

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Generic Prescription
3 Drug Fairness Act of 2005”.

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

9 (a) **INCLUSION WITH OTHER REPORTED AVERAGE**
10 **MANUFACTURER AND BEST PRICES.**—Section
11 1927(b)(3)(A) (42 U.S.C. 1396r-8(b)(3)(A)) is amend-
12 ed—

13 (1) by striking clause (i) and inserting the fol-
14 lowing:

15 “(i) not later than 30 days after the
16 last day of each rebate period under the
17 agreement—

18 “(I) on the average manufacturer
19 price (as defined in subsection (k)(1))
20 for each covered outpatient drug for
21 the rebate period under the agreement
22 (including for each such drug that is
23 an authorized generic drug or is any
24 other drug sold under a new drug ap-
25 plication approved under section

1 505(c) of the Federal Food, Drug,
2 and Cosmetic Act); and

3 “(II) for each single source drug,
4 innovator multiple source drug, au-
5 thORIZED generic drug, and any other
6 drug sold under a new drug applica-
7 tion approved under section 505(c) of
8 the Federal Food, Drug, and Cos-
9 metic Act, on the manufacturer’s best
10 price (as defined in subsection
11 (c)(1)(C)) for such drug for the rebate
12 period under the agreement;” and

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

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

20 (1) in subsection (c)(1)(C)—

21 (A) in clause (i), in the matter preceding
22 subclause (I), by striking “or innovator multiple
23 source drug of a manufacturer” and inserting
24 “, innovator multiple source drug, or authorized
25 generic drug of a manufacturer, or any other

1 drug of a manufacturer that is sold under a
2 new drug application approved under section
3 505(c) of the Federal Food, Drug, and Cos-
4 metic Act”; and

5 (B) in clause (ii)—

6 (i) in subclause (II), by striking
7 “and” at the end;

8 (ii) in subclause (III), by striking the
9 period at the end and inserting “; and”;
10 and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(IV) in the case of a manufac-
14 turer that approves, allows, or other-
15 wise permits an authorized generic
16 drug or any other drug of the manu-
17 facturer to be sold under a new drug
18 application approved under section
19 505(c) of the Federal Food, Drug,
20 and Cosmetic Act, shall be inclusive of
21 the lowest price for such authorized
22 generic or other drug available from
23 the manufacturer during the rebate
24 period to any wholesaler, retailer, pro-
25 vider, health maintenance organiza-

1 tion, nonprofit entity, or governmental
2 entity within the United States, ex-
3 cluding those prices described in sub-
4 clauses (I) through (IV) of clause
5 (i).”; and

6 (2) in subsection (k)—

7 (A) in paragraph (1)—

8 (i) by striking “The term” and insert-
9 ing the following:

10 “(A) IN GENERAL.—The term”; and

11 (ii) by adding at the end the fol-
12 lowing:

13 “(B) INCLUSION OF AUTHORIZED GENERIC
14 DRUGS.—In the case of a manufacturer that
15 approves, allows, or otherwise permits an au-
16 thorized generic drug or any other drug of the
17 manufacturer to be sold under a new drug ap-
18 plication approved under section 505(c) of the
19 Federal Food, Drug, and Cosmetic Act, such
20 term shall be inclusive of the average price paid
21 for such authorized generic or other drug by
22 wholesalers for drugs distributed to the retail
23 pharmacy class of trade, after deducting cus-
24 tomary prompt pay discounts.”; and

25 (B) by adding at the end the following:

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

5 “(A) has been approved under section
6 505(c) of such Act; and

7 “(B) is marketed, sold, or distributed di-
8 rectly or indirectly to retail class of trade under
9 a different labeling, packaging (other than re-
10 packaging as the listed drug in blister packs,
11 unit doses, or similar packaging for use in insti-
12 tutions), product code, labeler code, trade name,
13 or trade mark than the listed drug.”.

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

16 **SEC. 3. APPLICATION OF BASIC REBATE FOR SINGLE**
17 **SOURCE AND INNOVATOR MULTIPLE SOURCE**
18 **DRUGS.**

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

21 (1) in subparagraph (A), in the matter pre-
22 ceding clause (i), by striking “or an innovator mul-
23 tiple source drug” and inserting “, an innovator
24 multiple source drug, or an authorized generic drug
25 or any other drugs sold under a new drug applica-

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

3 (2) in subparagraph (C)(i), by striking “or in-
4 novator multiple source drug” and inserting “, an
5 innovator multiple source drug, or an authorized ge-
6 neric drug or any other drugs sold under a new drug
7 application approved under section 505(c) of the
8 Federal Food, Drug, and Cosmetic Act”.

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

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