

115TH CONGRESS
1ST SESSION

S. 204

AN ACT

To authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Trickett Wendler,
3 Frank Mongiello, Jordan McLinn, and Matthew Bellina
4 Right to Try Act of 2017”.

5 **SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY**
6 **PATIENTS DIAGNOSED WITH A TERMINAL**
7 **ILLNESS.**

8 (a) IN GENERAL.—Chapter V of the Federal Food,
9 Drug, and Cosmetic Act is amended by inserting after sec-
10 tion 561A (21 U.S.C. 360bbb–0) the following:

11 **“SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGI-**
12 **BLE PATIENTS.**

13 “(a) DEFINITIONS.—For purposes of this section—

14 “(1) the term ‘eligible patient’ means a pa-
15 tient—

16 “(A) who has been diagnosed with a life-
17 threatening disease or condition (as defined in
18 section 312.81 of title 21, Code of Federal Reg-
19 ulations (or any successor regulations));

20 “(B) who has exhausted approved treat-
21 ment options and is unable to participate in a
22 clinical trial involving the eligible investigational
23 drug, as certified by a physician, who—

24 “(i) is in good standing with the phy-
25 sician’s licensing organization or board;
26 and

1 “(ii) will not be compensated directly
2 by the manufacturer for so certifying; and

3 “(C) who has provided to the treating phy-
4 sician written informed consent regarding the
5 eligible investigational drug, or, as applicable,
6 on whose behalf a legally authorized representa-
7 tive of the patient has provided such consent;

8 “(2) the term ‘eligible investigational drug’
9 means an investigational drug (as such term is used
10 in section 561)—

11 “(A) for which a Phase 1 clinical trial has
12 been completed;

13 “(B) that has not been approved or li-
14 censed for any use under section 505 of this
15 Act or section 351 of the Public Health Service
16 Act;

17 “(C)(i) for which an application has been
18 filed under section 505(b) of this Act or section
19 351(a) of the Public Health Service Act; or

20 “(ii) that is under investigation in a clin-
21 ical trial that—

22 “(I) is intended to form the primary
23 basis of a claim of effectiveness in support
24 of approval or licensure under section 505

1 of this Act or section 351 of the Public
2 Health Service Act; and

3 “(II) is the subject of an active inves-
4 tigational new drug application under sec-
5 tion 505(i) of this Act or section 351(a)(3)
6 of the Public Health Service Act, as appli-
7 cable; and

8 “(D) the active development or production
9 of which is ongoing and has not been discon-
10 tinued by the manufacturer or placed on clinical
11 hold under section 505(i); and

12 “(3) the term ‘phase 1 trial’ means a phase 1
13 clinical investigation of a drug as described in sec-
14 tion 312.21 of title 21, Code of Federal Regulations
15 (or any successor regulations).

16 “(b) EXEMPTIONS.—Eligible investigational drugs
17 provided to eligible patients in compliance with this section
18 are exempt from sections 502(f), 503(b)(4), 505(a), and
19 505(i) of this Act, section 351(a) of the Public Health
20 Service Act, and parts 50, 56, and 312 of title 21, Code
21 of Federal Regulations (or any successor regulations), pro-
22 vided that the sponsor of such eligible investigational drug
23 or any person who manufactures, distributes, prescribes,
24 dispenses, introduces or delivers for introduction into
25 interstate commerce, or provides to an eligible patient an

1 eligible investigational drug pursuant to this section is in
2 compliance with the applicable requirements set forth in
3 sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code
4 of Federal Regulations (or any successor regulations) that
5 apply to investigational drugs.

6 “(c) USE OF CLINICAL OUTCOMES.—

7 “(1) IN GENERAL.—Notwithstanding any other
8 provision of this Act, the Public Health Service Act,
9 or any other provision of Federal law, the Secretary
10 may not use a clinical outcome associated with the
11 use of an eligible investigational drug pursuant to
12 this section to delay or adversely affect the review or
13 approval of such drug under section 505 of this Act
14 or section 351 of the Public Health Service Act un-
15 less—

16 “(A) the Secretary makes a determination,
17 in accordance with paragraph (2), that use of
18 such clinical outcome is critical to determining
19 the safety of the eligible investigational drug; or

20 “(B) the sponsor requests use of such out-
21 comes.

