114TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Ms. BALDWIN (for herself and Mr. MCCAIN) introduced the following bill; which was read twice and referred to the Committee on _____

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 2016''.

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

''(2) 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.

''(3) 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 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.

"(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 average manu-

facturer price of that drug that is equal to 10 percent or more over a 12-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 average manufacturer price 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 occurred during the 12-month period described in subsection (b)(1);

''(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; and

"(v) carrying out postmarket requirements related to such drug, including those under section 505(o)(3) of such 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 the 12-month period described in subsection (b)(1);

"(B) the amount the manufacturer has spent on dividends and stock repurchases and the specific metrics used by the manufacturer to determine executive compensation, including any stock-based performance metrics, for the12-month period described in subsection (b)(1); 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) COMPLIANCE DETERMINATIONS.—In determining whether a manufacturer may have been required to submit a report under this section, and otherwise making determinations about manufacturer compliance with the requirements of this section, the Inspector General of the Department of Health and Human Services shall annually review and consider the average manufacturer price information submitted under section 447.510 of title 42, Code of Federal Regulations, or any successor regulations.

"(f) 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 ensure the protection of confidential commercial information and trade secrets.''.

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

''The Secretary shall collect the civil penalties under section 399OO, in addition to any other amounts available, and without further appropriation, and shall use such funds 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 ensure the protection of confidential commercial information and trade secrets.''.