

114TH CONGRESS
2D SESSION

S. 3239

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 SENATE OF THE UNITED STATES

JULY 14, 2016

Mr. BENNET (for himself and Mr. RUBIO) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

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.**

4 This Act may be cited as the “Research to Accelerate
5 Cures and Equity for Children Act” or the “RACE for
6 Children Act”.

1 **SEC. 2. REQUIRED PEDIATRIC ASSESSMENTS.**

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

5 (1) in subsection (a)(1)—

6 (A) in subparagraph (A), by striking “or”
7 at the end;

8 (B) in subparagraph (B), by inserting “or”
9 after “administration,”; and

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

12 “(C) under section 505 of this Act or sec-
13 tion 351 of the Public Health Service Act, as
14 described in subparagraph (A) or (B), that is
15 directed at a molecular target present in one or
16 more cancers in one or more pediatric popu-
17 lations,”; and

18 (2) in subsection (b)(1)—

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

21 “(A)(i) the drug or biological product is
22 used for a substantial number of pediatric pa-
23 tients—

24 “(I) for the labeled indications; or

1 “(II) with respect to 1 or more spe-
2 cific molecular targets present in cancers
3 in pediatric populations; and”;

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

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

10 “(i) for 1 or more of the claimed indi-
11 cations; or

12 “(ii) with respect to 1 or more specific
13 molecular targets present in cancers in pe-
14 diatric populations; or”; and

15 (C) by amending paragraph (2) of sub-
16 section (c) to read as follows:

17 “(2) the drug or biological product is in a class
18 of products, is for an indication, or is directed at a
19 specific molecular target present in cancers in pedi-
20 atric populations, for which there is need for addi-
21 tional options.”.

22 (b) EARLY MEETING ON PEDIATRIC STUDY PLAN.—

23 (1) IN GENERAL.—Clause (i) of section
24 505B(e)(2)(C) of the Federal Food, Drug, and Cos-

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

3 “(i) shall meet with the applicant—

4 “(I) if requested by the applicant
5 with respect to a drug that is directed
6 at a molecular target that is present
7 in one or more cancers in one or more
8 pediatric populations, as described in
9 subsection (a)(1)(C), to discuss, not
10 later than the end-of-Phase 1 meeting
11 (as such term is used in section
12 312.82(b) of title 21, Code of Federal
13 Regulations, or successor regulations),
14 preparation of the initial pediatric
15 study plan;

16 “(II) to discuss the initial pedi-
17 atric study plan as soon as prac-
18 ticable, but not later than 90 calendar
19 days after the receipt of such plan
20 under subparagraph (A); and

21 “(III) to discuss any scientific or
22 operational challenges that may be the
23 basis of a deferral under subsection
24 (a)(3) or a full or partial waiver under
25 subsection (a)(4);”.

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

4 (A) in the heading of paragraph (2), by
5 striking “MEETING” and inserting “MEETINGS”;

6 (B) in the heading of paragraph (2)(C), by
7 striking “MEETING” and inserting “MEET-
8 INGS”;

9 (C) in clauses (ii) and (iii) of paragraph
10 (2)(C), by striking “no meeting” each place it
11 appears and inserting “no meeting under clause
12 (i)(II)”;

13 (D) in paragraph (3) by striking “meeting
14 under paragraph (2)(C)(i)” and inserting
15 “meeting under paragraph (2)(C)(i)(II)”.

16 (c) ORPHAN DRUGS.—Section 505B(k) of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k))
18 is amended by inserting “except in the case of a drug or
19 biological product that is the subject of an application de-
20 scribed in subsection (a)(1)(C),” after “regulation,”.

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

1 this section), including study designs and molecular tar-
2 gets likely to be present in one or more cancers in pedi-
3 atric populations that are appropriate for assessment
4 under the amendments made by this Act.

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

12 (f) REPORT TO CONGRESS.—Not later than July 12,
13 2021, the Secretary of Health and Human Services, acting
14 through the Commissioner of Food and Drugs, shall sub-
15 mit to Congress a report on the implementation of the
16 amendments made by this section, together with any rec-
17 ommendations of the Secretary regarding such amend-
18 ments.

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

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