



(Original Signature of Member)

117TH CONGRESS  
2D SESSION

# H. R. 6972

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities of the Food and Drug Administration regarding the conduct of pediatric investigations of molecularly targeted drugs to treat cancer, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

Mr. BUTTERFIELD introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities of the Food and Drug Administration regarding the conduct of pediatric investigations of molecularly targeted drugs to treat cancer, 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 2022”.

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) AUTHORITY REGARDING INVESTIGATION OF  
7 NOVEL COMBINATION DRUGS.—Section  
8 505B(a)(1)(B) of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 355c(a)(1)(B)) is amended, in  
10 the matter preceding clause (i), by inserting after  
11 “Public Health Service Act,” the following: “or an  
12 application under such section 505 or such section  
13 351 for a drug or biological product that contains a  
14 novel combination of two or more active ingredients  
15 (subject to paragraph (3)(B)(iii))”

16 (2) ADDITIONAL ACTIVE INGREDIENT FOR AP-  
17 PPLICATION DRUG; LIMITATION REGARDING NOVEL-  
18 COMBINATION APPLICATION DRUG.—Section  
19 505B(a)(3) of the Federal Food, Drug, and Cos-  
20 metic Act (21 U.S.C. 355c(a)(3)) is amended—

21 (A) by redesignating subparagraphs (B)  
22 and (C) as subparagraphs (C) and (D), respec-  
23 tively; and

24 (B) by striking subparagraph (A) and in-  
25 serting the following:

1           “(A) IN GENERAL.—For purposes of para-  
2 graph (1)(B), the investigation described in this  
3 paragraph is (as determined by the Secretary)  
4 a molecularly targeted pediatric cancer inves-  
5 tigation of—

6           “(i) the drug or biological product for  
7 which the application referred to in such  
8 paragraph is submitted; or

9           “(ii) the active ingredient or ingredi-  
10 ents of such drug or biological product in  
11 combination with—

12           “(I) an active ingredient of a  
13 drug for which an approved applica-  
14 tion under section 505(j) is in effect  
15 or an active ingredient of a biological  
16 product for which an approved applica-  
17 tion under section 351(k) of the  
18 Public Health Service Act is in effect,  
19 which drug or biological product is de-  
20 termined by the Secretary to be the  
21 standard of care for treating a pedi-  
22 atric cancer;

23           “(II) an active ingredient of a  
24 drug for which an approved applica-  
25 tion under section 505(b) is in effect

1 to treat an adult cancer, or an active  
2 ingredient of a biological product for  
3 which an approved application under  
4 section 351(a) of the Public Health  
5 Service Act is in effect to treat an  
6 adult cancer, which approved applica-  
7 tion is held by the same person sub-  
8 mitting the application referred to in  
9 paragraph (1)(B); or

10 “(III) an active ingredient of a  
11 drug or biological product for which  
12 there is in effect an exemption for in-  
13 vestigational use under section 505(i),  
14 which drug or biological product is  
15 under such exemption being studied  
16 jointly by the person submitting the  
17 application referred to in paragraph  
18 (1)(B) and by another person pursu-  
19 ant to an agreement between such  
20 persons.

21 “(B) ADDITIONAL REQUIREMENTS.—

22 “(i) DESIGN OF INVESTIGATION.—A  
23 molecularly targeted pediatric cancer inves-  
24 tigation referred to in subparagraph (A)  
25 shall be designed to yield clinically mean-

1           ingful pediatric study data, gathered using  
2           appropriate formulations for each age  
3           group for which the study is required, re-  
4           garding dosing, safety, and preliminary ef-  
5           ficacy.

6           “(ii) PURPOSE OF INVESTIGATION.—  
7           The purpose of a molecularly targeted pe-  
8           diatric cancer investigation referred to in  
9           subparagraph (A) shall be—

10                   “(I) in the case of such an inves-  
11                   tigation conducted with respect to a  
12                   drug or biological product referred to  
13                   in clause (i) of such subparagraph, to  
14                   inform potential pediatric labeling of  
15                   the drug or biological product for  
16                   which the application referred to in  
17                   paragraph (1)(B) is submitted; and

18                   “(II) in the case of such an in-  
19                   vestigation conducted with respect to  
20                   a combination of active ingredients  
21                   described to in clause (ii) of such sub-  
22                   paragraph, to assist in determining  
23                   the relevance of its molecular target  
24                   to the growth or progression of a pe-  
25                   diatric cancer.

1           “(iii) LIMITATION REGARDING INVES-  
2           TIGATION OF NOVEL COMBINATION.—For  
3           purposes of paragraph (1)(B), a novel  
4           combination is a combination of two or  
5           more active ingredients for which an appli-  
6           cation under section 505 of this Act or sec-  
7           tion 351 of the Public Health Service Act  
8           for such combination has not previously  
9           been approved. A pediatric investigation  
10          under this paragraph of such novel com-  
11          bination is required only if each of the ac-  
12          tive ingredients in the combination has  
13          been approved under such section 505 or  
14          such section 351 to treat an adult cancer.

