

114TH CONGRESS
1ST SESSION

H. R. 3012

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 HOUSE OF REPRESENTATIVES

JULY 9, 2015

Mr. SALMON (for himself, Mr. STUTZMAN, and Mr. GOSAR) 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 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 “Right to Try Act of
5 2015”.

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 the production, manufacture, distribution, prescribing,
10 dispensing, possession, or use of an experimental drug, bi-
11 ological product, or device that—

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

14 (2) is authorized by, and in accordance with,
15 State law.

16 (b) DEFINITIONS.—In this section:

17 (1) The term “biological product” has the
18 meaning given to such term in section 351 of the
19 Public Health Service Act (42 U.S.C. 262).

20 (2) The terms “device” and “drug” have the
21 meanings given to such terms in section 201 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 321).

24 (3) The term “experimental drug, biological
25 product, or device” means a drug, biological product,
26 or device that—

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

3 (B) remains under investigation in a clin-
4 ical trial approved by the Food and Drug Ad-
5 ministration; and

6 (C) is not approved, licensed, or cleared for
7 commercial distribution under section 505,
8 510(k), or 515 of the Federal Food, Drug, or
9 Cosmetic Act (21 U.S.C. 355, 360(k), 360(e))
10 or section 351 of the Public Health Service Act
11 (42 U.S.C. 262).

12 (4) The term “phase 1 clinical investigation”
13 means a phase 1 clinical investigation, as described
14 in section 312.21 of title 21, Code of Federal Regu-
15 lations (or any successor regulations).

16 (5) The term “terminal illness” has the mean-
17 ing given to such term in the State law specified in
18 subsection (a)(2).

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