

115TH CONGRESS
1ST SESSION

H. R. 2368

To authorize the use of experimental drugs, biological products, and devices by patients diagnosed with a terminal illness in accordance with State law, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 4, 2017

Mr. FITZPATRICK (for himself, Ms. SINEMA, and Mr. BIGGS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To authorize the use of experimental drugs, biological products, and devices 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Right to Try Act”.

1 **SEC. 2. USE OF UNAPPROVED MEDICAL PRODUCTS BY PA-**
2 **TIENTS DIAGNOSED WITH A TERMINAL ILL-**
3 **NESS.**

4 (a) **IN GENERAL.**—Notwithstanding the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),
6 the Controlled Substances Act (21 U.S.C. 801 et seq.),
7 and any other provision of Federal law, the Federal Gov-
8 ernment shall not take any action to prohibit or restrict—

9 (1) the production, manufacture, distribution,
10 prescribing, or dispensing of an experimental drug,
11 biological product, or device that—

12 (A) is intended to treat a patient who has
13 been diagnosed with a terminal illness; and

14 (B) is authorized by, and in accordance
15 with, State law; and

16 (2) the possession or use of an experimental
17 drug, biological product, or device—

18 (A) that is described in subparagraphs (A)
19 and (B) of paragraph (1); and

20 (B) for which the patient has received a
21 certification from the patient’s treating physi-
22 cian in accordance with subsection (b).

23 (b) **PHYSICIAN CERTIFICATION.**—A certification by
24 the patient’s treating physician referred to in subsection
25 (a)(2)(B) must include each of the following:

26 (1) A certification that the physician—

1 (A) is in good standing with the physi-
2 cian's certifying organization or board; and

3 (B) has personally examined the patient.

4 (2) A certification that there is no reason to
5 conclude the experimental drug, biological product,
6 or device poses an unreasonable and significant risk
7 of danger to the patient.

8 (3) A certification that the patient has been di-
9 agnosed with a terminal disease or condition and
10 does not have any treatment options that—

11 (A) are comparable to treatment using the
12 experimental drug, biological product, or device
13 or otherwise satisfactory; and

14 (B) are approved, licensed, or cleared for
15 commercial distribution under section 505,
16 510(k), or 515 of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 355, 360(k), 360(e))
18 or section 351 of the Public Health Service Act
19 (42 U.S.C. 262) and are available to diagnose,
20 monitor, or treat the patient's disease or condi-
21 tion.

22 (4) A certification that the probable risk to the
23 patient from the experimental drug, biological prod-
24 uct, or device is not greater than the probable risk
25 from the patient's disease or condition.

1 (5) A certification that the physician has pro-
2 vided the patient with a written statement and oral
3 explanation of the medical treatment to be provided
4 using the experimental drug, biological product, or
5 device.

6 (6) An acknowledgement signed by the patient
7 (or the patient's legal representative) that the physi-
8 cian has provided the written statement and oral ex-
9 planation required by paragraph (5), and has dis-
10 closed the following:

11 (A) That the medical treatment using the
12 experimental drug, biological product, or device
13 is experimental or nonconventional.

14 (B) That the experimental drug, biological
15 product, or device has not been approved, li-
16 censed, or cleared for commercial distribution
17 under section 505, 510(k), or 515 of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C.
19 355, 360(k), 360(e)) or section 351 of the Pub-
20 lic Health Service Act (42 U.S.C. 262) for any
21 indication.

22 (C) The material risks generally recognized
23 by a reasonably prudent physician of the med-
24 ical treatment's side effects.

1 (D) An explanation of the medical treat-
2 ment, including the expected frequency and du-
3 ration of the treatment.

4 (c) NO LIABILITY OR USE OF OUTCOMES.—

5 (1) NO LIABILITY.—Notwithstanding any other
6 provision of law, no liability shall lie against a pro-
7 ducer, manufacturer, distributor, prescriber, dis-
8 penser, possessor, or user of an experimental drug,
9 biological product, or device for the production, man-
10 ufacture, distribution, prescribing, dispensing, pos-
11 session, or use of an experimental drug, biological
12 product, or device that is in compliance, with sub-
13 section (a).

14 (2) NO USE OF OUTCOMES.—Notwithstanding
15 any other provision of law, the outcome of any pro-
16 duction, manufacture, distribution, prescribing, dis-
17 pensing, possession, or use of an experimental drug,
18 biological product, or device that was done in com-
19 pliance with subsection (a) shall not be used by a
20 Federal agency reviewing the experimental drug, bio-
21 logical product, or device to delay or otherwise ad-
22 versely impact review or approval of such experi-
23 mental drug, biological product, or device.

24 (d) RULES OF CONSTRUCTION.—Nothing in this Act
25 shall be construed to—

1 (1) require a manufacturer or other person to
2 make available any experimental drug, biological
3 product, or device; or

4 (2) prohibit a manufacturer or other person
5 from receiving compensation or recovering costs for
6 the production, manufacture, distribution, or sale of
7 an experiment drug, biological product, or device.

8 (e) DEFINITIONS.—In this section:

9 (1) BIOLOGICAL PRODUCT.—The term “biologi-
10 cal product” has the meaning given to such term in
11 section 351 of the Public Health Service Act (42
12 U.S.C. 262).

13 (2) DEVICE; DRUG.—The terms “device” and
14 “drug” have the meanings given to such terms in
15 section 201 of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 321).

17 (3) EXPERIMENTAL DRUG, BIOLOGICAL PROD-
18 UCT, OR DEVICE.—The term “experimental drug, bi-
19 ological product, or device” means a drug, biological
20 product, or device that—

21 (A) has successfully completed a phase 1
22 clinical investigation;

23 (B) remains under investigation in a clin-
24 ical trial approved by the Food and Drug Ad-
25 ministration; and

1 (C) is not approved, licensed, or cleared for
2 commercial distribution under section 505,
3 510(k), or 515 of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 355, 360(k), 360(e))
5 or section 351 of the Public Health Service Act
6 (42 U.S.C. 262).

7 (4) PHASE 1 CLINICAL INVESTIGATION.—The
8 term “phase 1 clinical investigation” means a phase
9 1 clinical investigation, as described in section
10 312.21 of title 21, Code of Federal Regulations (or
11 any successor regulations).

12 (5) TERMINAL ILLNESS.—The term “terminal
13 illness” has the meaning given to such term in the
14 State law specified in subsection (a)(1)(B).

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