

115TH CONGRESS
1ST SESSION

H. R. 4116

To amend the Public Health Service Act to require reporting by drug manufacturers to increase transparency in drug pricing, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 25, 2017

Mr. DOGGETT (for himself, Mr. CUMMINGS, Ms. DELAURO, Mr. ELLISON, Mr. POCAN, Mr. GRIJALVA, Mr. CICILLINE, Mr. COHEN, Mr. CONYERS, Mr. HIGGINS of New York, Ms. KAPTUR, Mr. NADLER, and Mr. RASKIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to require reporting by drug manufacturers to increase transparency in drug pricing, 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 “Transparent Drug
5 Pricing Act of 2017”.

1 **SEC. 2. DRUG MANUFACTURER REPORTING.**

2 Part P of title III of the Public Health Service Act
3 (42 U.S.C. 280g et seq.) is amended by adding at the end
4 the following:

5 **“SEC. 399V-7. DRUG MANUFACTURER REPORTING.**

6 “(a) MANDATORY REPORTING.—A drug manufac-
7 turer shall submit to the Secretary and to Congress an
8 annual report specifying with respect to the previous cal-
9 endar year (except as provided in subsection (d)(2))—

10 “(1) the total expenditures of the manufacturer
11 on—

12 “(A) domestic and foreign drug research
13 and development, including an itemized descrip-
14 tion of—

15 “(i) basic and preclinical research;

16 “(ii) clinical research, reported sepa-
17 rately for each clinical trial;

18 “(iii) development of alternative dos-
19 age forms and strengths for the drug mol-
20 ecule or combinations, including the mol-
21 ecule;

22 “(iv) other drug development activi-
23 ties, such as nonclinical laboratory studies
24 and record and report maintenance;

25 “(v) pursuing new or expanded indica-
26 tions for such drug through supplemental

1 applications under section 505 of the Fed-
2 eral Food, Drug, and Cosmetic Act;

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

6 “(vii) carrying out risk evaluation and
7 mitigation strategies in accordance with
8 section 505–1 of such Act; and

9 “(viii) marketing research;

10 “(B) the acquisition of drug components
11 and packaging, in total and per unit sold, bro-
12 ken out by source and cost and identifying spe-
13 cific costs that reflect internal transfers within
14 the manufacturer’s company;

15 “(C) other acquisitions relating to drugs,
16 including for the purchase of patents and li-
17 censing or the acquisition of any corporate enti-
18 ty owning any rights to a drug during or after
19 development of the drug; and

20 “(D) marketing, advertising, and educating
21 for the promotion of a drug, including a break-
22 down of amounts aimed at consumers, pre-
23 scribers, managed care organizations, and oth-
24 ers, irrespective of whether a particular drug is

1 mentioned in the marketing, advertising, or
2 educating;

3 “(2) the gross revenue, net revenue, gross prof-
4 it, and net profit of the manufacturer with respect
5 to drugs;

6 “(3) the total number of units of each type of
7 drug that were sold in interstate commerce;

8 “(4) pricing information with respect to the sale
9 of drugs, including—

10 “(A) wholesale acquisition cost;

11 “(B) net average price realized by pre-
12 scription drug benefit managers for drugs pro-
13 vided to individuals in the United States, after
14 accounting for any rebates or other payments
15 from the manufacturer to the pharmacy benefit
16 manager and from the pharmacy benefit man-
17 ager to the manufacturer; and

18 “(C) the net price of each drug, after ac-
19 counting for discounts, rebates, or other finan-
20 cial considerations, charged to purchasers in
21 each applicable country of the Organisation for
22 Economic Co-operation and Development;

23 “(5) any Federal benefits received by the manu-
24 facturer with respect to a drug, including the
25 amounts and periods of impact for each such ben-

1 efit, including tax credits; Federal grants, including
2 from the National Institutes of Health, the Depart-
3 ment of Defense, the Department of Energy, the
4 Centers for Disease Control and Prevention, or other
5 Federal departments or agencies; patent applications
6 that benefitted from such grants; patent extensions;
7 exclusivity periods; and waivers of fees;

8 “(6) the percentage of research and develop-
9 ment expenditures described in clauses (i) through
10 (v) of paragraph (1)(A) that were derived from Fed-
11 eral funds;

12 “(7) executive compensation for the chief execu-
13 tive officer, chief financial officer, and the 3 other
14 most highly compensated executive officers, includ-
15 ing bonuses, paid by such manufacturer, and stock
16 options affiliated with the manufacturer that were
17 offered to or accrued by such officers; and

18 “(8) any other information as the Secretary
19 may require.

