

## AMENDMENTS TO SENATE BILL NO. 3

Sponsor: REPRESENTATIVE BAKER

Printer's No. 889

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

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

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

9 Section 1. Short title.

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

12 Section 2. Definitions.

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

16 "Eligible patient." As follows:

17 (1) A person who has:

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

20 (ii) carefully considered all other treatment  
21 options approved by the United States Food and Drug  
22 Administration;

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

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

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

1 guardian has given written, informed consent on the  
2 patient's behalf; and

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

6 (2) A person with a qualifying medical condition who  
7 seeks to use only an investigational cannabis product.

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

10 "Hospital." As defined in section 802.1 of the act of July  
11 19, 1979 (P.L.130, No.48), known as the Health Care Facilities  
12 Act.

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

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

25 "Physician." As defined in section 2 of the act of December  
26 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of  
27 1985.

28 "Qualifying medical condition." As follows:

- 29 (1) Cancer.
- 30 (2) Epilepsy and seizures.
- 31 (3) Amyotrophic lateral sclerosis.
- 32 (4) Cachexia/wasting syndrome.
- 33 (5) Parkinson's disease.
- 34 (6) Traumatic brain injury and postconcussion syndrome.
- 35 (7) Multiple sclerosis.
- 36 (8) Spinocerebellar ataxia (SCA).
- 37 (9) HIV/AIDS.
- 38 (10) Glaucoma.

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

42 "Written, informed consent." A written document signed by  
43 the patient and attested to by the patient's treating physician  
44 and a witness that, at a minimum:

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

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

1 (3) Clearly identifies the specific proposed  
2 investigational drug, biological product or device or  
3 investigational cannabis product that the patient is seeking  
4 to use.

5 (4) Describes the potentially best and worst outcomes of  
6 using the investigational drug, biological product or device  
7 or investigational cannabis product with a realistic  
8 description of the most likely outcome, including the  
9 possibility that new, unanticipated, different or worse  
10 symptoms might result, and that death could be hastened by  
11 the proposed treatment, based on the physician's knowledge of  
12 the proposed treatment in conjunction with an awareness of  
13 the patient's condition.

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

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

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

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

33 Section 3. Access.

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

39 (b) Costs.--A manufacturer may:

40 (1) Provide an investigational drug, biological product  
41 or device or investigational cannabis product to an eligible  
42 patient without receiving compensation.

43 (2) Require an eligible patient to pay the costs of, or  
44 the costs associated with, the manufacture of the  
45 investigational drug, biological product or device or  
46 investigational cannabis product.

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

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

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

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

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

#### 12 Section 4. Unprofessional conduct.

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

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

#### 37 Section 5. Construction.

38 Nothing in this act shall be construed as creating a private  
39 cause of action against a manufacturer of an investigational  
40 drug, biological product or device or investigational cannabis  
41 product or against any other person or entity involved in the  
42 care of an eligible patient using an investigational drug,  
43 biological product or device or investigational cannabis product  
44 for any injury suffered by the eligible patient resulting from  
45 the investigational drug, biological product or device or  
46 investigational cannabis product as long as the manufacturer or  
47 other person or entity acted in accordance with this act, except  
48 when the injury results from a failure to exercise reasonable  
49 care.

#### 50 Section 6. Protection from prosecution.

51 In the prosecution for the unlawful possession of marijuana

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

8 Section 7. Effective date.

9 This act shall take effect in 60 days.