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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to improve the priority review voucher incentive program relating to tropical and rare pediatric diseases.

IN THE HOUSE OF REPRESENTATIVES

Mr. MCCAUL (for himself and Mr. BUTTERFIELD) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the priority review voucher incentive program relating to tropical and rare pediatric diseases.

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

SECTION 1. SHORT TITLE; REFERENCES.

(a) SHORT TITLE.—This Act may be cited as the ''Creating Hope Act of 2011''.

(b) REFERENCES.—Wherever in this Act an amendment is expressed in terms of an amendment to a section

or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 2. IMPROVEMENT OF THE TROPICAL DISEASE VOUCHER PROGRAM.

(a) HEADING.—The heading of section 524 (21 U.S.C. 360n) is amended to read as follows: ''**PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES AND RARE PEDIATRIC DISEASES**''.

(b) DEFINITIONS.—Section 524(a) (21 U.S.C. 360n(a)) is amended—

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

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

(3) by inserting after ''In this section:'', the following:

''(1) ELIGIBLE TREATMENT.—The term 'eligible treatment' means a new drug, including a biological product that is a new drug, that is the subject of an application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act, if that drug contains no active ingredient (including any ester or salt of the active ingredient) that has been previously approved in any

other application under section 505(b)(1), 505(b)(2), or 505(j) of this Act or section 351(a) or 351(k) of the Public Health Service Act.'';

(4) in paragraph (3), as so redesignated, by inserting ''or rare pediatric disease product application'' after ''tropical disease product application'' each place that phrase appears;

(5) by inserting after paragraph (3) the following:

''(4) RARE PEDIATRIC DISEASE.—The term 'rare pediatric disease' means a disease that meets each of the following criteria:

''(A) The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

''(B) The disease is a rare disease or condition, within the meaning of section 526.

''(5) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term 'rare pediatric disease product application' means a human drug application, as defined in section 735(1)—

''(A) for prevention or treatment of a rare pediatric disease;

''(B) that the Secretary deems eligible for priority review;

''(C) that is for an eligible treatment;

''(D) that relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; and

''(E) that does not seek approval for an adult indication in the original rare pediatric disease product application.'';

(6) in paragraph (6), as so redesignated—

(A) by redesignating subparagraph (Q) as subparagraph (R); and

(B) by inserting after subparagraph (P) the following:

''(Q) Chagas Disease.''; and

(7) by amending paragraph (7), as so redesignated, to read as follows:

''(7) TROPICAL DISEASE PRODUCT APPLICATION.—The term 'tropical disease product application' means a human drug application, as defined in section 735(1)—

''(A) for prevention or treatment of a tropical disease;

''(B) that the Secretary deems eligible for priority review;

''(C) that is for an eligible treatment; and

''(D) that the sponsor affirms in the application is for a drug that has not been approved for commercial marketing for any tropical disease indication by a government authority outside of the United States for more than 24 months before the tropical disease product application is submitted.''.

(c) RULES REGARDING USE AND TRANSFER OF PRIORITY REVIEW VOUCHERS.—Section 524(b) (21 U.S.C. 360n(b)) is amended—

(1) in paragraph (1), by inserting ''or rare pediatric disease product application'' after ''tropical disease product application'' each place that phrase appears;

(2) by amending paragraph (2) to read as follows:

''(2) TRANSFERABILITY.—

''(A) IN GENERAL.—The sponsor of a tropical disease product application or rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to

such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

''(B) CONDITIONS OF TRANSFER.—If a sponsor transfers a priority review voucher after such sponsor has provided notification to the Secretary under paragraph (4)(A) of the intent of such sponsor to use the voucher, the transfer shall be subject to the provisions of subparagraphs (B) and (C) of paragraph (4).

''(C) NOTIFICATION OF TRANSFER.—The person to whom a voucher is transferred under paragraph (4)(B)(i) shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.'';

(3) by amending paragraph (3) to read as follows:

''(3) LIMITATION FOR PRIOR APPLICATIONS.—

''(A) TROPICAL DISEASE PRODUCT APPLICATIONS.—A sponsor of a tropical disease product application may not receive a priority review voucher under this section if the tropical disease product application was submitted to the Secretary prior to September 27, 2007.

