118TH CONGRESS
1ST SESSION

S. _____

To require the Food and Drug Administration to determine whether to permit the use of enriched enrollment randomized withdrawal methodology with respect to clinical trials.

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 require the Food and Drug Administration to determine whether to permit the use of enriched enrollment randomized withdrawal methodology with respect to clinical trials.

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 Review of Efficacy of EERW Double-Blinds of Opioids Act'' or the ''FREED of Opioids Act''.

SEC. 2. CONSIDERATION OF ENRICHED ENROLLMENT RANDOMIZED WITHDRAWAL METHODOLOGY.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall convene a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the Food and Drug Administration to vote on whether to permit the use of the enriched enrollment randomized withdrawal methodology in clinical trials of drugs, including opioid drugs. In conducting such review, the Secretary shall consider the report issued by the National Academy of Sciences under subsection (c).

(b) PRESENTATIONS.—If the Secretary allows for formal presentations in support of the use of the enriched enrollment randomized withdrawal methodology at the meeting described in subsection (a), the Secretary shall also allow for equal time at such meeting for presentations that are critical of such methodology.

(c) NAS STUDY AND REPORT.—The Secretary shall seek to enter into a contract with the National Academy of Sciences under which the National Academy—

(1) conducts a study on the effectiveness of enriched enrollment randomized withdrawal method-

ology in demonstrating the efficacy of opioid drugs in treating chronic pain; and

(2) not later than 1 year after the date of enactment of this Act, submits a report on such study to the Secretary.

(d) POSTMARKET REVIEW.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall convene 1 or more meetings of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the Food and Drug Administration to review the approved labeling on all opioid drugs approved using enriched enrollment randomized withdrawal methodology under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) as of the date of the first such meeting, for the purpose of determining whether the indications on such labeling for such drugs are supported by the enriched enrollment randomized withdrawal methodology. The findings from such meetings shall be made publicly available on an internet website operated by the Secretary, acting through the Commissioner of Food and Drugs.