

# Union Calendar No. 571

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

# H. R. 3299

[Report No. 114–735]

To amend the Public Health Service Act to ensure preparedness for chemical, radiological, biological, and nuclear threats, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2015

Mrs. BROOKS of Indiana (for herself and Ms. ESHOO) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 9, 2016

Additional sponsors: Mr. FLORES, Mrs. ELLMERS of North Carolina, Mrs. BLACKBURN, Mr. MULLIN, Mr. HUNTER, Mrs. MIMI WALTERS of California, Mr. BISHOP of Michigan, Mr. LONG, Mr. NUNES, Mr. TURNER, Mr. BURGESS, Mr. KNIGHT, Mr. CARTER of Georgia, Mr. BILIRAKIS, Mr. GARAMENDI, Mr. GRIFFITH, Mr. SWALWELL of California, Mr. COLLINS of New York, Mr. LANCE, Mrs. COMSTOCK, Mr. GUTHRIE, Mr. HASTINGS, Mr. KINZINGER of Illinois, Mr. STEWART, Mr. VARGAS, Mr. BUCSHON, Mr. WALDEN, Mr. CRAMER, Mr. HUDSON, Mr. JOYCE, Mr. JOHNSON of Ohio, Mr. QUIGLEY, Mr. CRENSHAW, Mr. OLSON, Mr. DAVID SCOTT of Georgia, Mr. CÁRDENAS, Mr. WITTMAN, Mr. DENHAM, Mr. MESSER, Mr. RUPPERSBERGER, Mr. RUSH, Ms. SPEIER, Mr. SHIMKUS, Mrs. McMORRIS RODGERS, Mr. RODNEY DAVIS of Illinois, and Mr. PASCRELL

SEPTEMBER 9, 2016

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on July 29, 2015]

# **A BILL**

To amend the Public Health Service Act to ensure preparedness for chemical, radiological, biological, and nuclear threats, and for other purposes.

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) *SHORT TITLE.*—*This Act may be cited as the*  
 5 *“Strengthening Public Health Emergency Response Act of*  
 6 *2016”.*

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

*Sec. 1. Short title; table of contents.*

*Sec. 2. GAO report on State, local, and hospital preparedness programs.*

*Sec. 3. Strategic national stockpile.*

*Sec. 4. Project Bioshield procurement process.*

*Sec. 5. BARDA transaction authorities.*

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

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

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

11 (a) *IN GENERAL.*—*Not later than 1 year after the date*  
 12 *of enactment of this Act, the Comptroller General of the*  
 13 *United States shall submit a report to the Congress on the*  
 14 *programs for awarding cooperative agreements and grants*  
 15 *under section 319C–1 of the Public Health Service Act (42*  
 16 *U.S.C. 247d–3a; improving State and local public health*  
 17 *security) and section 319C–2 of such Act (42 U.S.C. 247d–*  
 18 *3b; partnerships for State and regional hospital prepared-*  
 19 *ness to improve surge capacity).*

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

1           (1) *The goals of the programs specified in sub-*  
2           *section (a).*

3           (2) *The extent to which such goals are being met,*  
4           *including performance metrics that could help to as-*  
5           *sess whether such programs are succeeding at the coa-*  
6           *lition and member level.*

7           (3) *How such programs could be improved, in-*  
8           *cluding how such programs could be modified to im-*  
9           *prove the medical preparedness of hospitals, health*  
10          *care coalitions, and the continuity of health care de-*  
11          *livery.*

12          (4) *How such programs complement other pre-*  
13          *paredness programs of the Department of Health and*  
14          *Human Services.*

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

18          (6) *Progress made toward State and local pre-*  
19          *paredness entities being self-sustaining.*

20          (7) *Whether the level of funding for such pro-*  
21          *grams is sufficient.*

22          (8) *How funding for such programs is being used*  
23          *to ensure preparedness for at-risk populations includ-*  
24          *ing children, pregnant women, senior citizens, and*  
25          *other individuals who may have unique needs in the*

