

RÉSUMÉ DIGEST

ACT 292 (HB 179)

2017 Regular Session

Stokes

Existing 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 existing law.

New law retains existing 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 existing law relative to consent if he is competent and able to indicate consent by other means.

Existing law provides that for purposes of existing 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.

New law provides that notwithstanding existing 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.

Effective August 1, 2017.

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