AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

I

115TH CONGRESS
1ST SESSION

H. R. 2376

To amend the Federal Food, Drug, and Cosmetic Act to protect and strengthen the drug supply chain in the United States by closing several statutory gaps in the penalty provisions of such Act that apply to drug diversion and counterfeiting.

IN THE HOUSE OF REPRESENTATIVES

MAY 4, 2017

Mr. LANCE (for himself, Mrs. DINGELL, Mr. BURGESS, and Mr. GENE GREEN of Texas) 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 to protect and strengthen the drug supply chain in the United States by closing several statutory gaps in the penalty provisions of such Act that apply to drug diversion and counterfeiting.

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 ''Drug Diversion and Counterfeit Crackdown Act of 2017''.

SEC. 2. SENSE OF CONGRESS.

It is the sense of the Congress that—

(1) there should not be differing penalties under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for illegally diverting drugs into the United States that arbitrarily turn on the location where the drugs were initially manufactured;

(2) such disparity should be addressed by providing the same penalties for diverting drugs made outside the United States and intended for a foreign market as the penalties that exist for diverting drugs made inside the United States and intended for a foreign market;

(3) there should not be unequal treatment of counterfeiting and diversion, enabling criminal enterprises to exploit statutory loopholes and jeopardize patient and consumer safety without fear of significant penalties; and

(4) such unequal treatment should be addressed by increasing the penalties for counterfeiting to match the penalties for diversion.

SEC. 3. PROTECTING AND STRENGTHENING THE DRUG SUPPLY CHAIN.

(a) DIVERTED DRUGS.—Paragraph (1) of section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

(1) by striking ''(d)(1) Except as'' and inserting ''(d)(1)(A) Except as''; and

(2) by adding at the end the following:

''(B) Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list in effect under section 506E, no drug that would be subject to section 503(b), and which is manufactured outside the United States and intended by the manufacturer or labeled to be marketed outside the United States, may be imported into the United States for sale or commercial use.''.

(b) COUNTERFEIT DRUGS.—Subsection (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(8) Notwithstanding subsection (a), any person who violates section 301(i)(3) by knowingly selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

○