114TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
114–735

STRENGTHENING PUBLIC HEALTH EMERGENCY RESPONSE ACT OF 2016

SEPTEMBER 9, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 3299]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3299) to amend the Public Health Service Act to ensure preparedness for chemical, radiological, biological, and nuclear threats, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

59–006

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Strengthening Public Health Emergency Response Act of 2016".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. GAO REPORT ON STATE, LOCAL, AND HOSPITAL PREPAREDNESS PROGRAMS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit a report to the Congress on the programs for awarding cooperative agreements and grants under section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a; improving State and local public health security) and section 319C–2 of such Act (42 U.S.C. 247d–3b; partnerships for State and regional hospital preparedness to improve surge capacity).

(b) CONTENTS.—The report under subsection (a) shall address each of the following:

(1) The goals of the programs specified in subsection (a).

(2) The extent to which such goals are being met, including performance metrics that could help to assess whether such programs are succeeding at the coalition and member level.

(3) How such programs could be improved, including how such programs could be modified to improve the medical preparedness of hospitals, health care coalitions, and the continuity of health care delivery.

(4) How such programs complement other preparedness programs of the Department of Health and Human Services.

(5) How funds awarded through such programs should be allocated and whether that allocation should be based on risk.

(6) Progress made toward State and local preparedness entities being self-sustaining.

(7) Whether the level of funding for such programs is sufficient.

(8) How funding for such programs is being used to ensure preparedness for at-risk populations including children, pregnant women, senior citizens, and other individuals who may have unique needs in the event of a public health emergency, such as individuals with disabilities.

(9)(A) How, and to what extent, entities are using the funds awarded to such entities through section 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3b) to directly fund regional health care coalitions and members of such coalitions.

(B) The amount each such entity retains for its own indirect and direct costs.

(C) The purposes for which such retained funds are used and whether these uses provide value for the program under such section 319C–2, regional health care coalitions, and members of such coalitions.

(10) The extent to which the funds awarded through the programs under sections 319C–1 and 319C–2 of the Public Health Service Act (42 U.S.C. 247d–3a, 247d–3b) have been used for overlapping purposes.

SEC. 3. STRATEGIC NATIONAL STOCKPILE.

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

(1) in subparagraph (G), by striking "and" at the end;

(2) in subparagraph (H), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(I) ensure procedures are in place to coordinate the ongoing stockpiling by the Biomedical Advanced Research and Development Authority and Centers for Disease Control and Prevention of qualified countermeasures (as defined in section 319F–1) for which funds have been made available under this part, security countermeasures (as defined in this section), and quali-

fied pandemic or epidemic products (as defined in section 319F–3) for which funds have been made available under section 319L in order to avoid any gaps in preparedness.".

SEC. 4. 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";

(2) in paragraph (6)—

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

(B) by striking "(6) RECOMMENDATIONS FOR PRESIDENT'S APPROVAL" and all that follows through "(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—" and inserting "(6) SUBSEQUENT SPECIFIC COUNTERMEASURES.—"; and

(3) in paragraph (7)—

(A) by striking subparagraph (A);

(B) by redesignating subparagraph (B) as subparagraph (A) and amending such subparagraph (A), as redesignated, to read as follows:

"(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. 5. BARDA TRANSACTION AUTHORITIES.

Section 319L(c)(5) of the Public Health Service Act (42 U.S.C. 247d–7e(c)(5)) is amended by adding at the end the following:

"(H) CONTRACTING AUTHORITY CLARIFICATION.—The Secretary shall delegate authority for negotiating and entering into any contracts, grants, or cooperative agreements under this section to the Director.".

SEC. 6. PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.

Section 2811(d)(2) of the Public Health Service Act (42 U.S.C. 300hh–10(d)(2)) is amended—

(1) in subparagraph (A), by inserting after "describe the chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation" the following: "(which shall include pandemic influenza)";

(2) by striking "and" at the end of subparagraph (J);

(3) by redesignating subparagraph (K) as subparagraph (L); and

(4) by inserting after subparagraph (J) the following:

"(K) report on the amount of time between the issuance of each request for a proposal or task order from the Biomedical Advanced Research and Development Authority and the award of a contract pursuant to such request for a proposal or task order; and".

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

(a) IN GENERAL.—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) PRIORITY REVIEW.—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 of 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 (Public Law 112–144).

"(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) of this Act 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) 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;

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

"(C) is approved after the date of enactment of the Strengthening Public Health Emergency Response 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 pursuant to any other application under section 505(b)(1) of this Act 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 application.

"(2) TRANSFERABILITY.—

"(A) IN GENERAL.—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) of this Act 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.

"(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after the date of such transfer.

"(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, 2016, 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 notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(3)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

"(B) COMPLETE APPLICATION.—An application described in 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 public 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 issued under any section of this Act with respect to the drug that is the subject of such application.

"(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.

"(g) MEDICAL COUNTERMEASURE POSTAPPROVAL REPORT.—

"(1) IN GENERAL.—Not later than 5 years after the date of approval of a material threat medical countermeasure application, the sponsor of such application shall submit a report to the Secretary on such medical countermeasure.

"(2) CONTENTS.—A report under paragraph (1) shall include, with respect to each of the first 2 years after approval of such material threat medical countermeasure application, a description of—

"(A) the sponsor's activities with Federal agencies related to the procurement, including stockpiling, of the approved medical countermeasure;

"(B) the sponsor's progress in fulfilling contracts entered into with Federal agencies, including the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, and the Department of Defense, related to such procurement;

"(C) the extent to which the Federal Government has fulfilled its stated medical countermeasure requirements for the threat intended to be treated by the approved medical countermeasure; and

"(D) the sponsor's plans, if any, to develop additional material threat medical countermeasures.

"(3) AVAILABILITY TO CONGRESSIONAL COMMITTEES.—The Secretary shall make each report submitted under this subsection available to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate upon request by either such Committee not later than 30 days after receipt of such request.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to permit the disclosure of confidential commercial or trade secret information or the disclosure of information that could compromise national security.".

(b) GAO REPORT.—

(1) 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 subsection (a), in providing incentives for the development of material threat medical countermeasure applications under such section 565A. In conducting such study, the Comptroller General shall examine the following:

(A) The impact of such priority review on the development of material threat medical countermeasures and the impact of such investment, as applicable, on the development of such countermeasures.

(B) How the drugs for which such priority review vouchers were awarded—

(i) addressed identified medical countermeasure needs; and

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

(C) How many material threat medical countermeasures were licensed or approved, or otherwise significantly advanced in clinical development, in the 15 years following the enactment of such section 565A compared to the 15 years prior to the enactment of such section, including a comparative analysis of Federal advanced development and procurement dollars available in the 15 years following such enactment compared to the prior 15 years.

(D) How material threat medical countermeasures developed after the date of enactment of this Act impact—

(i) the supply of products in the strategic national stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b); and

(ii) national preparedness.

(E) How the Federal Government supported sponsors of material threat medical countermeasures during the research, development, application review, and production of such drugs, including the use of government research, provision of resources through contracts or grants, and use of federally funded research facilities.

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

(i) 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(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

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

(I) if there was a currently marketed therapy approved to prevent or treat the same indication in the same patient population at the time the application was submitted to the Food and Drug Administration; and

(II) if the drug provided a significant benefit or improvement in safety and effectiveness compared to such currently marketed product;

(iii) the price of the priority review voucher if transferred or sold prior to redemption; and

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

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

(i) 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 15 years following the date of enactment of such section;

(ii) 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 if implementation of such section 565A prohibited the Food and Drug Administration from meeting drug application review goals;

(iii) recommendations on whether appropriate Federal funding for advanced development and research would necessitate the priority review voucher program for medical countermeasures;

(iv) the degree to which this incentive program impacts other priority review voucher programs; and

(v) the degree to which guaranteed Federal funding for advanced development and research is a greater incentive for new investment in research and the development of medical countermeasures than the uncertain values of vouchers.

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

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

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

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

(i) the Department of Health and Human Services, including the Office of the Assistant Secretary for Preparedness and Response, the Bio-

medical Advanced Research and Development Authority, and the Food and Drug Administration; and

(ii) the Department of Defense;

(D) biodefense stakeholders, as applicable; and

(E) drug manufacturers involved in the research and development of therapies that address—

(i) tropical diseases (as defined in section 524(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a))); or

(ii) rare pediatric diseases (as defined in section 529(a) of such Act (21 U.S.C. 360ff(a))).

