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THE GENERAL ASSEMBLY OF PENNSYLVANIA

# SENATE BILL

## No. 572 Session of 2017

INTRODUCED BY DINNIMAN, FONTANA, VULAKOVICH, MENSCH AND RAFFERTY, APRIL 6, 2017

REFERRED TO HEALTH AND HUMAN SERVICES, APRIL 6, 2017

AN ACT

Providing for the use of investigational drugs, biological products and devices by terminally ill patients under 18 years of age.

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 Right to Try for Terminally Ill Children 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 devices in the United States protects future patients from premature, ineffective and unsafe medications and treatments over the long run, but the process often takes many years.

(2) The Commonwealth is committed to providing access to life-saving treatments for its youngest and most vulnerable

populations. Patients under 18 years of age who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product or device receives final approval from the United States Food and Drug Administration.

(3) Patients under 18 years of age who have a terminal illness have a fundamental right to attempt to pursue the preservation of their lives by accessing available investigational drugs, biological products and devices.

(4) The use of available investigational drugs, biological products and devices is a decision that should be made by the parent or legal guardian of a patient under 18 years of age with a terminal illness in consultation with the patient's health care provider and the patient's health care team, if applicable.

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

(b) Intent.--It is the intent of the General Assembly to allow terminally ill patients under 18 years of age to use potentially life-saving investigational drugs, biological products and 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."

(1) A person who has:

(i) A terminal illness, attested to by the patient's

treating health care provider.

(ii) Carefully considered all other treatment options approved by the United States 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 health care provider for an investigational drug, biological product or device.

(v) A parent or legal guardian who has given written, informed consent on the patient's behalf for the use of the investigational drug, biological product or device.

(vi) Documentation from the patient's treating health care provider that the patient meets the requirements of this paragraph.

(vii) Not yet attained 18 years of age.

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

"Health care provider." A licensed hospital or health care facility, medical equipment supplier or person who is licensed, certified or otherwise regulated to provide health care services under the laws of this Commonwealth, including a physician, podiatrist, optometrist, psychologist, physical therapist, certified nurse practitioner, registered nurse, nurse midwife, physician's assistant, chiropractor, dentist, pharmacist or an individual accredited or certified to provide behavioral health

services.

"Investigational drug, biological product or device." A drug, biological product or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration for patients under 18 years of age and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

"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 a patient's medical record, signed by the patient's parent or legal guardian on the patient's behalf and attested to by the patient's treating health care provider and a witness that, at a minimum:

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

(2) Attests to the fact that the patient's parent or legal guardian concurs with the patient's treating health care provider in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(3) Clearly identifies the specific proposed investigational drug, biological product or device that the patient seeks to use.

(4) Describes the potentially best and worst outcomes of using the investigational drug, biological product or 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 health care provider's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

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

Section 4. Access.

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

(b) Costs.--A manufacturer may provide an investigational drug, biological product or device to an eligible patient without receiving compensation.

(c) Health insurers.--

(1) Except as provided in paragraph (2), a health insurer shall provide coverage for the cost of an investigational drug, biological product or device.

(2) Coverage may not be denied for a preexisting condition or in a case where coverage commenced prior to the time the eligible patient begins use of the investigational drug, biological product or device.

Section 5. Unprofessional conduct.

(a) Health care provider immunity.--No health care provider who in good faith recommends or participates in the use of an investigational drug, biological product or device under this

act shall be subject to criminal or civil liability or 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, no Commonwealth licensure board may revoke, suspend or otherwise take any action against an individual holding a license issued by the Commonwealth licensure board based solely on the individual's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device, as long as the recommendations are consistent with medical standards of care.

Section 6. Construction.

Nothing in this act shall be construed as creating a private cause of action against a manufacturer of an investigational drug, biological product or device or against any other person or entity involved in the care of an eligible patient using an investigational drug, biological product or device for any injury suffered by the eligible patient resulting from the investigational drug, biological product or 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.