

**AMENDMENT TO H.R. 3299**

**OFFERED BY M.** \_\_\_\_\_

Page 1, line 5, strike “2015” and insert “2016”.

Strike section 2 (relating to hospital preparedness program).

Page 2, lines 21 through 23, amend paragraph (2) to read as follows:

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

Page 2, line 24 after “improved” insert “, including how such programs could be modified to improve the medical preparedness of hospitals, health care coalitions, and the continuity of health care delivery”.

Page 3, line 8, insert the following:

5           (8) How current program funding is being used  
6           to ensure preparedness for at-risk populations in-  
7           cluding children, pregnant women, and individuals  
8           with disabilities.

Page 3, after line 10, insert the following:

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

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

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

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

Page 3, line 24, insert “for which funds have been  
made available under this part” after “319F–1”).

Page 6, line 18, insert “a” before “proposal”.

Page 6, line 22, insert “a” before “proposal”.

Beginning on page 6, line 23, amend section 8 to  
read as follows:

1 **SEC. 8. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**  
2 **FOR NATIONAL SECURITY THREATS.**

3 (a) TROPICAL DISEASE DEFINITION.—Section  
4 524(a)(3) of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 360n(a)(3)) is amended—

6 (1) by redesignating subparagraph (S) as sub-  
7 paragraph (T); and

8 (2) by inserting after subparagraph (R) the fol-  
9 lowing:

10 “(S) Any disease or other agent that is de-  
11 termined on or before the date of enactment of  
12 the Strengthening Public Health Emergency  
13 Response Act of 2016 to be a material threat  
14 under section 319F–2(c)(2)(A)(ii) of the Public  
15 Health Service Act, and with respect to which  
16 such determination remains in effect.”.

17 (b) TROPICAL DISEASE PRODUCT APPLICATION  
18 DEFINITION.—Subparagraph (C) of section 524(a)(4) of  
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 360n(a)(4)) is amended to read as follows:

21 “(C)(i) is for a human drug without an ac-  
22 tive ingredient (including any ester or salt of  
23 the active ingredient) that has been approved or  
24 licensed pursuant to any other application  
25 under section 505(b)(1) or section 351 of the  
26 Public Health Service Act; and

1           “(ii)(I) contains an attestation that the ac-  
2           tive ingredient (including any ester or salt of  
3           the active ingredient in such application) has  
4           not been previously approved or licensed by a  
5           regulatory authority in India, Brazil, Thailand,  
6           or any country that is a member of the Phar-  
7           maceutical Inspection Convention or the Phar-  
8           maceutical Inspection Cooperation Scheme; or

9           “(II) contains an attestation that novel  
10          phase 3 studies (as defined in section 312.21 of  
11          title 21, Code of Federal Regulations, or any  
12          successor regulations), with respect to the trop-  
13          ical disease product involved, other than a drug  
14          intended to prevent or treat a disease or agent  
15          specified in subsection (a)(3)(S), were—

16               “(aa) conducted or funded by the  
17               sponsor of such product; and

18               “(bb) conducted to support approval  
19               or licensure of such application under sec-  
20               tion 505 or section 351 of the Public  
21               Health Service Act and not previously sub-  
22               mitted to a regulatory authority of any of  
23               the countries referred to in subclause (I)  
24               for the purpose of obtaining initial ap-

1                   proval or licensure by such a regulatory  
2                   authority.”.

3           (c) PRIORITY REVIEW VOUCHERS.—Subsection (b) of  
4 section 524 of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 360n) is amended—

6           (1) by redesignating paragraphs (2), (3), and  
7           (4) as paragraphs (4), (5), and (6), respectively;

8           (2) by inserting after paragraph (1) the fol-  
9           lowing:

10           “(2) PUBLIC AVAILABILITY OF INTERNATIONAL  
11           PRODUCT STRATEGY.—A priority review voucher  
12           may be awarded under this section only if the spon-  
13           sor makes publicly available an international product  
14           strategy describing how the sponsor intends to work  
15           with the United States Government, the World  
16           Health Organization, or public-private partnerships  
17           to facilitate the product’s availability to relevant  
18           populations.

