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114TH CONGRESS
1ST SESSION

H. R. 471

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 22, 2015

Mr. MARINO (for himself, Mr. WELCH, Mrs. BLACKBURN, and Ms. CHU of California) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To improve enforcement efforts related to prescription drug diversion and abuse, and for other purposes.

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 "Ensuring Patient Access and Effective Drug Enforcement Act of 2015".

SEC. 2. REGISTRATION PROCESS UNDER CONTROLLED SUBSTANCES ACT.

(a) DEFINITIONS.—

(1) FACTORS AS MAY BE RELEVANT TO AND CONSISTENT WITH THE PUBLIC HEALTH AND SAFETY.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(i) In this section, the phrase 'factors as may be relevant to and consistent with the public health and safety' means factors that are relevant to and consistent with the findings contained in section 101.''.

(2) IMMINENT DANGER TO THE PUBLIC HEALTH OR SAFETY.—Section 304(d) of the Controlled Substances Act (21 U.S.C. 824(d)) is amended—

(A) by striking ''(d) The Attorney General'' and inserting ''(d)(1) The Attorney General''; and

(B) by adding at the end the following:

''(2) In this subsection, the phrase 'imminent danger to the public health or safety' means that, in the absence of an immediate suspension order, controlled substances—

''(A) will continue to be intentionally distributed or dispensed—

''(i) outside the usual course of professional practice; or

"(ii) in a manner that poses a present or foreseeable risk of serious adverse health consequences or death; or

"(B) will continue to be intentionally diverted outside of legitimate distribution channels.".

(b) OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN PRIOR TO REVOCATION OR SUSPENSION.—Subsection (c) of section 304 of the Controlled Substances Act (21 U.S.C. 824) is amended—

(1) by striking the last two sentences in such subsection;

(2) by striking "(c) Before" and inserting "(c)(1) Before"; and

(3) by adding at the end the following:

"(2) An order to show cause under paragraph (1) shall—

"(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

"(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but no less than thirty days after the date of receipt of the order; and

"(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

"(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

"(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

"(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).".

SEC. 3. REPORT TO CONGRESS ON EFFECTS OF LAW ENFORCEMENT ACTIVITIES ON PATIENT ACCESS TO MEDICATIONS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs and the Director of the Centers for Dis-

ease Control and Prevention, and in consultation with the Administrator of the Drug Enforcement Administration and the Director of National Drug Control Policy, shall submit a report to the Committee on the Judiciary of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, the Committee on the Judiciary of the Senate, and the Committee on Health, Education, Labor, and Pensions of the Senate identifying—

(1) obstacles to legitimate patient access to controlled substances;

(2) issues with diversion of controlled substances; and

(3) how collaboration between Federal, State, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances.

(b) CONSULTATION.—The report under subsection (a) shall incorporate feedback and recommendations from the following:

(1) Patient groups.

(2) Pharmacies.

(3) Drug manufacturers.

(4) Common or contract carriers and warehousemen.

(5) Hospitals, physicians, and other health care providers.

(6) State attorneys general.

(7) Federal, State, local, and tribal law enforcement agencies.

(8) Health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider.

(9) Wholesale drug distributors.

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