House Bill 34

By: Representatives Dudgeon of the 25th, Spencer of the 180th, Teasley of the 37th, Gravley of the 67th, Turner of the 21st, and others

A BILL TO BE ENTITLED

AN ACT

To amend Title 31 of the Official Code of Georgia Annotated, relating to health, so as to enact the "Georgia Right to Try Act"; to provide for investigational drugs, biological products, and devices for patients with advanced illnesses; to provide for a short title; to provide for legislative findings; to provide for definitions; to provide for eligibility criteria; to provide for written informed consent; to allow manufacturers to make such drugs available; to provide that health benefit coverage is not mandatory; to prohibit sanctions against a physician's license; to prohibit blocking access; to provide for statutory construction; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Title 31 of the Official Code of Georgia Annotated, relating to health, is amended by adding a new chapter to read as follows:

"CHAPTER 50

31-50-1.

This chapter shall be known and may be cited as the 'Georgia Right to Try Act.'

31-50-2.

(a) The General Assembly 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 advanced illnesses do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the federal Food and Drug Administration;

(3) Patients who have advanced illnesses have a fundamental right 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 a patient with an advanced illness in consultation with the patient's health care provider;

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

(6) Any investigational drug, biological product, or device that is manufactured and sold solely within Georgia is not subject to federal regulation as it does not constitute interstate commerce.

(b) It is the intent of the General Assembly to allow for patients with advanced illnesses to use potentially life-saving investigational drugs, biological products, and devices.

31-50-3.

As used in this chapter, the term:

(1) 'Advanced illness' means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of current federal Food and Drug Administration approved and available treatments, and that, without life-sustaining procedures, will soon result in death.

(2) 'Eligible patient' means a person who meets the requirements of Code Section 31-50-4.

(3) 'Investigational drug, biological product, or device' means a drug, biological product, or device which has successfully completed Phase I of a federal Food and Drug Administration approved clinical trial but has not yet been approved for general use by the federal Food and Drug Administration and currently remains under investigation in a federal Food and Drug Administration approved clinical trial.

(4) 'Written informed consent' means a written document that:

(A) Is signed by the patient; parent, if the patient is a minor; legal guardian; or health care agent designated by the patient in an advance directive for health care executed pursuant to Chapter 32 of Title 31;

(B) Is attested to by the patient's physician and a witness; and

(C) Meets the requirements of Code Section 31-50-5.

31-50-4.

In order for a person to be considered an eligible patient to access an investigational drug, biological product, or device pursuant to this chapter, a physician must document in writing that the person:

(1) Has an advanced illness;

(2) Has, in consultation with the physician, considered all other treatment options currently approved by the federal Food and Drug Administration;

(3) Has been given a prescription or recommendation by the physician for an investigational drug, biological product, or device; and

(4) Has given written informed consent for the use of the investigational drug, biological product, or device.

31-50-5.

Written informed consent shall, at a minimum, include the following:

(1) A description of the currently approved products and treatments for the advanced illness from which the patient suffers;

(2) An attestation 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;

(3) Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use;

(4) A description of the potential best and worst outcomes of using the investigational drug, biological product, or device and a realistic description of the most likely outcome. The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(5) A statement that the patient understands that his or her health benefit plan is not obligated to pay for the investigational drug, biological product, or device, or any care or treatment consequent to the use of such drug, product, or device, unless such health benefit plan is specifically required to do so by law or contract;

(6) A statement that the patient understands that his or her eligibility for hospice care may be withdrawn if he or she begins treatment with the investigational drug, biological product, or device but that such hospice care may be reinstated if such treatment ends and he or she meets hospice eligibility requirements; and

(7) A statement that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that such liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise.

31-50-6.

(a) A manufacturer of an investigational drug, biological product, or device may make available and an eligible patient may request access to the manufacturer's investigational drug, biological product, or device pursuant to this chapter; provided, however, that nothing in this chapter shall be construed to require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may provide an investigational drug, biological product, or device to an eligible patient:

(1) Without receiving compensation; or

(2) With the requirement that the eligible patient pays the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

31-50-7.

A health benefit plan or governmental agency may provide coverage for the cost of any investigational drug, biological product, or device pursuant to this chapter; provided, however, that nothing in this chapter shall be construed to require a health benefit plan or governmental agency to provide coverage for the cost of any investigational drug, biological product, or device pursuant to this chapter.

31-50-8.

The Georgia Composite Medical Board shall not revoke, suspend, sanction, fail to renew, or take any other action against a physician's license solely based on such physician's recommendation, prescription, or treatment of an eligible patient with an investigational drug, biological product, or device pursuant to this chapter.

31-50-9.

No official, employee, or agent of the state shall block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. Counseling, advice, or a recommendation for treatment consistent with medical standards of care shall not be construed as a violation of this Code section.

31-50-10.

(a) This chapter shall not be construed to 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 an investigational drug, biological product, or device for any harm done to the eligible patient resulting from the investigational drug, biological product, or device if the manufacturer or other person or entity is complying in good faith with the terms of this chapter and has exercised reasonable care.

(b) This chapter shall not be construed to affect any required health care coverage under Title 33 for patients in clinical trials.″

SECTION 2.

All laws and parts of laws in conflict with this Act are repealed.