1       *event of a public health emergency, such as individ-*  
 2       *uals with disabilities.*

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

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

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

14          (10) *The extent to which the funds awarded*  
 15       *through the programs under sections 319C–1 and*  
 16       *319C–2 of the Public Health Service Act (42 U.S.C.*  
 17       *247d–3a, 247d–3b) have been used for overlapping*  
 18       *purposes.*

19       **SEC. 3. STRATEGIC NATIONAL STOCKPILE.**

20       *Section 319F–2(a)(2) of the Public Health Service Act*  
 21       *(42 U.S.C. 247d–6b(a)(2)) is amended—*

22           (1) *in subparagraph (G), by striking “and” at*  
 23       *the end;*

24           (2) *in subparagraph (H), by striking the period*  
 25       *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 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.”.

**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)—

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

3                   (B) by striking “(6) *RECOMMENDATIONS*  
4                   *FOR PRESIDENT’S APPROVAL*” and all that fol-  
5                   lows through “(D) *SUBSEQUENT SPECIFIC COUN-*  
6                   *TERMEASURES.—*” and inserting “(6) *SUBSE-*  
7                   *QUENT SPECIFIC COUNTERMEASURES.—*”; and  
8                   (3) in paragraph (7)—

9                   (A) by striking subparagraph (A);

10                  (B) by redesignating subparagraph (B) as  
11                  subparagraph (A) and amending such subpara-  
12                  graph (A), as redesignated, to read as follows:

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

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

21 **SEC. 5. BARDA TRANSACTION AUTHORITIES.**

22                  Section 319L(c)(5) of the Public Health Service Act  
23                  (42 U.S.C. 247d–7e(c)(5)) is amended by adding at the end  
24                  the following:

1                   “(H) *CONTRACTING AUTHORITY CLARIFICATION.—The Secretary shall delegate authority for*  
 2                   *negotiating and entering into any contracts,*  
 3                   *grants, or cooperative agreements under this sec-*  
 4                   *tion to the Director.”.*

6   **SEC. 6. PUBLIC HEALTH EMERGENCY MEDICAL COUNTER-**  
 7                   **MEASURES ENTERPRISE STRATEGY AND IM-**  
 8                   **PLEMENTATION PLAN.**

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

11                   *(1) in subparagraph (A), by inserting after “de-*  
 12                   *scribe the chemical, biological, radiological, and nu-*  
 13                   *clear agent or agents that may present a threat to the*  
 14                   *Nation” the following: “(which shall include pan-*  
 15                   *demic influenza)”;*

16                   *(2) by striking “and” at the end of subpara-*  
 17                   *graph (J);*

18                   *(3) by redesignating subparagraph (K) as sub-*  
 19                   *paragraph (L); and*

20                   *(4) by inserting after subparagraph (J) the fol-*  
 21                   *lowing:*

22                   *“(K) report on the amount of time between*  
 23                   *the issuance of each request for a proposal or*  
 24                   *task order from the Biomedical Advanced Re-*  
 25                   *search and Development Authority and the*



1           *award of a contract pursuant to such request for*  
 2           *a proposal or task order; and”.*

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

6           (a) *IN GENERAL.*—Subchapter E of chapter V of the  
 7   *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb*  
 8   *et seq.) is amended by inserting after section 565 the fol-*  
 9   *lowing:*

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

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

14                   “(1) *PRIORITY REVIEW.*—The term ‘priority re-

15                   *view’, with respect to a human drug application as*  
 16                   *defined in section 735(1), means review and action by*  
 17                   *the Secretary on such application not later than 6*  
 18                   *months after receipt by the Secretary of such applica-*  
 19                   *tion, as described in the manual of policies and proce-*  
 20                   *dures of the Food and Drug Administration and goals*  
 21                   *identified in the letters described in section 101(b) of*  
 22                   *the Food and Drug Administration Safety and Inno-*  
 23                   *vation Act (Public Law 112–144).*

