

117TH CONGRESS
1ST SESSION

S. 1634

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

MAY 13, 2021

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

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 Review of Effi-
5 cacy of EERW Double-Blinds of Opioids Act” or the
6 “FREED of Opioids Act”.

1 **SEC. 2. CONSIDERATION OF ENRICHED ENROLLMENT RAN-**
2 **DOMIZED WITHDRAWAL METHODOLOGY.**

3 (a) IN GENERAL.—Not later than 2 years after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”), acting through the Commissioner of Food and
7 Drugs, shall convene a meeting of the Anesthetic and An-
8 algesic Drug Products Advisory Committee and the Drug
9 Safety and Risk Management Advisory Committee of the
10 Food and Drug Administration to vote on whether to per-
11 mit the use of the enriched enrollment randomized with-
12 drawal methodology in clinical trials of drugs, including
13 opioid drugs. In conducting such review, the Secretary
14 shall consider the report issued by the National Academy
15 of Sciences under subsection (c).

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

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

25 (1) conducts a study on the effectiveness of en-
26 riched enrollment randomized withdrawal method-

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

3 (2) not later than 1 year after the date of en-
4 actment of this Act, submits a report on such study
5 to the Secretary.

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