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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2633 Session of 2018

INTRODUCED BY GODSHALL, BARRAR, BERNSTINE, CALTAGIRONE, CHARLTON, DONATUCCI, DRISCOLL, PHILLIPS-HILL, HILL-EVANS, KEEFER, MARSHALL, J. McNEILL, MILLARD, PICKETT, QUIGLEY, READSHAW, SAYLOR, WARD AND ZIMMERMAN, SEPTEMBER 11, 2018

REFERRED TO COMMITTEE ON HEALTH, SEPTEMBER 11, 2018

AN ACT

Amending the act of October 11, 2017 (P.L.347, No.33), entitled "An act providing for the use of investigational drugs, biological products and medical devices by terminally ill patients," further providing for title of act, for legislative findings and intent, for definitions and for access; providing for the use of investigational stem cell treatments; and further providing for unprofessional conduct and for construction.

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

Section 1. The title and section 2 of the act of October 11, 2017 (P.L.347, No.33), known as the Right-to-Try Act, are amended to read:

An Act

Providing for the use of investigational drugs, biological products and medical devices by terminally ill patients <u>and for the use of investigational stem cell treatments by patients with terminal illnesses or severe chronic diseases</u>.

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 and investigational stem cell treatments 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 or severe chronic disease do not have the luxury of waiting until an investigational drug, biological product [or], medical device or investigational stem cell treatment receives final approval from the Food and Drug Administration.

(3) Patients who have a terminal illness or severe chronic disease should be allowed to attempt to pursue the preservation of their lives by accessing available investigational drugs, biological products [and], medical devices and investigational stem cell treatments.

(4) The use of available investigational drugs, biological products [and], medical devices and investigational stem cell treatments is a decision that should be made by the patient with a terminal illness or severe chronic disease 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 or investigational stem cell treatment 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[.] and to allow patients with terminal illnesses or severe chronic diseases to use potentially life-saving investigational stem cell treatments.

Section 2. The definition of "written, informed consent" in section 3 of the act is amended and the section is amended by adding definitions to read:

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:

"Adult stem cell." An undifferentiated cell that is:

(1) found in differentiated tissue; and

(2) able to renew itself and differentiate to yield all or nearly all of the specialized cell types of the tissue from which the cell originated.

"Department." The Department of Health of the Commonwealth.

"Eligible patient with terminal illness or severe chronic disease." An individual:

(1) Who has a terminal illness or severe chronic disease attested to by the patient's treating physician.

(2) Whose physician:

(i) in consultation with the patient, has considered all other treatment options currently approved by the United States Food and Drug Administration and determined that those treatment options are unavailable or unlikely to alleviate the significant impairment or severe pain associated with the terminal illness or severe chronic disease; and

(ii) has recommended or prescribed in writing that the patient use a specific class of investigational stem cell treatment.

(3) Who has given written, informed consent for the use of the investigational stem cell treatment, 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.

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"Investigational stem cell treatment." An adult stem cell treatment that:

(1) is under investigation in a clinical trial and being administered to human participants in that trial; and

(2) has not yet been approved for general use by the United States Food and Drug Administration.

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"Severe chronic disease." A condition, injury or illness that:

(1) may be treated;

(2) is never cured or eliminated; and

(3) entails significant functional impairment or severe pain.

* * *

"Patient." An eligible patient or an eligible patient with terminal or severe chronic disease

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"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 or investigational stem cell treatment 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 or investigational stem cell treatment 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 investigational stem cell treatment or any care or treatments consequent to the use of the investigational drug, biological product [or], medical device or investigational stem cell treatment.

(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 or investigational stem cell treatment, 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 or investigational stem cell treatment states otherwise.

Section 3. Section 4 of the act is amended to read:

Section 4. Access.

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

(b) Costs.--A manufacturer may:

(1) Provide an investigational drug, biological product [or], medical device or investigational stem cell treatment to [an eligible] a patient without receiving compensation.

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

(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 or investigational stem cell treatment, that would not otherwise be a covered benefit under [an eligible] a patient's health insurance policy.

Section 4. The act is amended by adding a section to read:

Section 4.1. Investigational stem cell treatments.

(a) Patient eligibility.--An eligible patient with terminal illness or severe chronic disease may access and use an investigational stem cell treatment in accordance with this section.

(b) Treatment requirements.--Investigational stem cell treatment provided under this section must be:

(1) Administered directly by a physician certified under subsection (c).

(2) Provided at:

(i) a hospital, 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

(ii) an ambulatory surgical facility, as defined in section 802.1 of the Health Care Facilities Act.

(c) Effect on other law.--This section does not:

(1) Affect the coverage of enrollees in clinical trials.

(2) Authorize a person to violate any law regulating the possession, use or transfer of fetal tissue, fetal stem cells, adult stem cells or human organs.

(d) Governmental interference prohibited.--A governmental entity may not interfere with an eligible patient with terminal illness or severe chronic disease access to or use of an authorized investigational stem cell treatment. For purposes of this subsection, the term "governmental entity" means the Commonwealth or a political subdivision and any person elected or appointed to any office of, or hired, employed or contracted by, the Commonwealth or a political subdivision when acting within the scope of those duties.

Section 5. Sections 5 and 6 of the act are amended to read:

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 or investigational stem cell treatment 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] a patient regarding access to or treatment with an investigational

drug, biological product [or], medical device or investigational stem cell treatment, 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 or investigational stem cell treatment 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 investigational stem cell treatment, or against any other person or entity involved in the care of [an eligible] a patient using an investigational drug, biological product [or], medical device or investigational stem cell treatment for any injury suffered by the [eligible] patient resulting from the investigational drug, biological product [or], medical device or investigational stem cell treatment, 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 6. This act shall take effect in 60 days.