

114TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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 _____

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 OF OPIOID DRUGS.**

7 (a) IN GENERAL.—Notwithstanding any other provi-
8 sion of law, the Commissioner of Food and Drugs (re-
9 ferred to in this Act as “the Commissioner”) shall ensure
10 that, with respect to each application for an opioid drug

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

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

9 (2) if a final decision to approve such drug is
10 inconsistent with the recommendation under para-
11 graph (1), such final decision shall be made by the
12 Commissioner and shall not be delegated.

13 (b) REPORTS TO CONGRESS.—If the advisory com-
14 mittee recommends under subsection (a)(1) that the Com-
15 missioner not approve an opioid drug under section 505
16 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355), and the Commissioner approves that drug under
18 subsection (a)(2), the Commissioner shall—

19 (1) submit a report to the Committee on
20 Health, Education, Labor, and Pensions of the Sen-
21 ate and the Committee on Energy and Commerce of
22 the House of Representatives, and to any member of
23 Congress that requests the report, that includes—

24 (A) medical and scientific evidence regard-
25 ing patient safety that clearly supports the

1 Commissioner's decision to approve the opioid
2 drug against the recommendation of the advi-
3 sory committee; and

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

10 (2) at the request of the Committee on Health,
11 Education, Labor, and Pensions of the Senate or the
12 Committee on Energy and Commerce of the House
13 of Representatives, testify before that committee re-
14 garding the Commissioner's decision to approve the
15 opioid drug against the recommendation of the advi-
16 sory committee.

17 (c) PROHIBITION ON MARKETING.—A drug described
18 in subsection (b) shall not be introduced or delivered for
19 introduction into interstate commerce until the report de-
20 scribed in subsection (b)(1) has been submitted to Con-
21 gress.