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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

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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.

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''.

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 the patient's treating physician in accordance with subsection (b).

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

(1) A certification that the physician—

(A) is in good standing with the physician's certifying organization or board; and

(B) has personally examined the patient.

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

(3) A certification that the patient has been diagnosed with a terminal disease or condition and does not have any treatment options that—

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

(B) are 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) and are available to diagnose, monitor, or treat the patient's disease or condition.

(4) A certification that the probable risk to the patient from the experimental drug, biological product, or device is not greater than the probable risk from the patient's disease or condition.

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

(6) An acknowledgement signed by the patient (or the patient's legal representative) that the physician has provided the written statement and oral explanation required by paragraph (5), and has disclosed the following:

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

(B) That the experimental drug, biological product, or device has not been 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) for any indication.

(C) The material risks generally recognized by a reasonably prudent physician of the medical treatment's side effects.

(D) An explanation of the medical treatment, including the expected frequency and duration of the treatment.

(c) 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.

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

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

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

(e) 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'' means a 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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