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.

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]

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Medical Countermeasure Innovation Act of 2015".~~

SEC. 2. MEDICAL COUNTERMEASURE GUIDELINES.

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

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

"(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile."; and

(2) in subsection (g)—

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

"(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the

Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d))."

SEC. 3. CLARIFICATION ON BARDA CONTRACTING AUTHORITY.

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

"(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and co-

operative agreements pursuant to this section and section 319L.''.

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

SEC. 4. COUNTERMEASURES BUDGET PLAN.

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

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

(2) in subparagraph (C), by striking ''; and'' and inserting a semicolon;

(3) in subparagraph (D), by striking ''to the appropriate committees of Congress upon request.'' and inserting '', not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and''; and

(4) by adding at the end the following:

''(E) not later than March 15 of each year, be made publicly available.''.

SEC. 5. PRIORITIZING THE ANIMAL RULE GUIDANCE.

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

''(3) WRITTEN EXPLANATION.—The Secretary shall provide to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a written explanation, not later than the last day of each month after the date of enactment of the Medical Countermeasure Innovation Act of 2015 in which the Secretary fails to finalize

such guidance, for why the Secretary has failed to finalize the guidance as required by this subsection.''.

SEC. 6. STREAMLINING THE PROJECT BIOSHIELD PROCUREMENT PROCESS.

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

(1) in paragraph (4)(A)(ii), by striking ''make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure'' and inserting ''make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable'';

(2) in paragraph (6)—

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

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (A) and (B), respectively;

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

''(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the

Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefore.''; and

(D) in the heading, by striking ''RECOMMENDATION FOR PRESIDENT'S APPROVAL'' and inserting ''RECOMMENDATIONS FOR PROCUREMENT''; and

(3) in paragraph (7)—

(A) by striking subparagraph (A);

(B) by striking subparagraph (B) and inserting the following:

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

made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.''; and

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

SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS.

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

''SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS.

''(a) DEFINITIONS.—In this section:

''(1) The term 'priority review' with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the

Food and Drug Administration Safety and Innovation Act.

''(2) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the material threat medical countermeasure application.

''(3) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term 'material threat medical countermeasure application' means an application that—

''(A) is a human drug application as defined in section 735(1)—

''(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act, or

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

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

"(B) the Secretary deems eligible for priority review;

"(C) is approved after the date of enactment of the Medical Countermeasure Innovation Act of 2015; and

"(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health Service Act.

"(b) PRIORITY REVIEW VOUCHER.—

"(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

"(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351 of the Public Health Service Act will be

submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

"(3) NOTIFICATION.—

"(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

"(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

‘‘(c) PRIORITY REVIEW USER FEE.—

‘‘(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

‘‘(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

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

‘‘(4) PAYMENT.—

‘‘(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351 of

the Public Health Service Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

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

''(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet Website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

''(1) The Secretary issues a priority review voucher under this section.

''(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher under this section.

''(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher with respect to such drug.

''(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.''.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Countermeasure Innovation Act of 2016".

SEC. 2. MEDICAL COUNTERMEASURE GUIDELINES.

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

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

"(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile."; and

(2) in subsection (g)—

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

"(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary

shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d))."; ***and***

SEC. 3. CLARIFICATION ON BARDA CONTRACTING AUTHORITY.

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

"(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for car-

rying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.".

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

SEC. 4. COUNTERMEASURES BUDGET PLAN.

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

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

(2) in subparagraph (C), by striking "; and" and inserting a semicolon;

(3) in subparagraph (D), by striking "to the appropriate committees of Congress upon request." and inserting ", not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and"; and

(4) by adding at the end the following:

"(E) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.".

SEC. 5. MEDICAL COUNTERMEASURES INNOVATION.

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

"(E) MEDICAL COUNTERMEASURES INNOVATION PARTNER.—

"(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts,

cooperative agreements, or other transactions as described in paragraph (5)) with an independent, non-profit entity to—

"(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

"(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

"(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

"(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

"(ii) ELIGIBILITY.—

"(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

"(aa) be an independent, non-profit entity;

"(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

"(cc) have experience in promoting novel technology innovation;

"(dd) be problem driven and solution focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

"(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

"(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

"(gg) not be within the Department of Health and Human Services.

