MISSISSIPPI LEGISLATURE REGULAR SESSION 2020

By: Senator(s) Harkins, Jackson (11th), Jordan

To: Public Health and Welfare

SENATE BILL NO. 2830

AN ACT TO AMEND SECTION 41-131-1, MISSISSIPPI CODE OF 1972, TO REVISE THE DEFINITION OF "ELIGIBLE PATIENT" TO INCLUDE THOSE PATIENTS WITH A TRAUMATIC INJURY; TO REVISE THE DEFINITION OF "INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE" TO INCLUDE ADULT AUTOLOGOUS MESENCHYMAL STEM CELL; AND FOR RELATED PURPOSES.

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

SECTION 1. Section 41-131-1, Mississippi Code of 1972, is amended as follows:

41-131-1. (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 debilitating disability, traumatic injury, terminal illness or life-threatening illness that has not responded or cannot be treated with currently approved products;

(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 adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, 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) "Adult autologous mesenchymal stem cell, investigational drug, biological product or device" means * * * an adult autologous mesenchymal stem cell, drug, biological product or device, any of which are used to treat the patient's disability, traumatic injury or illness, and the use of which has been either described in a United States Food and Drug Administration/National Institutes of Health (FDA/NIH) approved-protocol or study, or approved by an institutional review board (IRB), or successfully completed a safety study. The drug,

product or device must be produced in a manner consistent with the quality standards of an adult autologous mesenchymal stem cell, investigational drug, biological product or device in the United States (i.e., standards required by an FDA-approved trial) and must show prior evidence of safe usage in humans in the United States or other countries. The adult autologous mesenchymal stem cell, investigational drug, biological product or device must have 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 adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, 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 or required to pay for any cost of any adult autologous mesenchymal

stem cell, investigational drug, biological product or device or for any care or treatments consequent to the use of the adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, drug, biological product or device states otherwise. The patient's health plan or third-party administrator are not liable for any outstanding debt related to the treatment or lack of insurance consequent to the use of the adult autologous mesenchymal stem cell, investigational drug, biological product or device.

(3) A manufacturer of an adult autologous mesenchymal stem cell, investigational drug, biological product or device may make

available the manufacturer's adult autologous mesenchymal stem cell, investigational drug, biological product or device to eligible patients under this section. This section does not require that a manufacturer make available an adult autologous mesenchymal stem cell, investigational drug, biological product or device to an eligible patient. A manufacturer may:

(a) Provide an adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, investigational drug, biological product or device.

(4) This section does not require a health care insurer to provide coverage for the cost of any adult autologous mesenchymal stem cell, investigational drug, biological product or device. However, a health care insurer may provide coverage for an adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, 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., 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 adult autologous mesenchymal stem cell, 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 adult autologous mesenchymal stem cell, 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 an adult autologous mesenchymal stem cell, investigational 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, the patient's health plan, third-party administrator, or any person who manufactures, imports, distributes, prescribes, dispenses, compounds or administers an adult autologous mesenchymal stem cell, 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.

The immunity provided under this subsection (10) is fully applicable to the owner of a hospital or other licensed health care facility rendering services to an eligible patient where the investigational drug is used or purchased only with regard to the use of the adult autologous mesenchymal stem cell, investigational drug, biological product or device at the facility.

(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. This act shall take effect and be in force from and after its passage.

ST: Right-to-Try Act; revise definitions to include traumatic injury and adult autologous mesenchymal stem cell.