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112TH CONGRESS
1ST SESSION

H. R. 147

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs and the sale of such drugs through Internet sites.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 5, 2011

Mr. PAUL introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs and the sale of such drugs through Internet sites.

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 ''Prescription Drug Affordability Act''.

SEC. 2. FACILITATION OF IMPORTATION OF DRUGS APPROVED BY FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) by striking section 804; and

(2) in section 801(d)—

(A) by striking paragraph (2); and

(B) by striking ''(d)(1)'' and all that follows through the end of paragraph (1) and inserting the following:

''(d)(1)(A) A person who meets applicable legal requirements to be an importer of drugs described in subparagraph (B) may import such a drug (without regard to whether the person is a manufacturer of the drug) if the person submits to the Secretary an application to import the drug and the Secretary approves the application.

''(B) For purposes of subparagraph (A), the drugs described in this subparagraph are drugs that are subject to section 503(b)(1) or that are composed wholly or partly of insulin.

''(C) The Secretary shall approve an application under subparagraph (A) if the application demonstrates that the drug to be imported meets all requirements under

this Act for the admission of the drug into the United States, including demonstrating that—

''(i) an application for the drug has been approved under section 505, or as applicable, under section 351 of the Public Health Service Act; and

''(ii) the drug is not adulterated or misbranded.

''(D) Not later than 60 days after the date on which an application under subparagraph (A) is submitted to the Secretary, the Secretary shall—

''(i) approve the application; or

''(ii) refuse to approve the application and provide to the person who submitted the application the reason for such refusal.

''(E) This paragraph may not be construed as affecting any right secured by patent.''.

(b) CONFORMING AMENDMENTS.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

(1) by redesignating paragraphs (3) and (4) as paragraphs (2) and (3), respectively;

(2) in subclause (III) of paragraph (2)(A)(i) (as redesignated by this subsection), by striking ''paragraph (4)'' and inserting ''paragraph (3)''; and

(3) in paragraph (3) (as redesignated by this subsection), by striking ''paragraph (3)'' each place such term appears and inserting ''paragraph (2)''.

SEC. 3. INTERNET SALES OF PRESCRIPTION DRUGS.

Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) is amended by adding at the end the following paragraph:

''(6)(A) With respect to the interstate sale of a prescription drug through an Internet site, the Secretary may not with respect to such sale take any action under this Act against any of the persons involved if—

''(i) the sale was made in compliance with this Act, the Controlled Substances Act, and State laws that are applicable to the sale of the drug; and

''(ii) accurate information regarding compliance with this Act, the Controlled Substances Act, and such State laws is posted on the Internet site.

''(B) For purposes of subparagraph (A), the sale of a prescription drug by a person shall be considered to be an interstate sale of the drug through an Internet site if—

''(i) the purchaser of the drug submits the purchase order for the drug, or conducts any other part of the sales transaction for the drug, through an Internet site; and

"(ii) pursuant to such sale, the person introduces the drug into interstate commerce or delivers the drug for introduction into such commerce.

"(C) Subparagraph (A) may not be construed as authorizing the Secretary to enforce any violation of State law.

"(D) For purposes of this paragraph, the term 'prescription drug' means a drug that is subject to paragraph (1).".

SEC. 4. REGULATIONS OF SECRETARY OF HEALTH AND HUMAN SERVICES; EFFECTIVE DATE.

(a) REGULATIONS.—Before the expiration of the period specified in subsection (b), the Secretary of Health and Human Services shall promulgate regulations to carry out the amendments to the Federal Food, Drug, and Cosmetic Act that are made by sections 2 and 3.

(b) EFFECTIVE DATE.—The amendments to the Federal Food, Drug, and Cosmetic Act that are made by sections 2 and 3 take effect upon the expiration of the one-year period beginning on the date of the enactment of this Act, without regard to whether the regulations required in subsection (a) have been promulgated.

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