1           *the user fee to be assessed in accordance with this*  
2           *section.*

3                   “(B) *TRANSFER AFTER NOTICE.*—*The spon-*  
4                   *sor of a human drug application that provides*  
5                   *notification of the intent of such sponsor to use*  
6                   *the voucher for the human drug application*  
7                   *under subparagraph (A) may transfer the vouch-*  
8                   *er after such notification is provided, if such*  
9                   *sponsor has not yet submitted the human drug*  
10                   *application described in the notification.*

11           “(c) *PRIORITY REVIEW USER FEE.*—

12                   “(1) *IN GENERAL.*—*The Secretary shall establish*  
13                   *a user fee program under which a sponsor of a*  
14                   *human drug application that is the subject of a pri-*  
15                   *ority review voucher shall pay to the Secretary a fee*  
16                   *determined under paragraph (2). Such fee shall be in*  
17                   *addition to any fee required to be submitted by the*  
18                   *sponsor under chapter VII.*

19                   “(2) *FEE AMOUNT.*—*The amount of the priority*  
20                   *review user fee shall be determined each fiscal year by*  
21                   *the Secretary and based on the average cost incurred*  
22                   *by the agency in the review of a human drug applica-*  
23                   *tion subject to priority review in the previous fiscal*  
24                   *year.*

1           “(3) *ANNUAL FEE SETTING.*—*The Secretary shall*  
2           *establish, before the beginning of each fiscal year be-*  
3           *ginning after September 30, 2015, for that fiscal year,*  
4           *the amount of the priority review user fee.*

5           “(4) *PAYMENT.*—

6           “(A) *IN GENERAL.*—*The priority review*  
7           *user fee required by this subsection shall be due*  
8           *upon the submission of a human drug applica-*  
9           *tion under section 505(b)(1) or section 351(a) of*  
10           *the Public Health Services Act for which the pri-*  
11           *ority review voucher is used.*

12           “(B) *COMPLETE APPLICATION.*—*An appli-*  
13           *cation described under subparagraph (A) for*  
14           *which the sponsor requests the use of a priority*  
15           *review voucher shall be considered incomplete if*  
16           *the fee required by this subsection and all other*  
17           *applicable user fees are not paid in accordance*  
18           *with the Secretary’s procedures for paying such*  
19           *fees.*

20           “(C) *NO WAIVERS, EXEMPTIONS, REDUC-*  
21           *TIONS, OR REFUNDS.*—*The Secretary may not*  
22           *grant a waiver, exemption, reduction, or refund*  
23           *of any fees due and payable under this section.*

24           “(5) *OFFSETTING COLLECTIONS.*—*Fees collected*  
25           *pursuant to this subsection for any fiscal year—*



1           “(A) shall be deposited and credited as off-  
2           setting collections to the account providing ap-  
3           propriations to the Food and Drug Administra-  
4           tion; and

5           “(6) shall not be collected for any fiscal year ex-  
6           cept to the extent provided in advance in appropria-  
7           tion Acts.

8           “(d) NOTICE OF ISSUANCE OF VOUCHER AND AP-  
9           PROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary  
10          shall publish a notice in the Federal Register and on the  
11          Internet Website of the Food and Drug Administration not  
12          later than 30 calendar days after the occurrence of each of  
13          the following:

14                 “(1) The Secretary issues a priority review  
15                 voucher under this section.

16                 “(2) The Secretary approves a drug pursuant to  
17                 an application submitted under section 505(b) of this  
18                 Act or section 351(a) of the Public Health Service Act  
19                 for which the sponsor of the application used a pri-  
20                 ority review voucher under this section.

21           “(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing  
22          in this section precludes a sponsor who seeks a priority re-  
23          view voucher under this section from participating in any  
24          other incentive program, including under this Act, except  
25          that no sponsor of a material threat medical counter-

1 *measure application may receive more than one priority*  
2 *review voucher issued under any section of this Act with*  
3 *respect to such drug.*

4       “(f) *RELATION TO OTHER PROVISIONS.*—*The provi-*  
5 *sions of this section shall supplement, not supplant, any*  
6 *other provisions of this Act or the Public Health Service*  
7 *Act that encourage the development of medical counter-*  
8 *measures.”.*

9 **SEC. 8. GAO REPORT.**

10       (a) *STUDY.*—*The Comptroller General of the United*  
11 *States shall conduct a study on the effectiveness of priority*  
12 *review vouchers under section 565A of the Federal Food,*  
13 *Drug, and Cosmetic Act (as added by section 7) in pro-*  
14 *viding incentives for the development of material threat*  
15 *medical countermeasures applications under such section*  
16 *565A. In conducting such study, the Comptroller General*  
17 *shall examine the following:*

18               (1) *The impact of the priority review voucher in*  
19 *attracting investment into the development of mate-*  
20 *rial threat medical countermeasures and the impact*  
21 *of such investment, as applicable, on the development*  
22 *of such countermeasures.*

23               (2) *How the drugs for which priority review*  
24 *vouchers were awarded under such section 565A—*

1           (A) addressed identified medical counter-  
2           measure needs; and

3           (B) impacted United States preparedness  
4           against chemical, biological, radiological, and  
5           nuclear threats, including both identified threats  
6           and naturally-occurring threats.

