Baldwin #1, as modified

Tammy Baldwin

AMENDMENT NO._____ Calendar No._____

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

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

S. 1339

To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. BALDWIN (for herself and Mr. BRAUN)

Viz:

At the appropriate place, insert the following:

SEC. ___. 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 this Act; or

"(B) who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription 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) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;

"(ii) not a vaccine; and

"(iii) not an antibiotic; 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 planned increase in price 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 effective date of such planned increase in price.

"(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 planned increase in price;

"(B) a justification for, and description of, each manufacturer's planned increase in price 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, that shall be accompanied by information to substantiate the basis for the justification and a certification that, to the manufacturer's knowledge and belief, the justification is truthful and nonmisleading and does not describe uses of the drug beyond those listed as an indication or use in its approved labeling;

"(C) the identity of the initial developer of the drug, if applicable;

"(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, as applicable;

"(E) the current wholesale acquisition cost of the drug;

"(F) the total expenditures of the manufacturer for the 3 years preceding the planned increase in price 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 the 3 years preceding the planned increase in price for such drug that is necessary to demonstrate that it meets applicable standards for approval under section 505 of the Federal Food, Drug,

and Cosmetic Act or licensure under such section 351, as applicable;

"(I) the total expenditures of the manufacturer on research and development for such drug that is pursuing new or expanded indications for such drug through supplemental applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of this Act;

"(J) the total expenditures of the manufacturer on research and development for such drug that is carrying out postmarket requirements related to such drug, including those under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

"(K) 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

"(L) 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—

"(i) for the 12-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(A);

"(ii) for the 36-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(B);

"(B) all stock-based performance metrics used by the manufacturer to determine executive compensation—

"(i) for the 12-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(A); or

"(ii) for the 36-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(B); 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, conducted with the intent of using the data to support approval of a new drug application or a biologics license application, but for which the new drug application or biologics license application was not submitted or filed, or, failed to receive approval by the Food and Drug Administration; and

"(3) such other related information as the Secretary considers appropriate, as specified through notice and comment rulemaking.

"(d) CIVIL MONEY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, or knowingly provides false information, shall be subject to a civil money 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, accompanied by language indicating that such public posting does not

represent an endorsement or validation of the reports content by the Secretary.

"(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.—This section does not authorize the disclosure of confidential commercial information or 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 find, 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 section 399OO.

"(b) TRADE SECRETS AND CONFIDENTIAL INFORMATION.— This section does not authorize the disclosure of confidential commercial information or trade secrets.".