

115TH CONGRESS  
1ST SESSION

# H. R. 2439

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

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## IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2017

Ms. SCHAKOWSKY (for herself, Ms. DELAURO, Mr. DOGGETT, Mr. CUMMINGS, and Mr. WELCH) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 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 website 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 applicable law concerning the  
14 protection of confidential commercial information  
15 and 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 website of the Department of Health and Human Services  
2 in a way that is easy to use and understand, an annual  
3 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  
11          enforce applicable law concerning the protection of con-  
12          fidential commercial information and trade secrets.”.

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