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.

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.

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 ''Trickett Wendler Right to Try Act of 2016''.

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'' 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, or 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).

SEC. 3. FDA REPORT TO CONGRESS.

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

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