MISSISSIPPI LEGISLATURE REGULAR SESSION 2015

By: Senator(s) Harkins, Collins, Hill

To: Public Health and Welfare

SENATE BILL NO. 2485
(As Sent to Governor)

AN ACT ENTITLED THE "RIGHT TO TRY ACT"; TO AUTHORIZE LICENSED PHYSICIANS TO PRESCRIBE OR RECOMMEND CERTAIN INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS OR DEVICES TO CERTAIN ELIGIBLE TERMINALLY ILL PATIENTS; TO PROVIDE DEFINITIONS; TO AMEND SECTION 73-25-37, MISSISSIPPI CODE OF 1972, IN CONFORMITY; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. (1) This section shall be known and may be cited as the "Right to Try Act."

(2) For purposes of this section:

(a) "Eligible patient" means a person who meets all of the following requirements:

(i) Has a terminal illness, or a disability that will lead to the person's death;

(ii) Has considered all other treatment options currently approved by the United States Food and Drug Administration and all relevant clinical trials conducted in this state;

(iii) Has received a prescription or recommendation from the person's physician for an investigational drug, biological product or device;

(iv) Has given written informed consent, which shall be at least as comprehensive as the consent used in clinical trials 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

(v) Has documentation from the person's physician that the person has met all of the requirements of this subsection.

(b) "Investigational drug, biological product or device" means a drug, biological product or device, any of which are used to treat the patient's terminal illness, that has successfully completed phase one of a clinical trial but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial. The term shall not include Schedule I controlled substances.

(c) "Terminal illness" means a disease that without life-sustaining procedures will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

(d) "Written informed consent" means a written document that is:

(i) Signed by the:

1. Patient;

2. Parent, if the patient is a minor;

3. Legal guardian; or

4. Patient advocate designated by the patient under the Uniform Health-Care Decisions Act, Section 41-41-201 et seq.; and

(ii) Attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:

1. An explanation of the currently approved products and treatments for the disease or condition 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 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;

5. A statement that the patient's health plan or third-party administrator and provider are not obligated 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;

6. 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; 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 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.

(3) 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 under this section. This section does not require that a

manufacturer make available an investigational drug, biological product or device to an eligible patient. A manufacturer may:

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

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

(4) This section does not require a health care insurer to provide coverage for the cost of any investigational drug, biological product or device. However, a health care insurer may provide coverage for an investigational drug, biological product or device.

(5) This section does not require the Mississippi Department of Corrections or any other governmental agency to provide coverage for the cost of any investigational drug, biological product or device.

(6) This section does not require a licensed hospital or nursing home to provide new or additional services, unless approved by the hospital or facility.

(7) This section does not require a licensed physician to offer any investigational drug, biological product or device.

(8) Notwithstanding any other provision of law to the contrary, no state agency or regulatory board shall revoke, fail to renew, or take any other action against a physician's license

under Section 73-25-1 et seq., Mississippi Code of 1972, or against a pharmacist's license under Section 73-21-71 et seq., based solely on the physician's or pharmacist's recommendation to an eligible patient regarding prescription for or treatment with an investigational drug, biological product or device. 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.

(9) If the clinical trial is closed due to lack of efficacy or toxicity, the drug shall not be offered. If notice is given on a drug, product or device taken by a patient outside of a clinical trial, the pharmaceutical company or patient's physician shall notify the patient of the information from the safety committee of the clinical trial.

(10) Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, compounds or administers an investigational drug or device to an eligible patient with a terminal illness in accordance with this section shall not be liable in any action under state law for any loss, damage or injury arising out of, relating to, or resulting from:

(a) The design, development, clinical testing and investigation, manufacturing, labeling, distribution, sale,

purchase, donation, dispensing, compounding, prescription, administration, or use of the drug or device; or

(b) The safety or effectiveness of the drug or device.

(11) If a provision of this section or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

SECTION 2. Section 73-25-37, Mississippi Code of 1972, is amended as follows:

73-25-37. (1) No duly licensed, practicing physician, physician assistant, dentist, registered nurse, licensed practical nurse, certified registered emergency medical technician, or any other person who, in good faith and in the exercise of reasonable care, renders emergency care to any injured person at the scene of an emergency, or in transporting the injured person to a point where medical assistance can be reasonably expected, shall be liable for any civil damages to the injured person as a result of any acts committed in good faith and in the exercise of reasonable care or omissions in good faith and in the exercise of reasonable care by such persons in rendering the emergency care to the injured person.

(2) (a) Any person who in good faith, with or without compensation, renders emergency care or treatment by the use of an Automated External Defibrillator (AED) in accordance with the

provisions of Sections 41-60-31 through 41-60-35, as well as the person responsible for the site where the AED is located if the person has provided for compliance with the provisions of Sections 41-60-31 through 41-60-35, shall be immune from civil liability for any personal injury as a result of that care or treatment, or as a result of any act, or failure to act, in providing or arranging further medical treatment, where the person acts as an ordinary, reasonably prudent person would have acted under the same or similar circumstances and the person's actions or failure to act does not amount to willful or wanton misconduct or gross negligence.

(b) A person who has not complied with the provisions of Sections 41-60-31 through 41-60-35, but who has access to an AED and uses it in good faith in an emergency as an ordinary prudent person would have done in the same or similar circumstances, shall be immune from civil liability for any personal injury as a result of an act or omission related to the operation of or failure to operate an AED if the person's actions or failure to act do not amount to willful or wanton misconduct or gross negligence.

(3) Any employee of a local public school district, a private school, or parochial school, trained in the administration of auto-injectable epinephrine, who provides, administers, or assists in the administration of auto-injectable epinephrine, in accordance with the provisions of Section 37-11-71, to a student

believed in good faith to be having an anaphylactic reaction, shall be immune from civil liability for any personal injury as a result of that care or treatment if the employee's actions or failure to act do not amount to willful or wanton misconduct or gross negligence.

(4) The immunity from civil liability for any personal injury under subsection (2) of this section includes the licensed physician who authorizes, directs or supervises the installation or provision of AED equipment in or on any premises or conveyance other than a medical facility, the owner of the premises where an AED is used, the purchaser of the AED, a person who uses an AED during an emergency for the purpose of attempting to save the life of another person who is or who appears to be in cardiac arrest, and the person who provides the CPR and AED training.

(5) The immunity from civil liability for any personal injury under subsection (3) of this section includes the licensed physician who prescribes the auto-injectable epinephrine, the school district, or any other entity, that legally obtained the auto-injectable epinephrine, and the person who provides the training in the administration of auto-injectable epinephrine.

(6) The immunity from civil liability under subsection (2) and subsection (3) of this section does not apply if the personal injury results from the gross negligence or willful or wanton misconduct of the person rendering the emergency care.

(7) Except in cases of gross negligence or willful misconduct, civil immunity shall apply to any licensed physician or licensed pharmacist who prescribes or makes recommendation to an eligible patient regarding prescription for or treatment with an investigational drug, biological product or device under the provisions of Section 1 of this act, and the State Board of Medical Licensure and/or the State Board of Pharmacy, as the case may be, shall be prohibited from taking any adverse action against the license of such physician or pharmacist based solely on the physician's action under the provisions of Section 1 of this act.

SECTION 3. This act shall take effect and be in force from and after July 1, 2015.