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114TH CONGRESS
2D SESSION

H. R. 5858

To amend the Federal Food, Drug, and Cosmetic Act to establish a program to provide additional incentives for the development of new drugs to treat pediatric cancers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2016

Mr. MCCAUL (for himself, Mr. BUTTERFIELD, Mr. DUFFY, and Mr. VAN HOLLEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a program to provide additional incentives for the development of new drugs to treat pediatric cancers, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Research to Accelerate Cures and Equity for Children Act'' or the ''RACE for Children Act''.

SEC. 2. REQUIRED PEDIATRIC ASSESSMENTS.

(a) MOLECULAR TARGETS REGARDING CANCER DRUGS.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (A), by striking ''or'' at the end;

(B) in subparagraph (B), by inserting ''or'' after ''administration,''; and

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

''(C) under section 505 of this Act or section 351 of the Public Health Service Act, as described in subparagraph (A) or (B), that is directed at a molecular target present in one or more cancers in one or more pediatric populations,''; and

(2) in subsection (b)(1)—

(A) by amending subparagraph (A)(i) to read as follows:

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients—

''(I) for the labeled indications; or

''(II) with respect to one or more specific molecular targets present in cancers in pediatric populations; and'';

(B) by amending subparagraph (B) to read as follows:

''(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients—

''(i) for one or more of the claimed indications; or

''(ii) with respect to one or more specific molecular targets present in cancers in pediatric populations; or''; and

(C) by amending paragraph (2) of subsection (c) to read as follows:

''(2) the drug or biological product is in a class of products, is for an indication, or is directed at a specific molecular target present in cancers in pediatric populations, for which there is need for additional options.''.

(b) EARLY MEETING ON PEDIATRIC STUDY PLAN.—

(1) IN GENERAL.—Clause (i) of section 505B(e)(2)(C) of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 355c(e)(2)(C)) is amended to read as follows:

"(i) shall meet with the applicant—

"(I) if requested by the applicant with respect to a drug that is directed at a molecular target that is present in one or more cancers in one or more pediatric populations, as described in subsection (a)(1)(C), to discuss, not later than the end-of-Phase1 meeting (as such term is used in section 312.82(b) of title 21, Code of Federal Regulations, or successor regulations), preparation of the initial pediatric study plan;

"(II) to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A); and

"(III) to discuss any scientific or operational challenges that may be the basis of a deferral under subsection (a)(3) or a full or partial waiver under subsection (a)(4);".

(2) CONFORMING CHANGES.—Section 505B(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)) is amended—

(A) in the heading of paragraph (2), by striking ''MEETING'' and inserting ''MEETINGS'';

(B) in the heading of paragraph (2)(C), by striking ''MEETING'' and inserting ''MEETINGS'';

(C) in clauses (ii) and (iii) of paragraph (2)(C), by striking ''no meeting'' each place it appears and inserting ''no meeting under clause (i)(II)''; and

(D) in paragraph (3) by striking ''meeting under paragraph (2)(C)(i)'' and inserting ''meeting under paragraph (2)(C)(i)(II)''.

(c) ORPHAN DRUGS.—Section 505B(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k)) is amended by inserting ''except in the case of a drug or biological product that is the subject of an application described in subsection (a)(1)(C),'' after ''regulation,''.

(d) GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance on the implementation of this section (including the amendments made by

this section), including study designs and molecular targets likely to be present in one or more cancers in pediatric populations that are appropriate for assessment under the amendments made by this Act.

(e) APPLICABILITY.—This Act and the amendments made by this Act apply with respect to applications for a drug submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date that is 18 months after the date of enactment of this Act.

(f) REPORT TO CONGRESS.—Not later than July 12, 2021, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to Congress a report on the implementation of the amendments made by this section, together with any recommendations of the Secretary regarding such amendments.

(g) RULE OF CONSTRUCTION.—Nothing in this Act, including the amendments made by this Act, shall limit the authority of the Secretary of Health and Human Services to issue written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a).

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