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

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.

- 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 "Prescription Drug Af-
- 5 fordability Act".

1	SEC. 2. FACILITATION OF IMPORTATION OF DRUGS AP-
2	PROVED BY FOOD AND DRUG ADMINISTRA-
3	TION.
4	(a) In General.—Chapter VIII of the Federal
5	Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
6	is amended—
7	(1) by striking section 804; and
8	(2) in section 801(d)—
9	(A) by striking paragraph (2); and
10	(B) by striking " $(d)(1)$ " and all that fol-
11	lows through the end of paragraph (1) and in-
12	serting the following:
13	``(d)(1)(A) A person who meets applicable legal re-
14	quirements to be an importer of drugs described in sub-
15	paragraph (B) may import such a drug (without regard
16	to whether the person is a manufacturer of the drug) if
17	the person submits to the Secretary an application to im-
18	port the drug and the Secretary approves the application.
19	"(B) For purposes of subparagraph (A), the drugs
20	described in this subparagraph are drugs that are subject
21	to section 503(b)(1) or that are composed wholly or partly
22	of insulin.
23	"(C) The Secretary shall approve an application
24	under subparagraph (A) if the application demonstrates
25	that the drug to be imported meets all requirements under

1 this Act for the admission of the drug into the United 2 States, including demonstrating that— 3 "(i) an application for the drug has been ap-4 proved under section 505, or as applicable, under 5 section 351 of the Public Health Service Act; and 6 "(ii) the drug is not adulterated or misbranded. "(D) Not later than 60 days after the date on which 7 8 an application under subparagraph (A) is submitted to the 9 Secretary, the Secretary shall— "(i) approve the application; or 10 "(ii) refuse to approve the application and pro-11 12 vide to the person who submitted the application the 13 reason for such refusal. 14 "(E) This paragraph may not be construed as affect-15 ing any right secured by patent.". 16 (b) Conforming Amendments.—Section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended— 18 19 (1) by redesignating paragraphs (3) and (4) as 20 paragraphs (2) and (3), respectively; 21 (2) in subclause (III) of paragraph (2)(A)(i) (as redesignated by this subsection), by striking "para-22 graph (4)" and inserting "paragraph (3)"; and 23

1	(3) in paragraph (3) (as redesignated by this
2	subsection), by striking "paragraph (3)" each place
3	such term appears and inserting "paragraph (2)".
4	SEC. 3. INTERNET SALES OF PRESCRIPTION DRUGS.
5	Section 503(b) of the Federal Food, Drug, and Cos-
6	metic Act (21 U.S.C. 353(b)) is amended by adding at
7	the end the following paragraph:
8	"(6)(A) With respect to the interstate sale of a pre-
9	scription drug through an Internet site, the Secretary may
10	not with respect to such sale take any action under this
11	Act against any of the persons involved if—
12	"(i) the sale was made in compliance with this
13	Act, the Controlled Substances Act, and State laws
14	that are applicable to the sale of the drug; and
15	"(ii) accurate information regarding compliance
16	with this Act, the Controlled Substances Act, and
17	such State laws is posted on the Internet site.
18	"(B) For purposes of subparagraph (A), the sale of
19	a prescription drug by a person shall be considered to be
20	an interstate sale of the drug through an Internet site if—
21	"(i) the purchaser of the drug submits the pur-
22	chase order for the drug, or conducts any other part
23	of the sales transaction for the drug, through an
24	Internet site; and

- 1 "(ii) pursuant to such sale, the person intro-
- 2 duces the drug into interstate commerce or delivers
- 3 the drug for introduction into such commerce.
- 4 "(C) Subparagraph (A) may not be construed as au-
- 5 thorizing the Secretary to enforce any violation of State
- 6 law.
- 7 "(D) For purposes of this paragraph, the term 'pre-
- 8 scription drug' means a drug that is subject to paragraph
- 9 (1).".
- 10 SEC. 4. REGULATIONS OF SECRETARY OF HEALTH AND
- 11 HUMAN SERVICES; EFFECTIVE DATE.
- 12 (a) Regulations.—Before the expiration of the pe-
- 13 riod specified in subsection (b), the Secretary of Health
- 14 and Human Services shall promulgate regulations to carry
- 15 out the amendments to the Federal Food, Drug, and Cos-
- 16 metic Act that are made by sections 2 and 3.
- 17 (b) Effective Date.—The amendments to the Fed-
- 18 eral Food, Drug, and Cosmetic Act that are made by sec-
- 19 tions 2 and 3 take effect upon the expiration of the one-
- 20 year period beginning on the date of the enactment of this
- 21 Act, without regard to whether the regulations required
- 22 in subsection (a) have been promulgated.

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