

112TH CONGRESS  
1ST SESSION

# S. 373

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

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 16, 2011

Mr. ROCKEFELLER (for himself, Mrs. SHAHEEN, Mr. LEAHY, Mr. INOUE, Ms. STABENOW, and Mr. SCHUMER) 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.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fair Prescription Drug  
5 Competition Act”.

6 **SEC. 2. PROHIBITION OF AUTHORIZED GENERICS.**

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

1       “(w) PROHIBITION OF AUTHORIZED GENERIC  
2 DRUGS.—

3           “(1) IN GENERAL.—Notwithstanding any other  
4 provision of this Act, no holder of a new drug appli-  
5 cation approved under subsection (c) shall manufac-  
6 ture, market, sell, or distribute an authorized ge-  
7 neric drug, directly or indirectly, or authorize any  
8 other person to manufacture, market, sell, or dis-  
9 tribute an authorized generic drug.

10          “(2) AUTHORIZED GENERIC DRUG.—For pur-  
11 poses of this subsection, the term ‘authorized generic  
12 drug’—

13           “(A) means any version of a listed drug  
14 (as such term is used in subsection (j)) that the  
15 holder of the new drug application approved  
16 under subsection (c) for that listed drug seeks  
17 to commence marketing, selling, or distributing,  
18 directly or indirectly, after receipt of a notice  
19 sent pursuant to subsection (j)(2)(B) with re-  
20 spect to that listed drug; and

21           “(B) does not include any drug to be mar-  
22 keted, sold, or distributed—

23           “(i) by an entity eligible for 180-day  
24 exclusivity with respect to such drug under  
25 subsection (j)(5)(B)(iv); or

1                   “(ii) after expiration or forfeiture of  
2                   any 180-day exclusivity with respect to  
3                   such drug under such subsection  
4                   (j)(5)(B)(iv).”.

5           (b) CONFORMING AMENDMENT.—Section 505(t)(3)  
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 355(t)(3)) is amended by striking “In this section” and  
8 inserting “In this subsection”.

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