

By: Parker, Springer, Paul,  
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H.B. No. 810

Substitute the following for H.B. No. 810:

By: Price

C.S.H.B. No. 810

A BILL TO BE ENTITLED

1 AN ACT

2 relating to the provision of certain investigational stem cell  
3 treatments to patients with certain severe chronic diseases or  
4 terminal illnesses and regulating the possession, use, and transfer  
5 of adult stem cells; creating a criminal offense.

6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

7 SECTION 1. Chapter 1003, Health and Safety Code, is amended  
8 by designating Sections 1003.001, 1003.002, and 1003.003 as  
9 Subchapter A and adding a subchapter heading to read as follows:

10 SUBCHAPTER A. GENERAL PROVISIONS

11 SECTION 2. Chapter 1003, Health and Safety Code, is amended  
12 by adding Subchapter B to read as follows:

13 SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO  
14 PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES

15 Sec. 1003.051. DEFINITIONS. In this subchapter:

16 (1) "Investigational stem cell treatment" means an  
17 adult stem cell treatment that:

18 (A) is under investigation in a clinical trial  
19 and being administered to human participants in that trial; and

20 (B) has not yet been approved for general use by  
21 the United States Food and Drug Administration.

22 (2) "Severe chronic disease" means a condition,  
23 injury, or illness that:

24 (A) may be treated;

1                   (B) is never cured or eliminated; and

2                   (C) entails significant functional impairment or  
3 severe pain.

4                   (3) "Terminal illness" means an advanced stage of a  
5 disease with an unfavorable prognosis that, without  
6 life-sustaining procedures, will soon result in death or a state of  
7 permanent unconsciousness from which recovery is unlikely.

8                   Sec. 1003.052. RULES. The executive commissioner shall  
9 adopt rules designating the medical conditions that constitute a  
10 severe chronic disease or terminal illness for purposes of this  
11 subchapter.

12                   Sec. 1003.053. PATIENT ELIGIBILITY. A patient is eligible  
13 to access and use an investigational stem cell treatment under this  
14 subchapter if:

15                   (1) the patient has a severe chronic disease or  
16 terminal illness listed in the rules adopted under Section 1003.052  
17 and attested to by the patient's treating physician; and

18                   (2) the patient's physician:

19                   (A) in consultation with the patient, has  
20 considered all other treatment options currently approved by the  
21 United States Food and Drug Administration and determined that  
22 those treatment options are unavailable or unlikely to alleviate  
23 the significant impairment or severe pain associated with the  
24 severe chronic disease or terminal illness; and

25                   (B) has recommended or prescribed in writing that  
26 the patient use a specific class of investigational stem cell  
27 treatment.

1       Sec. 1003.054. INFORMED CONSENT. (a) Before receiving an  
2 investigational stem cell treatment, an eligible patient must sign  
3 a written informed consent.

4       (b) If the patient is a minor or lacks the mental capacity to  
5 provide informed consent, a parent, guardian, or conservator may  
6 provide informed consent on the patient's behalf.

7       (c) The executive commissioner by rule may adopt a form for  
8 the informed consent under this section.

9       Sec. 1003.055. NO CAUSE OF ACTION CREATED. This subchapter  
10 does not create a private or state cause of action against a  
11 developer of an investigational stem cell treatment or against any  
12 other person or entity involved in the care of an eligible patient  
13 using the investigational stem cell treatment for any harm done to  
14 the eligible patient resulting from the investigational stem cell  
15 treatment.

16       Sec. 1003.056. EFFECT ON OTHER LAW. (a) This subchapter  
17 does not affect the coverage of enrollees in clinical trials under  
18 Chapter 1379, Insurance Code.

19       (b) This subchapter does not affect or authorize a person to  
20 violate any law regulating the possession, use, or transfer of  
21 fetal tissue, fetal stem cells, adult stem cells, or human organs,  
22 including Sections 48.02 and 48.03, Penal Code.

23       Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE  
24 PROHIBITED. Notwithstanding any other law, the Texas Medical Board  
25 may not revoke, fail to renew, suspend, or take any action against  
26 a physician's license under Subchapter B, Chapter 164, Occupations  
27 Code, based solely on the physician's recommendations to an

1 eligible patient regarding access to or use of an investigational  
2 stem cell treatment, provided that the care provided or  
3 recommendations made to the patient meet the standard of care and  
4 the requirements of this subchapter.

5 Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED. (a)  
6 In this section, "governmental entity" means this state or an  
7 agency or political subdivision of this state.

8 (b) A governmental entity or an officer, employee, or agent  
9 of a governmental entity may not interfere with an eligible  
10 patient's access to or use of a stem cell treatment authorized under  
11 this subchapter.

12 SECTION 3. Chapter 48, Penal Code, is amended by adding  
13 Section 48.03 to read as follows:

14 Sec. 48.03. PROHIBITION ON PURCHASE AND SALE OF ADULT STEM  
15 CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS. (a) In this  
16 section:

17 (1) "Adult stem cell" means an undifferentiated cell  
18 that is:

19 (A) found in differentiated tissue; and  
20 (B) able to renew itself and differentiate to  
21 yield all or nearly all of the specialized cell types of the tissue  
22 from which the cell originated.

23 (2) "Investigational stem cell treatment" means an  
24 adult stem cell treatment that:

25 (A) is under investigation in a clinical trial  
26 and being administered to human participants in that trial; and

27 (B) has not yet been approved for general use by

1 the United States Food and Drug Administration.

2 (b) A person commits an offense if the person knowingly  
3 offers to buy, offers to sell, acquires, receives, sells, or  
4 otherwise transfers any adult stem cells for valuable consideration  
5 for use in an investigational stem cell treatment.

6 (c) It is an exception to the application of this section  
7 that the valuable consideration is:

8 (1) a fee paid to a physician or to other medical  
9 personnel for services rendered in the usual course of medical  
10 practice or a fee paid for hospital or other clinical services;

11 (2) reimbursement of legal or medical expenses  
12 incurred for the benefit of the ultimate receiver of the  
13 investigational stem cell treatment; or

14 (3) reimbursement of expenses of travel, housing, and  
15 lost wages incurred by the donor of adult stem cells in connection  
16 with the donation of the adult stem cells.

17 (d) It is an exception to the application of this section  
18 that the actor engaged in conduct authorized under Chapter 162,  
19 Health and Safety Code.

20 (e) A violation of this section is a Class A misdemeanor.

21 SECTION 4. As soon as practicable after the effective date  
22 of this Act, the executive commissioner of the Health and Human  
23 Services Commission shall adopt rules necessary to implement  
24 Subchapter B, Chapter 1003, Health and Safety Code, as added by this  
25 Act.

26 SECTION 5. This Act takes effect September 1, 2017.