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H. R. 5247

IN THE SENATE OF THE UNITED STATES

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AN ACT

To authorize the use of eligible investigational drugs by eligible patients who have been diagnosed with a stage of a disease or condition in which there is reasonable likelihood that death will occur within a matter of months, or with another eligible illness, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Trickett Wendler,
5 Frank Mongiello, Jordan McLinn, and Matthew Bellina
6 Right to Try Act of 2018”.

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

10 (a) IN GENERAL.—Subchapter E of chapter V of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb
12 et seq.) is amended by inserting after section 561A (21
13 U.S.C. 360bbb–0) the following:

14 **“SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGI-**
15 **BLE PATIENTS.**

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

17 “(1) The term ‘eligible patient’ means a pa-
18 tient—

19 “(A) who has been diagnosed with an eligi-
20 ble illness;

21 “(B) who has exhausted approved treat-
22 ment options and is not eligible to participate
23 in (for a reason such as the patient not meeting
24 inclusion criteria) a clinical trial designed to
25 evaluate an investigational drug for the treat-

1 ment of such eligible illness with which the pa-
2 tient has been diagnosed, including one involv-
3 ing the eligible investigational drug, or for
4 whom participation in such a clinical trial is not
5 feasible (for a reason such as a lack of geo-
6 graphic proximity to the clinical trial), as cer-
7 tified by a physician, who—

8 “(i) is in good standing with the phy-
9 sician’s licensing organization or board;
10 and

11 “(ii) will not be compensated for so
12 certifying; and

13 “(C) who has provided to the treating phy-
14 sician written informed consent, as described in
15 part 50 of title 21, Code of Federal Regulations
16 (or any successor regulations), regarding the el-
17 igible investigational drug, or, as applicable, on
18 whose behalf a legally authorized representative
19 of the patient has provided such consent.

20 “(2) The term ‘eligible investigational drug’
21 means an investigational drug (as such term is used
22 in section 561)—

23 “(A) for which a phase 1 clinical trial has
24 been completed;

1 “(B) that has not been approved or li-
2 censed for any use under section 505 of this
3 Act or section 351 of the Public Health Service
4 Act;

5 “(C)(i) for which an application has been
6 filed under section 505(b) of this Act or section
7 351(a) of the Public Health Service Act, as ap-
8 plicable, that is active; or

9 “(ii) that is under investigation in a clin-
10 ical trial that—

11 “(I) is intended to form the primary
12 basis of a claim of effectiveness in support
13 of approval or licensure under section 505
14 of this Act or section 351 of the Public
15 Health Service Act; and

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

21 “(D) the active development or production
22 of which—

23 “(i) is ongoing;

24 “(ii) has not been discontinued by the
25 manufacturer; and

1 “(iii) is not the subject of a clinical
2 hold under the regulations implementing
3 section 505(i) or section 351(a)(3) of the
4 Public Health Service Act, as applicable.

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

9 “(4) The term ‘eligible illness’ means—

10 “(A) a stage of a disease or condition in
11 which there is reasonable likelihood that death
12 will occur within a matter of months; or

13 “(B) a disease or condition that would re-
14 sult in significant irreversible morbidity that is
15 likely to lead to severely premature death.

16 “(b) ALTERNATIVE PATHWAY FOR ELIGIBLE PA-
17 TIENTS WITH A TERMINAL ILLNESS.—

18 “(1) IN GENERAL.—Eligible investigational
19 drugs provided to eligible patients in compliance
20 with this section are exempt from sections 502(f),
21 503(b)(4), and subsections (a) and (i) of section 505
22 of this Act, and section 351(a) of the Public Health
23 Service Act so long as the conditions specified in
24 paragraphs (2), (3), and (4) are met with respect to
25 the provision of such investigational drugs.

1 “(2) COMPLIANCE WITH CERTAIN REGULA-
2 TIONS.—The conditions specified in this paragraph,
3 with respect to an eligible investigational drug re-
4 ferred to in paragraph (1), are that—

5 “(A) the eligible investigational drug is la-
6 beled in accordance with section 312.6 of title
7 21, Code of Federal Regulations (or any suc-
8 cessor regulations); and

9 “(B) the provision of such eligible inves-
10 tigational drug occurs in compliance with the
11 applicable requirements set forth in sections
12 312.7 and 312.8(d)(1) of title 21, Code of Fed-
13 eral Regulations (or any successor regulations)
14 that apply to investigational drugs, subject to
15 paragraph (5).

16 “(3) NOTIFICATION.—The condition specified in
17 this paragraph, with respect to an eligible investiga-
18 tional drug referred to in paragraph (1), is that the
19 sponsor of such eligible investigational drug notifies
20 the Secretary of the provision of such eligible inves-
21 tigational drug for use by an eligible patient pursu-
22 ant to this section. Such notification shall be sub-
23 mitted within 7 business days of the provision of
24 such eligible investigational drug as correspondence

1 to the investigational new drug application described
2 in subsection (a)(2).

3 “(4) ADVERSE EVENT REPORTING.—The condi-
4 tion specified in this paragraph, with respect to an
5 eligible investigational drug referred to in paragraph
6 (1), is that the sponsor or manufacturer of such eli-
7 gible investigational drug has required, as a condi-
8 tion of providing the drug to a physician for use by
9 an eligible patient pursuant to this section, that such
10 physician will immediately report to such sponsor or
11 manufacturer any serious adverse events, as such
12 term is defined in section 312.32 of title 21, Code
13 of Federal Regulations (or any successor regula-
14 tions), associated with the use of the eligible inves-
15 tigational drug by the eligible patient.