''(B) RARE PEDIATRIC DISEASE PRODUCT APPLICATIONS.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Creating Hope Act of 2011.''; and

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

''(4) NOTIFICATION.—

''(A) TIMING.—At least 90 days before the date on which a human drug application for which the sponsor intends to use a priority review voucher is submitted, the sponsor of such human drug application shall notify the Secretary of the intent of such sponsor to submit the human drug application.

''(B) TRANSFER OF VOUCHER AFTER NOTIFICATION.—

''(i) IN GENERAL.—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 may transfer the voucher after such

notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

''(ii) EXCEPTION.—The person to whom a voucher is transferred under clause (i) (referred to in this paragraph as the 'transferee') shall give notification of the intent of such transferee to use the voucher in accordance with this subsection, unless—

''(I) the transferee uses the voucher for a human drug application including the same indications as the human drug application described in the transferor's notification; and

''(II) the transferee notifies the Secretary within 30 days of the transfer of the intent of such transferee to use the voucher for such purpose.

''(iii) INTERNAL TRANSFER.—If the sponsor transfers a voucher internally for use with a drug application including one or more indications that were not included in the drug application that was the subject of the notification of such sponsor, the

sponsor shall notify the Secretary of the transfer in accordance with this subsection.

''(C) FEE DUE UPON NOTIFICATION; CREDIT FOR TRANSFERRED VOUCHER.—

''(i) DUE UPON NOTIFICATION.—The notification under this subsection shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section. Such fee shall be payable by the sponsor upon the submission by such sponsor of such notification.

''(ii) CREDIT.—If a sponsor pays a user fee upon providing notification of the intent of such sponsor to use a priority review voucher, but later transfers the voucher for which such sponsor gave notification, the Secretary shall credit the user fees paid to the next human drug application for which a sponsor provides notification of the intent of such sponsor to use the same transferred voucher.

''(iii) DIFFERENCE IN FEE.—The Secretary may require a sponsor using a transferred voucher to pay the difference between the credit associated with the

transferred voucher and the user fee prevailing at the time the sponsor submits notification of the intent of such sponsor to use the transferred voucher. This provision does not apply in cases where a transferee is exempted from submitting notification under this paragraph.''.

(d) PAYMENT.—Section 524(c)(4) (21 U.S.C. 360n(c)(4)) is amended—

(1) in subparagraph (A), by striking ''submission of a human drug application under section 505(b)(1) or section 351 of the Public Health Services Act for which the priority review voucher is used.'' and inserting ''notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(4)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.''; and

(2) in subparagraph (C), by striking the period at the end and inserting '', except as specified in subsection (b)(4)(C).''.

(e) DESIGNATION PROCESS; PRODUCT IMPLEMENTATION REQUIREMENT.—Section 524 (21 U.S.C. 360n) is

amended by adding at the end the following new subsections:

"(d) DESIGNATION PROCESS.—

"(1) DESIGNATION OF RARE PEDIATRIC DISEASES.—

"(A) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate that the new drug is for a rare pediatric disease. Such a request for designation, if sought, shall be made when requesting designation of orphan disease status under section 526 or fast-track designation under section 506. Requesting designation of rare pediatric disease status under this paragraph is not a prerequisite to receiving a priority review voucher.

"(B) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under subparagraph (A), the Secretary shall determine whether the disease or condition that is the subject of such request is a rare pediatric disease.

"(2) DESIGNATION OF ELIGIBLE TREATMENTS.—

''(A) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate that a new drug is an eligible treatment. Such a request for designation, if sought, shall be made when requesting fast-track designation under section 506. Requesting designation that a new drug is an eligible treatment is not a prerequisite to receiving a priority review voucher.

''(B) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under subparagraph (A), the Secretary shall determine whether the new drug that is the subject of such request is an eligible treatment.

