2017 Regular Session

HOUSE BILL NO. 179

BY REPRESENTATIVES STOKES, BAGLEY, CHANEY, COX, HENSGENS, HOFFMANN, HORTON, JACKSON, JOHNSON, LEBAS, MARINO, DUSTIN MILLER, MORENO, POPE, RICHARD, SIMON, AND STAGNI AND SENATOR MARTINY

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

HEALTH SERVICES: Provides relative to devices authorized for use by the Right To Try Act

AN ACT

To amend and reenact R.S. 40:1169.2(3) and 1169.3(1)(d) and (2), relative to investigational drugs, products, and devices for use by terminally ill patients pursuant to the Right To Try Act; to revise certain definitions and legislative findings of such law; to provide relative to consent for the use of investigational drugs, biological products, or devices; to authorize the prescription and use of certain devices which have not completed phase one of a federally approved clinical trial; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:1169.2(3) and 1169.3(1)(d) and (2) are hereby amended and reenacted to read as follows:

§1169.2. Legislative findings

The Legislature of Louisiana hereby finds and declares the following:

* * *

(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 <u>or devices</u> to terminally ill patients.

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§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:

* * *

(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.

* * *

(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.

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DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

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Abstract: Amends the Right To Try Act to provide for means of consent and to include certain devices within the law's definition of "investigational drug, biological product, or device".

Present law known as the "Right To Try Act" authorizes the prescription of investigational drugs, biological products, and devices to certain terminally ill patients who have given informed written consent to investigational treatment and who meet other criteria necessary to be deemed "eligible patients" pursuant to present law.

Proposed law retains present law and stipulates that 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 present law relative to consent if he is competent and able to indicate consent by other means.

Present law provides that for purposes of present law, "investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a U.S. Food and Drug Administration (FDA) approved clinical trial, but has not been approved for general use by the FDA and remains under investigation in a clinical trial.

Proposed law provides that notwithstanding present law, "investigational drug, biological product, or device" shall include any device possessing the following characteristics regardless of whether it has successfully completed phase one of an FDA approved clinical trial:

(1) If of a robotic nature (defined to mean capable of independent motion or moving the user), 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 applicable federal guidelines for robotics safety.

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

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

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

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

(Amends R.S. 40:1169.2(3) and 1169.3(1)(d) and (2))