19           “(3) POSTAPPROVAL PRODUCT REPORT.—

20           “(A) IN GENERAL.—The sponsor of an ap-  
21           proved tropical disease product shall submit a  
22           report to the Secretary not later than 3 years  
23           after the approval of the applicable tropical dis-  
24           ease product application.

1           “(B) PUBLIC AVAILABILITY.—The Sec-  
2           retary shall post such report on the public  
3           website of the Food and Drug Administration.

4           “(C) CONTENTS.—Such report shall pro-  
5           vide, with respect to each of the first 2 years  
6           following the approval of the tropical disease  
7           product application under section 505(b)(1) or  
8           section 351 of the Public Health Service Act—

9                   “(i) the estimated population world-  
10                  wide suffering from the tropical disease in-  
11                  volved;

12                   “(ii) the estimated demand worldwide  
13                  for the tropical disease product involved;  
14                  and

15                   “(iii) the actual amount of such trop-  
16                  ical disease product distributed world-  
17                  wide.”;

18           (3) in paragraph (4) (as redesignated by para-  
19           graph (1) of this subsection)—

20                   (A) by striking “The sponsor of a tropical  
21                  disease product shall notify” and inserting the  
22                  following:

23                   “(A) IN GENERAL.—The sponsor of a trop-  
24                  ical disease product shall notify”; and

25                   (B) by adding at the end the following:

1           “(B) TRANSFER AFTER NOTIFICATION OF  
2           INTENT TO USE VOUCHER.—The sponsor of a  
3           human drug application that provides notifica-  
4           tion under subparagraph (A) of the intent of  
5           such sponsor to use the voucher for the human  
6           drug application may transfer the voucher after  
7           such notification is provided, if such sponsor  
8           has not yet submitted the human drug applica-  
9           tion described in the notification.

10           “(C) NOTIFICATION OF TRANSFER OF  
11           OWNERSHIP OF VOUCHER.—Each person to  
12           whom a priority review voucher is transferred  
13           under this section shall notify the Secretary of  
14           the change in ownership of such voucher not  
15           later than 30 days after the date on which such  
16           transfer occurs.”; and

17           (4) in paragraph (5) (as redesignated by para-  
18           graph (1) of this subsection), by striking subpara-  
19           graph (A) and inserting the following:

20           “(A) NO AWARD FOR PRIOR APPROVED AP-  
21           PLICATION.—A sponsor of a tropical disease  
22           product may not receive a priority review  
23           voucher under this section if—

1           “(i) the tropical disease product appli-  
2           cation was submitted to the Secretary  
3           prior to September 27, 2007; or

4           “(ii) in the case of a tropical disease  
5           product intended by the sponsor to prevent  
6           or treat a tropical disease specified in  
7           paragraph (a)(3)(S), the tropical disease  
8           product application was submitted to the  
9           Secretary prior to the date of enactment of  
10          the Strengthening Public Health Emer-  
11          gency Response Act of 2016.”.

12          (d) GAO REPORT.—

13           (1) IN GENERAL.—The Comptroller General of  
14          the United States shall—

15           (A) beginning 7 years after the date of en-  
16          actment of this Act, conduct a study of the ef-  
17          fectiveness of awarding priority review vouchers  
18          under section 524 of the Federal Food, Drug,  
19          and Cosmetic Act (21 U.S.C. 360n) on the de-  
20          velopment and availability of human drugs that  
21          prevent or treat tropical diseases; and

22           (B) not later than one year after the date  
23          on which the Comptroller General commences  
24          such study, submit to the Committee on Energy  
25          and Commerce of the House of Representatives



1           and the Committee on Health, Education,  
2           Labor, and Pensions of the Senate a report on  
3           the results of the study.

4           (2) CONTENTS.—In conducting the study under  
5           paragraph (1), the Comptroller General of the  
6           United States shall examine the following:

7                   (A) Whether the tropical disease priority  
8                   review voucher program established under sec-  
9                   tion 524 of the Federal Food, Drug, and Cos-  
10                  metic Act (21 U.S.C. 360n) has incentivized  
11                  new research on, and investment in, the devel-  
12                  opment of human drugs to prevent or treat  
13                  tropical diseases, and the impact of such re-  
14                  search and investment on the development of  
15                  such drugs.

