SUBJECT: Allowing patients to access investigational stem cell treatments

COMMITTEE: Public Health — committee substitute recommended

VOTE: 11 ayes — Price, Sheffield, Arévalo, Burkett, Coleman, Collier, Cortez, Guerra, Klick, Oliverson, Zedler

0 nays

WITNESSES: For — Rick Hardcastle, Celltex Therapeutics; Mary Martin, Jennifer Perez; Beverly Kotsanis, Kotsanis Institute; Jennifer Ziegler, Patients For Stem Cells; Sheila Hemphill, Texas Right To Know; and eight individuals; (*Registered, but did not testify*: V.A. Stephens, Michelle Wittenburg, and Adam Jones, KK125 Foundation; Jennifer Allmon, Texas Catholic Conference of Bishops; and 16 individuals)

Against — None

On — David Bales, Texans for Cures; (*Registered, but did not testify*: Jonathan Huss, Department of State Health Services; Robert Bredt, Scott Freshour and Monique Johnston, Texas Medical Board)

BACKGROUND: In 2015, the 84th Legislature enacted HB 21 by Kacal, the Right to Try Act, which allows patients with certain terminal illnesses to access certain investigational drugs, biological products, and devices that were being used in clinical trials.

DIGEST: CSHB 810 would allow a patient to be eligible to access and use an investigational stem cell treatment if:

- the patient had a severe chronic disease or terminal illness that was listed in rules adopted by the Health and Human Services Commission (HHSC) executive commissioner and attested to by the patient's treating physician;
- the patient's physician, in consultation with the patient, had considered all other treatment options currently approved by the

United States Food and Drug Administration and determined that those treatment options were unavailable or unlikely to alleviate the significant impairment or severe pain associated with the severe chronic disease or terminal illness; and

- the patient's physician had recommended or prescribed in writing that the patient use a specific class of investigational stem cell treatment.

The bill would define an "investigational stem cell treatment" to mean an adult stem cell treatment that was under investigation in a clinical trial and being administered to human participants in that trial and that had not yet been approved for general use by the United States Food and Drug Administration.

Before receiving an investigational stem cell treatment, CSHB 810 would require an eligible patient to sign a written informed consent. The patient's parent, guardian, or conservator could provide informed consent on the patient's behalf if the patient was a minor or lacked the mental capacity to provide informed consent. The HHSC executive commissioner could adopt a form for providing informed consent.

CSHB 810 would not create a private or state cause of action against a developer of an investigational stem cell treatment or against any other person or entity involved in the care of an eligible patient under the bill for any harm done to the eligible patient resulting from the investigational stem cell treatment. The bill's provisions would not affect, or authorize a person to violate, any law regulating the possession, use, or transfer of fetal tissue, fetal stem cells, adult stem cells, or human organs, including Texas law prohibiting the purchase and sale of human organs and the prohibition on purchase and sale of adult stem cells for certain investigational treatments that would be added to Penal Code by CSHB 810.

The bill would make it a class A misdemeanor (up to one year in jail and/or a maximum fine of $4,000) to knowingly offer to buy, offer to sell, acquire, receive, sell, or otherwise transfer any adult stem cells for

valuable consideration for use in an investigational stem cell treatment. The bill would make exceptions to the misdemeanor offense if the actor engaged in conduct related to a blood bank or blood donation, or if the "valuable consideration" was:

- a fee paid to a physician or to other medical personnel for services rendered in the usual course of medical practice or a fee paid for hospital or other clinical services;
- reimbursement of legal or medical expenses incurred for the benefit of the ultimate receiver of the treatment; or
- reimbursement of travel and housing expenses and lost wages incurred by the donor of adult stem cells in connection with the donation.

Notwithstanding any other law, the Texas Medical Board could not revoke, fail to renew, suspend, or take any action against a physician's license based solely on the physician's recommendation to an eligible patient about an investigational stem cell treatment, provided the care or recommendations provided met the standard of care specified by CSHB 810. The bill would prohibit a governmental entity or an officer, employee, or agent of a governmental entity from interfering with an eligible patient's access to, or use of, an authorized investigational stem cell treatment.

As soon as practicable after the bill's effective date of September 1, 2017, the HHSC executive commissioner would have to adopt rules necessary to implement the relevant provisions of CSHB 810, including rules designating the medical conditions that would constitute a severe chronic disease or terminal illness for the purposes of the bill.

SUPPORTERS SAY:

CSHB 810 would make it easier for patients who had a chronic condition or who were terminally ill to access investigational stem cell treatments. The bill also would allow physicians to prescribe these treatments without fear of losing their license. The current process to test, approve, and bring a new stem cell treatment to market can take decades, which is longer than patients with a chronic illness or a terminal illness can wait.

CSHB 810 would make these treatments, which many Texas patients have traveled to other countries to use, available for certain Texans who had exhausted all other options for treatment, given informed consent, and had a written recommendation or prescription from their physician to undergo stem cell treatment. The bill would not open the door to reckless behavior on behalf of a physician or patient, but rather would allow the patient to balance the risks and benefits of potential treatment without government interference. A physician would not recommend a treatment that would interact badly with the patient's illness.

The bill would help Texas be a leader in adult stem cell medicine. Texas companies and researchers have worked on adult stem cell treatments for decades and report that they can safely use the patient's own stem cells to reduce the severity of a patient's illness and improve the patient's quality of life.

The FDA structure exists for a purpose, but informed Texas patients need to have the same access to these treatments as patients in other states who have passed this legislation. Restricting the available treatments under the bill to only those that have passed phase one clinical trials would unnecessarily restrict access to these treatments for patients.

The bill also would protect patients by prohibiting the purchase and sale of stem cells by bad actors and would apply only to treatments involving adult stem cells, not fetal stem cells.

OPPONENTS SAY:

CSHB 810 could cause patients with a chronic disease or terminal illness to be exposed to expensive treatments that could make their condition worse or cause serious side effects. Patients need data to make informed decisions, and long-term data is not yet available on the adverse effects of these treatments.

It is also unclear whether the bill actually would increase access to these investigational treatments beyond what the FDA currently allows.

OTHER OPPONENTS SAY:

CSHB 810 should add language specifying that the authorized investigational stem cell treatments would have successfully completed phase one of a clinical trial but had not yet been approved for general use. Limiting the bill to these treatments would improve safety for patients.