

SENATE, No. 1143

STATE OF NEW JERSEY 219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

Sponsored by:

Senator JOSEPH F. VITALE

District 19 (Middlesex)

SYNOPSIS

Establishes “Right to Try Act” permitting terminally ill patients to access investigational drugs and treatment.

CURRENT VERSION OF TEXT

As introduced.



1 **AN ACT** concerning access to investigational health care treatment
2 and supplementing Title 26 of the Revised Statutes.

3

4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

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7 1. This act shall be known and may be cited as the “Right to
8 Try Act.”

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10 2. The Legislature finds and declares that:

11 a. The process of approval for investigational drugs, biological
12 products, and devices in the United States often takes many years.

13 b. Patients who are terminally ill do not have the luxury of
14 waiting until an investigational drug, biological product, or device
15 receives final approval from the United States Food and Drug
16 Administration.

17 c. The standards of the United States Food and Drug
18 Administration for the use of investigational drugs, biological
19 products, and devices may deny the benefits of potentially life-
20 saving treatments to patients who have a terminal illness.

21 d. Patients who are terminally ill have a fundamental right to
22 attempt to pursue the preservation of their lives by accessing
23 available investigational drugs, biological products, and devices.

24 e. The use of available investigational drugs, biological
25 products, and devices is a decision that should be made by the
26 patient in consultation with the patient’s health care provider and is
27 not a decision to be made by the government.

28 f. The decision to use an investigational drug, biological
29 product, or device should be made with full awareness of the
30 potential risks, benefits, and consequences to the patient and the
31 patient’s family.

32 g. It is the intent of the Legislature to allow patients who are
33 terminally ill to use potentially life-saving investigational drugs,
34 biological treatments, and devices.

35

36 3. As used in this act:

37 “Eligible patient” means a person who has:

38 (1) A terminal illness;

39 (2) Considered all other treatment options currently approved by
40 the United States Food and Drug Administration in consultation
41 with a physician licensed pursuant to Title 45 of the Revised
42 Statutes;

43 (3) Received a prescription or recommendation by a physician
44 for an investigational drug, biological product, or device;

45 (4) Given informed, written consent for the use of the
46 investigational drug, biological product, or device. If the patient is
47 a minor or lacks the mental capacity to provide informed consent, a

1 parent or legal guardian may provide informed, written consent on
2 the patient's behalf; and

3 (5) Documentation from the physician indicating the person has
4 met these requirements.

5 "Investigational drug, biological product, or device" means a
6 drug, biological product, or device that has successfully completed
7 phase one of a clinical trial approved by the United States Food and
8 Drug Administration, but has not been approved for general use by
9 the United States Food and Drug Administration and remains under
10 investigation in a clinical trial approved by the United States Food
11 and Drug Administration.

12 "Terminal illness" means a medical condition that results in a
13 patient's life expectancy being 12 months or less as determined by a
14 physician.

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16 4. a. A manufacturer of an investigational drug, biological
17 product, or device may make available the manufacturer's
18 investigational drug, biological product, or device to eligible
19 patients pursuant to this act. Nothing in this act shall be construed
20 to require a manufacturer to make an investigational drug,
21 biological product, or device available.

22 b. A manufacturer may:

23 (1) Provide an investigational drug, biological product, or
24 device to an eligible patient without receiving compensation; or

25 (2) Require an eligible patient to pay the costs associated with
26 the manufacture of the investigational drug, biological product, or
27 device.

28

29 5. A government medical assistance program or private health
30 insurer may, but is not required to, provide coverage for the cost of
31 an investigational drug, biological product, or device.

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33 6. The State Board of Medical Examiners shall not revoke a
34 license, fail to renew a license, or take any other disciplinary action
35 under Title 45 of the Revised Statutes against a physician solely
36 based on the physician's recommendation, prescription, or
37 treatment of an eligible patient with an investigational drug,
38 biological product, or device consistent with this act.

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40 7. Any official, employee, or agent of a State or local
41 government who attempts to block or who does block access of an
42 eligible patient to an investigational drug, biological product, or
43 device is a disorderly person.

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45 8. If any provision of this act or its application to any person or
46 circumstance is held invalid, the invalidity shall not affect any other
47 provision or application of the act which can be given effect

1 without the invalid provision or application, and to this end the
2 provisions of this act are severable.

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4 9. This act shall take effect immediately.

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STATEMENT

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9 This bill would permit patients who are terminally ill to access
10 investigational drugs, biological products, and devices that have not
11 yet been approved by the United States Food and Drug
12 Administration (FDA).

13 To use an investigational drug, biological product, or device, the
14 patient would be required to: have a medical condition that results
15 in a life expectancy of less than 12 months; have consulted with a
16 physician and considered all other treatment options currently
17 approved by the FDA; have received a prescription or
18 recommendation from a physician for the investigational drug,
19 biological product, or device; and give informed, written consent to
20 use of the investigational drug, biological product, or device. The
21 physician would be required to document that the patient has met
22 these requirements.

23 The bill would require that the investigational drug, biological
24 product, or device has successfully completed phase one of an
25 FDA-approved clinical trial and remains under investigation in an
26 FDA-approved clinical trial. The manufacturer would be permitted
27 to provide the investigational drug, biological product, or device
28 without compensation or require the patient pay the costs associated
29 with its manufacture. Government medical assistance programs and
30 private health insurers would not be required to provide coverage
31 for the cost of an investigational drug, biological product, or device,
32 but private insurers would be permitted to provide coverage if they
33 so choose.

34 The bill would prohibit the State Board of Medical Examiners
35 from revoking a license, failing to renew a license, or taking any
36 other disciplinary action against a physician solely based on the
37 physician's recommendation, prescription, or treatment of an
38 eligible patient with an investigational drug, biological product, or
39 device consistent with the provisions of the bill.

40 Any official, employee, or agent of a State or local government
41 who attempts to block or who does block access of an eligible
42 patient to an investigational drug, biological product, or device
43 would be a disorderly person, which offense is punishable by
44 imprisonment for up to six months, a \$1,000 fine, or both.