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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 45 Session of  
2017

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JANUARY 23, 2017

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SENATOR BAKER, HEALTH AND HUMAN SERVICES, IN SENATE, AS AMENDED,  
JUNE 21, 2017

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AN ACT

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

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

5 Section 1. Short title.

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

8 Section 2. Legislative findings and intent.

9 (a) Findings and declarations.--The General Assembly finds  
10 and declares as follows:

11 (1) The process of approval for investigational drugs,  
12 biological products and medical devices in the United States  
13 by the Federal Food and Drug Administration protects future  
14 patients from premature, ineffective and unsafe medications

1 and treatments over the long run, but the process often takes  
2 many years.

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

7 (3) Patients who have a terminal illness ~~have a~~ <--  
8 ~~fundamental right~~ SHOULD BE ALLOWED to attempt to pursue the <--  
9 preservation of their lives by accessing available  
10 investigational drugs, biological products and medical  
11 devices.

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

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

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

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

30 Section 3. Definitions.

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

4       "Eligible patient." As follows:

5           (1) An individual who has:

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

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

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

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

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

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

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

30       "Health care provider." A licensed health care facility, as

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

7 "Investigational drug, biological product or medical device."

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

13 "Physician." As defined in section 2 of the act of December  
14 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of  
15 1985.

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

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

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

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

30 (3) Identifies clearly the specific proposed

1 investigational drug, biological product or medical device  
2 that the patient is seeking to use.

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

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

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

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

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

30 Section 4. Access.

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

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

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

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

12 (c) Insurers.--Nothing in this act may be construed to  
13 require a health insurer to provide coverage for any health care  
14 services, including investigational drugs, biological products  
15 or medical devices, that would not otherwise be a covered  
16 benefit under an eligible patient's health insurance policy.  
17 Section 5. Unprofessional conduct.

18 (a) Health care provider immunity.--A health care provider  
19 who ~~in good faith~~ WHILE EXERCISING REASONABLE CARE recommends or <--  
20 participates in the use of an investigational drug, biological  
21 product or medical device under this act may not be subject to  
22 criminal or civil liability, nor be found to have committed an  
23 act of unprofessional conduct under any law of this Commonwealth  
24 relating to licensure.

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

28 (1) an individual holding a license issued by a  
29 Commonwealth licensure board based solely on the health care  
30 provider's recommendations to an eligible patient regarding

1 access to or treatment with an investigational drug,  
2 biological product or medical device, as long as the  
3 recommendations are consistent with medical standards of  
4 care; or

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

9 Section 6. Construction.

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

20 Section 7. Effective date.

21 This act shall take effect in 60 days.