117TH CONGRESS
2D SESSION

S. _____

To clarify that the Federal Right to Try law applies to schedule I substances for which a phase I clinical trial has been completed and to provide access for eligible patients to such substances pursuant to the Federal Right to Try law.

IN THE SENATE OF THE UNITED STATES

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

A BILL

To clarify that the Federal Right to Try law applies to schedule I substances for which a phase I clinical trial has been completed and to provide access for eligible patients to such substances pursuant to the Federal Right to Try law.

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 ''Right to Try Clarification Act''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) The Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Public Law 115–176) was enacted in 2018.

(2) Section 561B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a), as added by the Act described in paragraph (1) (referred to in this section as the ''Federal Right to Try law''), does not exclude from the application of such law schedule I substances for which a phase I clinical trial has been completed.

(3) Multiple schedule I drugs have progressed through phase I clinical trials and have been designated by the Food and Drug Administration as breakthrough therapies under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) because of preliminary clinical evidence indicating that such drugs demonstrate substantial improvement over existing therapies, but eligible patients have not been permitted access to these drugs pursuant to the Federal Right to Try law.

SEC. 3. AMENDMENT TO FEDERAL RIGHT TO TRY LAW.

Section 561B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a(b)) is amended by inserting ''any provision of the Controlled Substances Act (21

U.S.C. 801 et seq.) that prohibits the unauthorized use, possession, distribution, dispensation, or transportation of an eligible investigational drug,'' before ''and parts''.