

115TH CONGRESS
1ST SESSION

S. 1131

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

IN THE SENATE OF THE UNITED STATES

MAY 16, 2017

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

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 2017”.

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 the Public Health
12 Service Act; or

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

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

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

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

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

3 “(ii) not designated as a drug for a
4 rare disease or condition under section 526
5 of the Federal Food, Drug, and Cosmetic
6 Act; and

7 “(iii) not designated by the Secretary
8 as a vaccine; and

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

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

21 “(b) REPORT.—

22 “(1) REPORT REQUIRED.—The manufacturer of
23 a qualifying drug shall submit a report to the Sec-
24 retary for each price increase of a qualifying drug

1 that will result in an increase in the wholesale acqui-
2 sition cost of that drug that is equal to—

3 “(A) 10 percent or more over a 12-month
4 period; or

5 “(B) 25 percent or more over a 36-month
6 period.

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

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

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

14 “(A) the percentage by which the manufac-
15 turer will raise the wholesale acquisition cost of
16 the drug on the planned effective date of such
17 price increase;

18 “(B) a justification for, and description of,
19 each manufacturer’s price increase that oc-
20 curred during the 12-month period described in
21 subsection (b)(1)(A) or the 36-month period de-
22 scribed in subsection (b)(1)(B), as applicable;

23 “(C) the identity of the initial developer of
24 the drug;

1 “(D) a description of the history of the
2 manufacturer’s price increases for the drug
3 since the approval of the application for the
4 drug under section 505 of the Federal Food,
5 Drug, and Cosmetic Act or the issuance of the
6 license for the drug under section 351, or since
7 the manufacturer acquired such approved appli-
8 cation or license;

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

10 “(F) the total expenditures of the manu-
11 facturer on—

12 “(i) materials and manufacturing for
13 such drug; and

14 “(ii) acquiring patents and licensing
15 for such drug;

16 “(G) the percentage of total expenditures
17 of the manufacturer on research and develop-
18 ment for such drug that was derived from Fed-
19 eral funds;

20 “(H) the total expenditures of the manu-
21 facturer on research and development for such
22 drug that is used for—

23 “(i) basic and preclinical research;

24 “(ii) clinical research;

25 “(iii) new drug development;

1 “(iv) pursuing new or expanded indi-
2 cations for such drug through supple-
3 mental applications under section 505 of
4 the Federal Food, Drug, and Cosmetic
5 Act; and

6 “(v) carrying out postmarket require-
7 ments related to such drug, including those
8 under section 505(o)(3) of such Act;

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

17 “(J) the total costs associated with mar-
18 keting and advertising for the qualifying drug;

19 “(2) with respect to the manufacturer—

20 “(A) the total revenue and the net profit
21 of the manufacturer for the 12-month period
22 described in subsection (b)(1)(A) or the 36-
23 month period described in subsection (b)(1)(B),
24 as applicable;

1 “(B) all stock-based performance metrics
2 used by the manufacturer to determine execu-
3 tive compensation for the 12-month period de-
4 scribed in subsection (b)(1)(A) or the 36-month
5 period described in subsection (b)(1)(B), as ap-
6 plicable; and

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

10 “(i) drug research and development;

11 or

12 “(ii) clinical trials on drugs that failed
13 to receive approval by the Food and Drug
14 Administration; and

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

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

21 “(e) PUBLIC POSTING.—

22 “(1) IN GENERAL.—Subject to paragraph (3),
23 not later than 30 days after the submission of a re-
24 port under subsection (b), the Secretary shall post

1 the report on the public Web site of the Department
2 of Health and Human Services.

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

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

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

17 “The Secretary shall collect the civil penalties under
18 section 39900, in addition to any other amounts avail-
19 able, and without further appropriation, and shall use
20 such funds to carry out activities described in this part
21 and to improve consumer and provider information about
22 drug value and drug price transparency.

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

24 “(a) **IN GENERAL.**—Subject to subsection (b), the
25 Secretary shall submit to Congress, and post on the public

1 Web site of the Department of Health and Human Serv-
2 ices in a way that is easy to find, use, and understand,
3 an annual report—

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

6 “(2) including copies of the reports and sup-
7 porting detailed economic analyses submitted pursu-
8 ant to such section.

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

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