

**SUBJECT:** Allowing patients with terminal illnesses to access investigational drugs

**COMMITTEE:** Public Health — committee substitute recommended

**VOTE:** 7 ayes — Crossover, Coleman, S. Davis, R. Miller, Sheffield, Zedler, Zerwas

0 nays

4 absent — Naishtat, Blanco, Collier, Guerra

**WITNESSES:** For — Kurt Altman, Goldwater Institute; Michelle Wittenburg, KK-125 Ovarian Cancer Research Foundation (*Registered, but did not testify*: Mary Amador, Catholic Bishops Advocacy Day; Steve Bruno, Ron Hinkle, Kym Olson, Bonnie Bruce, Dale Laine, and Allen Blakemore, KK-125 Ovarian Cancer Research Foundation; Rene Lara, Texas AFL-CIO; Maxcine Tomlinson, Texas New Mexico Hospice Organization; Thomas Ratliff, Texas Nurse Practitioners Association; and eight individuals)

Against — None

On — David Bales and Will Decker, Texans for Stem Cell Research; Mari Robinson, Texas Medical Board; Charles Levenback, University of Texas MD Anderson Cancer Center (*Registered, but did not testify*: Karen Tannert, Department of State Health Services; Pat Brewer, Texas Department of Insurance)

**BACKGROUND:** Federal law defines an “investigational drug” under 21 C.F.R. sec. 312.3 to mean a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes.

A “biological product” is defined in federal law under 42 U.S.C. sec. 262 to include a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or protein applicable to

the prevention, treatment, or cure of a person's disease or condition.

**DIGEST:**

**Legislative intent.** CSHB 21 would be known as the "Right To Try Act." The bill would specify that the Legislature intends to allow for patients with a terminal illness to use potentially life-saving investigational drugs, biological products, and devices.

**Eligibility.** Under the bill, a patient with an terminal illness would be eligible to access and use an investigational drug, biological product, or device if the patient's physician had considered all other treatment options currently approved by the U.S. Food and Drug Administration (FDA) and determined that those treatment options were unavailable or unlikely to prolong the patient's life and the physician had recommended or prescribed in writing that the patient use a specific class of investigational drug, biological product, or device. A Texas prisoner covered by the state's correctional managed health care plan would be eligible under the bill if the Offender Health Services Plan and federal law governing offender participation in biomedical research permit their eligibility. The bill would not affect coverage for enrollees in clinical trials under Insurance Code, ch. 1379.

**Definitions.** CSHB 21 would define an "investigational drug, biological product, or device" to mean a drug, biological product or device that has successfully completed phase one of a clinical trial but has not yet been approved by the FDA for general use and remains in the clinical trial. "Terminal illness" would mean an advanced stage of a disease with an unfavorable prognosis that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.

**Informed consent.** To receive an investigational drug, biological product, or device, an eligible patient or their parent or legal guardian would have to sign an informed consent form and provide it to the manufacturer of the drug, product, or device. The bill would allow the executive commissioner of the Health and Human Services Commission, in collaboration with the Texas Medical Board, to adopt by rule an informed consent form for this

purpose.

**Manufacturer requirements.** The bill would not require a manufacturer to provide an investigational drug, biological product, or device to an eligible patient. Under the bill, a manufacturer could choose whether to charge a patient for the cost of the manufacture of the investigational drug, biological product, or device. A health insurance plan could, but would not be required to, provide coverage for the cost of an investigational drug, biological product, or device.

**Lawsuits.** The bill would not create a private or state cause of action for a lawsuit against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient for any harm done to the patient as a result of the treatment.

**Patient access and physician licensing.** Under the bill, a state of Texas official, employee, or agent could not block or attempt to block an eligible patient's access to an investigational drug, biological product, or device. The Texas Medical Board could not revoke, fail to renew, suspend, or take any action against a physician's license based solely on a physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, as long as the care and recommendations the physician provided to the patient met the standard of care and requirements of the bill.

**Effective date.** This bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect September 1, 2015.

SUPPORTERS  
SAY:

CSHB 21 would make it easier for patients who are terminally ill to access investigational drugs. The current process to test, approve, and bring a new drug to market under federal regulations can take a decade or more, which is longer than patients with a terminal illness can wait. Under the bill, manufacturers would not be required to provide investigational drugs. The bill would encourage manufacturers to make the drugs

available by specifying that the bill did not create a cause of action for a lawsuit after the patient signed an informed consent form and consulted with the patient's physician.

Terminal patients would have the opportunity to be treated with drugs that had passed phase one of the FDA trials and could be effective in treating their condition. Passing phase one indicates that a drug has been proven not to be harmful to humans. A physician would still have to evaluate the patient, and would not recommend a drug for a patient that would interact badly with the patient's illness. The bill would not open the door to reckless behavior on the behalf of a patient or physician, but rather would allow the patient to balance the risks and benefits of potential treatments and make the highly personal decision to try to save the person's life using every means available.

The bill would not discourage a patient's participation in a clinical trial because manufacturers typically provide the treatment for free in clinical trials. Additionally, many patients are not eligible for clinical trials or cannot travel to participate in a clinical trial, so this bill would expand those patients' ability to access investigational drugs.

The FDA structure exists for a purpose, but an informed patient in Texas needs to have the same access to drugs as patients in other states that have passed similar legislation.

**OPPONENTS  
SAY:**

The bill could cause patients with terminal illnesses to be exposed to unnecessary harm because investigational drugs that have passed phase one trials have not undergone thorough testing for a patient's specific condition and could cause negative side effects for a patient. The bill also would not necessarily increase patient access to drugs because the bill would not require manufacturers or health insurance plans to provide the treatment or pay for the treatment's cost, as manufacturers usually do for patients enrolled in a clinical trial.

By allowing patients to access investigational drugs outside of a clinical trial, the bill also could discourage patients from enrolling in clinical trials

and thus could make it harder for drugs to be approved by the FDA.

It is the responsibility of the federal Food and Drug Administration to control patient access to drugs, not the states. It is unclear whether the bill would actually increase access to these investigational drugs beyond what the FDA allows.

NOTES:

The committee substitute differs from the introduced bill by:

- removing a provision stating that the Legislature finds that a patient should make a decision to use investigational drugs in consultation with the patient's family;
- removing a requirement that the written informed consent signed by a patient must be attested to by the patient's physician and a witness;
- replacing a requirement that a patient who is a minor or lacks the mental capacity to provide informed consent have a guardian or conservator provide informed consent on the patient's behalf with a requirement that a legal guardian provide informed consent on the patient's behalf;
- making it permissive instead of a requirement that the Health and Human Services executive commissioner adopt by rule an informed consent form and adding a requirement that the executive commissioner collaborate with the Texas Medical Board in adopting the form;
- adding a provision making a person covered by a correctional managed health care plan an eligible patient under the bill;
- adding the language "provided that the care provided or recommendations made to the patient meet the standard of care and the requirements of this chapter" to sec. 489.151 prohibiting action against a physician's license based solely on the physician's recommendations to an eligible patient regarding an investigational drug, biological product, or device; and
- removing a deadline for when the Health and Human Services executive commissioner had to adopt an informed consent form.

A similar bill, SB 694 by Bettencourt, was approved by the Senate on April 9.