

# STATE OF NEW YORK

3932

2017-2018 Regular Sessions

## IN ASSEMBLY

January 30, 2017

Introduced by M. of A. ROSENTHAL, GUNTHER, GALEF, ZEBROWSKI, BENEDETTO, ARROYO, COLTON, M. G. MILLER, COOK -- Multi-Sponsored by -- M. of A. BLAKE, SIMON -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to establishing the "right to try act"

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. This act shall be known and may be cited as the "right to try act".

§ 2. The public health law is amended by adding a new article 29-CCCC to read as follows:

### ARTICLE 29-CCCC

#### RIGHT TO TRY ACT

#### Section 2994-aaa. Definitions.

2994-bbb. Manufacturers' obligations.

2994-ccc. Coverage.

2994-ddd. Liability for patient debt.

2994-eee. Actions against license or certification.

2994-fff. Immunity.

2994-ggg. Access to treatment.

2994-hhh. Cause of action.

§ 2994-aaa. Definitions. The following words and terms within this article shall have the following meanings, unless the context clearly indicates otherwise.

1. "Terminal illness", for purposes of this article only, means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating health care provider to be reversible even with administration of current United States food and drug administration approved and available treatments and that, without life-sustaining procedures, will soon result in death.

EXPLANATION--Matter in italics (underscored) is new; matter in brackets [-] is old law to be omitted.

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1     2. "Eligible patient" means an individual who meets all of the follow-  
2 ing conditions:

3     (a) has a terminal illness, attested to by the patient's treating  
4 health care provider.

5     (b) has considered all other treatment options currently approved by  
6 the United States food and drug administration.

7     (c) has received a recommendation from his or her treating health care  
8 provider for an investigational drug, biological product or device.

9     (d) has given written, informed consent for the use of the investiga-  
10 tional drug, biological product or device.

11     (e) has documentation from his or her treating health care provider  
12 that he or she meets the requirements of this subdivision.

13     3. "Investigational drug, biological product or device" means a drug,  
14 biological product or device that has successfully completed phase one  
15 of a clinical trial but has not yet been approved for general use by the  
16 United States food and drug administration and remains under investi-  
17 gation in a United States food and drug administration-approved clinical  
18 trial.

19     4. "Written, informed consent" means a written document that is signed  
20 by the patient; parent, if the patient is a minor; legal guardian; or  
21 health care agent designated by the patient under article twenty-nine-C  
22 of this chapter and attested to by the patient's treating health care  
23 provider and a witness and that, at a minimum, includes all of the  
24 following:

25     (a) an explanation of the currently approved products and treatments  
26 for the disease or condition from which the patient suffers.

27     (b) an attestation that the patient concurs with his or her treating  
28 health care provider in believing that all currently approved and  
29 conventionally recognized treatments are unlikely to prolong the  
30 patient's life.

31     (c) clear identification of the specific proposed investigational  
32 drug, biological product or device that the patient is seeking to use.

33     (d) a description of the potentially best and worst outcomes of using  
34 the investigational drug, biological product or device and a realistic  
35 description of the most likely outcome. The description shall include  
36 the possibility that new, unanticipated, different or worse symptoms  
37 might result and that death could be hastened by the proposed treatment.  
38 The description shall be based on the health care provider's knowledge  
39 of the proposed treatment in conjunction with an awareness of the  
40 patient's condition.

41     (e) a statement that the patient's health plan or third party adminis-  
42 trator and provider are not obligated to pay for any care or treatments  
43 consequent to the use of the investigational drug, biological product or  
44 device, unless they are specifically required to do so by law or  
45 contract.

46     (f) a statement that the patient's eligibility for hospice care may be  
47 withdrawn if the patient begins curative treatment with the investiga-  
48 tional drug, biological product or device and that care may be rein-  
49 stated if this treatment ends and the patient meets hospice eligibility  
50 requirements.

51     (g) a statement that the patient understands that he or she is liable  
52 for all expenses consequent to the use of the investigational drug,  
53 biological product or device and that this liability extends to the  
54 patient's estate, unless a contract between the patient and the manufac-  
55 turer of the drug, biological product or device states otherwise.

1     § 2994-bbb. Manufacturers' obligations. 1. A manufacturer of an inves-  
2 tigational drug, biological product or device may make available and an  
3 eligible patient may request the manufacturer's investigational drug,  
4 biological product or device under this section. This section does not  
5 require that a manufacturer make available an investigational drug,  
6 biological product or device to an eligible patient.

7     2. A manufacturer may:

8     (a) provide an investigational drug, biological product or device to  
9 an eligible patient without receiving compensation; or

10    (b) require an eligible patient to pay the costs of, or the costs  
11 associated with, the manufacture of the investigational drug, biological  
12 product or device.

13    § 2994-ccc. Coverage. 1. This article does not expand the coverage  
14 required of an insurer under the insurance law or any other applicable  
15 laws.

16    2. A health plan, third party administrator, or governmental agency  
17 may, but is not required to, provide coverage for the cost of an inves-  
18 tigational drug, biological product or device or the cost of services  
19 related to the use of an investigational drug, biological product or  
20 device under this article.

21    3. This article does not require any governmental agency to pay costs  
22 associated with the use, care or treatment of a patient with an investi-  
23 gational drug, biological product or device.

24    4. This article does not require a hospital or facility established  
25 under article twenty-eight of this chapter to provide new or additional  
26 services, unless approved by the hospital or facility.

27    5. This article does not affect any mandatory health care coverage for  
28 participation in clinical trials under the insurance law or other appli-  
29 cable laws.

30    § 2994-ddd. Liability for patient debt. If a patient dies while being  
31 treated by an investigational drug, biological product or device, the  
32 patient's heirs are not liable for any outstanding debt related to the  
33 treatment or lack of insurance due to the treatment.

34    § 2994-eee. Actions against license or certification. A licensing  
35 board or disciplinary subcommittee shall not revoke, fail to renew,  
36 suspend or take any action against a health care provider's license  
37 based solely on the provider's recommendations to an eligible patient  
38 regarding access to or treatment with an investigational drug, biolog-  
39 ical product or device. An entity responsible for medicare certification  
40 shall not take action against a health care provider's medicare certifi-  
41 cation based solely on the health care provider's recommendation that  
42 an eligible patient have access to an investigational drug, biological  
43 product or device.

44    § 2994-fff. Immunity. If as a result of the investigational drug,  
45 biological product or device, a patient's symptoms worsen or change or a  
46 patient dies, no health care provider shall be subject to civil liabil-  
47 ity provided that such health care provider participated in good faith  
48 compliance with the provisions of this article and obtained written,  
49 informed consent from the patient.

50    § 2994-ggg. Access to treatment. An official, employee or agent of  
51 this state shall not block or attempt to block an eligible patient's  
52 access to an investigational drug, biological product or device. Coun-  
53 seling, advice or a recommendation consistent with medical standards of  
54 care from a licensed health care provider is not a violation of this  
55 section.

1     § 2994-hhh. Cause of action. This section does not create a private  
2 cause of action against a manufacturer of an investigational drug,  
3 biological product or device or against any other person or entity  
4 involved in the care of an eligible patient using the investigational  
5 drug, biological product or device for any harm done to the eligible  
6 patient resulting from the investigational drug, biological product or  
7 device, if the manufacturer or other person or entity is complying in  
8 good faith with the terms of this article and has exercised reasonable  
9 care.

10     § 3. This act shall take effect on the ninetieth day after it shall  
11 have become a law.