(3) INITIAL ASSESSMENT.—Not later than 10 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 subsection (a).

(4) REPORT.—Not later than 16 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 paragraph (1).

(5) PROTECTION OF NATIONAL SECURITY.—The Comptroller General of the United States shall conduct the study under paragraph (1) and issue the assessment and report under paragraphs (3) and (4) in a manner that does not compromise national security.

PURPOSE AND SUMMARY

The purpose of H.R. 3299 is to enhance America's preparedness for biological threats and resulting public health emergencies. H.R. 3299 would improve and enhance our national preparedness in several ways: first, a Government Accountability Office (GAO) study would evaluate our current local and state emergency preparedness efforts to determine how to increase effectiveness; second, the bill would require coordination between Centers for Disease Control (CDC) and Biomedical Advanced Research and Development Authority (BARDA); third, the bill would increase the efficiency for contracting with companies to develop and procure products; fourth, the bill would amend an existing five year budget plan requirement to include pandemic influenza; and finally, the bill would provide a necessary and valuable incentive to ensure innovators develop medical products for national defense.

H.R. 3299 also would establish a new priority review voucher (PRV) program at the Food and Drug Administration (FDA). Under this program, the Secretary would award a priority review voucher to sponsors of drugs that meet certain criteria, including that the drug prevent or treat harm from a biological, chemical, radiological, or nuclear agent that has been identified as a material threat by the Department of Homeland Security.

BACKGROUND AND NEED FOR LEGISLATION

The past several years have demonstrated the global nature of biological threats. The Ebola outbreak in Western Africa and the emergence of Zika illustrate the importance of preparedness. A bipartisan report, issued on October 28, 2016, by the Blue Ribbon Study Panel on Biodefense, stated that "[t]he United States is underprepared for biological threats. . . . The Nation is dangerously vulnerable to a biological event. The root cause of this continuing vulnerability is the lack of strong centralized leadership at

the highest level of government."[1] H.R. 3299 will address "serious gaps and inadequacies that continue to leave the Nation vulnerable to threats from nature and terrorists alike."[2]

HEARINGS

The Subcommittee on Health held a hearing on H.R. 3299 on May 19, 2016. The Subcommittee received testimony from:

- Col. Russell Coleman, Ph.D., Joint Program Manager, Medical Countermeasures Systems, U.S. Department of Defense;
- Richard Hatchett, M.D., Acting Director, Biomedical Advanced Research and Development Authority, U.S. Department of Health and Human Services; and,
- Michael Mair, Director of Strategic Operations, Office of Counterterrorism and Emerging Threats, U.S. Food and Drug Administration.

COMMITTEE CONSIDERATION

On June 7 and 8, 2016, the Subcommittee on Health met in open markup session and forwarded H.R. 3299 to the full Committee, as amended, by a voice vote. On July 12, 13, and 14, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 3299 reported to the House, as amended, by a recorded vote of 36 yeas and 15 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

[1] *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts.* Bipartisan Reform of the Blue Ribbon Study Panel on Biodefense. P. iv

[2] Ibid. P. iv.

COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 75

BILL: H.R. 3299, "Strengthening Public Health Emergency Response Act of 2016"

AMENDMENT: An amendment to the amendment in the nature of a substitute offered by Mr. Pallone, No. 1b, to terminate the Secretary's authority to award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such application after September 30, 2023, and to amend a report by the Comptroller General of the United States.

DISPOSITION: NOT AGREED TO, by a roll call vote of 14 yeas and 38 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Pallone	X		
Mr. Barton		X		Mr. Rush	X		
Mr. Whitfield		X		Ms. Eshoo		X	
Mr. Shimkus		X		Mr. Engel	X		
Mr. Pitts		X		Mr. Green	X		
Mr. Walden		X		Ms. DeGette	X		
Mr. Murphy		X		Ms. Capps		X	
Mr. Burgess		X		Mr. Doyle		X	
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield		X	
Mr. Latta		X		Ms. Matsui		X	
Mrs. McMorris Rodgers				Ms. Castor	X		
Mr. Harper		X		Mr. Sarbanes	X		
Mr. Lance		X		Mr. McNerney		X	
Mr. Guthrie		X		Mr. Welch	X		
Mr. Olson		X		Mr. Lujan		X	
Mr. McKinley		X		Mr. Tonko	X		
Mr. Pompeo		X		Mr. Yarmuth	X		
Mr. Kinzinger		X		Ms. Clarke	X		
Mr. Griffith		X		Mr. Loebsack	X		
Mr. Bilirakis		X		Mr. Schrader	X		
Mr. Johnson		X		Mr. Kennedy	X		
Mr. Long		X		Mr. Cardenas		X	
Mrs. Ellmers		X					
Mr. Bucshon		X					
Mr. Flores		X					
Mrs. Brooks		X					
Mr. Mullin		X					
Mr. Hudson		X					
Mr. Collins		X					
Mr. Cramer		X					

07/13/2016

COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 76

BILL: H.R. 3299, "Strengthening Public Health Emergency Response Act of 2016"

AMENDMENT: An amendment offered by Mr. Green, No. 1c, to terminate the Secretary's authority to award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such application after September 30, 2028, and to amend a report by the Comptroller General of the United States.

DISPOSITION: NOT AGREED TO, by a roll call vote of 17 yeas and 34 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Pallone	X		
Mr. Barton		X		Mr. Rush	X		
Mr. Whitfield		X		Ms. Eshoo		X	
Mr. Shimkus		X		Mr. Engel	X		
Mr. Pitts		X		Mr. Green	X		
Mr. Walden		X		Ms. DeGette	X		
Mr. Murphy		X		Ms. Capps			
Mr. Burgess		X		Mr. Doyle	X		
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield		X	
Mr. Latta		X		Ms. Matsui		X	
Mrs. McMorris Rodgers				Ms. Castor		X	
Mr. Harper		X		Mr. Sarbanes	X		
Mr. Lance		X		Mr. McNerney	X		
Mr. Guthrie		X		Mr. Welch	X		
Mr. Olson		X		Mr. Lujan	X		
Mr. McKinley		X		Mr. Tonko	X		
Mr. Pompeo		X		Mr. Yarmuth	X		
Mr. Kinzinger		X		Ms. Clarke	X		
Mr. Griffith		X		Mr. Loebsack	X		
Mr. Bilirakis		X		Mr. Schrader	X		
Mr. Johnson		X		Mr. Kennedy	X		
Mr. Long		X		Mr. Cardenas		X	
Mrs. Ellmers		X					
Mr. Bucshon		X					
Mr. Flores		X					
Mrs. Brooks		X					
Mr. Mullin		X					
Mr. Hudson		X					
Mr. Collins		X					
Mr. Cramer		X					

07/13/2016

COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 77

BILL: H.R. 3299, "Strengthening Public Health Emergency Response Act of 2016"

AMENDMENT: A motion by Mr. Upton to order H.R. 3299 favorably reported to the House, as amended. (Final Passage)

DISPOSITION: AGREED TO, by a roll call vote of 36 yeas and 15 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton	X			Mr. Pallone		X	
Mr. Barton	X			Mr. Rush		X	
Mr. Whitfield	X			Ms. Eshoo	X		
Mr. Shimkus	X			Mr. Engel	X		
Mr. Pitts	X			Mr. Green		X	
Mr. Walden	X			Ms. DeGette		X	
Mr. Murphy	X			Ms. Capps			
Mr. Burgess	X			Mr. Doyle	X		
Mrs. Blackburn	X			Ms. Schakowsky		X	
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta	X			Ms. Matsui	X		
Mrs. McMorris Rodgers				Ms. Castor		X	
Mr. Harper	X			Mr. Sarbanes		X	
Mr. Lance	X			Mr. McNerney	X		
Mr. Guthrie	X			Mr. Welch		X	
Mr. Olson	X			Mr. Lujan		X	
Mr. McKinley	X			Mr. Tonko		X	
Mr. Pompeo	X			Mr. Yarmuth		X	
Mr. Kinzinger	X			Ms. Clarke		X	
Mr. Griffith	X			Mr. Loebsack		X	
Mr. Bilirakis	X			Mr. Schrader		X	
Mr. Johnson	X			Mr. Kennedy		X	
Mr. Long	X			Mr. Cardenas	X		
Mrs. Ellmers	X						
Mr. Bucshon	X						
Mr. Flores	X						
Mrs. Brooks	X						
Mr. Mullin	X						
Mr. Hudson	X						
Mr. Collins	X						
Mr. Cramer	X						

07/13/2016

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 3299 would increase American emergency preparedness by increasing administrative efficiency within the Office of Assistant Secretary for Preparedness and Response ("ASPR") in the U.S. Department of Health and Human Services ("HHS") and provide incentives for companies to develop medical countermeasures for public health emergencies and biochemical attacks.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3299 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 3299 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 7, 2016.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3299, the Strengthening Public Health Emergency Response Act of 2016.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

KEITH HALL.

