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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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Fair Accountability and Innovative Research Drug Pricing Act of 2019'' or the ''FAIR Drug Pricing Act of 2019''.

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

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART W—DRUG PRICE REPORTING; DRUG VALUE FUND

"SEC. 399OO. REPORTING ON JUSTIFICATION FOR DRUG PRICE INCREASES.

"(a) DEFINITIONS.—In this section:

"(1) MANUFACTURER.—The term 'manufacturer' means the person—

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

"(B) who is responsible for setting the price for the drug.

"(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of this Act—

"(A) that has a wholesale acquisition cost of $100 or more per month supply or per a

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

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

"(II) commonly administered by hospitals (as determined by the Secretary);

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

"(iii) not designated by the Secretary as a vaccine; and

"(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State Medicaid plan under title XIX of such Act (42 U.S.C. 1396 et seq.) or under a waiver of such plan.

"(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

''(b) REPORT.—

''(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary for each price increase of a qualifying drug that will result in an increase in the wholesale acquisition cost of that drug that is equal to—

''(A) 10 percent or more over a 12-month period; or

''(B) 25 percent or more over a 36-month period.

''(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary not later than 30 days prior to the planned effective date of such price increase.

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

''(1) with respect to the qualifying drug—

''(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of the drug on the planned effective date of such price increase;

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

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

"(C) the identity of the initial developer of the drug;

"(D) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the manufacturer acquired such approved application or license;

"(E) the current list price of the drug;

"(F) the total expenditures of the manufacturer on—

"(i) materials and manufacturing for such drug; and

"(ii) acquiring patents and licensing for such drug;

"(G) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

"(H) the total expenditures of the manufacturer on research and development for such drug that is used for—

"(i) basic and preclinical research;

"(ii) clinical research;

"(iii) new drug development;

"(iv) pursuing new or expanded indications for such drug through supplemental applications under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act; and

"(v) carrying out postmarket requirements related to such drug, including those under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

"(I) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the manufacturer acquired such approved application or license; and

"(J) the total costs associated with marketing and advertising for the qualifying drug;

"(2) with respect to the manufacturer—

"(A) the total revenue and the net profit of the manufacturer for each of the 12- and 36-month periods preceding the submission of the report;

"(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 12- and 36-month periods preceding the submission of the report; and

"(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

"(i) drug research and development; or

"(ii) clinical trials on drugs that failed to receive approval by the Food and Drug Administration; and

"(3) such other related information as the Secretary considers appropriate.

"(d) CIVIL PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as

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

''(e) PUBLIC POSTING.—

''(1) IN GENERAL.—Subject to paragraph (3), not later than 30 days after the submission of a report under subsection (b), the Secretary shall post the report on the public website of the Department of Health and Human Services.

''(2) FORMAT.—In developing the format of such report for public posting, the Secretary shall consult stakeholders, including beneficiary groups, and shall seek feedback on the content and format from consumer advocates and readability experts to ensure such public reports are user-friendly to the public and are written in plain language that consumers can readily understand.

''(3) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

''SEC. 399OO–1. USE OF CIVIL PENALTY AMOUNTS.

''The Secretary shall, without further appropriation, collect civil penalties under section 399OO and use the funds derived from such civil penalties, in addition to any

other amounts available to the Secretary, to carry out activities described in this part and to improve consumer and provider information about drug value and drug price transparency.

"SEC. 399OO–2. ANNUAL REPORT TO CONGRESS.

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

''(1) summarizing the information reported pursuant to section 399OO; and

''(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section.

''(b) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.''.

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