

112TH CONGRESS
2D SESSION

S. _____

To permit manufacturers of generic drugs to provide additional warnings with respect to such drugs in the same manner that the Food and Drug Administration allows brand names to do so.

IN THE SENATE OF THE UNITED STATES

Mr. LEAHY (for himself, Mr. FRANKEN, Mr. COONS, Mr. WHITEHOUSE, Mr. BINGAMAN, Mr. BROWN of Ohio, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To permit manufacturers of generic drugs to provide additional warnings with respect to such drugs in the same manner that the Food and Drug Administration allows brand names to do so.

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 “Patient Safety and
5 Generic Labeling Improvement Act”.

1 **SEC. 2. WARNING LABELING WITH RESPECT TO GENERIC**
2 **DRUGS.**

3 Section 505(j) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355(j)) is amended by adding at the
5 end the following:

6 “(11)(A) Notwithstanding any other provision
7 of this Act, the holder of an approved application
8 under this subsection may change the labeling of a
9 drug so approved in the same manner authorized by
10 regulation for the holder of an approved new drug
11 application under subsection (b).

12 “(B) In the event of a labeling change made
13 under subparagraph (A), the Secretary may order
14 conforming changes to the labeling of the equivalent
15 listed drug and each drug approved under this sub-
16 section that corresponds to such listed drug.”.