Enclosure.

H.R. 3299—Strengthening Public Health Emergency Response Act of 2016

Summary: H.R. 3299 would establish an incentive program that awards vouchers for priority review to companies that obtain approval from the Food and Drug Administration (FDA) for certain drugs that can be used to counter the effects of biological, chemical, radiological, or nuclear agents. The bill also would make several changes to the processes used to procure medical countermeasures in the Department of Health and Human Services (HHS). Finally, the Government Accountability Office (GAO) would be required to report on programs to improve state, local, and hospital preparedness. CBO estimates that implementing H.R. 3299 would cost $20 million over the 2017–2021 period, assuming appropriation of the necessary amounts. Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

CBO estimates that enacting H.R. 3299 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

H.R. 3299 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 3299 is shown in the following table. The costs of this legislation fall primarily within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2017	2018	2019	2020	2021	2017–2021
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level	5	5	4	4	4	21
Estimated Outlays	4	4	4	4	4	20

Notes: Components do not sum to totals because of rounding.

Basis of estimate: For this estimate, CBO assumes that the bill will be enacted near the beginning of fiscal year 2017 and that the necessary amounts will be appropriated.

FDA: The bill would create an incentive program that awards vouchers for priority review to companies when they obtain FDA approval of certain drugs to counter the effects from biological, chemical, radiological, or nuclear agents. Such vouchers can be used to accelerate review of a future drug application. To redeem the voucher, a sponsor must pay an extra fee set by FDA each year to cover the agency's cost for the accelerated review. Such fees would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. (Estimated collections and related spending offset each other in the year fees are paid by sponsors.)

To establish the new voucher program, CBO expects FDA would issue guidance containing the definition of the types of products that would be eligible for a voucher. Based on an analysis of information from FDA for similar programs, CBO estimates that those activities would require about 10 employees to establish and to maintain the program. Assuming appropriation of the necessary

amounts, CBO estimates implementing the new voucher program would cost FDA $18 million over the 2017–2021 period.

HHS: The Office of the Assistant Secretary for Preparedness and Response (ASPR) within HHS is required to work with other HHS agencies to issue a Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan (SIP) each year. The SIP outlines a strategy and an accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. H.R. 3299 would require ASPR to include specific information about pandemic influenza in the SIP. It also would require ASPR to report on the amount of time it takes the Biomedical Advanced Research and Development Authority (BARDA) to award contracts once requests for proposals are issued. Based on information from HHS, CBO estimates that including these new elements in the SIP would require one employee to implement. Assuming appropriation of the necessary amounts, CBO estimates this section would cost HHS about $1 million over the 2017–2021 period.

GAO: H.R. 3299 would require GAO to report on programs to improve state, local, and hospital preparedness for public health emergencies. CBO estimates implementing that provision would cost about $500,000 over the 2017–2021 period; such spending would be subject to the availability of appropriated funds.

Pay-As-You-Go considerations: None

Increase in long-term direct spending and deficits: CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2027.

Intergovernmental and private-sector impact: H.R. 3299 contains no intergovernmental or private-sector mandates as defined in the UMRA and would not affect the budgets of state, local, or tribal governments.

Previous CBO estimates: On August 8, 2016, CBO transmitted a cost estimate for S. 2055, the Medical Countermeasure Innovation Act of 2016, as reported by the Senate Committee on Health, Education, Labor, and Pensions on March 14, 2016. Several provisions are similar to provisions in H.R. 3299; however, S. 2055 would also authorize an additional program to invest in research and provide incentives for the development of medical countermeasures and would require HHS to prepare a five-year budget plan for such countermeasures. H.R. 3299 would authorize one program and modify existing requirements for an annual strategy and implementation plan. CBO's estimate of the budgetary effects reflects those differences.

Estimate prepared by: Federal costs: Andrea Noda, Ellen Werble, and Rebecca Yip; Impact on state, local, and tribal governments: Zachary Byrum; Impact on the private sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 3299 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 3299 specifically directs to be completed no rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; Table of contents

Section 1 provides that this Act may be cited as the "Strengthening Public Health Emergency Response Act of 2016".

Section 2. GAO report on state, local and hospital preparedness programs

This section requires GAO to submit a report to Congress within one year of enactment regarding the programs for awarding cooperative agreements and grants and partnerships for State and regional hospital preparedness to improve surge capacity.

Section 3. Strategic national stockpile

This section requires that the Biomedical Advanced Research and Development Authority and Centers for Disease Control (BARDA) and Centers for Disease Control and Prevention (CDC) have procedures in place to coordinate ongoing stockpiling.

Section 4. Project Bioshield procurement process

This section removes the requirement for Office of Management and Budget (OMB) to review all BioShield contracts independently. This independent review is no longer necessary because the funds, which were originally housed at Department of Homeland Security (DHS) is now housed at HHS. This will remove an unnecessary level of bureaucracy and expedite the contracting process.

Section 5. BARDA transaction authority

This section would give BARDA the sole authority to negotiate and award its own medical countermeasure research and development contracts.

Section 6. Public health emergency medical countermeasures enterprise strategy and implementation plan

The 2013 Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) legislation required ASPR to create a 5-year medical countermeasure budget plan. The purpose of this plan was to anticipate countermeasure funding needs and spending plans across all chemical, biological, radiological and nuclear (CBRN) threats. In addition to CBRN, this section would require the 5-year budget to include planning for pandemic influenza, one of the largest public health threats we face today.

Section 7. Priority review to encourage treatments for agents that present national security threats

This section creates a new, permanent PRV program. This program would award a qualifying sponsor of a material threat medical countermeasures application a PRV, which entitles the sponsor to a second priority review of any other human drug application. To qualify for the award, a material threat medical countermeasure application must be for a human drug indicated to prevent, or treat harm from, a biological, chemical, radiological, or nuclear agent identified as a material threat. Additionally, the Secretary must deem the medical countermeasure application eligible for priority review and the medical countermeasure application must be approved after the date of enactment. The PRV is transferrable and there is no limit on how many times a voucher may be transferred or sold before it is used. The sponsor must notify FDA of its intent to transfer the voucher. Additionally, when a sponsor uses the PRV, it must notify FDA 90 days in advance of submitting an application for priority review and is required to pay an additional user fee, which shall be determined by the Secretary at the beginning of each fiscal year, starting after September 30, 2016.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * * * *

SEC. 319F–2. STRATEGIC NATIONAL STOCKPILE AND SECURITY COUNTERMEASURE PROCUREMENTS.

(a) STRATEGIC NATIONAL STOCKPILE.—

(1) IN GENERAL.—The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies in such numbers, types, and amounts as are determined consistent with section 2811 by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security.

(2) PROCEDURES.—The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 319F(a);

(B) ensure that adequate procedures are followed with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, and local officials, take into consideration the timing and location of special events;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;

(E) devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;

(F) deploy the stockpile as required by the Secretary of Homeland Security to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety; [and]

(H) ensure the adequate physical security of the stockpile[.]*; and*

(I) ensure procedures are in place to coordinate the ongoing stockpiling by the Biomedical Advanced Research and Development Authority and Centers for Disease Control and Prevention of qualified countermeasures (as defined in section 319F–1) for which funds have been made available under this part, security countermeasures (as defined in this section), and qualified pandemic or epidemic products (as defined in section 319F–3) for which funds have been made available under section 319L in order to avoid any gaps in preparedness.

(b) SMALLPOX VACCINE DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) ADDITIONAL AUTHORITY REGARDING PROCUREMENT OF CERTAIN COUNTERMEASURES; AVAILABILITY OF SPECIAL RESERVE FUND.—

(1) IN GENERAL.—

(A) USE OF FUND.—A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) SECURITY COUNTERMEASURE.—For purposes of this subsection, the term "security countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 351(i) of this Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)(I) the Secretary determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, 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, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical expe-

rience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act.

