

118TH CONGRESS  
2D SESSION

# H. R. 6963

To direct the Secretary of Health and Human Services to enter into agreements with drug manufacturers to establish reserve supplies of covered pediatric cancer drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 11, 2024

Ms. ESHOO (for herself, Ms. DEGETTE, and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To direct the Secretary of Health and Human Services to enter into agreements with drug manufacturers to establish reserve supplies of covered pediatric cancer drugs, 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 “Pediatric Cancer Drug  
5 Supply Act of 2024”.

1 **SEC. 2. ESTABLISHMENT OF ESSENTIAL PEDIATRIC CAN-**  
2 **CER DRUG MARKETPLACE STABILITY PILOT**  
3 **PROGRAM.**

4 (a) IN GENERAL.—The Secretary shall carry out a  
5 pilot program under which the Secretary enters into agree-  
6 ments with manufacturers to purchase and maintain not  
7 less than a 6-month reserve supply, to be held by such  
8 manufacturers, of each covered pediatric cancer drug.

9 (b) PILOT PROGRAM.—

10 (1) PREFERENCE FOR MULTIPLE MANUFACTUR-  
11 ERS.—To the greatest extent practicable, the Sec-  
12 retary shall seek to enter into agreements described  
13 in subsection (a) with more than 1 manufacturer for  
14 each covered pediatric cancer drug.

15 (2) IMPLEMENTATION GOALS.—To the greatest  
16 extent practicable, the Secretary shall implement the  
17 pilot program under this section in a manner that—

18 (A) minimizes the impact on the market-  
19 place for drugs included on the essential pedi-  
20 atric cancer drug list established under section  
21 3;

22 (B) increases domestic manufacturing ca-  
23 pacity;

24 (C) encourages competition in the market-  
25 place;

1 (D) assures that any covered pediatric can-  
2 cer drugs that the Secretary distributes or or-  
3 ders to be distributed under section 4 are used  
4 to treat pediatric cancer patients; and

5 (E) rewards manufacturing quality.

6 (3) REQUIRED AGREEMENT TERMS.—Each  
7 agreement under this section between the Secretary  
8 and a manufacturer of a covered pediatric cancer  
9 drug shall include the following:

10 (A) The identity and quantity of each cov-  
11 ered pediatric cancer drug that the manufac-  
12 turer agrees to hold in reserve supply.

13 (B) A requirement that such quantities  
14 shall be in addition to the average levels of in-  
15 ventory for the relevant covered pediatric cancer  
16 drug held by the manufacturer during the pre-  
17 vious year.

18 (C) A provision to ensure that each drug  
19 held in reserve supply has an expiration date at  
20 least 1 year beyond the current date.

21 (D) A provision to allow the manufacturer  
22 to sell and replace, through normal commercial  
23 channels, any drug in reserve supply in order to  
24 remain in compliance with the provision de-  
25 scribed in subparagraph (C).

1           (E) A requirement that the covered pedi-  
2           atric cancer drugs in reserve supply may only  
3           be held at a location in the United States.

4           (F) In the case of a covered pediatric can-  
5           cer drug manufactured at an eligible source fa-  
6           cility that is not located in the United States,  
7           the manufacturer of such drug may comply  
8           with subparagraph (E)—

9                   (i) by storing the drug at an establish-  
10                  ment located in the United States that  
11                  is—

12                           (I) registered under section 510  
13                           of the Federal Food, Drug, and Cos-  
14                           metic Act (21 U.S.C. 360); and

15                           (II) under common ownership  
16                           and control with the manufacturer; or

17                           (ii) by contracting with an authorized  
18                           third-party logistics provider (as defined in  
19                           section 581 of the Federal Food Drug, and  
20                           Cosmetic Act (21 U.S.C. 360eee)) located  
21                           in the United States to store the drug in  
22                           the United States.

23           (G) A requirement that any covered pedi-  
24           atric cancer drug held in reserve supply be  
25           manufactured and held in accordance with—

1 (i) good manufacturing practice re-  
2 quirements;

3 (ii) the approved application for such  
4 drug under section 505 of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C.  
6 355) or section 351 of the Public Health  
7 Service Act (42 U.S.C. 262); and

8 (iii) applicable law.

9 (H) A provision that allows the Secretary,  
10 or a third party designated by the Secretary, to  
11 audit the manufacturer and the eligible source  
12 facility for compliance with the terms of the  
13 agreement and applicable law—

14 (i) on an annual basis; or

15 (ii) more frequently, if the Secretary  
16 has a reasonable basis to believe that the  
17 manufacturer or eligible source facility is  
18 not complying with the terms of the agree-  
19 ment or applicable law.

20 (I) A requirement that the manufacturer  
21 certify to the Secretary on an annual basis com-  
22 pliance with the terms of the agreement.