15          “(iv) PRECLINICAL DATA.—The Sec-  
16          retary may require that reports on an in-  
17          vestigation required pursuant to paragraph  
18          (1)(B) shall include the results of all pre-  
19          clinical studies on which the decision to  
20          conduct such investigation was based.

21          “(v) RULE OF CONSTRUCTION RE-  
22          GARDING INACTIVE INGREDIENTS.—With  
23          respect to a combination of active ingredi-  
24          ents referred to in subparagraph (A)(ii),  
25          such subparagraph may not be construed

1 as addressing the use of inactive ingredi-  
2 ents with such combination.”.

3 (3) CLARIFYING APPLICABILITY OF CERTAIN  
4 PROVISIONS.—Section 505B(a)(3) of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C.  
6 355c(a)(3)), as amended by paragraph (2), is fur-  
7 ther amended by adding at the end the following:

8 “(E) INTERNAL COMMITTEE REVIEW; LA-  
9 BELING CHANGES; DISSEMINATION OF INFOR-  
10 MATION; ADVERSE EVENTS; SCOPE OF AUTHOR-  
11 ITY.—Subsections (f) through (j) shall apply  
12 with respect to investigations described in this  
13 paragraph to the same extent and in the same  
14 manner as such subsections apply with respect  
15 to the assessments required under paragraph  
16 (1)(A), except that subsection (g) does not  
17 apply with respect to an investigation referred  
18 to in subparagraph (A)(ii) of this paragraph.”.

19 (4) CONFORMING AMENDMENTS.—Section  
20 505B(a) of the Federal Food, Drug, and Cosmetic  
21 Act (21 U.S.C. 355c(a)) is amended—

22 (A) in paragraph (3)(C), as redesignated  
23 by paragraph (2)(A) of this subsection, by  
24 striking “investigations described in this para-

1 graph” and inserting “investigations referred to  
2 in subparagraph (A)(i)”;

3 (B) in paragraph (3)(D), as redesignated  
4 by paragraph (2)(A) of this subsection, by  
5 striking “the assessments under paragraph  
6 (2)(B)” and inserting “the assessments re-  
7 quired under paragraph (1)(A)”;

8 (C) in paragraph (5)(D), by inserting be-  
9 fore the period at the end the following: “, ex-  
10 cept this subparagraph is not applicable to an  
11 investigation referred to in paragraph  
12 (3)(A)(ii)”.

13 (b) AUTHORITY REGARDING PRECLINICAL STUD-  
14 IES.—Section 505B(a)(1) of the Federal Food, Drug, and  
15 Cosmetic Act (21 U.S.C. 355c(a)(1)), as amended by sub-  
16 section (a)(1), is further amended by adding at the end  
17 the following:

18 “(C) PRECLINICAL STUDIES GEN-  
19 ERALLY.—

20 “(i) IN GENERAL.—With respect to an  
21 application for an exemption for investiga-  
22 tional use under section 505(i) for a drug  
23 or biological product that is intended for  
24 the treatment of an adult cancer, the Sec-  
25 retary may require, as a condition of per-



1           mitting the exemption to go into effect,  
2           that the sponsor involved enter into an  
3           agreement with the Secretary to conduct  
4           not more than two preclinical studies of  
5           the drug or biological product in order to  
6           assist in determining the relevance of its  
7           molecular target to the growth or progres-  
8           sion of a pediatric cancer.

9           “(ii) TIMEFRAME FOR PRECLINICAL  
10          STUDIES.—With respect to the drug or bi-  
11          ological product involved, an agreement  
12          under clause (i) for a preclinical study  
13          shall specify the date by which an initial  
14          plan for the study will be submitted to the  
15          Secretary except that the Secretary may  
16          not require the submission of such plan  
17          any earlier than one year after the exemp-  
18          tion referred to in clause (i) goes into ef-  
19          fect. The results of the preclinical study  
20          shall be submitted to the Secretary in ac-  
21          cordance with a timeframe to which the  
22          Secretary and the sponsor involved have  
23          agreed. Such timeframe shall provide for  
24          deferrals equivalent to deferrals under  
25          paragraph (4).”.

1           (c) APPLICABILITY.—The amendments made by this  
2 section apply with respect to any application under section  
3 505(i) of the Federal Food, Drug, and Cosmetic Act (21  
4 U.S.C. 355(i)), any application under section 505 of such  
5 Act (21 U.S.C. 355), and any application under section  
6 351(a) of the Public Health Service Act (42 U.S.C. 262),  
7 that is submitted on or after the expiration of the 3-year  
8 period beginning on the date of the enactment of this Act.