**RS 40:1169.1**

PART IV. RIGHTS

SUBPART A. ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS

§1169.1. Short title

            This Subpart shall be known and may be cited as the "Right To Try Act".

§1169.2. Legislative findings

            The Legislature of Louisiana hereby finds and declares the following:

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

            (2) A patient who has a terminal illness does not have the luxury of waiting until an investigational drug, biological product, or device receives final approval from the United States Food and Drug Administration.

            (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 or devices to terminally ill patients.

            (4) A patient with a terminal illness has a fundamental right to attempt to preserve his own life by accessing available investigational drugs, biological products, and devices.

            (5) Whether to use available investigational drugs, biological products, or devices is a decision that rightfully should be made by the patient with a terminal illness in consultation with his physician, and is not a decision to be made by the government.

§1169.3. Definitions

            As used in this Subpart, the following terms have the meaning ascribed to them in this Section:

            (1) "Eligible patient" means a person to whom all of the following criteria apply:

            (a) Has a terminal illness.

            (b) As determined by the person's physician, has no comparable or satisfactory treatment options that are approved by the United States Food and Drug Administration and available to diagnose, monitor, or treat the person's disease or condition, and the probable risk to the person from the investigational drug, biological product, or device is not greater than the probable risk from the person's disease or condition.

            (c) Has received a prescription or recommendation from his physician for an investigational drug, biological product, or device.

            (d)(i) Has given his consent in writing for the use of the investigational drug, biological product, or device; or, if he is a minor or lacks the mental capacity to provide consent, a parent or legal guardian has given consent in writing on his behalf.

            (ii) A person who can understand and comprehend spoken English but is physically unable to talk or write may be deemed as meeting the criteria of this Subparagraph if he is competent and able to indicate consent by other means.

            (e) Has documentation from his physician indicating that he has met the requirements provided in this Subpart.

            (2)(a) "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.

            (b) Notwithstanding Subparagraph (a) of this Paragraph, for purposes of this Subpart, "investigational drug, biological product, or device" shall include any device possessing the following characteristics regardless of whether it has successfully completed phase one of a United States Food and Drug Administration approved clinical trial:

            (i)(aa) If of a robotic nature, the device is designed such that any failure in a multitude of continuous tests of its internal subsystems should cause motion to stop, consistent with the Guidelines For Robotics Safety from the Occupational Safety and Health Administration of the United States Department of Labor (Directive Number STD 01-12-002).

            (bb) For purposes of this Item, "robotic nature" shall mean capable of independent motion or moving the user.

            (ii) The device has all of the following features for intentional control:

            (aa) The motion of the device responds to specific controls from the user.

            (bb) The device has no machine state in which motion continues without a specific command from the user.

            (iii) The device has an emergency stop button which allows an assistant to force the motion of the device to stop.

            (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 speciality.

§1169.4. 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.

            (2) 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.

§1169.5. Limitation of liability; no cause of action created

            A. 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 Subpart shall be immune from civil liability, including but not limited to any cause of action arising under R.S. 40:1231.1 et seq., for any adverse action, condition, or other outcome resulting from the patient's use of the investigational drug, biological product, or device.

            B. Nothing in this Section shall be construed as creating a cause of action by or on behalf of any person against a manufacturer of an investigational drug, biological product, or device, or against any person or entity involved in the care of an eligible patient using the investigational drug, biological product, or device, for any harm done to the eligible patient resulting from the investigational drug, biological product, or device.