118TH CONGRESS
1ST SESSION

S. 607

To allow the Secretary of Health and Human Services to deny approval of a new drug application for an opioid analgesic drug on the basis of such drug not being clinically superior to other commercially available drugs.

IN THE SENATE OF THE UNITED STATES

MARCH 1, 2023

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

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A BILL

To allow the Secretary of Health and Human Services to deny approval of a new drug application for an opioid analgesic drug on the basis of such drug not being clinically superior to other commercially available drugs.

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 ''Ensuring the FDA Fully Examines Clinical Trial Impact and Vitalness before Endorsement Act'' or the ''EFFECTIVE Act''.

SEC. 2. REQUIREMENT FOR APPROVAL OF NEW OPIOID ANALGESICS.

Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following:

''(6) Notwithstanding any other provision of this section, the Secretary may deny approval of an application submitted under subsection (b) for an opioid analgesic drug if the Secretary determines that such drug does not provide a significant advantage, in terms of greater safety or effectiveness, compared to an appropriate comparator drug, as determined by the Secretary.''.

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