"(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering

with the Federal Government to meet identified strategic needs.

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

"(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

"(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

"(II) develop a description of work to be performed by the entity under the agreement;

"(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent devel-

opment and partnerships consistent with the needs and requirements set forth in this subparagraph;

"(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

"(V) ensure, as a condition of the agreement—

"(aa) a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

"(bb) protection against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

"(cc) that the entity provides monthly accounting on the use of funds provided under such agreement; and

"(dd) that the entity provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

"(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

"(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

"(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

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

actment of this subparagraph, the Government Accountability Office shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

"(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2022.".

SEC. 6. STREAMLINING THE PROJECT BIOSHIELD PROCUREMENT PROCESS.

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

(1) in paragraph (4)(A)(ii), by striking "make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure" and inserting "and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable";

(2) in paragraph (6)—

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

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (A) and (B), respectively;

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

"(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefore."; and

(D) in the heading, by striking "RECOMMENDATION FOR PRESIDENT'S APPROVAL" and inserting "RECOMMENDATIONS FOR PROCUREMENT"; and

(3) in paragraph (7)—

(A) by striking subparagraph (A);

(B) by striking subparagraph (B) and inserting the following:

"(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph."; and

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

SEC. 7. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS.

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

"SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS.

"(a) DEFINITIONS.—In this section:

"(1) The term 'priority review' with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

"(2) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the material threat medical countermeasure application.

"(3) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term 'material threat medical countermeasure application' means an application that—

"(A) is a human drug application as defined in section 735(1)—

"(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act, or

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

"(B) the Secretary deems eligible for priority review;

"(C) is approved after the date of enactment of the Medical Countermeasure Innovation Act of 2016; and

"(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351(a) of the Public Health Service Act.

"(b) PRIORITY REVIEW VOUCHER.—

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

threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

"(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351(a) of the Public Health Service Act will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

"(3) NOTIFICATION.—

"(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for

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

"(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

"(c) PRIORITY REVIEW USER FEE.—

"(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

"(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

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

"(4) PAYMENT.—

"(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Services Act for which the priority review voucher is used.

"(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

"(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

"(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

"(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

"(6) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

"(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet Website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

"(1) The Secretary issues a priority review voucher under this section.

"(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher under this section.

"(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical counter-

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

"(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.".

SEC. 8. GAO REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the effectiveness of priority review vouchers under section 565A of the Federal Food, Drug, and Cosmetic Act (as added by section 7) in providing incentives for the development of material threat medical countermeasures applications under such section 565A. In conducting such study, the Comptroller General shall examine the following:

(1) The impact of the priority review voucher in attracting investment into the development of material threat medical countermeasures and the impact of such investment, as applicable, on the development of such countermeasures.

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

(A) addressed identified medical countermeasure needs; and

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

(3) How many material threat medical countermeasures were licensed or approved, or otherwise significantly advanced in clinical development, in the 10 years following the enactment of such section 565A compared to the 10 years prior to the enactment of such section.

(4) An analysis of the drugs for which such priority review vouchers were used, which shall include—

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

(B) whether unmet medical needs were addressed through the approval of such drugs, including, for each such drug—

(i) if an alternative therapy was previously available to treat the indication; and

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

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

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

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

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

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

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

better achieve the objective of incentivizing the timely development of medical countermeasures to address identified chemical, biological, radiological, and nuclear threats, including for medical countermeasures that might otherwise not be developed, potentially eligible for an emergency use authorization, licensed, or approved.

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

(1) drug manufacturers involved in the research and development of medical countermeasures to address biological, chemical, radiological, and nuclear threats;

(2) stakeholders involved in investing in the research and development of medical countermeasures, including venture capitalists;

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

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

Authority, and the Food and Drug Administration; and

(B) the Department of Defense; and

(4) biodefense stakeholders, as applicable.

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

(d) REPORT.—Not later than 12 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a).

(e) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study and issue the assessment and report under this section in a manner that does not compromise national security.

Calendar No. 388

114TH CONGRESS
2D SESSION

S. 2055

A BILL

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

MARCH 14, 2016

Reported with an amendment