(2) DETERMINATION OF MATERIAL THREATS.—

(A) MATERIAL THREAT.—The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) PUBLIC HEALTH IMPACT; NECESSARY COUNTERMEASURES.—The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) NOTICE TO CONGRESS.—The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress that a determination has been made pursuant to subparagraph (A) or (B).

(D) ASSURING ACCESS TO THREAT INFORMATION.—In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 202 of the Homeland Security Act of 2002, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) ASSESSMENT OF AVAILABILITY AND APPROPRIATENESS OF COUNTERMEASURES.—

(A) IN GENERAL.—The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) INFORMATION.—The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5, United States Code.

(4) CALL FOR DEVELOPMENT OF COUNTERMEASURES; COMMITMENT FOR RECOMMENDATION FOR PROCUREMENT.—

(A) PROPOSAL TO THE PRESIDENT.—If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, **[**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**]** *make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure*.

(B) COUNTERMEASURE SPECIFICATIONS.—The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) PRESIDENTIAL APPROVAL.—If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) SECRETARY'S DETERMINATION OF COUNTERMEASURES APPROPRIATE FOR FUNDING FROM SPECIAL RESERVE FUND.—

(A) IN GENERAL.—The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to

in this subsection individually as a "procurement under this subsection").

(B) REQUIREMENTS.—In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) [RECOMMENDATION FOR PRESIDENT'S APPROVAL.—] *SUBSEQUENT SPECIFIC COUNTERMEASURES.*—

[(A) RECOMMENDATION FOR PROCUREMENT.—In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure.

[(B) PRESIDENTIAL APPROVAL.—The special reserve fund as defined in subsection (h) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure.

[(C) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary and the Homeland Security Secretary shall notify the appropriate congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund as defined in subsection (h) for procurement of such a countermeasure, including, where available, the number of, 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 therefor.

[(D) SUBSEQUENT SPECIFIC COUNTERMEASURES.—]Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear

agent. Such a determination by the Secretary is committed to agency discretion.

[(E) RULE OF CONSTRUCTION.—Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund as defined in subsection (h) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts.]

(7) PROCUREMENT.—

[(A) IN GENERAL.—For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C).

[(B) INTERAGENCY AGREEMENT; COST.—The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions of this paragraph. The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for such procurement.]

(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.

[(C)] *(B)* PROCUREMENT.—

(i) IN GENERAL.—The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) CONTRACT TERMS.—A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) PAYMENT CONDITIONED ON DELIVERY.—The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase man-

ufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) DISCOUNTED PAYMENT.—The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract (including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) CONTRACT DURATION.—The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years.

(IV) STORAGE BY VENDOR.—The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping,

handling, storage, and related costs for such product.

(V) PRODUCT APPROVAL.—The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) NON-STOCKPILE TRANSFERS OF SECURITY COUNTERMEASURES.—The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) SALES EXCLUSIVITY.—The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)).

(VIII) WARM BASED SURGE CAPACITY.—The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) CONTRACT TERMS.—The Secretary, in any contract for procurement under this section—

(aa) may specify—

(AA) THE DOSING AND ADMINISTRATION REQUIREMENTS FOR THE COUNTERMEASURE TO BE

DEVELOPED AND PROCURED;
(BB) THE AMOUNT OF FUNDING THAT WILL BE DEDICATED BY THE SECRETARY FOR ADVANCED RESEARCH, DEVELOPMENT, AND PROCUREMENT OF THE COUNTERMEASURE; AND
(CC) THE SPECIFICATIONS THE COUNTERMEASURE MUST MEET TO QUALIFY FOR PROCUREMENT UNDER A CONTRACT UNDER THIS SECTION; AND

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) AVAILABILITY OF SIMPLIFIED ACQUISITION PROCEDURES.—

(I) IN GENERAL.—If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11)), for purposes of application to such procurement, pursuant to section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a)), of—

(aa) section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A)) and its implementing regulations; and

(bb) section 302A(b) of such Act (41 U.S.C. 252a(b)) and its implementing regulations.

(II) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40, United States Code (relating to contract work hours and safety standards).

(bb) Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b)).

(cc) Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d) (relating to the examination of contractor records).

(dd) Section 3131 of title 40, United States Code (relating to bonds of contractors of public buildings or works).

(ee) Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a)) (relating to contingent fees to middlemen).

(ff) Section 6002 of the Solid Waste Disposal Act (42 U.S.C. 6962).

(gg) Section 1354 of title 31, United States Code (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) INTERNAL CONTROLS TO BE ESTABLISHED.—The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) AUTHORITY TO LIMIT COMPETITION.—In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) PROCEDURES OTHER THAN FULL AND OPEN COMPETITION.—

(I) IN GENERAL.—In using the authority provided in section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1)) to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase "available from only one responsible source" in such section 303(c)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(II) RELATION TO OTHER AUTHORITIES.—The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) APPLICABLE GOVERNMENT-WIDE REGULATIONS.—The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 303(c)(1) (including requirements that offers

be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(v) PREMIUM PROVISION IN MULTIPLE AWARD CONTRACTS.—

(I) IN GENERAL.—If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) DETERMINATION OF GOVERNMENT'S REQUIREMENT NOT REVIEWABLE.—If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) EXTENSION OF CLOSING DATE FOR RECEIPT OF PROPOSALS NOT REVIEWABLE.—A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) LIMITING COMPETITION TO SOURCES RESPONDING TO REQUEST FOR INFORMATION.—In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B)) if such request has given notice that the Secretary may so exclude such a source.

(viii) FLEXIBILITY.—In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and

other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) INTERAGENCY COOPERATION.—

(A) IN GENERAL.—In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, United States Code, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) LIMITATION.—An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) DISCLOSURES.—No Federal agency shall disclose under section 552 of title 5, United States Code, any information identifying the location at which materials in the stockpile under subsection (a) are stored.

(e) DEFINITION.—For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) AUTHORIZATION OF APPROPRIATIONS.—

(1) STRATEGIC NATIONAL STOCKPILE.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $533,800,000 for each of fiscal years 2014 through 2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) SMALLPOX VACCINE DEVELOPMENT.—For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) SPECIAL RESERVE FUND.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section

319L (relating to the Biomedical Advanced Research and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

(2) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 319L) or for procurement of a security countermeasure under subsection (c)(7).

(4) REPORT.—Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in 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)).

(h) DEFINITIONS.—In this section:

(1) The term "advanced research and development" has the meaning given such term in section 319L(a).

(2) The term "special reserve fund" means the "Biodefense Countermeasures" appropriations account, any appropriation made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to subsection (g)(1).

* * * * * * *

SEC. 319L. BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.

(a) DEFINITIONS.—In this section:

(1) BARDA.—The term "BARDA" means the Biomedical Advanced Research and Development Authority.

(2) FUND.—The term "Fund" means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) OTHER TRANSACTIONS.—The term "other transactions" means transactions, other than procurement contracts, grants, and cooperative agreements, such as the Secretary of Defense may enter into under section 2371 of title 10, United States Code.

(4) QUALIFIED COUNTERMEASURE.—The term "qualified countermeasure" has the meaning given such term in section 319F–1.

(5) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term "qualified pandemic or epidemic product" has the meaning given the term in section 319F–3.

(6) ADVANCED RESEARCH AND DEVELOPMENT.—

(A) IN GENERAL.—The term "advanced research and development" means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

(B) ACTIVITIES INCLUDED.—The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to improve the shelf-life of the product or technologies for administering the product; and

(v) such other activities as are part of the advanced stages of testing, refinement, improvement, or preparation of the product for such use and as are specified by the Secretary.

(7) SECURITY COUNTERMEASURE.—The term "security countermeasure" has the meaning given such term in section 319F–2.

(8) RESEARCH TOOL.—The term "research tool" means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) PROGRAM MANAGER.—The term "program manager" means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

(10) PERSON.—The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

(b) STRATEGIC PLAN FOR COUNTERMEASURE RESEARCH, DEVELOPMENT, AND PROCUREMENT.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of the Pandemic and All-Hazards Preparedness Act, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 2802.

(2) CONTENT.—The strategic plan under paragraph (1) shall guide—

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as "countermeasure and product advanced research and development"); and

(C) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) IN GENERAL.—Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by—

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development;

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) DIRECTOR.—The BARDA shall be headed by a Director (referred to in this section as the "Director") who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section.

