

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 204

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

- 1 Strike all after the enacting clause and insert the fol-
- 2 lowing:
- 3 **SECTION 1. SHORT TITLE.**
- 4 This Act may be cited as the “Trickett Wendler,
- 5 Frank Mongiello, and Jordan McLinn Right to Try Act
- 6 of 2017”.

1 **SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY**
2 **PATIENTS DIAGNOSED WITH A TERMINAL**
3 **ILLNESS.**

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

7 **“SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGI-**
8 **BLE PATIENTS.**

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

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

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

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

20 “(i) is in good standing with the phy-
21 sician’s licensing organization or board;
22 and

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

25 “(C) who has provided to the treating phy-
26 sician written informed consent regarding the

1 eligible investigational drug, or, as applicable,
2 on whose behalf a legally authorized representa-
3 tive of the patient has provided such consent;

4 “(2) the term ‘eligible investigational drug’
5 means an investigational drug (as such term is used
6 in section 561)—

7 “(A) for which a Phase 1 clinical trial has
8 been completed;

9 “(B) that has not been approved or li-
10 censed for any use under section 505 of this
11 Act or section 351 of the Public Health Service
12 Act;

13 “(C)(i) for which an application has been
14 filed under section 505(b) of this Act or section
15 351(a) of the Public Health Service Act; or

16 “(ii) that is under investigation in a clin-
17 ical trial that—

18 “(I) is intended to form the primary
19 basis of a claim of effectiveness in support
20 of approval or licensure under section 505
21 of this Act or section 351 of the Public
22 Health Service Act; and

23 “(II) is the subject of an active inves-
24 tigational new drug application under sec-
25 tion 505(i) of this Act or section 351(a)(3)

1 of the Public Health Service Act, as appli-
2 cable; and

3 “(D) the active development or production
4 of which is ongoing and has not been discon-
5 tinued by the manufacturer or placed on clinical
6 hold under section 505(i); and

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

11 “(b) EXEMPTIONS.—Eligible investigational drugs
12 provided to eligible patients in compliance with this section
13 are exempt from sections 502(f), 503(b)(4), 505(a), and
14 505(i) of this Act, section 351(a) of the Public Health
15 Service Act, and parts 50, 56, and 312 of title 21, Code
16 of Federal Regulations (or any successor regulations), pro-
17 vided that the sponsor of such eligible investigational drug
18 or any person who manufactures, distributes, prescribes,
19 dispenses, introduces or delivers for introduction into
20 interstate commerce, or provides to an eligible patient an
21 eligible investigational drug pursuant to this section is in
22 compliance with the applicable requirements set forth in
23 sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code
24 of Federal Regulations (or any successor regulations) that
25 apply to investigational drugs.

1 “(c) USE OF CLINICAL OUTCOMES.—

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

11 “(A) the Secretary makes a determination,
12 in accordance with paragraph (2), that use of
13 such clinical outcome is critical to determining
14 the safety of the eligible investigational drug; or

15 “(B) the sponsor requests use of such out-
16 comes.

17 “(2) LIMITATION.—If the Secretary makes a
18 determination under paragraph (1)(A), the Sec-
19 retary shall provide written notice of such deter-
20 mination to the sponsor, including a public health
21 justification for such determination, and such notice
22 shall be made part of the administrative record.
23 Such determination shall not be delegated below the
24 director of the agency center that is charged with

1 the premarket review of the eligible investigational
2 drug.

3 “(d) REPORTING.—

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

18 “(2) POSTING OF INFORMATION.—The Sec-
19 retary shall post an annual summary report of the
20 use of this section on the internet website of the
21 Food and Drug Administration, including the num-
22 ber of drugs for which clinical outcomes associated
23 with the use of an eligible investigational drug pur-
24 suant to this section was—

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

3 “(B) used accordance with subsection
4 (c)(1)(B); and

5 “(C) not used in the review of an applica-
6 tion under section 505 of this Act or section
7 351 of the Public Health Service Act.”.

8 (b) NO LIABILITY.—

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

16 (A) a sponsor or manufacturer; or

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

23 (2) DETERMINATION NOT TO PROVIDE DRUG.—

24 No liability shall lie against a sponsor manufacturer,
25 prescriber, dispenser or other individual entity for its

1 determination not to provide access to an eligible in-
2 vestigational drug under section 561B of the Fed-
3 eral Food, Drug, and Cosmetic Act.

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

10 **SEC. 3. SENATE OF THE SENATE.**

11 It is the sense of the Senate that section 561B of
12 the Federal Food, Drug, and Cosmetic Act, as added by
13 section 2—

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

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

19 (3) only expands the scope of individual liberty
20 and agency among patients, in limited cir-
21 cumstances;

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

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

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

9 (7) establishes national standards and rules by
10 which investigational drugs may be provided to ter-
11 minally ill patients.