109TH CONGRESS
1ST SESSION

S. 1903

To amend title XIX of the Social Security Act to require drug manufacturers to report the average manufacturer price and the best price of authorized generic drugs and any other drugs sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act to the Secretary of Health and Human Services.

IN THE SENATE OF THE UNITED STATES

OCTOBER 20, 2005

Mr. ROCKEFELLER (for himself, Mr. SPECTER, Mr. SCHUMER, and Mr. MCCAIN) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend title XIX of the Social Security Act to require drug manufacturers to report the average manufacturer price and the best price of authorized generic drugs and any other drugs sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act to the Secretary of Health and Human Services.

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 ''Generic Prescription Drug Fairness Act of 2005''.

SEC. 2. IMPROVED REGULATION OF AUTHORIZED GENERIC DRUGS AND OTHER DRUGS SOLD UNDER A NEW DRUG APPLICATION APPROVED UNDER SECTION 505(C) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) INCLUSION WITH OTHER REPORTED AVERAGE MANUFACTURER AND BEST PRICES.—Section 1927(b)(3)(A) (42 U.S.C. 1396r–8(b)(3)(A)) is amended—

(1) by striking clause (i) and inserting the following:

''(i) not later than 30 days after the last day of each rebate period under the agreement—

''(I) on the average manufacturer price (as defined in subsection (k)(1)) for each covered outpatient drug for the rebate period under the agreement (including for each such drug that is an authorized generic drug or is any other drug sold under a new drug application approved under section

505(c) of the Federal Food, Drug, and Cosmetic Act); and

''(II) for each single source drug, innovator multiple source drug, authorized generic drug, and any other drug sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drug for the rebate period under the agreement;''; and

(2) in clause (ii), by inserting ''(including for such drugs that are authorized generic drugs or are any other drugs sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act)'' after ''drugs''.

(b) CONFORMING AMENDMENTS.—Section 1927 of such Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (c)(1)(C)—

(A) in clause (i), in the matter preceding subclause (I), by striking ''or innovator multiple source drug of a manufacturer'' and inserting '', innovator multiple source drug, or authorized generic drug of a manufacturer, or any other

drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act''; and

(B) in clause (ii)—

(i) in subclause (II), by striking ''and'' at the end;

(ii) in subclause (III), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(IV) in the case of a manufacturer that approves, allows, or otherwise permits an authorized generic drug or any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized generic or other drug available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organiza-

tion, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).''; and

(2) in subsection (k)—

(A) in paragraph (1)—

(i) by striking ''The term'' and inserting the following:

''(A) IN GENERAL.—The term''; and

(ii) by adding at the end the following:

''(B) INCLUSION OF AUTHORIZED GENERIC DRUGS.—In the case of a manufacturer that approves, allows, or otherwise permits an authorized generic drug or any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such authorized generic or other drug by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.''; and

(B) by adding at the end the following:

''(10) AUTHORIZED GENERIC DRUG.—The term 'authorized generic drug' means a listed drug (as that term is used in section 505(j) of the Federal Food, Drug, and Cosmetic Act that—

''(A) has been approved under section 505(c) of such Act; and

''(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.''.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on October 1, 2005.

SEC. 3. APPLICATION OF BASIC REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.

(a) IN GENERAL.—Section 1927(c)(1) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)) is amended—

(1) in subparagraph (A), in the matter preceding clause (i), by striking ''or an innovator multiple source drug'' and inserting '', an innovator multiple source drug, or an authorized generic drug or any other drugs sold under a new drug applica-

tion approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act''; and

(2) in subparagraph (C)(i), by striking ''or innovator multiple source drug'' and inserting '', an innovator multiple source drug, or an authorized generic drug or any other drugs sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of enactment of this Act and shall apply to rebate agreements entered into or renewed on or after that date.

○