''(e) PRODUCT IMPLEMENTATION FOR RARE PEDIATRIC DISEASE PRODUCTS.—

''(1) IN GENERAL.—The Secretary shall deem a rare pediatric disease product application incomplete if such application does not contain a description of the plan of the sponsor of such application to market the product in the United States.

''(2) GOOD FAITH INTENT TO MARKET.—

''(A) GOOD FAITH INTENT.—The Secretary may refuse to issue a priority review

voucher upon the approval of a rare pediatric disease product application if the Secretary finds that the sponsor of such application lacks a good faith intention to market the product in the United States. The Secretary may consider any fact relevant to this determination, including the history of such sponsor of producing rare pediatric disease products for which such sponsor received a priority review voucher, orphan drugs for which the sponsor received exclusivity under section 527, or pediatric drugs for which the sponsor received an additional 6 months of exclusivity under section 505A.

''(B) PRESUMPTION.—The sponsor may establish a presumption of good faith by demonstrating that such sponsor has allocated sufficient resources or otherwise arranged for the production (by the sponsor or by another manufacturer) of the rare pediatric disease product in a manner sufficient to meet the expected demand for the product during the 5-year period following approval of the application.

''(C) GUIDANCE.—If the Secretary requires sponsors seeking a priority review voucher to demonstrate a good faith intent to market

the rare pediatric disease product in the United States, the Secretary shall first issue a guidance document setting forth the required evidentiary support necessary to demonstrate such a good faith intent.

''(3) POSTAPPROVAL PRODUCTION REPORT.—

''(A) REPORT REQUIRED.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare pediatric disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

''(i) The estimated population in the United States suffering from the rare pediatric disease.

''(ii) The estimated demand in the United States for such rare pediatric disease product.

''(iii) The actual amount of such rare pediatric disease product distributed in the United States.

''(B) PUBLICATION UPON FAILURE TO DEMONSTRATE GOOD FAITH EFFORT TO MAR-

KET.—The Secretary may publish the results of a report submitted under subparagraph (A) in the Federal Register if the Secretary finds that the sponsor that submitted such report has not made a good faith effort to meet the demand in the United States for the product that is the subject of such report during each of the first 4 years after approval of such product.

''(f) PRODUCTION REPORT FOR TROPICAL DISEASE PRODUCTS.—

''(1) REPORT REQUIRED.—The sponsor of an approved tropical disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare tropical disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

''(A) The estimated global population suffering from the tropical disease.

''(B) The estimated global demand for such tropical disease product.

''(C) The actual amount of such tropical disease product distributed globally.

''(2) PUBLICATION UPON FAILURE TO DEMONSTRATE GOOD FAITH EFFORT TO MARKET.—The

Secretary may publish the results of a report submitted under paragraph (1) in the Federal Register if the Secretary finds that the sponsor that submitted such report has not made a good faith effort to meet the global demand for the product that is the subject of such report during each of the first 4 years after approval of such product.

''(g) NOTICE OF ISSUANCE AND USE OF VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Web site of the Food and Drug Administration not later than 30 days after the occurrence of each of the following:

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

''(2) A sponsor submits a human drug application for which such sponsor uses a priority review voucher.

''(h) ELIGIBILITY FOR OTHER PROGRAMS.—A sponsor who seeks a priority review voucher under this section may participate in any other incentive program, including the programs the Secretary has implemented under this Act, if the sponsor meets the applicable criteria of such other incentive program.

''(i) RELATION TO OTHER PROVISIONS.—This 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 drugs for tropical diseases and rare pediatric diseases.''.

(f) CONFORMING AMENDMENT.—Section 740(b) of the Agricultural, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010 (21 U.S.C. 360aa note) is amended by striking ''(a)(3)'' each place such term appears and inserting ''(a)(6)''.

SEC. 3. EFFECTIVE DATE.

This Act (and the amendments made by this Act) shall take effect on the date that is 90 days after the date of enactment of this Act.