

114TH CONGRESS
2D SESSION

S. 3335

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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 15, 2016

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 2016”.

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) AVERAGE MANUFACTURER PRICE.—The
7 term ‘average manufacturer price’ has the meaning
8 given the term in section 1927(k)(1) of the Social
9 Security Act (42 U.S.C. 1396r–8(k)(1)).

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

12 “(A) that holds the application for a drug
13 approved under section 505 of the Federal
14 Food, Drug, and Cosmetic Act or the license
15 issued under section 351 of the Public Health
16 Service Act; or

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

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

24 “(A) that is—

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

4 “(II) commonly administered by hos-
5 pitals (as determined by the Secretary);

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

10 “(iii) not designated by the Secretary
11 as a vaccine; and

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

20 “(b) REPORT.—

21 “(1) REPORT REQUIRED.—The manufacturer of
22 a qualifying drug shall submit a report to the Sec-
23 retary for each price increase of a qualifying drug
24 that will result in an increase in the average manu-

1 manufacturer price of that drug that is equal to 10 per-
2 cent or more over a 12-month 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 average manufacturer price
12 of the drug on the planned effective date of
13 such price increase;

14 “(B) a justification for, and description of,
15 each manufacturer’s price increase that oc-
16 curred during the 12-month period described in
17 subsection (b)(1);

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

20 “(D) a description of the history of the
21 manufacturer’s price increases for the drug
22 since the approval of the application for the
23 drug under section 505 of the Federal Food,
24 Drug, and Cosmetic Act or the issuance of the
25 license for the drug under section 351, or since

1 the manufacturer acquired such approved appli-
2 cation or license;

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

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

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

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

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

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

17 “(i) basic and preclinical research;

18 “(ii) clinical research;

19 “(iii) new drug development;

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

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

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

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

15 “(A) the total revenue and the net profit
16 of the manufacturer for the 12-month period
17 described in subsection (b)(1);

18 “(B) the amount the manufacturer has
19 spent on dividends and stock repurchases and
20 the specific metrics used by the manufacturer
21 to determine executive compensation, including
22 any stock-based performance metrics, for the
23 12-month period described in subsection (b)(1);
24 and

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

4 “(i) drug research and development;
5 or

6 “(ii) clinical trials on drugs that failed
7 to receive approval by the Food and Drug
8 Administration; and

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

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

15 “(e) COMPLIANCE DETERMINATIONS.—In determin-
16 ing whether a manufacturer may have been required to
17 submit a report under this section, and otherwise making
18 determinations about manufacturer compliance with the
19 requirements of this section, the Inspector General of the
20 Department of Health and Human Services shall annually
21 review and consider the average manufacturer price infor-
22 mation submitted under section 447.510 of title 42, Code
23 of Federal Regulations, or any successor regulations.

24 “(f) PUBLIC POSTING.—

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

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

14 “(3) TRADE SECRETS AND CONFIDENTIAL IN-
15 FORMATION.—In carrying out this section the Sec-
16 retary shall ensure the protection of confidential
17 commercial information and trade secrets.”.

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

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

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

2 “(a) IN GENERAL.—Subject to subsection (b), the
3 Secretary shall submit to Congress, and post on the public
4 Web site of the Department of Health and Human Serv-
5 ices in a way that is easy to use and understand, an an-
6 nual report—

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

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

12 “(b) TRADE SECRETS AND CONFIDENTIAL INFORMA-
13 TION.—In carrying out this section the Secretary shall en-
14 sure the protection of confidential commercial information
15 and trade secrets.”.

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