

1-1 By: Parker, et al. (Senate Sponsor - Bettencourt) H.B. No. 810
 1-2 (In the Senate - Received from the House May 15, 2017;
 1-3 May 15, 2017, read first time and referred to Committee on Health &
 1-4 Human Services; May 22, 2017, reported favorably by the following
 1-5 vote: Yeas 9, Nays 0; May 22, 2017, sent to printer.)

1-6 COMMITTEE VOTE

	Yea	Nay	Absent	PNV
1-7				
1-8	X			
1-9	X			
1-10	X			
1-11	X			
1-12	X			
1-13	X			
1-14	X			
1-15	X			
1-16	X			

1-17 A BILL TO BE ENTITLED
 1-18 AN ACT

1-19 relating to the provision of certain investigational stem cell
 1-20 treatments to patients with certain severe chronic diseases or
 1-21 terminal illnesses and regulating the possession, use, and transfer
 1-22 of adult stem cells; creating a criminal offense.

1-23 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-24 SECTION 1. This Act shall be known as Charlie's Law.

1-25 SECTION 2. Chapter 1003, Health and Safety Code, is amended
 1-26 by designating Sections 1003.001, 1003.002, and 1003.003 as
 1-27 Subchapter A and adding a subchapter heading to read as follows:

1-28 SUBCHAPTER A. GENERAL PROVISIONS

1-29 SECTION 3. Chapter 1003, Health and Safety Code, is amended
 1-30 by adding Subchapter B to read as follows:

1-31 SUBCHAPTER B. PROVISION OF INVESTIGATIONAL STEM CELL TREATMENTS TO
 1-32 PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES

1-33 Sec. 1003.051. DEFINITIONS. In this subchapter:

1-34 (1) "Investigational stem cell treatment" means an
 1-35 adult stem cell treatment that:

1-36 (A) is under investigation in a clinical trial
 1-37 and being administered to human participants in that trial; and

1-38 (B) has not yet been approved for general use by
 1-39 the United States Food and Drug Administration.

1-40 (2) "Severe chronic disease" means a condition,
 1-41 injury, or illness that:

1-42 (A) may be treated;

1-43 (B) is never cured or eliminated; and

1-44 (C) entails significant functional impairment or
 1-45 severe pain.

1-46 (3) "Terminal illness" means an advanced stage of a
 1-47 disease with an unfavorable prognosis that, without
 1-48 life-sustaining procedures, will soon result in death or a state of
 1-49 permanent unconsciousness from which recovery is unlikely.

1-50 Sec. 1003.052. RULES. The executive commissioner shall
 1-51 adopt rules designating the medical conditions that constitute a
 1-52 severe chronic disease or terminal illness for purposes of this
 1-53 subchapter.

1-54 Sec. 1003.053. PATIENT ELIGIBILITY. A patient is eligible
 1-55 to access and use an investigational stem cell treatment under this
 1-56 subchapter if:

1-57 (1) the patient has a severe chronic disease or
 1-58 terminal illness listed in the rules adopted under Section 1003.052
 1-59 and attested to by the patient's treating physician; and

1-60 (2) the patient's physician:

1-61 (A) in consultation with the patient, has

2-1 considered all other treatment options currently approved by the
 2-2 United States Food and Drug Administration and determined that
 2-3 those treatment options are unavailable or unlikely to alleviate
 2-4 the significant impairment or severe pain associated with the
 2-5 severe chronic disease or terminal illness; and

2-6 (B) has recommended or prescribed in writing that
 2-7 the patient use a specific class of investigational stem cell
 2-8 treatment.

2-9 Sec. 1003.054. INFORMED CONSENT. (a) Before receiving an
 2-10 investigational stem cell treatment, an eligible patient must sign
 2-11 a written informed consent.

2-12 (b) If the patient is a minor or lacks the mental capacity to
 2-13 provide informed consent, a parent, guardian, or conservator may
 2-14 provide informed consent on the patient's behalf.

2-15 (c) The executive commissioner by rule may adopt a form for
 2-16 the informed consent under this section.