20 “(b) VOLUNTARY SUPPLEMENTAL REPORTING.—A
21 drug manufacturer may supplement a report under sub-
22 section (a) with any additional information the manufac-
23 turer chooses to provide related to drug pricing decisions,
24 such as—

1 “(1) total expenditures on drug research, drug
2 development, and clinical trials on drugs that failed
3 to receive approval by the Food and Drug Adminis-
4 tration; and

5 “(2) a list of drugs and drug prices of other
6 manufacturers for purposes of comparison with the
7 manufacturer’s own drugs and drug prices.

8 “(c) SPECIAL RULE.—A drug manufacturer shall—

9 “(1) to the extent possible, disaggregate the in-
10 formation required to be reported by this section by
11 the particular drug involved; and

12 “(2) submit all information required to be re-
13 ported by this section with respect to each applicable
14 drug in a single annual report.

15 “(d) SUBMISSION OF REPORTS.—

16 “(1) IN GENERAL.—

17 “(A) SUBMISSION BY DRUG MANUFACTUR-
18 ERS.—Drug manufacturers shall submit the an-
19 nual reports required under this section to the
20 Secretary in a usable format, as the Secretary
21 may require.

22 “(B) COLLATION BY THE SECRETARY.—

23 The Secretary shall collate the reports received
24 as described in subparagraph (A) and submit
25 such collated reports to Congress, together with

1 an analysis of the reports by the Secretary that
2 includes—

3 “(i) a summary of data from the re-
4 ports;

5 “(ii) consideration of factors such as
6 trends on research and development costs,
7 Federal benefits, and manufacturer patient
8 assistance programs; and

9 “(iii) the relationship between the fac-
10 tors described in clause (ii) and prescrip-
11 tion drug prices.

12 “(C) PUBLIC AVAILABILITY.—The Sec-
13 retary shall make the reports submitted by
14 manufacturers as described in subparagraph
15 (A) and the collated reports together with the
16 analysis of the Secretary described in subpara-
17 graph (B) publicly available, including by post-
18 ing such reports to the internet website of the
19 Department of Health and Human Services, in
20 a searchable format.

21 “(2) INITIAL REPORT.—

22 “(A) IN GENERAL.—A drug manufacturer
23 shall submit an initial report pursuant to this
24 section not later than one year after the date of
25 enactment of the Transparent Drug Pricing Act

1 of 2017 (except as provided in subparagraph
2 (B)).

3 “(B) REPORTING PERIOD.—Notwith-
4 standing the requirement in subsection (a) that
5 each report under such subsection be for the
6 previous calendar year, the initial report of a
7 drug manufacturer under subsection (a) shall
8 include, for each drug marketed by the manu-
9 facturer, the information described in para-
10 graphs (1) through (6) of subsection (a) for the
11 calendar year period beginning with the later
12 of—

13 “(i) the calendar year in which the
14 drug was approved under section 505 of
15 the Federal Food, Drug, and Cosmetic
16 Act, was licensed under section 351 of this
17 Act, or received an exemption under sec-
18 tion 505(i) of the Federal Food, Drug, and
19 Cosmetic Act or section 351(a)(3) of this
20 Act; and

21 “(ii) the calendar year in which the
22 manufacturer acquired the drug so ap-
23 proved, licensed, or exempted.

24 “(C) SMALL BUSINESSES.—In the case of
25 a drug manufacturer that has fewer than 500

1 employees, the initial report required by in sub-
2 paragraph (A) shall be submitted by a date de-
3 termined by the Secretary, which shall be—

4 “(i) not earlier than the deadline de-
5 scribed in subparagraph (A); and

6 “(ii) not later than the date that is 3
7 years after the date of enactment of the
8 Transparent Drug Pricing Act of 2017.

9 “(e) AUDIT BY THIRD PARTY.—The Secretary shall
10 select a percentage (to be determined by the Secretary)
11 of the reports submitted under subsection (a) for a fiscal
12 year to be audited by an accredited third-party auditor
13 (to be selected by the Secretary).

14 “(f) PENALTY FOR NONCOMPLIANCE.—The Sec-
15 retary shall report to the Office of the Inspector General
16 any manufacturer’s failure to submit a complete report as
17 required under this section. Any manufacturer that fails
18 to submit a complete report required under this section
19 shall be subject to a civil penalty of up to \$200,000 for
20 each day on which the violation continues. The Secretary
21 shall collect the civil penalties under this subsection and,
22 without further appropriation, shall use such funds to sup-
23 port research of the National Institutes of Health.

24 “(g) DEFINITION.—In this section, the term ‘drug
25 manufacturer’ means the manufacturer of an approved

1 drug (including a drug approved under subsection (c) or
2 (j) of section 505 of the Federal Food, Drug, and Cos-
3 metic Act and a biological product licensed under sub-
4 section (a) or (k) of section 351 of this Act).”.

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