No. 2017-33

AN ACT

HB 45

Providing for the use of investigational drugs, biological products and medical devices by terminally ill patients.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Right-to-Try Act.

Section 2. Legislative findings and intent.

(a) Findings and declarations.—The General Assembly finds and declares as follows:

(1) The process of approval for investigational drugs, biological products and medical devices in the United States by the Food and Drug Administration protects future patients from premature, ineffective and unsafe medications and treatments over the long run, but the process often takes many years.

(2) Patients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product or medical device receives final approval from the Food and Drug Administration.

(3) Patients who have a terminal illness should be allowed to attempt to pursue the preservation of their lives by accessing available investigational drugs, biological products and medical devices.

(4) The use of available investigational drugs, biological products and medical devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's treating physician and the patient's health care team, if applicable.

(5) The decision to use an investigational drug, biological product or medical device should be made with full awareness of the potential risks, benefits and consequences to the patient and the patient's family.

(6) The Food and Drug Administration recently, in June 2016, implemented a more streamlined process for individual patient access to investigational drugs and biological products through its Individual Patient Expanded Access program - Form FDA 3926, which may be useful in some situations.

(b) Intent.—It is the intent of the General Assembly to allow terminally ill patients to use potentially life-saving investigational drugs, biological products and medical devices.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Eligible patient." As follows:

(1) An individual who has:

(i) a terminal illness, attested to by the patient's treating physician;

(ii) carefully considered all other treatment options approved by the Food and Drug Administration;

(iii) been unable to participate in a clinical trial for the terminal illness that is located within 100 miles of the patient's home address or has not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(iv) received a recommendation from the patient's treating physician for an investigational drug, biological product or medical device;

(v) given written, informed consent for the use of the investigational drug, biological product or medical device, or, if the patient is either a minor or lacks the mental capacity to provide informed consent, a parent or legally authorized representative has given written, informed consent on the patient's behalf; and

(vi) documentation from the patient's treating physician that the patient meets the requirements of this paragraph.

(2) The term does not include an individual being treated as an inpatient in any hospital.

"Health care provider." A licensed health care facility, as defined in section 802.1 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, or a person who is licensed, certified or otherwise regulated to provide health care services under the laws of this Commonwealth, including, but not limited to, as a physician, a certified nurse practitioner or a physician's assistant.

"Investigational drug, biological product or medical device." A drug, biological product or medical device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the Food and Drug Administration and remains under investigation in a clinical trial approved by the Food and Drug Administration.

"Physician." As defined in section 2 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985.

"Terminal illness." A disease or condition that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

"Written, informed consent." A written document placed in the eligible patient's medical record signed by the eligible patient and attested to by the eligible patient's treating physician and a witness that, at a minimum:

(1) Explains the currently approved products and treatments for the disease or condition from which the eligible patient suffers.

(2) Attests to the fact that the eligible patient concurs with the eligible patient's treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the eligible patient's life.

(3) Identifies clearly the specific proposed investigational drug, biological product or medical device that the eligible patient is seeking to use.

(4) Describes the potentially best and worst outcomes of using the investigational drug, biological product or medical device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different or worse symptoms might result, and that death could be hastened by the proposed treatment, based on the treating physician's knowledge of the proposed treatment and the patient's condition.

(5) Makes clear that the eligible patient's health insurer and health care provider are not obligated to pay for the use of the investigational drug, biological product or medical device or any care or treatments consequent to the use of the investigational drug, biological product or medical device.

(6) Makes clear that the patient's eligibility for hospice care may be withdrawn if the eligible patient begins curative treatment and care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(7) Makes clear that in-home health care may be denied if treatment begins.

(8) States that the eligible patient understands that the eligible patient is liable for all expenses consequent to the use of the investigational drug, biological product or medical device, and that this liability extends to the eligible patient's estate, unless a contract between the eligible patient and the manufacturer of the investigational drug, biological product or medical device states otherwise.

Section 4. Access.

(a) General rule.—A manufacturer of an investigational drug, biological product or medical device may make available the manufacturer's investigational drug, biological product or medical device to eligible patients in accordance with this act.

(b) Costs.—A manufacturer may:

(1) Provide an investigational drug, biological product or medical device to an eligible patient without receiving compensation.

(2) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product or medical device.

(c) Insurers.—Nothing in this act may be construed to require a health insurer to provide coverage for any health care services, including investigational drugs, biological products or medical devices, that would not otherwise be a covered benefit under an eligible patient's health insurance policy.

Section 5. Unprofessional conduct.

(a) Health care provider immunity.—A health care provider who while exercising reasonable care recommends or participates in the use of an investigational drug, biological product or medical device under this act may not be subject to criminal or civil liability nor be found to have committed an act of unprofessional conduct under any law of this Commonwealth relating to licensure.

(b) Health care provider licensure not affected.—Notwithstanding any other law to the contrary, a licensure board may not revoke, suspend or otherwise take any action against:

(1) an individual holding a license issued by a Commonwealth licensure board based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or medical device, as long as the recommendations are consistent with medical standards of care; or

(2) any other licensee of the Commonwealth solely for participating in the use of an investigational drug, biological product or medical device in good faith and in accordance with the provisions of this act.

Section 6. Construction.

Nothing in this act may be construed as creating a private cause of action against a manufacturer of an investigational drug, biological product or medical device, or against any other person or entity involved in the care of an eligible patient using an investigational drug, biological product or medical device for any injury suffered by the eligible patient resulting from the investigational drug, biological product or medical device, as long as the manufacturer or other person or entity acted in accordance with this act, except when the injury results from a failure to exercise reasonable care.

Section 7. Effective date.

This act shall take effect in 60 days.

APPROVED—The 11th day of October, A.D. 2017

TOM WOLF