

116TH CONGRESS
1ST SESSION

H. R. 2296

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 12, 2019

Ms. SCHAKOWSKY (for herself and Mr. ROONEY of Florida) 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 2019” or
6 the “FAIR Drug Pricing Act of 2019”.

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) MANUFACTURER.—The term ‘manufac-
 12 turer’ means the person—

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

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

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

25 “(A) that has a wholesale acquisition cost
 26 of \$100 or more per month supply or per a

1 course of treatment that lasts less than a
2 month and is—

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

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

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

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

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

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

1 “(b) REPORT.—

2 “(1) REPORT REQUIRED.—The manufacturer of
3 a qualifying drug shall submit a report to the Sec-
4 retary for each price increase of a qualifying drug
5 that will result in an increase in the wholesale acqui-
6 sition cost of that drug that is equal to—

7 “(A) 10 percent or more over a 12-month
8 period; or

9 “(B) 25 percent or more over a 36-month
10 period.

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

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

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

18 “(A) the percentage by which the manufac-
19 turer will raise the wholesale acquisition cost of
20 the drug on the planned effective date of such
21 price increase;

22 “(B) a justification for, and description of,
23 each manufacturer’s price increase that will
24 occur during the 12-month period described in

1 subsection (b)(1)(A) or the 36-month period de-
2 scribed in subsection (b)(1)(B), as applicable;

3 “(C) the identity of the initial developer of
4 the drug;

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

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

14 “(F) the total expenditures of the manu-
15 facturer on—

16 “(i) materials and manufacturing for
17 such drug; and

18 “(ii) acquiring patents and licensing
19 for such drug;

20 “(G) the percentage of total expenditures
21 of the manufacturer on research and develop-
22 ment for such drug that was derived from Fed-
23 eral funds;

1 “(H) the total expenditures of the manu-
2 facturer on research and development for such
3 drug that is used for—

4 “(i) basic and preclinical research;

5 “(ii) clinical research;

6 “(iii) new drug development;

7 “(iv) pursuing new or expanded indi-
8 cations for such drug through supple-
9 mental applications under section 505 of
10 the Federal Food, Drug, and Cosmetic Act
11 or section 351 of the Public Health Service
12 Act; and

13 “(v) carrying out postmarket require-
14 ments related to such drug, including those
15 under section 505(o)(3) of the Federal
16 Food, Drug, and Cosmetic Act;

17 “(I) the total revenue and the net profit
18 generated from the qualifying drug for each cal-
19 endar year since the approval of the application
20 for the drug under section 505 of the Federal
21 Food, Drug, and Cosmetic Act or the issuance
22 of the license for the drug under section 351,
23 or since the manufacturer acquired such ap-
24 proved application or license; and

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

4 “(A) the total revenue and the net profit
5 of the manufacturer for each of the 12- and 36-
6 month periods preceding the submission of the
7 report;

8 “(B) all stock-based performance metrics
9 used by the manufacturer to determine execu-
10 tive compensation for each of the 12- and 36-
11 month periods preceding the submission of the
12 report; and

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

16 “(i) drug research and development;
17 or

18 “(ii) clinical trials on drugs that failed
19 to receive approval by the Food and Drug
20 Administration; and

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

23 “(d) CIVIL PENALTY.—Any manufacturer of a quali-
24 fying drug that fails to submit a report for the drug as

1 required by this section shall be subject to a civil penalty
2 of \$100,000 for each day on which the violation continues.

3 “(e) PUBLIC POSTING.—

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

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

17 “(3) TRADE SECRETS AND CONFIDENTIAL IN-
18 FORMATION.—In carrying out this section, the Sec-
19 retary shall enforce applicable law concerning the
20 protection of confidential commercial information
21 and trade secrets.

22 **“SEC. 39900–1. USE OF CIVIL PENALTY AMOUNTS.**

23 “The Secretary shall, without further appropriation,
24 collect civil penalties under section 39900 and use the
25 funds derived from such civil penalties, in addition to any

1 other amounts available to the Secretary, to carry out ac-
2 tivities described in this part and to improve consumer and
3 provider information about drug value and drug price
4 transparency.

5 **“SEC. 39900–2. ANNUAL REPORT TO CONGRESS.**

6 “(a) IN GENERAL.—Subject to subsection (b), the
7 Secretary shall submit to Congress, and post on the public
8 website of the Department of Health and Human Services
9 in a way that is easy to use and understand, an annual
10 report—

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

13 “(2) including copies of the reports and sup-
14 porting detailed economic analyses submitted pursu-
15 ant to such section.

16 “(b) TRADE SECRETS AND CONFIDENTIAL INFORMA-
17 TION.—In carrying out this section, the Secretary shall
18 enforce applicable law concerning the protection of con-
19 fidential commercial information and trade secrets.”.

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