22 “(2) LIMITATION.—If the Secretary makes a
23 determination under paragraph (1)(A), the Sec-
24 retary shall provide written notice of such deter-
25 mination to the sponsor, including a public health

1 justification for such determination, and such notice
2 shall be made part of the administrative record.
3 Such determination shall not be delegated below the
4 director of the agency center that is charged with
5 the premarket review of the eligible investigational
6 drug.

7 “(d) REPORTING.—

8 “(1) IN GENERAL.—The manufacturer or spon-
9 sor of an eligible investigational drug shall submit to
10 the Secretary an annual summary of any use of such
11 drug under this section. The summary shall include
12 the number of doses supplied, the number of pa-
13 tients treated, the uses for which the drug was made
14 available, and any known serious adverse events.
15 The Secretary shall specify by regulation the dead-
16 line of submission of such annual summary and may
17 amend section 312.33 of title 21, Code of Federal
18 Regulations (or any successor regulations) to require
19 the submission of such annual summary in conjunc-
20 tion with the annual report for an applicable inves-
21 tigational new drug application for such drug.

22 “(2) POSTING OF INFORMATION.—The Sec-
23 retary shall post an annual summary report of the
24 use of this section on the internet website of the
25 Food and Drug Administration, including the num-

1 ber of drugs for which clinical outcomes associated
2 with the use of an eligible investigational drug pur-
3 suant to this section was—

4 “(A) used in accordance with subsection
5 (c)(1)(A);

6 “(B) used in accordance with subsection
7 (c)(1)(B); and

8 “(C) not used in the review of an applica-
9 tion under section 505 of this Act or section
10 351 of the Public Health Service Act.”.

11 (b) NO LIABILITY.—

12 (1) ALLEGED ACTS OR OMISSIONS.—With re-
13 spect to any alleged act or omission with respect to
14 an eligible investigational drug provided to an eligi-
15 ble patient pursuant to section 561B of the Federal
16 Food, Drug, and Cosmetic Act and in compliance
17 with such section, no liability in a cause of action
18 shall lie against—

19 (A) a sponsor or manufacturer; or

20 (B) a prescriber, dispenser, or other indi-
21 vidual entity (other than a sponsor or manufac-
22 turer), unless the relevant conduct constitutes
23 reckless or willful misconduct, gross negligence,
24 or an intentional tort under any applicable
25 State law.

1 (2) DETERMINATION NOT TO PROVIDE DRUG.—
2 No liability shall lie against a sponsor manufacturer,
3 prescriber, dispenser or other individual entity for its
4 determination not to provide access to an eligible in-
5 vestigational drug under section 561B of the Fed-
6 eral Food, Drug, and Cosmetic Act.

7 (3) LIMITATION.—Except as set forth in para-
8 graphs (1) and (2), nothing in this section shall be
9 construed to modify or otherwise affect the right of
10 any person to bring a private action under any State
11 or Federal product liability, tort, consumer protec-
12 tion, or warranty law.

13 **SEC. 3. SENSE OF THE SENATE.**

14 It is the sense of the Senate that section 561B of
15 the Federal Food, Drug, and Cosmetic Act, as added by
16 section 2—

17 (1) does not establish a new entitlement or
18 modify an existing entitlement, or otherwise estab-
19 lish a positive right to any party or individual;

20 (2) does not establish any new mandates, direc-
21 tives, or additional regulations;

22 (3) only expands the scope of individual liberty
23 and agency among patients, in limited cir-
24 cumstances;

1 (4) is consistent with, and will act as an alter-
2 native pathway alongside, existing expanded access
3 policies of the Food and Drug Administration;

4 (5) will not, and cannot, create a cure or effec-
5 tive therapy where none exists;

6 (6) recognizes that the eligible terminally ill pa-
7 tient population often consists of those patients with
8 the highest risk of mortality, and use of experi-
9 mental treatments under the criteria and procedure
10 described in such section 561A involves an informed
11 assumption of risk; and

12 (7) establishes national standards and rules by
13 which investigational drugs may be provided to ter-
14 minally ill patients.

Passed the Senate August 3, 2017.

Attest:

Secretary.

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