24                   “(2) *PRIORITY REVIEW VOUCHER.*—The term

25                   ‘priority review voucher’ means a voucher issued by

1     *the Secretary to the sponsor of a material threat med-*  
 2     *ical countermeasure application that entitles the hold-*  
 3     *er of such voucher to priority review of a single*  
 4     *human drug application submitted under section*  
 5     *505(b)(1) of this Act or section 351(a) of the Public*  
 6     *Health Service Act after the date of approval of the*  
 7     *material threat medical countermeasure application.*

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

12             “(A) *is a human drug application as de-*  
 13     *finied in section 735(1) to prevent, or treat harm*  
 14     *from, a biological, chemical, radiological, or nu-*  
 15     *clear agent identified as a material threat under*  
 16     *section 319F–2(c)(2)(A)(ii) of the Public Health*  
 17     *Service Act;*

18             “(B) *the Secretary deems eligible for pri-*  
 19     *ority review;*

20             “(C) *is approved after the date of enactment*  
 21     *of the Strengthening Public Health Emergency*  
 22     *Response Act of 2016; and*

23             “(D) *is for a human drug, no active ingre-*  
 24     *dient (including any ester or salt of the active*  
 25     *ingredient) of which has been approved pursuant*

1           *to any other application under section 505(b)(1)*  
2           *of this Act or section 351(a) of the Public Health*  
3           *Service Act.*

4           “(b) *PRIORITY REVIEW VOUCHER.*—

5                 “(1) *IN GENERAL.*—*The Secretary shall award a*  
6           *priority review voucher to the sponsor of a material*  
7           *threat medical countermeasure application upon ap-*  
8           *proval by the Secretary of such application.*

9                 “(2) *TRANSFERABILITY.*—

10                         “(A) *IN GENERAL.*—*The sponsor of a mate-*  
11           *rial threat medical countermeasure application*  
12           *that receives a priority review voucher under*  
13           *this section may transfer (including by sale) the*  
14           *entitlement to such voucher to a sponsor of a*  
15           *human drug for which an application under sec-*  
16           *tion 505(b)(1) of this Act or section 351(a) of the*  
17           *Public Health Service Act will be submitted after*  
18           *the date of the approval of the material threat*  
19           *medical countermeasure application. There is no*  
20           *limit on the number of times a priority review*  
21           *voucher may be transferred before such voucher is*  
22           *used.*

23                         “(B) *NOTIFICATION OF TRANSFER.*—*Each*  
24           *person to whom a voucher is transferred shall*  
25           *notify the Secretary of such change in ownership*

1       *of the voucher not later than 30 days after the*  
2       *date of such transfer.*

3       “(3) *NOTIFICATION.*—

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

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

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

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

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

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

12 “(3) *ANNUAL FEE SETTING.—The Secretary shall*  
13 *establish, before the beginning of each fiscal year be-*  
14 *ginning after September 30, 2016, for that fiscal year,*  
15 *the amount of the priority review user fee.*

16 “(4) *PAYMENT.—*

17 “(A) *IN GENERAL.—The priority review*  
18 *user fee required by this subsection shall be due*  
19 *upon the notification by a sponsor of the intent*  
20 *of such sponsor to use the voucher, as specified*  
21 *in subsection (b)(3)(A). All other user fees associ-*  
22 *ated with the human drug application shall be*  
23 *due as required by the Secretary or under appli-*  
24 *cable law.*

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

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

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

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

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

21          “(d) *NOTICE OF ISSUANCE OF VOUCHER AND AP-*  
22          *PROVAL OF PRODUCTS UNDER VOUCHER.*—*The Secretary*  
23          *shall publish a notice in the Federal Register and on the*  
24          *public website of the Food and Drug Administration not*

1 *later than 30 calendar days after the occurrence of each of*  
2 *the following:*

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

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

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

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

23          “(g) *MEDICAL COUNTERMEASURE POSTAPPROVAL RE-*  
24 *PORT.—*

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

6           “(2) *CONTENTS.*—A report under paragraph (1)  
7           shall include, with respect to each of the first 2 years  
8           after approval of such material threat medical coun-  
9           termeasure application, a description of—

