

118TH CONGRESS
1ST SESSION

S. 2897

To amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 21, 2023

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 with respect to molecularly targeted pediatric cancer investigations, 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 “Give Kids a Chance
5 Act of 2023”.

1 **SEC. 2. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDI-**
 2 **TIONAL AUTHORITIES OF FOOD AND DRUG**
 3 **ADMINISTRATION REGARDING MOLECU-**
 4 **LARLY TARGETED CANCER DRUGS.**

5 (a) IN GENERAL.—

6 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-
 7 PPLICATION DRUG; LIMITATION REGARDING NOVEL-
 8 COMBINATION APPLICATION DRUG.—Section
 9 505B(a)(3) of the Federal Food, Drug, and Cos-
 10 metic Act (21 U.S.C. 355c(a)(3)) is amended—

11 (A) by redesignating subparagraphs (B)
 12 and (C) as subparagraphs (C) and (D), respec-
 13 tively; and

14 (B) by striking subparagraph (A) and in-
 15 serting the following:

16 “(A) IN GENERAL.—For purposes of para-
 17 graph (1)(B), the investigation described in this
 18 paragraph is (as determined by the Secretary)
 19 a molecularly targeted pediatric cancer inves-
 20 tigation of—

21 “(i) the drug or biological product for
 22 which the application referred to in such
 23 paragraph is submitted; or

24 “(ii) such drug or biological product
 25 in combination with—

1 “(I) an active ingredient of a
2 drug or biological product—

3 “(aa) for which an approved
4 application under section 505(j)
5 under this Act or under section
6 351(k) of the Public Health
7 Service Act is in effect; and

8 “(bb) that is determined by
9 the Secretary to be the standard
10 of care for treating a pediatric
11 cancer; or

12 “(II) an active ingredient of a
13 drug or biological product—

14 “(aa) for which an approved
15 application under section 505(b)
16 of this Act or section 351(a) of
17 the Public Health Service Act to
18 treat an adult cancer is in effect
19 and is held by the same person
20 submitting the application under
21 paragraph (1)(B); and

22 “(bb) that is directed at a
23 molecular target that the Sec-
24 retary determines to be substan-

1 tially relevant to the growth or
2 progression of a pediatric cancer.

3 “(B) ADDITIONAL REQUIREMENTS.—

4 “(i) DESIGN OF INVESTIGATION.—A
5 molecularly targeted pediatric cancer inves-
6 tigation referred to in subparagraph (A)
7 shall be designed to yield clinically mean-
8 ingful pediatric study data that is gathered
9 using appropriate formulations for each
10 age group for which the study is required,
11 regarding dosing, safety, and preliminary
12 efficacy to inform potential pediatric label-
13 ing.

14 “(ii) LIMITATION.—An investigation
15 described in subparagraph (A)(ii) may be
16 required only if the drug or biological
17 product for which the application referred
18 to in paragraph (1)(B) contains either—

19 “(I) a single new active ingre-
20 dient; or

21 “(II) more than one active ingre-
22 dient, if an application for the com-
23 bination of active ingredients has not
24 previously been approved but each ac-

1 tive ingredient has been previously ap-
2 proved to treat an adult cancer.

3 “(iii) RESULTS OF ALREADY-COM-
4 PLETED PRECLINICAL STUDIES OF APPLI-
5 CATION DRUG.—The Secretary may re-
6 quire that reports on an investigation re-
7 quired pursuant to paragraph (1)(B) in-
8 clude the results of all preclinical studies
9 on which the decision to conduct such in-
10 vestigation was based.

11 “(iv) RULE OF CONSTRUCTION RE-
12 GARDING INACTIVE INGREDIENTS.—With
13 respect to a combination of active ingredi-
14 ents referred to in subparagraph (A)(ii),
15 such subparagraph shall not be construed
16 as addressing the use of inactive ingredi-
17 ents with such combination.”.

18 (2) DETERMINATION OF APPLICABLE REQUIRE-
19 MENTS.—Section 505B(e)(1) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is
21 amended by adding at the end the following: “The
22 Secretary shall determine whether subparagraph (A)
23 or (B) of subsection (a)(1) shall apply with respect
24 to an application before the date on which the appli-

1 cant is required to submit the initial pediatric study
2 plan under paragraph (2)(A).”.

3 (3) CLARIFYING APPLICABILITY.—Section
4 505B(a)(1) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355c(a)(1)) is amended by
6 adding at the end the following:

7 “(C) RULE OF CONSTRUCTION.—No appli-
8 cation that is subject to the requirements of
9 subparagraph (B) shall be subject to the re-
10 quirements of subparagraph (A), and no appli-
11 cation (or supplement to an application) that is
12 subject to the requirements of subparagraph
13 (A) shall be subject to the requirements of sub-
14 paragraph (B).”.

15 (4) CONFORMING AMENDMENTS.—Section
16 505B(a) of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 355c(a)) is amended—

18 (A) in paragraph (3)(C), as redesignated
19 by paragraph (1)(A) of this subsection, by
20 striking “investigations described in this para-
21 graph” and inserting “investigations referred to
22 in subparagraph (A)”; and

23 (B) in paragraph (3)(D), as redesignated
24 by paragraph (1)(A) of this subsection, by
25 striking “the assessments under paragraph

1 (2)(B)” and inserting “the assessments re-
2 quired under paragraph (1)(A)”.

3 (b) GUIDANCE.—The Secretary shall—

4 (1) not later than 1 year after the date of en-
5 actment of this Act, issue draft guidance on the im-
6 plementation of the requirements in subsection (a);
7 and

8 (2) not later than 1 year after closing the com-
9 ment period on such draft guidance, finalize such
10 guidance.

11 (c) APPLICABILITY.—The amendments made by this
12 section apply with respect to any application under section
13 505(b) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355(b)) and any application under section 351(a)
15 of the Public Health Service Act (42 U.S.C. 262(a)), that
16 is submitted on or after the date that is 3 years after the
17 date of enactment of this Act.

18 (d) REPORTS TO CONGRESS.—

19 (1) SECRETARY OF HEALTH AND HUMAN SERV-
20 ICES.—Not later than 2 years after the date of en-
21 actment of this Act, the Secretary of Health and
22 Human Services shall submit to the Committee on
23 Energy and Commerce of the House of Representa-
24 tives and the Committee on Health, Education,
25 Labor, and Pensions of the Senate a report on the

1 Secretary's efforts, in coordination with industry, to
2 ensure implementation of the amendments made by
3 subsection (a).

4 (2) GAO STUDY AND REPORT.—

5 (A) STUDY.—Not later than 3 years after
6 the date of enactment of this Act, the Comp-
7 troller General of the United States shall con-
8 duct a study of the effectiveness of requiring
9 assessments and investigations described in sec-
10 tion 505B of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355c), as amended by
12 subsection (a), in the development of drugs and
13 biological products for pediatric cancer indica-
14 tions.

15 (B) FINDINGS.—Not later than 7 years
16 after the date of enactment of this Act, the
17 Comptroller General shall submit to the Com-
18 mittee on Energy and Commerce of the House
19 of Representatives and the Committee on
20 Health, Education, Labor, and Pensions of the
21 Senate a report containing the findings of the
22 study conducted under subparagraph (A).

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