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)]

Stokes HB No. 891

Abstract: Authorizes access to investigational drugs, biological products, and devices for terminally ill patients.

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

Proposed law provides the following definitions for purposes of proposed law:

(1) "Eligible patient" means a person who meets all of the following criteria:

(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 U.S. 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) 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 informed consent, a parent or legal guardian has given informed consent in writing on his behalf.

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

(2) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial, but has not been approved for general use by the U.S. 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. Provides that this diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate speciality.

Proposed law authorizes manufacturers of investigational drugs, biological products, and devices to make available those drugs, products, and devices to eligible patients. Provides, however, that nothing in proposed law shall be construed to require provision of any drug, product, or device by a manufacturer.

Proposed law authorizes a manufacturer to provide an investigational drug, biological product, or device to an eligible patient with or without compensation.

Proposed law authorizes health insurers to provide coverage for the cost of an investigational drug, biological product, or device. Specifies that nothing in proposed law shall be construed to require such coverage by health insurers.

Proposed law provides that a physician who prescribes an investigational drug, biological product, or device pursuant to proposed law shall be immune from civil liability, including but not limited to any cause of action arising under medical malpractice provisions of present law, for any adverse outcome resulting from a patient's use of the investigational drug, biological product, or device pursuant to proposed law.

Proposed law provides that proposed law shall be known and may be cited as the Right To Try Act. Declares that allowing for the provisions of the Right To Try Act to apply to patients with nonterminal illnesses furthers the purpose of proposed law.

(Adds R.S. 40:1300.381-1300.385)

Summary of Amendments Adopted by House

Committee Amendments Proposed by House Committee on Health and Welfare to the original bill.

1. In the set of criteria for a person to be considered an "eligible patient" pursuant to proposed law, deleted consideration by the person of all other treatment options approved by the U.S. Food and Drug Administration (FDA); and added in lieu thereof determination by a physician that the person has no comparable or satisfactory FDA-approved treatment options available, and the probable risk from the investigational treatment is not greater than the probable risk from the disease or condition.

2. Relative to consent for types of treatment provided for in proposed law, deleted requirement that the consent the patient gives in writing be informed consent.

3. Revised definition of "terminal illness" in proposed law to provide that such illness be one that, without life-sustaining procedures, will result in death in the near future or a

state of permanent unconsciousness from which recovery is unlikely. Provided that this diagnosis shall be confirmed by a second independent evaluation by a board-certified physician in an appropriate speciality.

4. Deleted provision prohibiting the La. State Board of Medical Examiners from revoking, failing to renew, or taking any other action against the license of a physician based solely upon the physician's recommendation regarding or prescription for or treatment with an investigational drug, biological product, or device.

5. Added provision establishing that a physician who prescribes an investigational drug, biological product, or device pursuant to proposed law shall be immune from civil liability, including but not limited to any cause of action arising under medical malpractice provisions of present law, for any adverse outcome resulting from a patient's use of the investigational drug, biological product, or device.

6. Deleted provision establishing a fine of $1,500 or less to be imposed upon any official, employee, or agent of the state who blocks or attempts to block a patient's access to an investigational drug, biological product, or device provided for in proposed law.

7. Made technical changes.