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112TH CONGRESS
2D SESSION

H. R. 4384

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 HOUSE OF REPRESENTATIVES

APRIL 18, 2012

Mr. VAN HOLLEN (for himself and Mr. BRALEY of Iowa) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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 ''Patient Safety and Drug Labeling Improvement Act''.

SEC. 2. PERMITTING LABELING CHANGES FOR GENERICS.

Section 505(j) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

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

''(B) In the event of a labeling change made under subparagraph (A), the Secretary may order conforming changes to the labeling of the equivalent listed drug and each drug approved under this subsection that corresponds to such listed drug.''.

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