23 (4) OPTIONAL TERMS FOR ACQUISITION, CON-  
24 STRUCTION, ALTERATION, OR RENOVATION OF ES-  
25 TABLISHMENT.—An agreement under this section

1 between the Secretary and a manufacturer of a cov-  
2 ered pediatric cancer drug may include a provision  
3 to allow the manufacturer to acquire, construct,  
4 alter, or renovate a non-federally owned establish-  
5 ment for the purpose of manufacturing covered pedi-  
6 atric cancer drugs—

7 (A) as the Secretary determines necessary  
8 to ensure sufficient amounts of such drugs; or

9 (B) as the Secretary determines necessary  
10 to carry out or improve preparedness and re-  
11 sponse capability at the State and local levels.

12 (5) REASONABLE TIME FOR MANUFACTURE.—

13 The Secretary shall allow each manufacturer with  
14 whom the Secretary has entered into an agreement  
15 under this section a reasonable amount of time after  
16 entering into the agreement to manufacture the cov-  
17 ered pediatric cancer drugs that will be held in re-  
18 serve supply pursuant to the agreement.

19 (c) PAYMENT TERMS.—

20 (1) PAYMENT AMOUNTS.—

21 (A) IN GENERAL.—The amount paid to  
22 each manufacturer pursuant to an agreement  
23 with the Secretary under this section shall be  
24 based on—

1 (i) the quantity of each covered pedi-  
2 atric cancer drug the manufacturer agrees  
3 to hold in reserve supply; and

4 (ii) the wholesale acquisition cost of  
5 each such drug.

6 (B) ADMINISTRATIVE FEE.—The Secretary  
7 may pay a manufacturer an administrative fee  
8 pursuant to an agreement under this section,  
9 provided that the payment of the administrative  
10 fee does not cause the Secretary to exhaust the  
11 amounts appropriated for the pilot program  
12 under this section prior to securing adequate  
13 reserves for each covered pediatric cancer drug.

14 (2) PAYMENT CONDITIONED ON RESERVE SUP-  
15 PLY ADEQUACY.—

16 (A) IN GENERAL.—Except as provided in  
17 subparagraph (B), each agreement with a man-  
18 ufacturer under this section shall provide that  
19 no payment under the agreement may be made  
20 until the manufacturer demonstrates to the  
21 Secretary that the manufacturer has set aside  
22 a portion, as determined by the Secretary, of  
23 the total quantity of the covered pediatric can-  
24 cer drug to be held in reserve supply under the  
25 agreement.

1           (B) EXCEPTIONS FOR ADVANCE PAY-  
2           MENT.—An agreement under this section may  
3           provide that, if the Secretary determines that  
4           an advance payment or partial payment for sig-  
5           nificant milestones is necessary to ensure suc-  
6           cess of the terms of the agreement, the Sec-  
7           retary shall pay, in advance, an amount not to  
8           exceed 10 percent of the total amount to be  
9           paid to the manufacturer by the Secretary  
10          under the agreement.

11          (d) FORFEITURE.—If a manufacturer is unable or  
12          fails to distribute a covered pediatric cancer drug in ac-  
13          cordance with the terms of an agreement entered into  
14          under this section, the manufacturer shall—

15               (1) forfeit any payments it has received under  
16               the agreement; and

17               (2) not later than 30 days after the date of  
18               such inability or failure, refund such payments.

19          **SEC. 3. ESSENTIAL PEDIATRIC CANCER DRUG LIST.**

20          (a) IN GENERAL.—The Secretary, in consultation  
21          with the Commissioner of Food and Drugs and the Direc-  
22          tor of the National Cancer Institute, shall—

23               (1) not later than 150 days after the date of  
24               enactment of this Act, develop a list of



1       chemotherapeutic drugs that are essential for treat-  
2       ing pediatric cancer; and

3               (2) update such list on a schedule determined  
4       by the Secretary.

5       (b)    CRITERIA.—Under subsection (a), a  
6       chemotherapeutic drug shall be considered essential for  
7       treating pediatric cancer only if the drug—

8               (1) is approved under section 505 of the Fed-  
9       eral Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
10       or licensed under section 351 of the Public Health  
11       Service Act (42 U.S.C. 262) for use in the treatment  
12       of cancer;

13              (2) has the potential alone or in combination  
14       with other drugs to treat a pediatric cancer;

15              (3) is supported by 1 or more citations to treat  
16       a pediatric cancer included or approved for inclusion  
17       in—

18                       (A) the National Comprehensive Cancer  
19       Network Compendia;

20                       (B) American Hospital Formulary Service  
21       Drug Information;

22                       (C) the DRUGDEX Information System;

23       or

1 (D) the PDQ Cancer Information Sum-  
2 maries for Health Professionals of the National  
3 Cancer Institute; and

4 (4) meets price, quality, manufacturing con-  
5 centration, manufacturing complexity, and other ap-  
6 propriate metrics as determined by the Secretary.

