

118TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To require reporting regarding certain drug price increases, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

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Ms. BALDWIN introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

To require reporting regarding certain drug price increases, 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 “Fair Accountability  
5 and Innovative Research Drug Pricing Act of 2023”.

6 **SEC. 2. REPORTING ON JUSTIFICATION FOR DRUG PRICE**  
7 **INCREASES.**

8 Title III of the Public Health Service Act (42 U.S.C.  
9 241 et seq.) is amended by adding at the end the fol-  
10 lowing:

1           **“PART W—DRUG PRICE REPORTING; DRUG**  
2                                   **VALUE FUND**  
3   **“SEC. 39900. REPORTING ON JUSTIFICATION FOR DRUG**  
4                                   **PRICE INCREASES.**

5           “(a) DEFINITIONS.—In this section:

6                   “(1) MANUFACTURER.—The term ‘manufac-  
7           turer’ means the person—

8                           “(A) that holds the application for a drug  
9                           approved under section 505 of the Federal  
10                          Food, Drug, and Cosmetic Act or the license  
11                          issued under section 351 of this Act; or

12                           “(B) who is responsible for setting the  
13                          price for the drug.

14                   “(2) QUALIFYING DRUG.—The term ‘qualifying  
15           drug’ means any drug that is approved under sub-  
16           section (c) or (j) of section 505 of the Federal Food,  
17           Drug, and Cosmetic Act or licensed under subsection  
18           (a) or (k) of section 351 of this Act—

19                           “(A) that has a wholesale acquisition cost  
20                          of \$100 or more per month supply, or per a  
21                          course of treatment that lasts less than a  
22                          month, and is—

23                           “(i)(I) subject to section 503(b)(1) of  
24                          the Federal Food, Drug, and Cosmetic  
25                          Act; or

1                   “(II) commonly administered by hos-  
2                   pitals (as determined by the Secretary);  
3                   and

4                   “(ii) not designated by the Secretary  
5                   as a vaccine; and

6                   “(B) for which, during the previous cal-  
7                   endar year, at least 1 dollar of the total amount  
8                   of sales were for individuals enrolled under the  
9                   Medicare program under title XVIII of the So-  
10                  cial Security Act (42 U.S.C. 1395 et seq.) or  
11                  under a State Medicaid plan under title XIX of  
12                  such Act (42 U.S.C. 1396 et seq.) or under a  
13                  waiver of such plan.

14                  “(3) UNITED STATES MEDIAN HOUSEHOLD IN-  
15                  COME.—The term ‘United States median household  
16                  income’ means median household income for the  
17                  United States as published by the Census Bureau  
18                  for the most recent year for which data is available  
19                  .

20                  “(4) WHOLESALE ACQUISITION COST.—The  
21                  term ‘wholesale acquisition cost’ has the meaning  
22                  given that term in section 1847A(c)(6)(B) of the So-  
23                  cial Security Act (42 U.S.C. 1395w-3a(c)(6)(B)).

24                  “(b) REPORT.—

1           “(1) REPORT REQUIRED.—The manufacturer of  
2 a qualifying drug shall submit a report to the Sec-  
3 retary if, with respect to the qualifying drug—

4           “(A) there is an increase in the price of  
5 the qualifying drug that results in an increase  
6 in the wholesale acquisition cost of that drug  
7 that is equal to—

8           “(i) 10 percent or more over a 12-  
9 month period beginning on or after Janu-  
10 ary 1, 2024; or

11           “(ii) 25 percent or more over a 36-  
12 month period beginning on or after Janu-  
13 ary 1, 2024; or

14           “(B) the wholesale acquisition price of the  
15 qualifying drug for the applicable year or per  
16 normal course of treatment that lasts less than  
17 1 year, as determined by the Secretary, exceeds  
18 United States median household income begin-  
19 ning on or after January 1, 2024.

20           “(2) REPORT DEADLINE.—Each report de-  
21 scribed in paragraph (1) shall be submitted to the  
22 Secretary not later than 30 days prior to the  
23 planned effective date of such price increase.

24           “(c) CONTENTS.—A report under subsection (b)  
25 shall, at a minimum, include—

1 “(1) with respect to the qualifying drug—

2 “(A) the percentage by which the manufac-  
3 turer will raise the wholesale acquisition cost of  
4 the drug on the planned effective date of such  
5 price increase, as applicable;

6 “(B) a justification for, and description of,  
7 each manufacturer’s price increase that will  
8 occur during the 12-month period described in  
9 subsection (b)(1)(A) or the 36-month period de-  
10 scribed in subsection (b)(1)(B), as applicable;

11 “(C) an explanation for, and description  
12 of, the cost associated with a qualifying drug if  
13 such drug meets the criteria under subsection  
14 (b)(1)(B), as applicable;

15 “(D) the identity of the initial developer of  
16 the drug;

17 “(E) a description of the history of the  
18 manufacturer’s price increases for the drug  
19 since the approval of the application for the  
20 drug under section 505 of the Federal Food,  
21 Drug, and Cosmetic Act or the issuance of the  
22 license for the drug under section 351, or since  
23 the manufacturer acquired such approved appli-  
24 cation or license, as applicable;

25 “(F) the current list price of the drug;

1           “(G) the total expenditures of the manu-  
2           facturer on—

3                   “(i) materials and manufacturing for  
4           such drug; and

5                   “(ii) acquiring patents and licensing  
6           for such drug;

7           “(H) the percentage of total expenditures  
8           of the manufacturer on research and develop-  
9           ment for such drug that was derived from Fed-  
10          eral funds;

11          “(I) the total expenditures of the manufac-  
12          turer on research and development for such  
13          drug that is used for—

14                   “(i) basic and preclinical research;

15                   “(ii) clinical research;

16                   “(iii) new drug development;

17                   “(iv) pursuing new or expanded indi-  
18          cations for such drug through supple-  
19          mental applications under section 505 of  
20          the Federal Food, Drug, and Cosmetic Act  
21          or section 351 of this Act; and

22                   “(v) carrying out postmarket require-  
23          ments related to such drug, including those  
24          under section 505(o)(3) of the Federal  
25          Food, Drug, and Cosmetic Act;

1           “(J) the total revenue and the net profit  
2 generated from the qualifying drug for each cal-  
3 endar year since the approval of the application  
4 for the drug under section 505 of the Federal  
5 Food, Drug, and Cosmetic Act or the issuance  
6 of the license for the drug under section 351,  
7 or since the manufacturer acquired such ap-  
8 proved application or license; and

9           “(K) the total costs associated with mar-  
10 keting and advertising for the qualifying drug;  
11 “(2) with respect to the manufacturer—

12           “(A) the total revenue and the net profit  
13 of the manufacturer for each of the 12-month  
14 periods described in subsection (b)(1)(A) or for  
15 the 36-month period described in subsection  
16 (b)(1)(B), as applicable;

17           “(B) all stock-based performance metrics  
18 used by the manufacturer to determine execu-  
19 tive compensation for each of the 12-month pe-  
20 riods described in subsection (b)(1)(A) or the  
21 36-month periods described in subsection  
22 (b)(1)(B)(ii), as applicable; and

23           “(C) any additional information the manu-  
24 facturer chooses to provide related to drug pric-  
25 ing decisions, such as total expenditures on—

1 “(i) drug research and development;

2 or

3 “(ii) clinical trials on drugs that failed

4 to receive approval by the Food and Drug

5 Administration; and

6 “(3) such other related information as the Sec-

7 retary considers appropriate.

8 “(d) CIVIL PENALTY.—Any manufacturer of a quali-

9 fying drug that fails to submit a report for the drug as

10 required by this section shall be subject to a civil penalty

11 of \$100,000 for each day on which the violation continues.

12 “(e) PUBLIC POSTING.—

13 “(1) IN GENERAL.—Subject to paragraph (3),

14 not later than 30 days after the submission of a re-

15 port under subsection (b), the Secretary shall post

16 the report on the public website of the Department

17 of Health and Human Services.

18 “(2) FORMAT.—In developing the format of

19 such report for public posting, the Secretary shall

20 consult stakeholders, including beneficiary groups,

21 and shall seek feedback on the content and format

22 from consumer advocates and readability experts to

23 ensure such public reports are user-friendly to the

24 public and are written in plain language that con-

25 sumers can readily understand.

1           “(3) TRADE SECRETS AND CONFIDENTIAL IN-  
2           FORMATION.—In carrying out this section the Sec-  
3           retary shall enforce current law concerning the pro-  
4           tection of confidential commercial information and  
5           trade secrets.”.

6   **“SEC. 39900-1. USE OF CIVIL PENALTY AMOUNTS.**

7           “The Secretary shall, without further appropriation,  
8           collect civil penalties under section 39900 and use the  
9           funds derived from such civil penalties, in addition to any  
10          other amounts available to the Secretary, to carry out ac-  
11          tivities described in this part and to improve consumer and  
12          provider information about drug value and drug price  
13          transparency.

14   **“SEC. 39900-2. ANNUAL REPORT TO CONGRESS.**

15          “(a) IN GENERAL.—Subject to subsection (b), the  
16          Secretary shall submit to Congress, and post on the public  
17          website of the Department of Health and Human Services  
18          in a way that is easy to find, use, and understand, an  
19          annual report—

20                 “(1) summarizing the information reported pur-  
21                 suant to section 39900; and

22                 “(2) including copies of the reports and sup-  
23                 porting detailed economic analyses submitted pursu-  
24                 ant to such section.

1           “(b) TRADE SECRETS AND CONFIDENTIAL INFORMA-  
2 TION.—In carrying out this section the Secretary shall en-  
3 force current law concerning the protection of confidential  
4 commercial information and trade secrets.”.