SB357

167279-1

By Senators Ward, Scofield, Reed, Dunn, Waggoner and Stutts

RFD: Judiciary

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SYNOPSIS: This bill would authorize a terminally ill patient to use a drug or device that has completed phase 1 of a clinical trial under certain conditions.

A BILL

TO BE ENTITLED

AN ACT

To authorize access to and use of experimental treatments for patients with a terminal illness; to establish conditions for use of experimental treatment; to prohibit sanctions of health care providers solely for recommending or providing experimental treatment; to clarify duties of a health insurer with regard to experimental treatment authorized under this act; to prohibit certain actions by state officials, employees, and agents; and to restrict certain causes of action arising from experimental treatment.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. This act shall be known and may be cited as the Right to Try Act.

Section 2. As used in this act, the following words have the following meanings:

(1) ELIGIBLE PATIENT. An individual who meets all of the following conditions:

a. Has a terminal illness, attested to by the patient's treating physician.

b. Has considered all other treatment options currently approved by the U. S. Food and Drug Administration.

c. Has received a recommendation from his or her physician for an investigational drug, biological product, or device.

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

e. Has documentation from his or her physician that he or she meets the requirements of this subdivision.

(2) INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, or DEVICE. A drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not yet been approved for general use by the U. S. Food and Drug Administration and remains under investigation in a U. S. Food and Drug Administration approved clinical trial.

(3) TERMINAL ILLNESS. 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 drug administration approved and available treatments, and that, without life-sustaining procedures, will not soon result in death.

(4) WRITTEN, INFORMED CONSENT. A written document that is signed by the patient or the parent or legal guardian, if the patient is a minor, and attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

a. An explanation of the currently approved products and treatments for the disease or condition from which the patient suffers.

b. 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.

c. Clear identification of the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

d. A description of the potentially 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.

e. A statement that the patient's health plan or third party administrator and provider are not obliged to pay for any care or treatments consequent to the use of the investigational drug, biological product, or device, unless they are specifically required to do so by law or contract.

f. A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the investigational drug, biological product, or device and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.

g. 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 this 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.

Section 3. (a) The manufacturer of an investigational drug, biological product, or device may make available and an eligible patient may request the manufacturer's investigational drug, biological product, or device under this act. This act does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do all of the following:

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

(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.

Section 4. (a) This act does not expand the coverage required of an insurer.

(b) A health plan, third party administrator, or governmental agency is not required to but may provide coverage for the cost of an investigational drug, biological product, or device, or the cost of services related to the use of an investigational drug, biological product, or device under this act.

(c) This act does not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an investigational drug, biological product, or device.

(d) This act does not require a hospital or other health care facility to provide new or additional services, unless approved by the hospital or facility.

Section 5. 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.

Section 6. A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a health care provider's license issued under Title 34, Code of Alabama 1975, 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. An entity responsible for Medicare certification shall not take 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.

Section 7. 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.

Section 8. This act 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, if the manufacturer or other person or entity is complying in good

faith with the terms of this act and has exercised reasonable care.

Section 9. This act shall become effective on the first day of the third month following its passage and approval by the Governor, or its otherwise becoming law.