7 **SEC. 4. DISTRIBUTIONS FROM ESSENTIAL PEDIATRIC CAN-**  
8 **CER DRUG RESERVE SUPPLIES.**

9 (a) IN GENERAL.—If a covered pediatric cancer drug  
10 is in shortage (as defined in section 506C(h) of the Fed-  
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 356c(h))),  
12 or the Secretary has reason to believe that such a drug  
13 may be at risk of such a shortage, the Secretary may order  
14 a manufacturer with whom the Secretary has entered into  
15 an agreement under section 2 to distribute such drug from  
16 the reserve supply in accordance with such agreement in  
17 an effort to alleviate or prevent the shortage.

18 (b) PAYMENTS FOR DISTRIBUTION.—

19 (1) IN GENERAL.—The Secretary shall require  
20 a recipient of a covered pediatric cancer drug dis-  
21 tributed under subsection (a) to pay the Secretary  
22 for such drug. The amount of such payment shall  
23 not exceed the price for which the Secretary pur-  
24 chased such drug pursuant to an agreement under  
25 section 2.

1           (2) LIMITATION.—The Secretary may use pay-  
2           ments received pursuant to paragraph (1) only to re-  
3           plenish the reserve supply of the drugs distributed  
4           under subsection (a).

5           (c) INABILITY TO DISTRIBUTE OR MANAGE RESERVE  
6           SUPPLY.—

7           (1) INABILITY TO DISTRIBUTE.—If a manufac-  
8           turer is not able or willing to distribute drugs in ac-  
9           cordance with an order of the Secretary under sub-  
10          section (a), the Secretary may take possession of  
11          and distribute such drugs.

12          (2) INABILITY TO MANAGE RESERVE SUPPLY.—  
13          If a manufacturer can no longer hold or manage a  
14          reserve supply of covered pediatric cancer drugs in  
15          accordance with an agreement under section 2, the  
16          Secretary may take possession of the reserve supply.

17   **SEC. 5. REPORTS TO CONGRESS.**

18          (a) IN GENERAL.—For each year 1 or more drugs  
19          are held by a manufacturer in reserve supply pursuant to  
20          an agreement under section 2, the Secretary shall submit  
21          to Congress a report on the progress of the pilot program  
22          under such section.

23          (b) CONTENTS.—The reports referred to in sub-  
24          section (a) shall each include—

1 (1) the essential pediatric cancer drug list in ef-  
2 fect during the year covered by the report (including  
3 any changes made to the list throughout the year);

4 (2) the total number of agreements entered into  
5 under section 2 during such year;

6 (3) the total amount of each covered pediatric  
7 cancer drug purchased by the Secretary pursuant to  
8 such agreements during such year;

9 (4) the total amount of each covered pediatric  
10 cancer drug distributed from the reserve supplies  
11 under section 4 during such year; and

12 (5) any other information that the Secretary  
13 determines relevant.

14 **SEC. 6. DEFINITIONS.**

15 In this Act:

16 (1) COVERED PEDIATRIC CANCER DRUG.—The  
17 term “covered pediatric cancer drug” means a  
18 drug—

19 (A) that is included on the essential pedi-  
20 atric cancer drug list established under section  
21 3;

22 (B) that may be at risk of a meaningful  
23 disruption (as defined in section 506J(j) of the  
24 Federal Food, Drug, and Cosmetic Act (21  
25 U.S.C. 356j(j))) in the supply of the drug; and

1 (C) whose final dosage form is manufac-  
2 tured at an eligible source facility.

3 (2) DRUG.—The term “drug”—

4 (A) means a drug (as defined in section  
5 201(g) of the Federal Food, Drug, and Cos-  
6 metic Act (21 U.S.C. 321(g))); and

7 (B) includes a biological product (as de-  
8 fined in section 351(i) of the Public Health  
9 Service Act (42 U.S.C. 262(i))).

10 (3) ELIGIBLE SOURCE FACILITY.—The term  
11 “eligible source facility” means a facility—

12 (A) registered under section 510 of the  
13 Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 360);

15 (B) lawfully manufacturing a covered pedi-  
16 atric cancer drug; and

17 (C) located in—

18 (i) the United States; or

19 (ii) a country that is a member of the  
20 Organisation for Economic Co-operation  
21 and Development.

22 (4) ESSENTIAL PEDIATRIC CANCER DRUG  
23 LIST.—The term “essential pediatric cancer drug  
24 list” means the list under section 3(a).

1           (5) SECRETARY.—The term “Secretary” means  
2           the Secretary of Health and Human Services.

3           (6) UNITED STATES.—The term “United  
4           States” means each of the several States and the  
5           territories and possessions of the United States.

6 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

7           To carry out this Act, there are authorized to be ap-  
8           propriated \$500,000,000 for fiscal year 2024, to remain  
9           available until expended.

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