7           (3) How many material threat medical counter-  
8           measures were licensed or approved, or otherwise sig-  
9           nificantly advanced in clinical development, in the 10  
10          years following the enactment of such section 565A  
11          compared to the 10 years prior to the enactment of  
12          such section.

13          (4) An analysis of the drugs for which such pri-  
14          ority review vouchers were used, which shall in-  
15          clude—

16               (A) the indications for which such drugs  
17               were approved under section 505(b)(1) of the  
18               Federal Food, Drug, and Cosmetic Act (21  
19               U.S.C. 355) or section 351(a) of the Public  
20               Health Service Act (42 U.S.C. 262);

21               (B) whether unmet medical needs were ad-  
22               dressed through the approval of such drugs, in-  
23               cluding, for each such drug—

1                   (i) if an alternative therapy was pre-  
2                   viously available to treat the indication;  
3                   and

4                   (ii) if the drug provided a benefit or  
5                   advantage over another available therapy;

6                   (C) the value of the priority review voucher  
7                   if transferred; and

8                   (D) the length of time between the date on  
9                   which a priority review voucher was awarded  
10                  and the date on which it was used.

11                 (5) With respect to the priority review voucher  
12                 program under such section 565A—

13                   (A) how many priority review vouchers  
14                   were awarded under such section 565A and how  
15                   many of such awarded vouchers were redeemed  
16                   for priority review of a drug application in the  
17                   10 years following the date of enactment of such  
18                   section;

19                   (B) the resources associated with the Food  
20                   and Drug Administration implementation of  
21                   such section 565A and review of applications for  
22                   which a voucher awarded under such section  
23                   565A is redeemed for priority review; and

24                   (C) recommendations, if any, with respect  
25                   to how such section 565A could be improved to

1           *better achieve the objective of incentivizing the*  
2           *timely development of medical countermeasures*  
3           *to address identified chemical, biological, radio-*  
4           *logical, and nuclear threats, including for med-*  
5           *ical countermeasures that might otherwise not be*  
6           *developed, potentially eligible for an emergency*  
7           *use authorization, licensed, or approved.*

8           **(b) CONSULTATIONS.**—*In conducting the study under*  
9           *subsection (a), the Comptroller General of the United States*  
10          *shall consult with—*

11                 *(1) drug manufacturers involved in the research*  
12                 *and development of medical countermeasures to ad-*  
13                 *dress biological, chemical, radiological, and nuclear*  
14                 *threats;*

15                 *(2) stakeholders involved in investing in the re-*  
16                 *search and development of medical countermeasures,*  
17                 *including venture capitalists;*

18                 *(3) the Federal Government agencies responsible*  
19                 *for advancing, reviewing, and procuring medical*  
20                 *countermeasures, including—*

21                         *(A) the Department of Health and Human*  
22                         *Services, including the Office of the Assistant*  
23                         *Secretary for Preparedness and Response, the*  
24                         *Biomedical Advanced Research and Development*

1           *Authority, and the Food and Drug Administra-*  
2           *tion; and*

3                   *(B) the Department of Defense; and*

4           *(4) biodefense stakeholders, as applicable.*

5           *(c) INITIAL ASSESSMENT.—Not later than 7 years*  
6 *after the date of enactment of this Act, the Comptroller Gen-*  
7 *eral of the United States shall submit to the Committee on*  
8 *Health, Education, Labor, and Pensions of the Senate and*  
9 *the Committee on Energy and Commerce of the House of*  
10 *Representatives an initial assessment of the effectiveness of*  
11 *the priority review voucher program set forth in section*  
12 *565A of the Federal Food, Drug, and Cosmetic Act (as*  
13 *added by section 7).*

14           *(d) REPORT.—Not later than 12 years after the date*  
15 *of enactment of this Act, the Comptroller General of the*  
16 *United States shall submit to the Committee on Health,*  
17 *Education, Labor, and Pensions of the Senate and the Com-*  
18 *mittee on Energy and Commerce of the House of Represent-*  
19 *atives a report containing the results of the study conducted*  
20 *under subsection (a).*

21           *(e) PROTECTION OF NATIONAL SECURITY.—The Comp-*  
22 *troller General of the United States shall conduct the study*  
23 *and issue the assessment and report under this section in*  
24 *a manner that does not compromise national security.*



Calendar No. 388

114<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 2055**

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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.

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MARCH 14, 2016

Reported with an amendment