

114TH CONGRESS  
2D 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 (for herself and Mr. MCCAIN) 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 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        factorer 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 12-  
23                  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 deter-  
16                  mining whether a manufacturer may have been required  
17                  to submit a report under this section, and otherwise mak-  
18                  ing determinations about manufacturer compliance with  
19                  the requirements of this section, the Inspector General of  
20                  the Department of Health and Human Services shall an-  
21                  nually review and consider the average manufacturer price  
22                  information submitted under section 447.510 of title 42,  
23                  Code 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 website 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 website of the Department of Health and Human Services  
5 in a way that is easy to use and understand, an annual  
6 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.”.