

House Bill 34 (AS PASSED HOUSE AND SENATE)

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

1 To amend Title 31 of the Official Code of Georgia Annotated, relating to health, so as to
2 enact the "Georgia Right to Try Act"; to provide for investigational drugs, biological
3 products, and devices for patients with terminal illnesses; to provide for a short title; to
4 provide for legislative findings; to provide for definitions; to provide for eligibility criteria;
5 to provide for written informed consent; to allow manufacturers to make such drugs
6 available; to provide that health benefit coverage is not mandatory; to prohibit sanctions
7 against a physician's license; to prohibit blocking access; to provide for statutory
8 construction; to amend Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia
9 Annotated, relating to medical practice, so as to repeal a provision regarding access to
10 medical treatment and experimental and nonconventional medical treatments; to provide for
11 related matters; to repeal conflicting laws; and for other purposes.

12 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

13 style="text-align:center">**SECTION 1.**

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

16 style="text-align:center">"CHAPTER 52

17 31-52-1.

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

19 31-52-2.

20 (a) The General Assembly finds and declares that:

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

24 (2) Patients who have terminal illnesses do not have the luxury of waiting until an
 25 investigational drug, biological product, or device receives final approval from the federal
 26 Food and Drug Administration;

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

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

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

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

38 31-52-3.

39 As used in this chapter, the term:

40 (1) 'Eligible patient' means a person who meets the requirements of Code Section
 41 31-52-4.

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

47 (3) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of
 48 Chapter 34 of Title 43.

49 (4) 'Terminal illness' means a disease that, without life-sustaining procedures, will result
 50 in death in the near future and is not considered by a treating physician to be reversible
 51 even with administration of current federal Food and Drug Administration approved and
 52 available treatments.

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

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

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

58 (C) Meets the requirements of Code Section 31-52-5.

59 31-52-4.

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

63 (1) Has a terminal illness;

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

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

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

70 31-52-5.

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

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

74 (2) An attestation that the patient concurs with his or her physician in believing that all
75 currently approved and conventionally recognized treatments are unlikely to prolong the
76 patient's life; and the known risks of the investigational drug, biological product, or
77 device are not greater than the probable outcome of the patient's terminal illness;

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

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

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

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

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

98 31-52-6.

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

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

106 (1) Without receiving compensation; or

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

109 31-52-7.

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

115 31-52-8.

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

120 31-52-9.

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

125 31-52-10.

126 (a) This chapter shall not be construed to create a private cause of action against a
 127 manufacturer of an investigational drug, biological product, or device or against any other
 128 person or entity involved in the care of an eligible patient using an investigational drug,
 129 biological product, or device for any harm done to the eligible patient resulting from the
 130 investigational drug, biological product, or device if the manufacturer or other person or
 131 entity is complying in good faith with the terms of this chapter and has exercised
 132 reasonable care.

133 (a.1) This chapter shall not be construed to create a private cause of action against a
 134 physician who refuses to recommend an investigational drug, biological product, or device
 135 for any otherwise eligible patient.

136 (b) Any person or entity providing treatment to an eligible patient using an investigational
 137 drug, biological product, or device shall not be liable for injury or death to such eligible
 138 patient as a result of the investigational drug, biological product, or device under Code
 139 Section 51-1-27 or 51-4-1, et seq., unless it is shown that the person or entity failed to
 140 obtain written informed consent in compliance with Code Section 31-52-5.

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

143 **SECTION 2.**

144 Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated, relating to
 145 medical practice, is amended by repealing and reserving Code Section 43-34-38, relating to
 146 access to medical treatment and experimental and nonconventional medical treatments.

147 **SECTION 3.**

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