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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