AMENDMENT TO H.R.

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:

(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.

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:

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

Page 3, after line 10, insert the following:

(8)(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.

(9) 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.

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:

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

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

(1) by redesignating subparagraph (S) as subparagraph (T); and

(2) by inserting after subparagraph (R) the following:

''(S) Any disease or other agent that is determined on or before the date of enactment of the Strengthening Public Health Emergency Response Act of 2016 to be a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act, and with respect to which such determination remains in effect.''.

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

''(C)(i) is for a human drug without an active ingredient (including any ester or salt of the active ingredient) that has been approved or licensed pursuant to any other application under section 505(b)(1) or section 351 of the Public Health Service Act; and

''(ii)(I) contains an attestation that the active ingredient (including any ester or salt of the active ingredient in such application) has not been previously approved or licensed by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme; or

''(II) contains an attestation that novel phase 3 studies (as defined in section 312.21 of title 21, Code of Federal Regulations, or any successor regulations), with respect to the tropical disease product involved, other than a drug intended to prevent or treat a disease or agent specified in subsection (a)(3)(S), were—

''(aa) conducted or funded by the sponsor of such product; and

''(bb) conducted to support approval or licensure of such application under section 505 or section 351 of the Public Health Service Act and not previously submitted to a regulatory authority of any of the countries referred to in subclause (I) for the purpose of obtaining initial ap-

proval or licensure by such a regulatory authority.''.

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

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

(2) by inserting after paragraph (1) the following:

''(2) PUBLIC AVAILABILITY OF INTERNATIONAL PRODUCT STRATEGY.—A priority review voucher may be awarded under this section only if the sponsor makes publicly available an international product strategy describing how the sponsor intends to work with the United States Government, the World Health Organization, or public-private partnerships to facilitate the product's availability to relevant populations.

''(3) POSTAPPROVAL PRODUCT REPORT.—

''(A) IN GENERAL.—The sponsor of an approved tropical disease product shall submit a report to the Secretary not later than 3 years after the approval of the applicable tropical disease product application.

''(B) PUBLIC AVAILABILITY.—The Secretary shall post such report on the public website of the Food and Drug Administration.

''(C) CONTENTS.—Such report shall provide, with respect to each of the first 2 years following the approval of the tropical disease product application under section 505(b)(1) or section 351 of the Public Health Service Act—

''(i) the estimated population worldwide suffering from the tropical disease involved;

''(ii) the estimated demand worldwide for the tropical disease product involved; and

''(iii) the actual amount of such tropical disease product distributed worldwide.'';

(3) in paragraph (4) (as redesignated by paragraph (1) of this subsection)—

(A) by striking ''The sponsor of a tropical disease product shall notify'' and inserting the following:

''(A) IN GENERAL.—The sponsor of a tropical disease product shall notify''; and

(B) by adding at the end the following:

''(B) TRANSFER AFTER NOTIFICATION OF INTENT TO USE VOUCHER.—The sponsor of a human drug application that provides notification under subparagraph (A) of the intent of such sponsor to use the voucher for the human drug application 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) NOTIFICATION OF TRANSFER OF OWNERSHIP OF VOUCHER.—Each person to whom a priority review voucher is transferred under this section shall notify the Secretary of the change in ownership of such voucher not later than 30 days after the date on which such transfer occurs.''; and

(4) in paragraph (5) (as redesignated by paragraph (1) of this subsection), by striking subparagraph (A) and inserting the following:

''(A) NO AWARD FOR PRIOR APPROVED APPLICATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if—

''(i) the tropical disease product application was submitted to the Secretary prior to September 27, 2007; or

''(ii) in the case of a tropical disease product intended by the sponsor to prevent or treat a tropical disease specified in paragraph (a)(3)(S), the tropical disease product application was submitted to the Secretary prior to the date of enactment of the Strengthening Public Health Emergency Response Act of 2016.''.

(d) GAO REPORT.—

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

(A) beginning 7 years after the date of enactment of this Act, conduct a study of the effectiveness of awarding priority review vouchers under section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n) on the development and availability of human drugs that prevent or treat tropical diseases; and

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

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

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

(A) Whether the tropical disease priority review voucher program established under section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n) has incentivized new research on, and investment in, the development of human drugs to prevent or treat tropical diseases, and the impact of such research and investment on the development of such drugs.

(B) The resources associated with the implementation of such program by the Food and Drug Administration and the review of applications for which a voucher awarded under such program is redeemed for priority review, and whether such program impacted the ability of the Food and Drug Administration to meet drug application review goals.

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

of applications for drugs under such program that otherwise would not qualify for priority review.

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

(E) With respect to drugs awarded priority review vouchers under such program, other than a drug intended to prevent or treat a disease specified in subsection (a)(3)(S) of such section 524, the following information:

(i) Whether approval of the drug impacted global rates of disease.

(ii) Whether a sponsor of such drug followed the international product strategy required by subsection (b)(2) of such section 524, as added by subsection (c)(2) of this section, and any additional actions taken by the sponsor to facilitate availability of drugs approved under such program, taking into consideration applicable

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

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

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

(ii) How these drugs met identified United States Government needs to address, or prepare to address, chemical, biological, radiological, and nuclear threats, including identified threats and naturally occurring threats.

(iii) How the United States Government supported sponsors of such drugs in the research and development of such drugs, including through the provision resources.

(G) With respect to any human drug applications submitted for priority review using a voucher awarded under such section 524, the following information:

(i) The indications for which such drugs were approved or licensed 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).

(ii) Whether there was a currently marketed therapy approved to prevent or treat the same indication in the same patient population as the human drug involved at the time the application was submitted to the Food and Drug Administration for review.

(iii) If the drug provided a significant improvement in safety and effectiveness when compared to such a currently marketed product.

(iv) The value of the priority review voucher if transferred or sold prior to redemption.

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

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

(A) drug manufacturers involved in research on, and development of, drugs to prevent or treat tropical diseases;

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

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

(D) the Federal agencies responsible for advancing, reviewing, and procuring medical countermeasures, including the Department of Health and Human Services, the Office of the Assistant Secretary for Preparedness and Response, the Biomedical Advanced Research and Development Authority, and the Food and Drug Administration.

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

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