

115TH CONGRESS
1ST SESSION

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.

IN THE SENATE OF THE UNITED STATES

JANUARY 24, 2017

Mr. JOHNSON (for himself, Mr. BARRASSO, Mr. BLUNT, Mr. BOOZMAN, Mrs. CAPITO, Mr. COCHRAN, Mr. CORKER, Mr. COTTON, Mr. CRAPO, Mr. CRUZ, Mr. DAINES, Mr. DONNELLY, Mr. ENZI, Mrs. FISCHER, Mr. FLAKE, Mr. GARDNER, Mr. GRAHAM, Mr. GRASSLEY, Mr. HATCH, Mr. HELLER, Mr. HOEVEN, Mr. INHOFE, Mr. ISAKSON, Mr. KENNEDY, Mr. KING, Mr. LANKFORD, Mr. LEE, Mr. MANCHIN, Mr. MCCAIN, Mr. McCONNELL, Mr. MORAN, Ms. MURKOWSKI, Mr. PAUL, Mr. PERDUE, Mr. RISCH, Mr. ROUNDS, Mr. RUBIO, Mr. SASSE, Mr. SHELBY, Mr. SULLIVAN, Mr. TILLIS, Mr. TOOMEY, Mr. WICKER, and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Trickett Wendler Right
5 to Try Act of 2017”.

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 a physician, who is in good
22 standing with the physician’s certifying organi-
23 zation or board, that the patient has exhausted,
24 or otherwise does not meet qualifying criteria to
25 receive, any other available treatment options.

26 (b) NO LIABILITY OR USE OF OUTCOMES.—

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

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

20 (c) DEFINITIONS.—In this section:

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

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

5 (3) EXPERIMENTAL DRUG, BIOLOGICAL PROD-
6 UCT, OR DEVICE.—The term “experimental drug, bi-
7 ological product, or device” means a drug, biological
8 product, or device that—

9 (A) has successfully completed a phase 1
10 clinical investigation;

11 (B) remains under investigation in a clin-
12 ical trial approved by the Food and Drug Ad-
13 ministration; and

14 (C) is not approved, licensed, or cleared for
15 commercial distribution under section 505,
16 510(k), or 515 of the Federal Food, Drug, or
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).

20 (4) PHASE 1 CLINICAL INVESTIGATION.—The
21 term “phase 1 clinical investigation” means a phase
22 1 clinical investigation, as described in section
23 312.21 of title 21, Code of Federal Regulations (or
24 any successor regulations).

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

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