

114TH CONGRESS  
2D SESSION

# S. 2912

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

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IN THE SENATE OF THE UNITED STATES

MAY 10, 2016

Mr. JOHNSON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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 2016”.

6 **SEC. 2. USE OF UNAPPROVED MEDICAL PRODUCTS BY PA-**  
7 **TIENTS DIAGNOSED WITH A TERMINAL ILL-**  
8 **NESS.**

9 (a) IN GENERAL.—Notwithstanding the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),

1 the Controlled Substances Act (21 U.S.C. 801 et seq.),  
2 and any other provision of Federal law, the Federal Gov-  
3 ernment shall not take any action to prohibit or restrict—

4 (1) the production, manufacture, distribution,  
5 prescribing, or dispensing of an experimental drug,  
6 biological product, or device that—

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

9 (B) is authorized by, and in accordance  
10 with, State law; and

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

13 (A) that is described in subparagraphs (A)  
14 and (B) of paragraph (1); and

15 (B) for which the patient has received a  
16 certification from a physician, who is in good  
17 standing with the physician's certifying organi-  
18 zation or board, that the patient has exhausted,  
19 or otherwise does not meet qualifying criteria to  
20 receive, any other available treatment options.

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

22 (1) NO LIABILITY.—Notwithstanding any other  
23 provision of law, no liability shall lie against a pro-  
24 ducer, manufacturer, distributor, prescriber, dis-  
25 penser, possessor, or user of an experimental drug,

1 biological product, or device for the production, man-  
2 ufacture, distribution, prescribing, dispensing, pos-  
3 session, or use of an experimental drug, biological  
4 product, or device that is in compliance with sub-  
5 section (a).

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

16 (c) DEFINITIONS.—In this section:

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

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

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

5                   (A) has successfully completed a phase 1  
6           clinical investigation;

7                   (B) remains under investigation in a clin-  
8           ical trial approved by the Food and Drug Ad-  
9           ministration; and

10                  (C) is not approved, licensed, or cleared for  
11           commercial distribution under section 505,  
12           510(k), or 515 of the Federal Food, Drug, or  
13           Cosmetic Act (21 U.S.C. 355, 360(k), 360(e))  
14           or section 351 of the Public Health Service Act  
15           (42 U.S.C. 262).

16           (4) PHASE 1 CLINICAL INVESTIGATION.—The  
17           term “phase 1 clinical investigation” means a phase  
18           1 clinical investigation, as described in section  
19           312.21 of title 21, Code of Federal Regulations (or  
20           any successor regulations).

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

1 **SEC. 3. FDA REPORT TO CONGRESS.**

2 Not later than 30 days after the date of enactment  
3 of this Act, and every 30 days thereafter until implementa-  
4 tion is complete, the Commissioner of Food and Drugs  
5 shall report to Congress on progress in implementing the  
6 proposed streamlined expanded access application process  
7 for experimental drugs that are intended to treat a patient  
8 who has been diagnosed with a terminal illness.

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