AMENDMENTS TO SENATE BILL NO. 3

Sponsor: REPRESENTATIVE BAKER

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Amend Bill, page 1, lines 1 through 16; pages 2 and 3, lines 1 through 30; page 4, line 1; by striking out all of said lines on said pages and inserting

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

Amend Bill, page 4, lines 4 through 30; pages 5 through 68, lines 1 through 30; page 69, lines 1 through 27; by striking out all of said lines on said pages and inserting

Section 1. Short title.

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

Section 2. 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) A person who has:

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

(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 physician for an investigational drug, biological product or device;

(v) given written, informed consent for the use of the investigational drug, biological product or device or, if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal

guardian 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) A person with a qualifying medical condition who seeks to use only an investigational cannabis product.

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

"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.

"Investigational cannabis product." A pharmaceutical product which has been approved for study by the United States Food and Drug Administration, but is not yet approved for general use by the United States Food and Drug Administration, which contains a derivative of cannabis.

"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 and remains under investigation in a clinical trial approved by the United States 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.

"Qualifying medical condition." As follows:

(1) Cancer.

(2) Epilepsy and seizures.

(3) Amyotrophic lateral sclerosis.

(4) Cachexia/wasting syndrome.

(5) Parkinson's disease.

(6) Traumatic brain injury and postconcussion syndrome.

(7) Multiple sclerosis.

(8) Spinocerebellar ataxia (SCA).

(9) HIV/AIDS.

(10) Glaucoma.

"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 signed by the patient and attested to by the 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 patient suffers.

(2) Attests to the fact that the patient concurs with the patient's treating physician 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 or investigational cannabis product that the patient is seeking to use.

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

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

(6) 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.

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

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

Section 3. Access.

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

(b) Costs.--A manufacturer may:

(1) Provide an investigational drug, biological product or device or investigational cannabis product 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 device or investigational cannabis product.

(c) Insurers.--A health insurer may:

(1) In its discretion, provide coverage for the cost of an investigational drug, biological product or device or investigational cannabis product.

(2) Except as set forth in subsection (d), deny coverage

to an eligible patient from the time the eligible patient begins use of the investigational drug, biological product or device or investigational cannabis product through a period not to exceed six months from the time the investigational drug, biological product or device or investigational cannabis product is no longer used by the eligible patient.

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

Section 4. Unprofessional conduct.

(a) Physician immunity.--No physician who in good faith recommends or participates in the use of an investigational drug, biological product or device or investigational cannabis product under this act shall be subject to criminal or civil liability, nor shall a physician be found to have committed an act of unprofessional conduct under the act of October 5, 1978 (P.L.1109, No.261), known as the Osteopathic Medical Practice Act, or the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985.

(b) Physician licensure not affected.--Notwithstanding any other law to the contrary, the State Board of Medicine and the State Board of Osteopathic Medicine may not revoke, suspend or otherwise take any action against an individual holding a license issued under the Osteopathic Medical Practice Act or the Medical Practice Act of 1985 based solely on the individual's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device or investigational cannabis product as long as the recommendations are consistent with standards of care as set forth by the manufacturer. Any action against an individual or entity's Medicare certification based solely on recommendations that a patient have access to an investigational drug, biological product or device or investigational cannabis product is prohibited.

Section 5. 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 investigational cannabis product or against any other person or entity involved in the care of an eligible patient using an investigational drug, biological product or device or investigational cannabis product for any injury suffered by the eligible patient resulting from the investigational drug, biological product or device or investigational cannabis product 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. Protection from prosecution.

In the prosecution for the unlawful possession of marijuana

under the laws of this Commonwealth, it is an affirmative and complete defense to the prosecution that the individual has a qualifying illness and is using or possessing marijuana at the recommendation of a physician to use cannabis or the individual is the parent of a minor child with a terminal illness and is in possession of marijuana for the benefit of the minor child who has a recommendation of a physician to use cannabis.

Section 7. Effective date.

This act shall take effect in 60 days.