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115TH CONGRESS
1ST SESSION

H. R. 878

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

FEBRUARY 6, 2017

Mr. BIGGS (for himself, Mr. FITZPATRICK, Mr. CRAMER, Mr. GROTHMAN, Mr. MESSER, Mr. PITTENGER, Mr. STEWART, Mr. LANCE, Mr. OLSON, Mr. FRANKS of Arizona, Mr. LAMBORN, Mr. CARSON of Indiana, Ms. MCSALLY, Mr. YOHO, Mr. ROHRABACHER, Mr. DUNCAN of South Carolina, Mr. LEWIS of Minnesota, Mr. BARR, Mr. BRIDENSTINE, Mr. GOHMERT, Mr. BANKS of Indiana, Mr. SMUCKER, Mr. BRAT, Mr. SENSENBRENNER, Mr. SCHWEIKERT, Mr. MARINO, Mr. ROKITA, and Mr. ISSA) 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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Right to Try Act of 2017".

SEC. 2. USE OF UNAPPROVED MEDICAL PRODUCTS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) IN GENERAL.—Notwithstanding the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Controlled Substances Act (21 U.S.C. 801 et seq.), and any other provision of Federal law, the Federal Government shall not take any action to prohibit or restrict—

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

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

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

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

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

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

(b) NO LIABILITY OR USE OF OUTCOMES.—

(1) NO LIABILITY.—Notwithstanding any other provision of law, no liability shall lie against a producer, manufacturer, distributor, prescriber, dispenser, possessor, or user of an experimental drug, biological product, or device for the production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that is in compliance, with subsection (a).

(2) NO USE OF OUTCOMES.—Notwithstanding any other provision of law, the outcome of any production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that was done in compliance with subsection (a) shall not be used by a Federal agency reviewing the experimental drug, biological product, or device to delay or otherwise adversely impact review or approval of such experimental drug, biological product, or device.

(c) DEFINITIONS.—In this section:

(1) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) DEVICE; DRUG.—The terms ''device'' and ''drug'' have the meanings given to such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) EXPERIMENTAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE.—The term ''experimental drug, biological product, or device'' that—

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

(B) remains under investigation in a clinical trial approved by the Food and Drug Administration; and

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

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

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

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