Right to Try Act

The Act establishes findings concerning barriers that terminally ill patients may face in access to potentially life-preserving treatments.

Submitted as:
Louisiana
HB 891

Suggested State Legislation

(Title, enacting clause, etc.)

1 Section 1. [Legislative Findings.]
2 The Legislature of [Louisiana] hereby finds and declares the following:
3 (1) The process of approval for investigational drugs, biological products, and devices in the
4 United States often takes many years.
5 (2) A patient who has a terminal illness does not have the luxury of waiting until an
6 investigational drug, biological product, or device receives final approval from the United
7 States Food and Drug
8 (3) The standards of the United States Food and Drug Administration for the use of
9 investigational drugs, biological products, and devices may deny the benefits of potentially
10 life-saving treatments to terminally ill patients.
11 (4) A patient with a terminal illness has a fundamental right to attempt to preserve his own life
12 by accessing available investigational drugs, biological products, and devices.
13 (5) Whether to use available investigational drugs, biological products, or devices is a decision
14 that rightfully should be made by the patient with a terminal illness in consultation with his
15 physician, and is not a decision to be made by the government.

16 Section 2. [Definitions.]
17 As used in this Part, the following terms have the meaning ascribed to them in this Section:
18 (1) “Eligible patient” means a person to whom all of the following criteria apply:
19 (a) Has a terminal illness.
20 (b) As determined by the person's physician, has no comparable or satisfactory treatment
21 options that are approved by the United States Food and Drug Administration and
22 available to diagnose, monitor, or treat the person's disease or condition, and the probable
23 risk to the person from the investigational drug, biological product, or device is not
24 greater than the probable risk from the person's disease or condition.
25 (c) Has received a prescription or recommendation from his physician for an investigational
26 drug, biological product, or device.
27 (d) Has given his consent in writing for the use of the investigational drug, biological
28 product, or device; or, if he is a minor or lacks the mental capacity to provide consent, a
29 parent or legal guardian has given consent in writing on his behalf.
30 (e) Has documentation from his physician indicating that he has met the requirements
31 provided in this Part.
Investigational drug, biological product, or device” means a drug, biological product, or device that has successfully completed phase one of a United States Food and Drug Administration approved 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.

(3) “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. This diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty.

Section 3. [Availability of drugs, biological products, and devices; costs; insurance coverage.]
A.
(1) A manufacturer of an investigational drug, biological product, or device may make available such drug, product, or device to eligible patients in accordance with the provisions of this Section.
(2) Nothing in this Section shall be construed to require a manufacturer to make available any drug, product, or device.
B. A manufacturer may do any 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 associated with the manufacture of the investigational drug, biological product, or device.
C. (1) A health insurance issuer may choose to provide coverage for the cost of an investigational drug, biological product, or device.
D. Nothing in this Section shall be construed to require a health insurance issuer to provide coverage for the cost of any investigational drug, biological product, or device.

Section 4. [Limitation of liability.]
Notwithstanding any provision of law to the contrary, a physician who prescribes an investigational drug, biological product, or device to an eligible patient pursuant to the provisions of this Part shall be immune from civil liability, including but not limited to any cause of action arising under [Insert citation.], for any adverse action, condition, or other outcome resulting from the patient's use of the investigational drug, biological product, or device.

Section 5. [Action against physician license prohibited.]
Notwithstanding any provision of law to the contrary, the [Louisiana] State Board of Medical Examiners shall not revoke, fail to renew, or take any other action against the license of a physician issued pursuant to the provisions of [Insert citation.] based solely upon the recommendation of the physician to an eligible patient regarding, or prescription for, or treatment with, an investigational drug, biological product, or device when such recommendation, prescription, or treatment is undertaken in strict conformance with the provisions of this Part.