(4) DUTIES.—

(A) COLLABORATION.—To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest; and

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section; and

(iii) carry out the activities described in section 405 of the Pandemic and All-Hazards Preparedness Act.

(B) SUPPORT ADVANCED RESEARCH AND DEVELOPMENT.—To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act) and innovation in such areas

as the Secretary may identify as priority unmet need areas; and

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development.

(C) FACILITATING ADVICE.—To carry out the purpose described in paragraph (2)(C) the Secretary shall—

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products; and

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure.

(D) SUPPORTING INNOVATION.—To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

(i) innovation in technologies that may assist countermeasure and product advanced research and development;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies.

(5) TRANSACTION AUTHORITIES.—

(A) OTHER TRANSACTIONS.—

(i) IN GENERAL.—The Secretary shall have the authority to enter into other transactions under this subsection in the same manner as the Secretary of Defense enters into such transactions under section 2371 of title 10, United States Code.

(ii) LIMITATIONS ON AUTHORITY.—

(I) IN GENERAL.—Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845.

(II) WRITTEN DETERMINATIONS REQUIRED.—The authority of this subparagraph may be exercised

for a project that is expected to cost the Department of Health and Human Services in excess of $20,000,000 only upon a written determination by the senior procurement executive for the Department (as designated for purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c))), that the use of such authority is essential to promoting the success of the project. The authority of the senior procurement executive under this subclause may not be delegated.

(iii) GUIDELINES.—The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) EXPEDITED AUTHORITIES.—

(i) IN GENERAL.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 319F–1.

(ii) APPLICATION OF PROVISIONS.—Provisions in such section 319F–1 that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

(iii) AUTHORITY TO LIMIT COMPETITION.—For purposes of applying section 319F–1(b)(1)(D) to this paragraph, the phrase "BioShield Program under the Project BioShield Act of 2004" shall be deemed to mean the countermeasure and product advanced research and development program under this section.

(iv) AVAILABILITY OF DATA.—The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

(C) ADVANCE PAYMENTS; ADVERTISING.—The Secretary may waive the requirements of section 3324(a) of title 31, United States Code, or section 3709 of the Revised Statutes of the United States (41 U.S.C. 5) upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

(D) MILESTONE-BASED PAYMENTS ALLOWED.—In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

(E) FOREIGN NATIONALS ELIGIBLE.—The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

(F) ESTABLISHMENT OF RESEARCH CENTERS.—The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3)).

(G) GOVERNMENT PURPOSE.—In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(H) CONTRACTING AUTHORITY CLARIFICATION.—The Secretary shall delegate authority for negotiating and entering into any contracts, grants, or cooperative agreements under this section to the Director.

(6) AT-RISK INDIVIDUALS.—In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.

(7) PERSONNEL AUTHORITIES.—

(A) SPECIALLY QUALIFIED SCIENTIFIC AND PROFESSIONAL PERSONNEL.—

(i) IN GENERAL.—In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5, United States Code, governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

(II) compensate them in the same manner and subject to the same terms and conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(ii) MANNER OF EXERCISE OF AUTHORITY.—The authority provided for in this subparagraph shall be ex-

ercised subject to the same limitations described in section 319F–1(e)(2).

(iii) TERM OF APPOINTMENT.—The term limitations described in section 9903(c) of title 5, United States Code, shall apply to appointments under this subparagraph, except that the references to the "Secretary" and to the "Department of Defense's national security missions" shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

(B) SPECIAL CONSULTANTS.—In carrying out this section, the Secretary may appoint special consultants pursuant to section 207(f).

(C) LIMITATION.—

(i) IN GENERAL.—The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

(ii) REPORT.—The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

(d) FUND.—

(1) ESTABLISHMENT.—There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

(2) FUNDING.—To carry out the purposes of this section, there is authorized to be appropriated to the Fund $415,000,000 for each of fiscal years 2014 through 2018, such amounts to remain available until expended.

(e) INAPPLICABILITY OF CERTAIN PROVISIONS.—

(1) DISCLOSURE.—

(A) IN GENERAL.—The Secretary shall withhold from disclosure under section 552 of title 5, United States Code, specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5, United States Code.

(B) REVIEW.—Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) SUNSET.—This paragraph shall cease to have force or effect on the date that is 12 years after the date of enactment of the Pandemic and All-Hazards Preparedness Act.

(2) REVIEW.—Notwithstanding section 14 of the Federal Advisory Committee Act, a working group of BARDA under this

section and the National Biodefense Science Board under section 319M shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.

(f) INDEPENDENT EVALUATION.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) REPORT.—Not later than 1 year after the date of enactment of this subsection, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives; and

(C) the ability of flexible manufacturing activities carried out under this section to—

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents.

* * * * * * *

TITLE XXVIII—NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES

* * * * * * *

Subtitle B—All-Hazards Emergency Preparedness and Response

SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND RESPONSE TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—There is established within the Department of Health and Human Services the position of the Assistant Secretary for Preparedness and Response. The President, with the advice and consent of the Senate, shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

(b) DUTIES.—Subject to the authority of the Secretary, the Assistant Secretary for Preparedness and Response shall carry out the following functions:

(1) LEADERSHIP.—Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.

(2) PERSONNEL.—Register, credential, organize, train, equip, and have the authority to deploy Federal public health and medical personnel under the authority of the Secretary, including the National Disaster Medical System, and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals.

(3) COUNTERMEASURES.—Oversee advanced research, development, and procurement of 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).

(4) COORDINATION.—

(A) FEDERAL INTEGRATION.—Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.

(B) STATE, LOCAL, AND TRIBAL INTEGRATION.—Coordinate with State, local, and tribal public health officials, the Emergency Management Assistance Compact, health care systems, and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.

(C) EMERGENCY MEDICAL SERVICES.—Promote improved emergency medical services medical direction, system integration, research, and uniformity of data collection, treatment protocols, and policies with regard to public health emergencies.

(D) POLICY COORDINATION AND STRATEGIC DIRECTION.—Provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan developed pursuant to section 504(6) of the Homeland Security Act of 2002, or any successor plan, before, during, and following public health emergencies.

(E) IDENTIFICATION OF INEFFICIENCIES.—Identify and minimize gaps, duplication, and other inefficiencies in medical and public health preparedness and response activities and the actions necessary to overcome these obstacles.

(F) COORDINATION OF GRANTS AND AGREEMENTS.—Align and coordinate medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this Act, to the extent possible, including program requirements, timelines, and measurable goals, and in consultation with the Secretary of Homeland Security, to—

(i) optimize and streamline medical and public health preparedness and response capabilities and the ability of local communities to respond to public health emergencies; and

(ii) gather and disseminate best practices among grant and cooperative agreement recipients, as appropriate.

(G) DRILL AND OPERATIONAL EXERCISES.—Carry out drills and operational exercises, in consultation with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies, as necessary and appropriate, to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response, including exercises based on—

(i) identified threats for which countermeasures are available and for which no countermeasures are available; and

(ii) unknown threats for which no countermeasures are available.

(H) NATIONAL SECURITY PRIORITY.—On a periodic basis consult with, as applicable and appropriate, the Assistant to the President for National Security Affairs, to provide an update on, and discuss, medical and public health preparedness and response activities pursuant to this Act and the Federal Food, Drug, and Cosmetic Act, including progress on the development, approval, clearance, and licensure of medical countermeasures.

(5) LOGISTICS.—In coordination with the Secretary of Veterans Affairs, the Secretary of Homeland Security, the General Services Administration, and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies.

(6) LEADERSHIP.—Provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.

(7) COUNTERMEASURES BUDGET PLAN.—Develop, and update on an annual basis, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d). Each such plan shall—

(A) include consideration of the entire medical countermeasures enterprise, including—

(i) basic research and advanced research and development;

(ii) approval, clearance, licensure, and authorized uses of products; and

(iii) procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile;

(B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

(C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 319F–2; and

(D) be made available to the appropriate committees of Congress upon request.