16                  (B) The resources associated with the im-  
17                  plementation of such program by the Food and  
18                  Drug Administration and the review of applica-  
19                  tions for which a voucher awarded under such  
20                  program is redeemed for priority review, and  
21                  whether such program impacted the ability of  
22                  the Food and Drug Administration to meet  
23                  drug application review goals.

24                  (C) The impact of such program on the  
25                  public health as a result of the priority review

1 of applications for drugs under such program  
2 that otherwise would not qualify for priority re-  
3 view.

4 (D) Whether user fees received under such  
5 program are adequate for the Food and Drug  
6 Administration to hire and train new staff to  
7 support additional priority reviews and whether  
8 such fees were used to cover costs associated  
9 with application review other than such hiring  
10 and training.

11 (E) With respect to drugs awarded priority  
12 review vouchers under such program, other  
13 than a drug intended to prevent or treat a dis-  
14 ease specified in subsection (a)(3)(S) of such  
15 section 524, the following information:

16 (i) Whether approval of the drug im-  
17 pacted global rates of disease.

18 (ii) Whether a sponsor of such drug  
19 followed the international product strategy  
20 required by subsection (b)(2) of such sec-  
21 tion 524, as added by subsection (c)(2) of  
22 this section, and any additional actions  
23 taken by the sponsor to facilitate avail-  
24 ability of drugs approved under such pro-  
25 gram, taking into consideration applicable

1 postapproval product reports submitted  
2 under subsection (b)(3) of such section  
3 524, as added by subsection (c)(1) of this  
4 section.

5 (F) With respect to drugs awarded priority  
6 review vouchers under such program to treat a  
7 disease specified in subsection (a)(3)(S) of such  
8 section 524—

9 (i) The number of such drugs that  
10 were approved under section 505 of the  
11 Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 355) or licensed under section 351  
13 of the Public Health Service Act (42  
14 U.S.C. 262).

15 (ii) How these drugs met identified  
16 United States Government needs to ad-  
17 dress, or prepare to address, chemical, bio-  
18 logical, radiological, and nuclear threats,  
19 including identified threats and naturally  
20 occurring threats.

21 (iii) How the United States Govern-  
22 ment supported sponsors of such drugs in  
23 the research and development of such  
24 drugs, including through the provision re-  
25 sources.

1 (G) With respect to any human drug appli-  
2 cations submitted for priority review using a  
3 voucher awarded under such section 524, the  
4 following information:

5 (i) The indications for which such  
6 drugs were approved or licensed under sec-  
7 tion 505(b)(1) of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 355(b)(1)) or  
9 section 351(a) of the Public Health Service  
10 Act (42 U.S.C. 262).

11 (ii) Whether there was a currently  
12 marketed therapy approved to prevent or  
13 treat the same indication in the same pa-  
14 tient population as the human drug in-  
15 volved at the time the application was sub-  
16 mitted to the Food and Drug Administra-  
17 tion for review.

18 (iii) If the drug provided a significant  
19 improvement in safety and effectiveness  
20 when compared to such a currently mar-  
21 keted product.

22 (iv) The value of the priority review  
23 voucher if transferred or sold prior to re-  
24 demption.

1 (v) The length of time between the  
2 date on which a priority review voucher  
3 was awarded and the date on which it was  
4 redeemed.

5 (3) CONSULTATION.—In conducting the study  
6 under paragraph (1)(A), the Comptroller General of  
7 the United States shall consult with—

8 (A) drug manufacturers involved in re-  
9 search on, and development of, drugs to prevent  
10 or treat tropical diseases;

11 (B) stakeholders involved in investing in  
12 such research and development;

13 (C) stakeholders involved in the prevention  
14 or treatment of tropical diseases, including  
15 international medical and humanitarian aid  
16 groups; and

17 (D) the Federal agencies responsible for  
18 advancing, reviewing, and procuring medical  
19 countermeasures, including the Department of  
20 Health and Human Services, the Office of the  
21 Assistant Secretary for Preparedness and Re-  
22 sponse, the Biomedical Advanced Research and  
23 Development Authority, and the Food and  
24 Drug Administration.

1           (4) TERMS.—The terms in this section shall  
2           have the same meanings as the equivalent terms  
3           used in section 524 of the Federal Food, Drug, and  
4           Cosmetic Act (21 U.S.C. 360n).

