

117TH CONGRESS
2D SESSION

S. 4575

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

JULY 20, 2022

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

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.

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 “Right to Try Clarifica-
5 tion Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

1 (1) The Trickett Wendler, Frank Mongiello,
2 Jordan McLinn, and Matthew Bellina Right to Try
3 Act of 2017 (Public Law 115–176) was enacted in
4 2018.

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

12 (3) Multiple schedule I drugs have progressed
13 through phase I clinical trials and have been des-
14 ignated by the Food and Drug Administration as
15 breakthrough therapies under section 506 of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 356) because of preliminary clinical evidence indi-
18 cating that such drugs demonstrate substantial im-
19 provement over existing therapies, but eligible pa-
20 tients have not been permitted access to these drugs
21 pursuant to the Federal Right to Try law.

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

23 Section 561B(b) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 360bbb–0a(b)) is amended by insert-
25 ing “any provision of the Controlled Substances Act (21

- 1 U.S.C. 801 et seq.) that prohibits the unauthorized use,
- 2 possession, distribution, dispensation, or transportation of
- 3 an eligible investigational drug,” before “and parts”.