10               “(A) the sponsor’s activities with Federal  
11               agencies related to the procurement, including  
12               stockpiling, of the approved medical counter-  
13               measure;

14               “(B) the sponsor’s progress in fulfilling con-  
15               tracts entered into with Federal agencies, includ-  
16               ing the Biomedical Advanced Research and De-  
17               velopment Authority, the Centers for Disease  
18               Control and Prevention, and the Department of  
19               Defense, related to such procurement;

20               “(C) the extent to which the Federal Gov-  
21               ernment has fulfilled its stated medical counter-  
22               measure requirements for the threat intended to  
23               be treated by the approved medical counter-  
24               measure; and



1           “(D) the sponsor’s plans, if any, to develop  
2           additional material threat medical counter-  
3           measures.

4           “(3) AVAILABILITY TO CONGRESSIONAL COMMIT-  
5           TEES.—The Secretary shall make each report sub-  
6           mitted under this subsection available to the Com-  
7           mittee on Energy and Commerce of the House of Rep-  
8           resentatives and the Committee on Health, Education,  
9           Labor, and Pensions of the Senate upon request by ei-  
10          ther such Committee not later than 30 days after re-  
11          ceipt of such request.

12          “(4) RULE OF CONSTRUCTION.—Nothing in this  
13          subsection shall be construed to permit the disclosure  
14          of confidential commercial or trade secret information  
15          or the disclosure of information that could com-  
16          promise national security.”.

17          (b) GAO REPORT.—

18               (1) STUDY.—The Comptroller General of the  
19               United States shall conduct a study on the effective-  
20               ness of priority review vouchers under section 565A  
21               of the Federal Food, Drug, and Cosmetic Act, as  
22               added by subsection (a), in providing incentives for  
23               the development of material threat medical counter-  
24               measure applications under such section 565A. In

1       *conducting such study, the Comptroller General shall*  
2       *examine the following:*

3               *(A) The impact of such priority review on*  
4       *the development of material threat medical coun-*  
5       *termeasures and the impact of such investment,*  
6       *as applicable, on the development of such coun-*  
7       *termeasures.*

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

10              *(i) addressed identified medical coun-*  
11       *termeasure needs; and*

12              *(ii) impacted United States prepared-*  
13       *ness against chemical, biological, radio-*  
14       *logical, and nuclear threats, including both*  
15       *identified threats and naturally occurring*  
16       *threats.*

17              *(C) How many material threat medical*  
18       *countermeasures were licensed or approved, or*  
19       *otherwise significantly advanced in clinical de-*  
20       *velopment, in the 15 years following the enact-*  
21       *ment of such section 565A compared to the 15*  
22       *years prior to the enactment of such section, in-*  
23       *cluding a comparative analysis of Federal ad-*  
24       *vanced development and procurement dollars*

1       *available in the 15 years following such enact-*  
2       *ment compared to the prior 15 years.*

3               *(D) How material threat medical counter-*  
4       *measures developed after the date of enactment of*  
5       *this Act impact—*

6               *(i) the supply of products in the stra-*  
7       *tegic national stockpile under section 319F–*  
8       *2 of the Public Health Service Act (42*  
9       *U.S.C. 247d–6b); and*

10              *(ii) national preparedness.*

11              *(E) How the Federal Government supported*  
12       *sponsors of material threat medical counter-*  
13       *measures during the research, development, ap-*  
14       *plication review, and production of such drugs,*  
15       *including the use of government research, provi-*  
16       *sion of resources through contracts or grants, and*  
17       *use of federally funded research facilities.*

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

21              *(i) the indications for which such*  
22       *drugs were approved under section*  
23       *505(b)(1) of the Federal Food, Drug, and*  
24       *Cosmetic Act (21 U.S.C. 355(b)(1)) or sec-*

tion 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 mar-  
keted therapy approved to prevent or  
treat the same indication in the same  
patient population at the time the ap-  
plication was submitted to the Food  
and Drug Administration; and

