116TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. MANCHIN (for himself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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 Opioid Labeling Accuracy Act''.

SEC. 2. LABELING PROHIBITION.

(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') may not ap-

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

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

(A) treatment of pain related to cancer;

(B) end-of-life care; or

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

(2) the labeling is consistent with the regulations promulgated by the Secretary pursuant to subsection (b).

(b) STUDY AND LABELING REGULATIONS.—

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

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

(B) based on such study, promulgate regulations regarding the labeling for extended release or long-acting opioid analgesic drugs, as scientifically appropriate.

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