# WEST VIRGINIA LEGISLATURE

## 2016 REGULAR SESSION

## Introduced

# Senate Bill 416

BY SENATORS TAKUBO, TRUMP, BLAIR AND KESSLER

[Introduced January 28, 2016;

Referred to the Committee on Health and

Human Resources.]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §16-51-1, §16-51-2, §16-51-3, §16-51-4, §16-51-5, §16-51-6, §16-51-7 and §16-51-8, all relating to allowing terminally ill patients to have access to investigational products that have not been approved by the federal Food and Drug Administration that other patients have access to when they participate in clinical trials; establishing short title; setting out Legislative findings; defining terms; allowing drug manufacturers to provide investigative products; setting forth insurance requirements; and prohibiting action.

*Be it enacted by the Legislature of West Virginia:*

That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new article, designated §16-51-1, §16-51-2, §16-51-3, §16-51-4, §16-51-5, §16-51-6, §16-51-7 and §16-51-8, all to read as follows:

**ARTICLE 51. RIGHT TO TRY ACT.**

**§16-51-1. Short title.**

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

**§16-51-2. Legislative findings.**

(a) The Legislature finds and declares that:

(1) The process of approval for investigational drugs, biological products and devices in the United States protects future patients from premature, ineffective and unsafe medications and treatments over the long run, but the process often takes many years;

(2) Patients who have a terminal illness do not have the luxury of waiting until an investigational drug, biological product or device receives final approval from the United States Food and Drug Administration;

(3) Patients who have a terminal illness have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products and devices;

(4) The use of available investigational drugs, biological products and devices is a decision that should be made by the patient with a terminal illness in consultation with the patient's health care provider and the patient's health care team, if applicable; and

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

(b) It is the intent of the Legislature to allow for terminally ill patients to use potentially life-saving investigational drugs, biological products and devices.

**§16-51-3. Definitions.**

For the purposes of this article:

(1) "Eligible patient" means a person who has:

(A) A terminal illness attested to by the patient's treating physician;

(B) Considered all other treatment options currently approved by the United States Food and Drug Administration;

(C) Been unable to participate in a clinical trial for the terminal illness within one hundred miles of the patient's home address for the terminal illness, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(D) Received a recommendation from his or her physician for an investigational drug, biological product or device;

(E) 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

(F) Documentation from his or her physician that he or she meets the requirements of this subdivision.

(2) “Eligible patient” does not include a person being treated as an inpatient in a hospital licensed or certified pursuant to section one, article five-b, chapter sixteen of this code.

(3) “Investigational drug, biological product or device” means 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 United States Food and Drug Administration-approved clinical trial.

(4) “Terminal illness” means a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

(5) “Written, informed consent” means a written document signed by the patient and attested to by the patient’s physician and a witness that, at a minimum:

(A) Explains the currently approved products and treatments for the disease or condition from which the patient suffers;

(B) Attests to the fact that the patient concurs with his or her physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient’s life;

(C) Clearly identifies the specific proposed investigational drug, biological product or device that the patient is seeking to use;

(D) Describes the potentially best and worst outcomes of using the investigational drug, biological product or device 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;

(E) Makes clear that the patient’s health insurer and provider may not be obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product or device;

(F) 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;

(G) Makes clear that in-home health care may be denied if treatment begins; and

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

**§16-51-4. Drug manufacturers; availability of investigational drugs, biological products or devices; costs; insurance coverage.**

(a) A manufacturer of an investigational drug, biological product or device may make available the manufacturer's investigational drug, biological product or device to eligible patients pursuant to this article. This article does not require that a manufacturer make available an investigational drug, biological product or device to an eligible patient.

(b) A manufacturer may:

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

(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.

(c) Nothing in this article expands the coverage required by article fifteen, chapter thirty-three of this code.

(d) A health insurance carrier may, but is not required by this article to, provide coverage for the cost of an investigational drug, biological product or device.

(e) An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the investigational drug, biologic product or device through a period not to exceed six months from the time the investigational drug, biologic product or device is no longer used by

the eligible patient; except that coverage may not be denied for a preexisting condition and for coverage for benefits which commenced prior to the time the eligible patient begins use of such drug, biologic product or device.

(f) If a patient dies while being treated by an investigational drug, biological product or device, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment.

**§16-51-5. Action against health care provider's license or Medicare certification prohibited.**

Notwithstanding any other law, a licensing board may not revoke, fail to renew, suspend or take any action against a health care provider's license issued pursuant to chapter thirty of this code based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device as long as the recommendations are consistent with medical standards of care. Action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product or device is prohibited.

**§16-51-6. Access to investigational drugs, biological products and devices.**

An official, employee or agent of this state shall not block or attempt to block an eligible patient's access to an investigational drug, biological product or device. Counseling, advice or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

**§16-51-7. No cause of action created.**

This article does not create a private cause of action against a manufacturer of an investigational drug, biological product or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product or device, for any harm done to the eligible patient resulting from the investigational drug, biological product or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this article, unless there was a failure to exercise reasonable care.

**§16-51-8. Effect on health care coverage.**

Nothing in this section affects the mandatory health care coverage for participation in clinical trials pursuant to section two, article twenty-five-f, chapter thirty-three of this code.

NOTE: The purpose of this bill is to allow terminally ill patients to have access to investigational products that have not been approved by the federal food and drug administration that other patients have access to when they participate in clinical trials.

Strike-throughs indicate language that would be stricken from a heading or the present law, and underscoring indicates new language that would be added.