

BILL ANALYSIS

S.B. 773
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Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

In May 2018, the federal Right to Try Act was signed into law, creating a federal framework for patients to access new investigational drugs and biologics. In Texas, patient advocates such as KK125 Ovarian Cancer Research Foundation have made calls to provide more treatment options for those suffering from chronic disease.

S.B. 773, the Medical Freedom Act, seeks to address the issue of limited treatment options by permitting the use of investigational drugs, biological products, and devices for patients who, in consultation with their physician, have considered all other approved treatment options and determined they are unavailable or unlikely to provide relief.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 2 of this bill.

ANALYSIS

S.B. 773 amends the Health and Safety Code to make a patient eligible to access and use an investigational drug, biological product, or device under the following conditions:

- the patient has a severe chronic disease designated by the commissioner of state health services and that the patient's treating physician confirms in writing;
- use of the investigational drug, biological product, or device is consistent with the bill's provisions and the rules adopted thereunder; and
- the patient's physician has done the following:
 - in consultation with the patient, considers all other treatment options the FDA has currently approved and determines that those options are unavailable or unlikely to provide relief for the significant impairment or severe pain associated with the patient's severe chronic disease; and
 - recommends or prescribes in writing the patient's use of a specific class of investigational drug, biological product, or device.

The bill defines "investigational drug, biological product, or device" as such that has successfully completed phase one of a clinical trial but the FDA or its international equivalent has not yet approved for general use and that remains under investigation in the clinical trial, but does not include low-THC cannabis or a product containing marijuana, regardless of whether the cannabis or product successfully completed phase one of a clinical trial.

S.B. 773 requires an eligible patient, before receiving an investigational drug, biological product, or device, to sign a written informed consent, and authorizes a parent, guardian, or conservator to provide informed consent on the patient's behalf if the patient is a minor or lacks

the mental capacity to provide informed consent. The bill authorizes the commissioner of state health services to prescribe a form for the required informed consent and requires the commissioner, as soon as practicable after the bill's effective date, to designate the medical conditions considered to be severe chronic diseases, defined as a condition, injury, or illness that may be treated, may not be cured or eliminated, and entails significant functional impairment or severe pain, under the bill's provisions.

S.B. 773 authorizes a manufacturer of an investigational drug, biological product, or device to make available the manufacturer's investigational drug, biological product, or device to eligible patients in accordance with the bill's provisions if the patient provides to the manufacturer the required informed consent. The bill expressly does not require a manufacturer to make available an investigational drug, biological product, or device to an eligible patient. The bill requires a manufacturer that makes available an investigational drug, biological product, or device to an eligible patient under the bill's provisions to provide the investigational drug, biological product, or device to the eligible patient without receiving compensation.

S.B. 773 expressly does not create a private or state cause of action 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 using the drug, product, or device for any resulting harm to the patient. The bill expressly does not affect the coverage for routine patient care costs of enrollees in clinical trials as provided by applicable Insurance Code provisions.

S.B. 773 prohibits a state official, employee, or agent from blocking or attempting to block an eligible patient's access to an investigational drug, biological product, or device under the bill's provisions, unless the drug, biological product, or device is considered adulterated or misbranded under the Texas Food, Drug, and Cosmetic Act. The bill prohibits a governmental entity from considering the drug, biological product, or device to be adulterated or misbranded based solely on the FDA not yet finally approving the drug, biological product, or device. The bill prohibits the Texas Medical Board from revoking, failing to renew, suspending, or taking any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or treatment with such a drug, product, or device, provided that the recommendations meet the medical standard of care and the requirements of the bill's provisions.

S.B. 773 requires the executive commissioner of the Health and Human Services Commission, as soon as practicable after the bill's effective date, to adopt rules necessary to administer the bill's provisions. The bill authorizes the executive commissioner to adopt initial rules in the manner provided by law for emergency rules.

S.B. 773 includes legislative findings relating to the success of the Right To Try Act in saving the lives of many terminally ill patients; the long process for approving the use of investigational drugs, biological products, and devices by patients without a terminal illness; the urgency for final FDA approval for such among patients battling a severe chronic disease; restrictive FDA standards for using investigational drugs, biological products, and devices; and patients' rights to access and make decisions in consultation with their physician on the use of such drugs, products, and devices while being aware of the potential risks, benefits, and consequences of such. The bill establishes as legislative intent allowing patients with a severe chronic disease to use potentially life-altering investigational drugs, biological products, and devices.

EFFECTIVE DATE

On passage, or, if the bill does not receive the necessary vote, September 1, 2023.