Federal Right to Try Act of 2017

The **Federal Right to Try Act of 2017** (Public Law 115-176) was signed into law on **May 30, 2018** to expand access for patients with life-threatening diseases to certain investigational drugs, biological products, and medical devices that have not yet been approved by the FDA

1. Short title

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

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).