115TH CONGRESS
1ST SESSION

S. 1078

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

IN THE SENATE OF THE UNITED STATES

MAY 9, 2017

Mr. MANCHIN (for himself, Mrs. CAPITO, Mrs. MCCASKILL, and Mr. KING) 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 AGAINST THE RECOMMENDATION OF THE FDA ADVISORY COMMITTEE ON OPIOID DRUGS.

(a) IN GENERAL.—Any approval of an application or supplement to an application under section 505(b) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) for a drug that is an opioid against the recommendation of the advisory committee pursuant to section 106 of the Comprehensive Drug and Recovery Act of 2016 (Public Law 114–198) shall be made by the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') and shall not be delegated.

(b) REPORTS TO CONGRESS.—If the Commissioner approves a drug as described in subsection (a), 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); 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 approved as described in subsection (a) shall not be introduced or delivered for introduction into interstate commerce until the report described in subsection (b)(1) has been submitted to Congress.

(d) SCOPE OF ADVISORY COMMITTEE REVIEW.—Section 106(a)(1)(A) of the Comprehensive Drug and Recovery Act of 2016 (Public Law 114–198) is amended—

(1) by inserting ", or supplement to an application," after "application" each place such term appears; and

(2) by striking "of a new" and inserting "for".

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