(c) FUNCTIONS.—The Assistant Secretary for Preparedness and Response shall—

(1) have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction;

(2) have authority over and responsibility for—

(A) the National Disaster Medical System pursuant to section 2812;

(B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 319C–2;

(C) the Biomedical Advanced Research and Development Authority pursuant to section 319L;

(D) the Medical Reserve Corps pursuant to section 2813;

(E) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 319I; and

(F) administering grants and related authorities related to trauma care under parts A through C of title XII, such authority to be transferred by the Secretary from the Administrator of the Health Resources and Services Administration to such Assistant Secretary;

(3) exercise the responsibilities and authorities of the Secretary with respect to the coordination of—

(A) the Public Health Emergency Preparedness Cooperative Agreement Program pursuant to section 319C–1;

(B) the Strategic National Stockpile pursuant to section 319F–2; and

(C) the Cities Readiness Initiative; and

(4) assume other duties as determined appropriate by the Secretary.

(d) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, and every year thereafter, the Assistant Secretary for Preparedness and Response shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. In developing such a plan, the Assistant Secretary for Preparedness and Response shall consult with the Director of the Biomedical Advanced Research and Development Authority, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs. Such strategy and plan shall be known as the "Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan".

(2) REQUIREMENTS.—The plan under paragraph (1) shall—

(A) describe the chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation *(which shall include pandemic influenza)* and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), or qualified pandemic or

epidemic products (as defined in section 319F–3) for each threat;

(B) evaluate the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization;

(C) identify and prioritize near-, mid-, and long-term needs with respect to such countermeasures or products to address a chemical, biological, radiological, and nuclear threat or threats;

(D) identify, with respect to each category of threat, a summary of all awards and contracts, including advanced research and development and procurement, that includes—

(i) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination); and

(ii) an identification of projected timelines, anticipated funding allocations, benchmarks, and milestones for each medical countermeasure priority under subparagraph (C), including projected needs with regard to replenishment of the Strategic National Stockpile;

(E) be informed by the recommendations of the National Biodefense Science Board pursuant to section 319M;

(F) evaluate progress made in meeting timelines, allocations, benchmarks, and milestones identified under subparagraph (D)(ii);

(G) report on the amount of funds available for procurement in the special reserve fund as defined in section 319F–2(h) and the impact this funding will have on meeting the requirements under section 319F–2;

(H) incorporate input from Federal, State, local, and tribal stakeholders;

(I) identify the progress made in meeting the medical countermeasure priorities for at-risk individuals (as defined in 2802(b)(4)(B)), as applicable under subparagraph (C), including with regard to the projected needs for related stockpiling and replenishment of the Strategic National Stockpile, including by addressing the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile, including—

(i) a list of such countermeasures and products necessary to address the needs of pediatric populations;

(ii) a description of measures taken to coordinate with the Office of Pediatric Therapeutics of the Food and Drug Administration to maximize the labeling, dosages, and formulations of such countermeasures and products for pediatric populations;

(iii) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

(iv) an evaluation of the progress made in addressing priorities identified pursuant to subparagraph (C);

(J) identify the use of authority and activities undertaken pursuant to sections 319F–1(b)(1), 319F–1(b)(2), 319F–1(b)(3), 319F–1(c), 319F–1(d), 319F–1(e), 319F–2(c)(7)(C)(iii), 319F–2(c)(7)(C)(iv), and 319F–2(c)(7)(C)(v) of this Act, and subsections (a)(1), (b)(1), and (e) of section 564 of the Federal Food, Drug, and Cosmetic Act, by summarizing—

(i) the particular actions that were taken under the authorities specified, including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity;

(iv) whether, with respect to each procurement that is approved by the President under section 319F–2(c)(6), a contract was entered into within one year after such approval by the President; and

(v) with respect to section 319F–1(d), for the one-year period for which the report is submitted, the number of persons who were paid amounts totaling $100,000 or greater and the number of persons who were paid amounts totaling at least $50,000 but less than $100,000; [and]

(K) report on the amount of time between the issuance of each request for a proposal or task order from the Biomedical Advanced Research and Development Authority and the award of a contract pursuant to such request for a proposal or task order; and

[(K)] *(L)* be made publicly available.

(3) GAO REPORT.—

(A) IN GENERAL.—Not later than 1 year after the date of the submission to the Congress of the first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning such Strategy and Implementation Plan.

(B) CONTENT.—The report described in subparagraph (A) shall review and assess—

(i) the near-term, mid-term, and long-term medical countermeasure needs and identified priorities of the Federal Government pursuant to paragraph (2)(C);

(ii) the activities of the Department of Health and Human Services with respect to advanced research and development pursuant to section 319L; and

(iii) the progress made toward meeting the timelines, allocations, benchmarks, and milestones identified in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection.

(e) PROTECTION OF NATIONAL SECURITY.—In carrying out subsections (b)(7) and (d), the Secretary shall ensure that information and items that could compromise national security, contain confidential commercial information, or contain proprietary information are not disclosed.

* * * * * * *

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

* * * * * * *

SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

* * * * * * *

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

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—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 of 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 (Public Law 112–144).

(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) of this Act 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) to prevent, or treat harm from, a biological, chem-

ical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act;

(B) the Secretary deems eligible for priority review;

(C) is approved after the date of enactment of the Strengthening Public Health Emergency Response 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 pursuant to any other application under section 505(b)(1) of this Act 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 application.

(2) TRANSFERABILITY.—

(A) IN GENERAL.—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) of this Act 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.

(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after the date of such transfer.

(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, 2016, 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 notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(3)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

(B) COMPLETE APPLICATION.—An application described in 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 public 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 issued under any section of this Act with respect to the drug that is the subject of such application.

(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.

(g) MEDICAL COUNTERMEASURE POSTAPPROVAL REPORT.—

(1) IN GENERAL.—Not later than 5 years after the date of approval of a material threat medical countermeasure application, the sponsor of such application shall submit a report to the Secretary on such medical countermeasure.

(2) CONTENTS.—A report under paragraph (1) shall include, with respect to each of the first 2 years after approval of such material threat medical countermeasure application, a description of—

(A) the sponsor's activities with Federal agencies related to the procurement, including stockpiling, of the approved medical countermeasure;

(B) the sponsor's progress in fulfilling contracts entered into with Federal agencies, including the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, and the Department of Defense, related to such procurement;

(C) the extent to which the Federal Government has fulfilled its stated medical countermeasure requirements for the threat intended to be treated by the approved medical countermeasure; and

(D) the sponsor's plans, if any, to develop additional material threat medical countermeasures.

(3) AVAILABILITY TO CONGRESSIONAL COMMITTEES.—The Secretary shall make each report submitted under this subsection available to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate upon request by either such Committee not later than 30 days after receipt of such request.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to permit the disclosure of confidential commercial or trade secret information or the disclosure of information that could compromise national security.

* * * * * * *

DISSENTING VIEWS

We oppose the passage of H.R. 3299, the Strengthening Public Health Emergency Response Act of 2015, a bill that would make reforms to how the federal government acquires, procures, and develops medical countermeasures (MCMs) to prevent or treat biological threats. While this legislation attempts to address important recommendations on our nation's biodefense preparedness, we are concerned that it would not improve our nation's biodefense preparedness, includes policies that will undermine the Department of Health and Human Services' (HHS) oversight over biodefense contracting, and would further burden the Food and Drug Administration (FDA) by creating a new, permanent, and unnecessary priority review voucher (PRV) program to incentivize the development of MCMs without addressing underlying flaws inherent in this incentive program.

I. BACKGROUND

Following the September 11, 2001, terrorist attacks and the subsequent anthrax mailings, Congress passed legislation to address the threat of bioterrorism by increasing investments in research and preparedness to defend against biological weapons.[1] Significant legislation included the Homeland Security Act of 2002 and the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, which established new departments and agencies to address preparedness and bioterrorism response.[2]

Earlier this year the Subcommittee on Oversight and Investigations heard from members of the Blue Ribbon Panel on Biodefense and other experts about the current status of the United States' biodefense preparedness. A report released by the Blue Ribbon Panel on October 28, 2015, found:

> The nation has not come to fully appreciate the severity of the biological threat and our leaders have not demonstrated the political will to fully address it. We must address these shortcomings by prioritizing the following areas: 1) coordination and accountability among federal departments and agencies; 2) collaboration between federal and non-federal stakeholders; and 3) innovation that addresses both lingering and novel problems."[3]

Further, the report found that the United States "does not afford the biological threat the same level of attention as it does other

---

[1] Congressional Research Service, *Federal Efforts to Address the Threat of Bioterrorism: Selected Issues and Options for Congress* (Feb. 8, 2011) (R41123).