(II) if the drug provided a signifi-  
cant benefit or improvement in safety  
and effectiveness compared to such cur-  
rently marketed product;

(iii) the price of the priority review  
voucher if transferred or sold prior to re-  
demption; 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

1           *how many of such awarded vouchers were*  
2           *redeemed for priority review of a drug ap-*  
3           *plication in the 15 years following the date*  
4           *of enactment of such section;*

5                 *(ii) the resources associated with the*  
6           *Food and Drug Administration implemen-*  
7           *tation of such section 565A and review of*  
8           *applications for which a voucher awarded*  
9           *under such section 565A is redeemed for*  
10          *priority review and if implementation of*  
11          *such section 565A prohibited the Food and*  
12          *Drug Administration from meeting drug*  
13          *application review goals;*

14                *(iii) recommendations on whether ap-*  
15          *propriate Federal funding for advanced de-*  
16          *velopment and research would necessitate*  
17          *the priority review voucher program for*  
18          *medical countermeasures;*

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

22                *(v) the degree to which guaranteed*  
23          *Federal funding for advanced development*  
24          *and research is a greater incentive for new*  
25          *investment in research and the development*

1                   *of medical countermeasures than the uncer-*  
2                   *tain values of vouchers.*

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

6                   (A) *drug manufacturers involved in the re-*  
7                   *search and development of medical counter-*  
8                   *measures to address biological, chemical, radio-*  
9                   *logical, and nuclear threats;*

10                  (B) *stakeholders involved in investing in the*  
11                  *research and development of such medical coun-*  
12                  *termeasures, including venture capitalists;*

13                  (C) *the Federal Government agencies re-*  
14                  *sponsible for advancing, reviewing, and pro-*  
15                  *curing such medical countermeasures, includ-*  
16                  *ing—*

17                         (i) *the Department of Health and*  
18                         *Human Services, including the Office of the*  
19                         *Assistant Secretary for Preparedness and*  
20                         *Response, the Biomedical Advanced Re-*  
21                         *search and Development Authority, and the*  
22                         *Food and Drug Administration; and*

23                         (ii) *the Department of Defense;*

24                   (D) *biodefense stakeholders, as applicable;*

25                   *and*

1           (E) drug manufacturers involved in the re-  
2           search and development of therapies that ad-  
3           dress—

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

7                   (ii) rare pediatric diseases (as defined  
8                   in section 529(a) of such Act (21 U.S.C.  
9                   360ff(a))).

10          (3) *INITIAL ASSESSMENT.*—Not later than 10  
11          years after the date of enactment of this Act, the  
12          Comptroller General of the United States shall submit  
13          to the Committee on Health, Education, Labor, and  
14          Pensions of the Senate and the Committee on Energy  
15          and Commerce of the House of Representatives an  
16          initial assessment of the effectiveness of the priority  
17          review voucher program set forth in section 565A of  
18          the Federal Food, Drug, and Cosmetic Act, as added  
19          by subsection (a).

20          (4) *REPORT.*—Not later than 16 years after the  
21          date of enactment of this Act, the Comptroller General  
22          of the United States shall submit to the Committee on  
23          Health, Education, Labor, and Pensions of the Senate  
24          and the Committee on Energy and Commerce of the

1       *House of Representatives a report containing the re-*  
2       *sults of the study conducted under paragraph (1).*

3               (5) *PROTECTION OF NATIONAL SECURITY.—The*  
4       *Comptroller General of the United States shall con-*  
5       *duct the study under paragraph (1) and issue the as-*  
6       *essment and report under paragraphs (3) and (4) in*  
7       *a manner that does not compromise national security.*





Union Calendar No. 571

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

**H. R. 3299**

[Report No. 114-735]

# A BILL

To amend the Public Health Service Act to ensure preparedness for chemical, radiological, biological, and nuclear threats, and for other purposes.

SEPTEMBER 9, 2016

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed