

116TH CONGRESS  
1ST SESSION

# S. 1391

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

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IN THE SENATE OF THE UNITED STATES

MAY 9, 2019

Ms. BALDWIN (for herself, Mr. BRAUN, Ms. MURKOWSKI, and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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 2019”.

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:

**“PART W—DRUG PRICE REPORTING; DRUG  
VALUE FUND**

**“SEC. 39900. REPORTING ON JUSTIFICATION FOR DRUG  
PRICE INCREASES.**

“(a) DEFINITIONS.—In this section:

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

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

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

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

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

“(i)(I) subject to section 503(b)(1) of  
the Federal Food, Drug, and Cosmetic  
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) WHOLESALE ACQUISITION COST.—The  
 15 term ‘wholesale acquisition cost’ has the meaning  
 16 given that term in section 1847A(c)(6)(B) of the So-  
 17 cial Security Act (42 U.S.C. 1395w-3a(c)(6)(B)).

18 “(b) REPORT.—

19 “(1) REPORT REQUIRED.—The manufacturer of  
 20 a qualifying drug shall submit a report to the Sec-  
 21 retary for each price increase of a qualifying drug  
 22 that will result in an increase in the wholesale acqui-  
 23 sition cost of that drug that is equal to—

24 “(A) 10 percent or more over a 12-month  
 25 period; or

1 “(B) 25 percent or more over a 36-month  
2 period.

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

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

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

10 “(A) the percentage by which the manufac-  
11 turer will raise the wholesale acquisition cost of  
12 the drug on the planned effective date of such  
13 price increase;

14 “(B) a justification for, and description of,  
15 each manufacturer’s price increase that will  
16 occur during the 12-month period described in  
17 subsection (b)(1)(A) or the 36-month period de-  
18 scribed in subsection (b)(1)(B), as applicable;

19 “(C) the identity of the initial developer of  
20 the drug;

21 “(D) a description of the history of the  
22 manufacturer’s price increases for the drug  
23 since the approval of the application for the  
24 drug under section 505 of the Federal Food,  
25 Drug, and Cosmetic Act or the issuance of the

1 license for the drug under section 351, or since  
2 the manufacturer acquired such approved appli-  
3 cation or license;

4 “(E) the current list price of the drug;

5 “(F) the total expenditures of the manu-  
6 facturer on—

7 “(i) materials and manufacturing for  
8 such drug; and

9 “(ii) acquiring patents and licensing  
10 for such drug;

11 “(G) the percentage of total expenditures  
12 of the manufacturer on research and develop-  
13 ment for such drug that was derived from Fed-  
14 eral funds;

15 “(H) the total expenditures of the manu-  
16 facturer on research and development for such  
17 drug that is used for—

18 “(i) basic and preclinical research;

19 “(ii) clinical research;

20 “(iii) new drug development;

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

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

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

13 “(J) the total costs associated with mar-  
14 keting and advertising for the qualifying drug;  
15 “(2) with respect to the manufacturer—

16 “(A) the total revenue and the net profit  
17 of the manufacturer—

18 “(i) for the 12-month period pre-  
19 ceding the date of the report, in the case  
20 of a report based on an increase described  
21 in subsection (b)(1)(A); or

22 “(ii) for the 36-month period pre-  
23 ceding the date of the report, in the case  
24 of a report based on an increase described  
25 in subsection (b)(1)(B);

1 “(B) all stock-based performance metrics  
2 used by the manufacturer to determine execu-  
3 tive compensation—

4 “(i) for the 12-month period pre-  
5 ceding the date of the report, in the case  
6 of a report based on an increase described  
7 in subsection (b)(1)(A); or

8 “(ii) for the 36-month period pre-  
9 ceding the date of the report, in the case  
10 of a report based on an increase described  
11 in subsection (b)(1)(B); and

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

15 “(i) drug research and development;  
16 or

17 “(ii) clinical trials on drugs that failed  
18 to receive approval by the Food and Drug  
19 Administration; and

20 “(3) such other related information as the Sec-  
21 retary considers appropriate.

22 “(d) CIVIL PENALTY.—Any manufacturer of a quali-  
23 fying drug that fails to submit a report for the drug as  
24 required by this section shall be subject to a civil penalty  
25 of \$100,000 for each day on which the violation continues.

1 “(e) PUBLIC POSTING.—

2 “(1) IN GENERAL.—Subject to paragraph (3),  
3 not later than 30 days after the submission of a re-  
4 port under subsection (b), the Secretary shall post  
5 the report on the public website of the Department  
6 of Health and Human Services.

7 “(2) FORMAT.—In developing the format of  
8 such report for public posting, the Secretary shall  
9 consult stakeholders, including beneficiary groups,  
10 and shall seek feedback on the content and format  
11 from consumer advocates and readability experts to  
12 ensure such public reports are user-friendly to the  
13 public and are written in plain language that con-  
14 sumers can readily understand.

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

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

21 “The Secretary shall, without further appropriation,  
22 collect civil penalties under section 39900 and use the  
23 funds derived from such civil penalties, in addition to any  
24 other amounts available to the Secretary, to carry out ac-  
25 tivities described in this part and to improve consumer and



1 provider information about drug value and drug price  
2 transparency.

3 **“SEC. 39900–2. ANNUAL REPORT TO CONGRESS.**

4 “(a) IN GENERAL.—Subject to subsection (b), the  
5 Secretary shall submit to Congress, and post on the public  
6 website of the Department of Health and Human Services  
7 in a way that is easy to find, use, and understand, an  
8 annual report—

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

11 “(2) including copies of the reports and sup-  
12 porting detailed economic analyses submitted pursu-  
13 ant to such section.

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

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