2-17 Sec. 1003.055. NO CAUSE OF ACTION CREATED. This subchapter
 2-18 does not create a private or state cause of action against a
 2-19 developer of an investigational stem cell treatment or against any
 2-20 other person or entity involved in the care of an eligible patient
 2-21 using the investigational stem cell treatment for any harm done to
 2-22 the eligible patient resulting from the investigational stem cell
 2-23 treatment.

2-24 Sec. 1003.056. EFFECT ON OTHER LAW. (a) This subchapter
 2-25 does not affect the coverage of enrollees in clinical trials under
 2-26 Chapter 1379, Insurance Code.

2-27 (b) This subchapter does not affect or authorize a person to
 2-28 violate any law regulating the possession, use, or transfer of
 2-29 fetal tissue, fetal stem cells, adult stem cells, or human organs,
 2-30 including Sections 48.02 and 48.03, Penal Code.

2-31 Sec. 1003.057. ACTION AGAINST PHYSICIAN'S LICENSE
 2-32 PROHIBITED. Notwithstanding any other law, the Texas Medical Board
 2-33 may not revoke, fail to renew, suspend, or take any action against
 2-34 a physician's license under Subchapter B, Chapter 164, Occupations
 2-35 Code, based solely on the physician's recommendations to an
 2-36 eligible patient regarding access to or use of an investigational
 2-37 stem cell treatment, provided that the care provided or
 2-38 recommendations made to the patient meet the standard of care and
 2-39 the requirements of this subchapter.

2-40 Sec. 1003.058. GOVERNMENTAL INTERFERENCE PROHIBITED. (a)
 2-41 In this section, "governmental entity" means this state or an
 2-42 agency or political subdivision of this state.

2-43 (b) A governmental entity or an officer, employee, or agent
 2-44 of a governmental entity may not interfere with an eligible
 2-45 patient's access to or use of a stem cell treatment authorized under
 2-46 this subchapter.

2-47 SECTION 4. Chapter 48, Penal Code, is amended by adding
 2-48 Section 48.03 to read as follows:

2-49 Sec. 48.03. PROHIBITION ON PURCHASE AND SALE OF ADULT STEM
 2-50 CELLS FOR CERTAIN INVESTIGATIONAL TREATMENTS. (a) In this
 2-51 section:

2-52 (1) "Adult stem cell" means an undifferentiated cell
 2-53 that is:

2-54 (A) found in differentiated tissue; and
 2-55 (B) able to renew itself and differentiate to
 2-56 yield all or nearly all of the specialized cell types of the tissue
 2-57 from which the cell originated.

2-58 (2) "Investigational stem cell treatment" means an
 2-59 adult stem cell treatment that:

2-60 (A) is under investigation in a clinical trial
 2-61 and being administered to human participants in that trial; and

2-62 (B) has not yet been approved for general use by
 2-63 the United States Food and Drug Administration.

2-64 (b) A person commits an offense if the person knowingly
 2-65 offers to buy, offers to sell, acquires, receives, sells, or
 2-66 otherwise transfers any adult stem cells for valuable consideration
 2-67 for use in an investigational stem cell treatment.

2-68 (c) It is an exception to the application of this section
 2-69 that the valuable consideration is:

3-1 (1) a fee paid to a physician or to other medical
3-2 personnel for services rendered in the usual course of medical
3-3 practice or a fee paid for hospital or other clinical services;

3-4 (2) reimbursement of legal or medical expenses
3-5 incurred for the benefit of the ultimate receiver of the
3-6 investigational stem cell treatment; or

3-7 (3) reimbursement of expenses of travel, housing, and
3-8 lost wages incurred by the donor of adult stem cells in connection
3-9 with the donation of the adult stem cells.

3-10 (d) It is an exception to the application of this section
3-11 that the actor engaged in conduct authorized under Chapter 162,
3-12 Health and Safety Code.

3-13 (e) A violation of this section is a Class A misdemeanor.

3-14 SECTION 5. As soon as practicable after the effective date
3-15 of this Act, the executive commissioner of the Health and Human
3-16 Services Commission shall adopt rules necessary to implement
3-17 Subchapter B, Chapter 1003, Health and Safety Code, as added by this
3-18 Act.

3-19 SECTION 6. This Act takes effect September 1, 2017.

3-20 * * * * *