

116TH CONGRESS
1ST SESSION

S. 418

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 7, 2019

Mr. MANCHIN (for himself, Mrs. CAPITO, 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Accountability
5 for Public Safety Act”.

6 **SEC. 2. APPROVAL AGAINST THE RECOMMENDATION OF**
7 **THE FDA ADVISORY COMMITTEE ON OPIOID**
8 **DRUGS.**

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

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

8 (b) REPORTS TO CONGRESS.—If the Commissioner
9 approves a drug as described in subsection (a), the Com-
10 missioner shall—

11 (1) submit a report to the Committee on
12 Health, Education, Labor, and Pensions of the Sen-
13 ate and the Committee on Energy and Commerce of
14 the House of Representatives, and to any member of
15 Congress that requests the report, that includes—

16 (A) medical and scientific evidence regard-
17 ing patient safety that clearly supports the
18 Commissioner’s decision to approve the opioid
19 drug against the recommendation of the advi-
20 sory committee; and

21 (B) a disclosure of any potential conflicts
22 of interest that may exist regarding any official
23 of the Food and Drug Administration who was
24 involved in the decision to approve the drug

1 prior to the Commissioner’s final decision under
2 subsection (a); and

3 (2) at the request of the Committee on Health,
4 Education, Labor, and Pensions of the Senate or the
5 Committee on Energy and Commerce of the House
6 of Representatives, testify before that committee re-
7 garding the Commissioner’s decision to approve the
8 opioid drug against the recommendation of the advi-
9 sory committee.

10 (c) PROHIBITION ON MARKETING.—A drug approved
11 as described in subsection (a) shall not be introduced or
12 delivered for introduction into interstate commerce until
13 the report described in subsection (b)(1) has been sub-
14 mitted to Congress.

15 (d) SCOPE OF ADVISORY COMMITTEE REVIEW.—Sec-
16 tion 106(a)(1)(A) of the Comprehensive Addiction and Re-
17 covery Act of 2016 (Public Law 114–198) is amended—

18 (1) by inserting “, or supplement to an applica-
19 tion,” after “application” each place such term ap-
20 pears; and

21 (2) by striking “of a new” and inserting “for”.

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