113TH CONGRESS
2D SESSION

S. 2862

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 18, 2014

Mr. HATCH (for himself and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, 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 ''Regulatory Transparency, Patient Access, and Effective Drug Enforcement Act of 2014''.

SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (h) the following:

''(i) Within 45 days of receiving a recommendation from the Secretary to add a drug or substance that has never been marketed in the United States to a schedule under this title, the Attorney General shall, without regard to the findings required by subsection (a) of this section or section 202(b), issue an interim final rule, under the exception for good cause described in subparagraph (B) of section 553(b) of title 5, United States Code, placing the drug or substance into the schedule recommended by the Secretary. The interim final rule shall be made immediately effective under section 553(d)(3) of title 5, United States Code.''.

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by inserting after subsection (g) the following:

''(h)(1) A person who submits an application for registration to manufacture or distribute a controlled substance in accordance with this section may indicate on the registration application that the substance will be used only in connection with clinical trials of a drug in accord-

ance with section 505(i) of the Federal Food, Drug, and Cosmetic Act.

''(2) When an application for registration to manufacture or distribute a controlled substance includes an indication that the controlled substance will be used only in connection with clinical trials of a drug in accordance with section 505(i) of the Federal Food, Drug, and Cosmetic Act, the Attorney General shall—

''(A) make a final decision on the application for registration within 180 days; or

''(B) provide notice to the applicant in writing of—

''(i) the outstanding issues that must be resolved in order to reach a final decision on the application; and

''(ii) the estimated date on which a final decision on the application will be made.''.

SEC. 4. 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 will continue to be distributed or dispensed by a registrant who knows or should know through fulfilling the obligations of the registrant under this Act, or has reason to believe that—

''(A) the dispensing is outside the usual course of professional practice;

''(B) the distribution or dispensing poses a present or foreseeable risk of adverse health consequences or death due to the abuse or misuse of the controlled substances; or

''(C) the controlled substances will continue to be 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;

(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 not less than 30 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, United States Code. 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. 5. REPORT TO CONGRESS ON EFFECTS OF LAW ENFORCEMENT ACTIVITIES ON PATIENT ACCESS TO MEDICATIONS.

(a) IN GENERAL.—Not later than 1 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 Disease 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 Committees 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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