[2] *Id.*

[3] Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* (Oct. 2015).

threats."[4] This comprehensive review also offered 33 recommendations about how Congress and the Administration can improve our preparedness. H.R. 3299 was introduced in response to this report and includes provisions meant to address these recommendations, such as: putting in place procedures to coordinate the ongoing stockpiling of medical countermeasures by the Biomedical Advanced Research and Development Authority (BARDA) and the Centers for Disease Control and Prevention; providing BARDA with direct contracting authority; requiring a report by the Government Accountability Office (GAO) on programs for public health emergency preparedness; and creating a PRV program, which would award a voucher to the sponsor of a new drug or biological product to treat a material threat that entitles the sponsor to a six month review of any future new drug or biological product application of the sponsor's choosing.

While legislative efforts to increase our nation's preparedness and response to biological threats have historically enjoyed bipartisan support, H.R. 3299 fails to address concerns raised by the Administration regarding provisions that would limit oversight over contracting authority and would create a burdensome incentive program without addressing flaws in the underlying program's structure.

II. H.R. 3299: A Misguided Attempt To Reform Biodefense Contracting and Medical Countermeasure Development

A. H.R. 3299 REVISES BARDA TRANSACTION AUTHORITIES, UNDERMINING PROGRAM INTEGRITY

H.R. 3299 would grant BARDA the authority to directly negotiate and enter into contracts, grants, or cooperative agreements. The change to BARDA's contracting structure proposed by H.R. 3299 raises concerning program integrity issues. Currently, BARDA enters into contracts through the Office of Acquisition, Management, Contracts, and Grants (AMCG) and the Assistant Secretary for Preparedness and Response (ASPR) Office, its parent organization. This structure protects the integrity of the contracting process. The delegation of the function to negotiate and enter into contracts, grants, and cooperative agreements to the BARDA Director could result in the federal government not getting the best value for taxpayer dollars.

After Secretary Sebelius provided Congress with notice and published the required announcement in the Federal Registrar in 2010, contracting offices were removed from BARDA and other divisional entities within ASPR and consolidated into the AMCG along with other ASPR-wide reorganization efforts. The restructuring of the contract offices was done to streamline ASPR's contracting activity, to bolster program integrity, and to ensure that ASPR and all of its operating divisions conduct their business without either the perception or potentially the reality of undue influence by program officials. The restructuring also allowed the AMCG to get Head of Contracting Activity (HCA)—an authority that allows a contracting office to be a self-fulfilling, self-managed

[4] *Id.*

contracting office. This designation removed the need for the contracting office to go through an additional layer of approval at the departmental level before a contract could be completed. The current structure, which is consistent with procurement practices across the federal government, ensures the right balance between expert scientists that advance our national preparedness and expert contracting professionals that ensure the government is getting the best value for every taxpayer dollar.

The integrity-minded structure established by the ASPR in 2010 has not only contributed to a steadily improved contracting process but also one that has successfully withstood the few protests presented to the organization. The existence of undue influence could potentially compel a contracting officer to do something unethical or illegal at the direction of the BARDA director because they worry that the BARDA director, who would ultimately control their performance appraisal and promotions, might take adverse action against them. Overpaying for the research and development of medical countermeasures or for some products could limit our ability to enter into advanced development and procurement contracts for new medical countermeasures since only finite resources are available. This could weaken our preparedness for public health emergencies and protection against terrorist attacks by limiting the number of medical countermeasures we have in the pipeline to respond to chemical, biological, radiological, and nuclear (CBRN) threats as well as other public health threats.

1. Potentially Slows Down the Contracting Process

The changes proposed by H.R. 3299 could result in the contracting office losing its HCA designation, which would be consistent with the operation of the contracting office prior to its placement under ASPR. Since the reorganization of ASPR, which consolidated organization-wide contracting activities in the AMCG Office at ASPR, BARDA has experienced an acceleration in the delivery of medical countermeasures. For example, of the total 23 products that BARDA has supported that received FDA approval, licensure, or clearance, 14 of those approvals have occurred since 2011 and five have occurred in the last 16 months. BARDA is also currently supporting a pipeline of over 100 more.

If the contracting office loses that designation, BARDA contracts could be forced to go through an additional layer of approval at the department level that is not required by the current structure. As a result, the pace at which BARDA completes contracts is likely to slow down. This would be counter to the stated goals of this change and harm our ability to accelerate medical countermeasure development.

B. H.R. 3299 EXTENDS AN UNNECESSARY, UNPROVEN, AND INHERENTLY FLAWED INCENTIVE TO MEDICAL COUNTERMEASURES

As passed by the Committee, H.R. 3299 creates a new standalone and permanent PRV program for MCMs. The new permanent MCM PRV program would require FDA to review within six months any human drug application that is: (1) approved to prevent or treat harm from a material threat listed in section 319F–

2(c)(2)(A)(ii) of the Public Health Service Act; (2) eligible for priority review; (3) approved after the date of enactment of H.R. 3299; and, (4) includes no active ingredient previously approved by FDA.[5] If FDA approves such an application, the agency must award the sponsor a PRV which entitles its holder to a second six-month priority review of any other human drug application (the standard drug review time is ten months). A company awarded a PRV can redeem the voucher for expedited review of its own product, or transfer or sell the PRV to another company. The only requirement is that a company redeeming a PRV must provide FDA with 90 days advanced notice of its intent to redeem and pay FDA a priority review user fee to help offset the costly and resource-intensive priority review. The creation of this incentive is meant to spur continued and future development of MCMs.

1. Existing Authorities and Incentives Sufficient to Encourage MCM Development

While MCMs play an important role in our national security, H.R. 3299 extends an unnecessary incentive to drug companies. Companies that produce MCMs often receive significant federal support throughout the drug research and development, approval, and procurement process. A 2014 Congressional Research Service (CRS) report stated that, since 2004, the federal government has spent over $3 billion procuring MCMs.[6] Further, in addition to the billions spent post-approval by the government to purchase these products for stockpiling, lucrative federal contracts often support research and development of these drugs.[7]

FDA also devotes significant taxpayer funded resources to assist MCM sponsors throughout the drug development and approval process. For example, in fiscal year 2015 alone, FDA held 84 formal meetings with MCM developers or applicants to provide technical assistance or clarify regulatory requirements.[8] Since 2000, FDA has approved 89 medical countermeasures, 17 supplemental changes to already approved applications, and 71 modifications to diagnostic devices.[9] Drug companies developing MCMs also often utilize existing government research and develop and produce MCMs in government-funded research facilities and production sites.[10,11] The large number of approved MCMs and strong regulatory support demonstrate that sufficient incentives currently

---

[5] H.R. 3299, Section 7.

[6] Congressional Research Service, *The Project BioShield Act: Issues for the 113th Congress* (June 18, 2014) (R43607).

[7] For example, in the 2015 President's Budget, HHS reported it would spend over $830 million during the 2015 fiscal year to support medical countermeasure research, development, and procurement through BARDA and Project BioShield. Department of Health and Human Services, *FY2015 Budget in Brief,* (June 4, 2014) (www.hhs.gov/about/budget/fy2015/budget-in-brief/phssef/index.html#).

[8] House Committee on Energy and Commerce, Testimony of Michael Mair, Director of Strategic Operations, Food and Drug Administration, *Hearing on Examining H.R. 3299, Strengthening Public Health Response Act, 114th Cong.* (May 19, 2016)

[9] *Id.*

[10] Department of Health and Human Services, *Department Of Health And Human Services' Centers for Innovation in Advanced Development and Manufacturing (HHS–CIADM)* (www.medicalcountermeasures.gov/barda/core-services/ciadm.aspx).

[11] *Nanotherapeutics Celebrates Groundbreaking of its Advanced Development and Manufacturing Center (NANO–ADM) in Copeland Park, Alachua, FL*, Business Wire (Oct. 23, 2013) (www.businesswire.com/news/home/20131023005120/en/Nanotherapeutics-Celebrates-Groundbreaking-Advanced-Development-Manufacturing-Center).

exist for investments in MCM development. Providing an additional incentive of a PRV, the last of which sold for $350 million, is unnecessary and will amount to a windfall for many drug companies at the expense of American taxpayers.

