

116TH CONGRESS
1ST SESSION

S. 2089

To prohibit the labeling of certain opioid drugs recommending use for long-term chronic pain.

IN THE SENATE OF THE UNITED STATES

JULY 11, 2019

Mr. MANCHIN (for himself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To prohibit the labeling of certain opioid drugs recommending use for long-term chronic pain.

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 Opioid Labeling
5 Accuracy Act”.

6 **SEC. 2. LABELING PROHIBITION.**

7 (a) IN GENERAL.—Notwithstanding any other provi-
8 sion of law, the Secretary of Health and Human Services
9 (referred to in this Act as the “Secretary”) may not ap-

1 prove labeling for an extended release or long-acting opioid
2 analgesic drug unless, as applicable—

3 (1) the labeling provides that such drug is not
4 intended for the treatment of chronic pain, except in
5 the case of—

6 (A) treatment of pain related to cancer;

7 (B) end-of-life care; or

8 (C) a prescriber determination that, with
9 respect to a particular patient, other non-opioid
10 pain management treatments are inadequate or
11 inappropriate; or

12 (2) the labeling is consistent with the regula-
13 tions promulgated by the Secretary pursuant to sub-
14 section (b).

15 (b) STUDY AND LABELING REGULATIONS.—

16 (1) IN GENERAL.—Not later than 1 year after
17 the date of enactment of this Act, the Secretary
18 shall—

19 (A) conduct a study on the efficacy of
20 opioid analgesic drugs for long-term chronic
21 pain management; and

22 (B) based on such study, promulgate regu-
23 lations regarding the labeling for extended re-
24 lease or long-acting opioid analgesic drugs, as
25 scientifically appropriate.

1 (2) UPDATES.—The Secretary may update the
2 regulations promulgated under paragraph (1)(B), as
3 appropriate.

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