16 “(5) APPLICATION.—For purposes of this sec-
17 tion, the requirements set forth in sections 312.7
18 and 312.8(d)(1) of title 21 of the Code of Federal
19 Regulations (or any successor regulations) are
20 deemed to apply to any person who manufactures,
21 distributes, prescribes, dispenses, introduces or deliv-
22 ers for introduction into interstate commerce, or
23 provides to an eligible patient an eligible investiga-
24 tional drug pursuant to this section.

25 “(c) USE OF CLINICAL OUTCOMES.—

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

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

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

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

1 “(d) REPORTING.—The manufacturer or sponsor of
2 an eligible investigational drug that provides an eligible
3 investigational drug pursuant to this section shall post on
4 the same publicly available internet website used by the
5 manufacturer for purposes of section 561A(b) an annual
6 summary of any provision by the manufacturer or sponsor
7 of an eligible investigational drug under this section. The
8 summary shall include the number of requests received,
9 the number of requests granted, the number of patients
10 treated, the therapeutic area of the drug made available,
11 and any known or suspected serious adverse events, as
12 such term is defined in section 312.32 of title 21, Code
13 of Federal Regulations (or any successor regulations), as-
14 sociated with the use of the eligible investigational drug.

15 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed as limiting the authority of the Sec-
17 retary to require manufacturers or sponsors of investiga-
18 tional drugs to review and report information relevant to
19 the safety of such investigational drug obtained or other-
20 wise received by the sponsor pursuant to part 312 of title
21 21, Code of Federal Regulations (or successor regula-
22 tions).”.

23 (b) NO LIABILITY.—Section 561B of the Federal
24 Food, Drug, and Cosmetic Act, as added by subsection
25 (a), is amended by adding at the end the following:

1 “(f) LIABILITY.—

2 “(1) ALLEGED ACTS OR OMISSIONS.—

3 “(A) MANUFACTURER OR SPONSOR.—No
4 manufacturer or sponsor (or their agent or rep-
5 resentative) of an investigational drug shall be
6 liable for any alleged act or omission related to
7 the provision of such drug to a single patient or
8 small group of patients for treatment use in ac-
9 cordance with subsection (b) or (c) of section
10 561 or the provision of an eligible investiga-
11 tional drug to an eligible patient in accordance
12 with this section, including, with respect to the
13 provision of an investigational drug under sec-
14 tion 561 or an eligible investigational drug
15 under this section, the reporting of safety infor-
16 mation, from clinical trials or any other source,
17 as required by section 312.32 of title 21, Code
18 of Federal Regulations (or any successor regu-
19 lations).

20 “(B) PHYSICIAN, CLINICAL INVESTIGATOR,
21 OR HOSPITAL.—

22 “(i) No licensed physician, clinical in-
23 vestigator, or hospital shall be liable for
24 any alleged act or omission related to the
25 provision of an investigational drug to a

1 single patient or small group of patients
2 for treatment use in accordance with sub-
3 section (b) or (c) of section 561, as de-
4 scribed in clause (ii), or the provision of an
5 eligible investigational drug to an eligible
6 patient in accordance with this section, un-
7 less such act or omission constitutes on the
8 part of such physician, clinical investigator,
9 or hospital with respect to such investiga-
10 tional drug or eligible investigational
11 drug—

12 “(I) willful or criminal mis-
13 conduct;

14 “(II) reckless misconduct;

15 “(III) gross negligence relative to
16 the applicable standard of care and
17 practice with respect to the adminis-
18 tration or dispensing of such inves-
19 tigational drug; or

20 “(IV) an intentional tort under
21 applicable State law.

22 “(ii) The requirements described in
23 this clause are the requirements under
24 subsection (b) or (c) of section 561, includ-
25 ing—

1 “(I) the reporting of safety infor-
2 mation, from clinical trials or any
3 other source, as required by section
4 312.32 of title 21, Code of Federal
5 Regulations (or any successor regula-
6 tions);

7 “(II) ensuring that the informed
8 consent requirements of part 50 of
9 title 21, Code of the Federal Regula-
10 tions (or any successor regulations)
11 are met; and

12 “(III) ensuring that review by an
13 institutional review board is obtained
14 in a manner consistent with the re-
15 quirements of part 56 of title 21,
16 Code of the Federal Regulations (or
17 any successor regulations).

18 “(2) DETERMINATION NOT TO PROVIDE
19 DRUG.—No manufacturer, sponsor, licensed physi-
20 cian, clinical investigator, or hospital shall be liable
21 for determining not to provide access to an inves-
22 tigational drug under this section or for dis-
23 continuing any such access that it initially deter-
24 mined to provide.

25 “(3) LIMITATION.—

1 “(A) IN GENERAL.—Except as set forth in
2 paragraphs (1) and (2), nothing in this section
3 shall be construed to modify or otherwise affect
4 the right of any person to bring a private action
5 against a manufacturer or sponsor (or their
6 agent or representative), physician, clinical in-
7 vestigator, hospital, prescriber, dispenser, or
8 other entity under any State or Federal product
9 liability, tort, consumer protection, or warranty
10 law.

11 “(B) FEDERAL GOVERNMENT.—Nothing in
12 this section shall be construed to modify or oth-
13 erwise affect the authority of the Federal Gov-
14 ernment to bring suit under any Federal law.”.

Passed the House of Representatives March 21,
2018.

Attest:

KAREN L. HAAS,

Clerk.

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