

1 State of Arkansas
2 90th General Assembly
3 Regular Session, 2015
4

A Bill

SENATE BILL 4

5 By: Senators J. Cooper, Hester
6 By: Representatives Lundstrum, Womack, Sullivan, Ladyman, B. Smith, Tosh, Wallace
7

For An Act To Be Entitled

8
9 AN ACT CONCERNING TERMINALLY ILL PATIENT ACCESS TO
10 INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR
11 DEVICES; TO CREATE THE RIGHT TO TRY ACT; AND FOR
12 OTHER PURPOSES.
13

Subtitle

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15 CONCERNING TERMINALLY ILL PATIENT ACCESS
16 TO INVESTIGATIONAL DRUGS, BIOLOGICAL
17 PRODUCTS, OR DEVICES; AND TO CREATE THE
18 RIGHT TO TRY ACT.
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22 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
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24 SECTION 1. Arkansas Code Title 20, Chapter 15, is amended to add an
25 additional subchapter to read as follows:
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Subchapter 20 – Right to Try Act

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29 20-15-2001. Title.

30 This subchapter shall be known and may be cited as the “Right to Try
31 Act”.
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33 20-15-2002. Findings.

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

36 (1) The process of approval for investigational drugs,



1 biological products, and devices in the United States often takes many years;

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

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

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

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

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17 20-15-2003. Definitions.

18 As used in this subchapter:

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

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

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

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

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

31 (4) "Terminal illness" means a disease or illness that, without life-
32 sustaining measures, can reasonably be expected to result in death or a state
33 of permanent unconsciousness from which recovery is unlikely.

34
35 20-15-2004. Eligibility.

36 In order for a patient to access an investigational drug, biological

1 product, or device under this subchapter, a physician must document in the
2 patient’s medical record and chart that the patient:

3 (1) Has a terminal illness;

4 (2) Has considered, in consultation with a physician, all other
5 treatment options currently approved by the United States Food and Drug
6 Administration;

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

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

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

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

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

20
21 20-15-2005. Availability.

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

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26 20-15-2006. Costs.

27 A manufacturer of an investigational drug, biological product, or
28 device may:

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

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

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34 20-15-2007. Insurance coverage.

35 An insurance company may, but is not required to, provide coverage for
36 an investigational drug, biological product, or device.

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20-15-2008. Professional licensing.

A licensing board shall not revoke a license, fail to renew a license, or take any other action against a physician's license solely based on a physician's recommendation, prescription, or treatment with an investigational drug, biological product, or device.

20-15-2009. Remedy.

An official, employee, or agent of the State of Arkansas that blocks or attempts to block access of an eligible patient to an investigational drug, biological product, or device is guilty of a Class A misdemeanor.

20-15-2010. Immunity.

A manufacturer of an investigational drug, biological product, or device or person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device is immune from civil liability for any harm done to an eligible patient resulting from the investigational drug, biological product, or device so long as the manufacturer, person, or entity is complying in good faith with this subchapter, unless the manufacturer, person, or entity fails to exercise reasonable care.