

114TH CONGRESS  
2D SESSION

# H. R. 6043

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

---

## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 2016

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

---

## 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”.

1 **SEC. 2. REPORTING ON JUSTIFICATION FOR DRUG PRICE**  
2 **INCREASES.**

3 Title III of the Public Health Service Act (42 U.S.C.  
4 241 et seq.) is amended by adding at the end the fol-  
5 lowing:

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

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

10 “(a) DEFINITIONS.—In this section:

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

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

17 “(A) that holds the application for a drug  
18 approved under section 505 of the Federal  
19 Food, Drug, and Cosmetic Act or the license  
20 issued under section 351 of the Public Health  
21 Service Act; or

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

24 “(3) QUALIFYING DRUG.—The term ‘qualifying  
25 drug’ means any drug that is approved under sub-  
26 section (c) or (j) of section 505 of the Federal Food,

1 Drug, and Cosmetic Act or licensed under subsection  
2 (a) or (k) of section 351 of this Act—

3 “(A) that is—

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

7 “(II) commonly administered by hos-  
8 pitals (as determined by the Secretary);

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

13 “(iii) not designated by the Secretary  
14 as a vaccine; and

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

23 “(b) REPORT.—

24 “(1) REPORT REQUIRED.—The manufacturer of  
25 a qualifying drug shall submit a report to the Sec-

1       retary for each price increase of a qualifying drug  
2       that will result in an increase in the average manu-  
3       facturer price of that drug that is equal to 10 per-  
4       cent or more over a 12-month period.

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

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

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

12           “(A) the percentage by which the manufac-  
13       turer will raise the average manufacturer price  
14       of the drug on the planned effective date of  
15       such price increase;

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

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

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

1 Drug, and Cosmetic Act or the issuance of the  
2 license for the drug under section 351, or since  
3 the manufacturer acquired such approved appli-  
4 cation or license;

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

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

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

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

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

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

19 “(i) basic and preclinical research;

20 “(ii) clinical research;

21 “(iii) new drug development;

22 “(iv) pursuing new or expanded indi-  
23 cations for such drug through supple-  
24 mental applications under section 505 of

1 the Federal Food, Drug, and Cosmetic  
2 Act; and

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

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

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

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

20 “(B) the amount the manufacturer has  
21 spent on dividends and stock repurchases and  
22 the specific metrics used by the manufacturer  
23 to determine executive compensation, including  
24 any stock-based performance metrics, for the

1 12-month period described in subsection (b)(1);  
2 and

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

6 “(i) drug research and development;

7 or

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

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

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

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

1 “(f) 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 Web site 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 ensure the protection of confidential  
18 commercial information and trade secrets.”.

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

20 “The Secretary shall collect the civil penalties under  
21 section 39900, in addition to any other amounts avail-  
22 able, and without further appropriation, and shall use  
23 such funds to carry out activities described in this part  
24 and to improve consumer and provider information about  
25 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.”.

○