2. Lack of Evidence PRV Programs Work

It is unclear if existing PRV programs are having the intended effect of incentivizing investment in new research and development of drugs. At the May 19, 2016 Subcommittee on Health hearing on H.R. 3299, FDA testified that, to date, there is no evidence that the two existing PRV programs (rare pediatric diseases and neglected tropical diseases) are incentivizing new research and drug development, or benefiting those Congress intended.[12] For example, of the three PRVs awarded under the tropical disease PRV program, two were awarded to drugs that had been used for years outside the United States. One drug was approved in over 80 countries before the sponsor filed an application with FDA—an application that included only studies conducted before 2007 to obtain approval outside the United States.[13] The second drug was registered outside the United States for over a decade before an application was filed with FDA and the filed application only included studies conducted by a company that previously owned the drug.[14] However, under the terms of the program, FDA was forced to award two PRVs—one to a company that conducted no new research, and one to a company that conducted no research at all. Further, in the tropical disease PRV program, people afflicted with the disease have been unable to access approved drugs because, unlike the rare pediatric PRV program, there is no requirement that a sponsor market its drug after receiving the valuable PRV award in the tropical disease context. The underlying problems identified in the tropical disease PRV program have not been addressed in the creation of the MCM PRV program in H.R. 3299. H.R. 3299 does not limit a PRV award only to companies that invest in new drug research and development, and does not require a company that receives a PRV to produce and make the MCM available to the U.S. government for stockpiling purposes.

3. Proposed New PRV Program Does Not Meaningfully Limit Eligibility

Under H.R. 3299, FDA must approve a new drug application (NDA) for a drug to treat a material threat that: (1) qualifies for a six-month priority review;[15] (2) is approved after the date of enactment; and (3) contains no active ingredient previously approved

---

[12] House Committee on Energy and Commerce, Testimony of Michael Mair, Director of Strategic Operations, Food and Drug Administration, *Hearing on Examining H.R. 3299, Strengthening Public Health Response Act*, 114th Cong. (May 19, 2016)

[13] Tatum Anderson, *Novartis Under Fire for Accepting New Reward for Old Drug*, Lancet (Apr. 25, 2009).

[14] Aaron S. Kesselheim et al., *Experience With the Priority Review Voucher Program for Drug Development*, JAMA (Oct. 27, 2015)

[15] There is a set criteria FDA must adhere to when designating a drug as eligible for priority review and this should not be viewed as giving FDA significant discretion in determining PRV eligibility. To qualify for priority review, a drug must treat a serious condition (e.g., a material threat) and demonstrate only *potential* to be a significant improvement in safety or effectiveness. After receiving a request for a priority review designation, FDA only has 60 days to make this determination.

by FDA. If the sponsor's NDA meets these qualifications and is approved by FDA, the sponsor is then eligible for a PRV. The program created in the H.R. 3299 AINS does not preclude PRV awards to drug companies:

- With drug applications currently under review at FDA;
- That previously received approval of the MCM outside the United States; and,
- That are developing drugs that do not fulfill an existing federal government need (e.g., developing drugs for which there is an existing treatment in the strategic national stockpile).

Without appropriate safeguards, it is unclear that H.R. 3299 would appropriately award PRVs to new MCMs that are needed by the federal government, and could instead further flood the market with PRVs for products that may not be novel or necessary from a national preparedness perspective. This could have the unintended consequence of reducing the value of PRVs overall and thereby disincentivize development of new drugs under all PRV programs.

4. Creation of a New PRV Program Could Undermine FDA's Drug Review Process and Public Health Mission

Generally, FDA will grant a six-month priority review to drug applications that have potential to improve public health, such as a drug that will address an unmet medical need. However, PRVs awarded under the tropical and rare pediatric disease programs can be used to expedite review of a drug application that otherwise would not qualify. PRV programs essentially allow a drug sponsor to purchase a priority review at the expense of other public health priorities. Increasing the burden on FDA to expedite review of more applications with limited public health value undermines FDA's ability to fulfill its mission, manage its drug review workload, and threatens staff morale.

FDA drug product reviewers are organized into divisions that specialize in reviewing specific drug classes. Drug reviewers cannot be "reassigned" to assist another division in reviewing an application submitted for expedited review (e.g., a reviewer trained to review oncology drugs cannot be reassigned to help expedite review of a weight loss drug submitted with a PRV). A drug company utilizing a PRV must only provide FDA with 90 days' notice before submitting the new drug application for priority review, preventing FDA from hiring and training staff necessary to expedite review of applications submitted with a PRV. As a result, when a company redeems a PRV, FDA must divert resources from existing work to expedite review of a drug that may, under normal circumstances, be a lower priority. In addition, a new drug application that qualifies for the standard ten-month review generally is supported by large data sets that take FDA reviewers significant time to evaluate. When such an application is submitted with a PRV, it places a significant strain on FDA resources by reducing the time an FDA reviewer has to perform important work from ten to six months.

Some supporters of the new PRV program included in H.R. 3299 have suggested that this incentive comes at no cost to the taxpayer. However, expediting review of new drug applications that would

not ordinarily qualify for priority review, places an enormous strain on FDA's resources. This costs taxpayers money since it is tax dollars that fund this additional work. Additionally, it costs the American public when access to new drugs is delayed because a drug company "skipped the line" with a PRV and delayed FDA approval of other important drugs.

5. Expanding Eligibility for PRVs to MCMs May Diminish the Value for Tropical Disease and Rare Pediatric PRVs

David Ridley, the architect of the PRV program, cautioned against expanding the program to include MCMs. In a letter submitted for the record at the May 19, 2016, hearing on H.R. 3299, Mr. Ridley stated that such expansion could reduce the value of a PRV, as increasing the number of available PRVs would sharply decrease the expected price. This would make a PRV not only an ineffective incentive to develop MCMs, but also have the unintended consequence of disincentivizing development of drugs to treat rare pediatric and neglected tropical diseases as well. Mr. Ridley stated:

> Viewed in isolation, it makes perfect sense to add medical countermeasures to the diseases eligible for priority review vouchers. However, members of Congress should be aware that adding voucher-eligible diseases will drive down the price of vouchers and thus drive down the incentive to develop treatments for diseases already on the list. In the current issue of Health Affairs, my coauthor and I estimated that if one voucher is available in a year, it will be worth more than $200 million, but if four vouchers are available, then the price could fall below $100 million (Ridley and Régnier 2006). If voucher prices fall below $100 million, then the expected net present value of the voucher would fall below the typical cost of a Phase III clinical trial and FDA submission. Hence, the voucher would not provide sufficient incentive for drug development and additional incentives would be needed . . .[16]

Devaluation of a PRV can reduce the program's effectiveness by undermining incentives to develop new medicines for tropical or rare pediatric diseases.[17]

6. The Unjustified and Unnecessary MCM PRV Program Would Be Permanent

In other important areas, such as incentivizing development of drugs to help children, Congress thought it important to include a sunset date to allow for an opportunity to assess a program's impacts and determine if reauthorization is in the best interest of the American public. For example, the rare pediatric disease PRV program, the Best Pharmaceuticals for Children Act (BPCA), and the Pediatric Research Equity Act (PREA) included initial sunset dates

---

[16]Letter from Dr. David Ridley, Ph.D, Faculty Director, Health Sector Management, Duke University Fuqua School of Business, to Rep. Frank Pallone, Jr. and Rep. Gene Green, House Committee on Energy and Commerce (May 17, 2016).

[17]David B. Ridley and Stephane A. Regnier, *The Commercial Market For Priority Review Vouchers*, Health Affairs (May 1, 2016) (content.healthaffairs.org/content/35/5/776.full).

so that we, as members of Congress, could determine if the legislation we enacted was working as intended. Both BPCA and PREA were later enacted on a permanent basis; however, this was only after Congress had the opportunity to assess if the program's benefits outweighed its costs.[18]

There is no sunset in the MCM PRV program that would give Congress a similar opportunity to determine if the program is effective or working as intended. It is important to note that there has been only one study of existing priority review programs, which focused narrowly on one PRV program. In this study, the Government Accountability Office found a lack of evidence demonstrating that the rare pediatric disease program was incentivizing new investment in drug research and development. As there is no existing evidence—other than anecdotes from those that stand to gain from PRV programs—demonstrating that such programs are having the effect that Congress intended, it is unwise to create a new and permanent program for MCMs.

FRANK PALLONE, Jr.,
Ranking Member.
GENE GREEN,
Ranking Member, Subcommittee on Health.

○

[18] BPCA was enacted in 1997, and PREA was enacted in 2003. Both programs were made permanent as a part of the Food and Drug Administration Safety and Innovation Act in 2012.