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114TH CONGRESS
1ST SESSION

S. 954

To establish procedures regarding the approval of opioid drugs by the Food and Drug Administration.

IN THE SENATE OF THE UNITED STATES

APRIL 15, 2015

Mr. MANCHIN (for himself, Mr. VITTER, Mrs. CAPITO, and Mr. KAINE) 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 establish procedures regarding the approval of opioid drugs by the Food and Drug Administration.

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 ''FDA Accountability for Public Safety Act''.

SEC. 2. APPROVAL OF OPIOID DRUGS.

(a) IN GENERAL.—Notwithstanding any other provision of law, the Commissioner of Food and Drugs (referred to in this Act as ''the Commissioner'') shall ensure that, with respect to each application for an opioid drug

submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)—

(1) an advisory committee of the Center for Drug Evaluation and Research of the Food and Drug Administration evaluates the application and issues a recommendation regarding approval of such drug prior to a final decision to approve such drug; and

(2) if a final decision to approve such drug is inconsistent with the recommendation under paragraph (1), such final decision shall be made by the Commissioner and shall not be delegated.

(b) REPORTS TO CONGRESS.—If the advisory committee recommends under subsection (a)(1) that the Commissioner not approve an opioid drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and the Commissioner approves that drug under subsection (a)(2), the Commissioner shall—

(1) submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and to any member of Congress that requests the report, that includes—

(A) medical and scientific evidence regarding patient safety that clearly supports the

Commissioner's decision to approve the opioid drug against the recommendation of the advisory committee; and

(B) a disclosure of any potential conflicts of interest that may exist regarding any official of the Food and Drug Administration who was involved in the decision to approve the drug prior to the Commissioner's final decision under subsection (a)(2); and

(2) at the request of the Committee on Health, Education, Labor, and Pensions of the Senate or the Committee on Energy and Commerce of the House of Representatives, testify before that committee regarding the Commissioner's decision to approve the opioid drug against the recommendation of the advisory committee.

(c) PROHIBITION ON MARKETING.—A drug described in subsection (b) shall not be introduced or delivered for introduction into interstate commerce until the report described in subsection (b)(1) has been submitted to Congress.

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