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

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 re-
garding the Commissioner’s decision to approve the
opioid drug against the recommendation of the advi-
sory 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 sub-
mitted to Congress.

(d) SCOPE OF ADVISORY COMMITTEE REVIEW.—Sec-
tion 106(a)(1)(A) of the Comprehensive Drug and Recov-
ery Act of 2016 (Public Law 114–198) is amended—
(1) by inserting “, or supplement to an applica-
tion,” after “application” each place such term ap-
ppears; and
(2) by striking “of a new” and inserting “for”.

○