State of Arkansas *As Engrossed: S1/22/15 S2/2/15*
90th General Assembly **A Bill**
Regular Session, 2015 SENATE BILL 4

By: Senators J. Cooper, Hester, *Bledsoe, Burnett, E. Cheatham, L. Chesterfield, A. Clark, Collins-Smith, J. Dismang, Flippo, J. Hendren, Hickey, Irvin, B. Johnson, B. King, Maloch, B. Pierce, Rice, G. Stubblefield, E. Williams*
By: Representatives Lundstrum, Womack, Sullivan, Ladyman, B. Smith, Tosh, Wallace, *Bentley, Neal, Speaks*

For An Act To Be Entitled

AN ACT CONCERNING TERMINALLY ILL PATIENT ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES; TO CREATE THE RIGHT TO TRY ACT; AND FOR OTHER PURPOSES.

Subtitle

CONCERNING TERMINALLY ILL PATIENT ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES; AND TO CREATE THE RIGHT TO TRY ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 20, Chapter 15, is amended to add an additional subchapter to read as follows:

Subchapter 20 — Right to Try Act

20-15-2001. Title.

This subchapter shall be known and may be cited as the "Right to Try Act".

20-15-2002. Findings.

It is found and determined by the General Assembly of the State of Arkansas that:

(1) The process of approval for investigational drugs, biological products, and devices in the United States often takes many years;

(2) Patients who have a terminal disease do not have the luxury of waiting until an investigational drug, biological product, or device receives final approval;

(3) The standards of the United States Food and Drug Administration for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-saving treatments to terminally ill patients;

(4) The State of Arkansas recognizes that patients who have a terminal disease have a fundamental right to attempt to pursue the preservation of their own lives by accessing available investigational drugs, biological products, and devices; and

(5) The use of available investigational drugs, biological products*, or devices* is a decision that should be made by the patient with a terminal disease in consultation with his or her physician.

20-15-2003. Definitions.

As used in this subchapter:

(1) "Eligible patient" means a person who meets the requirements of eligibility in § 20-15-2004;

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that:

(A) Has successfully completed phase I of clinical trials but has not been approved for general use by the United States Food and Drug Administration; and

(B) Remains currently under investigation in a United States Food and Drug Administration clinical trial;

(3) "Physician" means an individual licensed to practice medicine in the State of Arkansas under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.; and

(4) "Terminal illness means an incurable and irreversible condition that without the administration of life-sustaining treatment will, in the opinion of the patient's physician, result in death within a relatively short

time.

20-15-2004. Eligibility.

In order for a patient to access an investigational drug, biological product, or device under this subchapter, a physician must document in the patient's medical record and chart that the patient:

(1) Has a terminal illness;

(2) Has a determination from a qualified physician that the patient has no comparable or satisfactory treatment options approved by the United States Food and Drug Administration available to treat the terminal illness and that the probable risk to the patient from the investigational drug, biological product, or device is not greater than the probable risk from the terminal illness;

(3) Has been unable to participate in a clinical trial for the terminal illness within one hundred miles (100 mi) of the patient's home address, or has not been accepted to the clinical trial within one (1) week of the completion of the clinical trial application process;

(4) Has been given a *prescription* by a physician for an investigational drug, biological product, or device;

(5)(A) Has given informed consent in writing for the use of the investigational drug, biological product, or device.

(B) If the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian may provide informed consent on the patient's behalf; and

(6) Has received written documentation from a physician that the patient meets the requirements of this subchapter.

20-15-2005. Availability.

A manufacturer of an investigational drug, biological product, or device may, but is not required to, make its investigational drug, biological product, or device available to eligible patients under this subchapter.

20-15-2006. Costs.

(a) A manufacturer of an investigational drug, biological product, or device may:

(1) Provide an investigational drug, biological product, or

device to an eligible patient without receiving compensation; or

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

(B) As used in this section, "costs associated with the manufacture of the investigational drug, biological product, or device" means the actual out-of-pocket costs incurred in providing the investigational drug, biological product, or device to the patient in the specific case.

(b) 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 to the manufacturer related to the investigational drug, biological product, or device.

20-15-2007. Insurance coverage.

An insurance company:

(1) May, but is not required to, provide coverage for an investigational drug, biological product, or device; and

(2) Shall not deny coverage for an item or service that is:

(A) Otherwise covered by an insurance contract between the eligible person and an insurance company; and

(B) Used separately or in conjunction with an investigational drug, biological product, or device.

20-15-2008. Prohibited sanctions.

The recommendation, prescription, treatment, or participation in the treatment of a terminal illness with an investigational drug, biological product, or device shall not permit:

(1) A licensing board to revoke a license, fail to renew a license, or take any other action against a physician's license;

(2) A state agency or licensing board to revoke a license, fail to renew a license, or take any other action against:

(A) A medical professional licensed under state law; or

(B) A hospital licensed under § 20-9-213; or

(3) An action against a hospital's Medicare certification.

20-15-2009. Remedy.

The counseling, advice, or recommendation by a medical professional who is licensed under the state law is not a violation of this subchapter.

20-15-2010. Immunity.

(a) Except in the case of gross negligence or willful misconduct, a person or entity that manufacturers, imports, distributes, prescribes, dispenses, administers, or is otherwise involved in the care of an eligible patient using an investigational drug, biological product, or device is immune from civil liability for any loss, damage, or injury arising out of, relating to, or resulting from the investigational drug, biological product, or device so long as the person or entity is substantially complying in good faith with this subchapter.

(b) This subchapter does not require a medical professional who is licensed under the laws of this state to counsel, advise, prescribe, dispense, administer, or otherwise be involved in the care of an eligible patient using an investigation drug, biological product, or device.

(c) This subchapter does not require a hospital licensed under § 20-9-213 to provide any service related to an investigational drug, biological product, or device.

20-15-2011. Medicaid coverage.

This subchapter does not require the Department of Human Services or the Arkansas Medicaid Program to provide additional coverage for an investigational drug, biological product, or device.

/s/J. Cooper