111TH CONGRESS
1ST SESSION

S. 501

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2009

Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. KOHL, Mr. LEAHY, Mr. BROWN, and Mr. INOUYE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

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 Prescription Drug Competition Act''.

SEC. 2. PROHIBITION OF AUTHORIZED GENERICS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(w) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—Notwithstanding any other provision of this Act, no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

''(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term 'authorized generic drug'—

''(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

''(B) does not include any drug to be marketed, sold, or distributed—

''(i) by an entity eligible for exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

"(ii) after expiration or forfeiture of any exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).".

(b) CONFORMING AMENDMENT.—Section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)(3)) is amended by striking "In this section" and inserting "In this subsection".

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