

1-1 By: Parker, et al. (Senate Sponsor - Bettencourt) H.B. No. 3148
1-2 (In the Senate - Received from the House May 9, 2019;
1-3 May 10, 2019, read first time and referred to Committee on Health &
1-4 Human Services; May 20, 2019, reported adversely, with favorable
1-5 Committee Substitute by the following vote: Yeas 9, Nays 0;
1-6 May 20, 2019, sent to printer.)

1-7 COMMITTEE VOTE

	Yea	Nay	Absent	PNV
1-8				
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	X			

1-18 COMMITTEE SUBSTITUTE FOR H.B. No. 3148 By: Perry

1-19 A BILL TO BE ENTITLED
1-20 AN ACT

1-21 relating to the administration and oversight of investigational
1-22 adult stem cell treatments administered to certain patients.

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

1-24 SECTION 1. Subchapter B, Chapter 1003, Health and Safety
1-25 Code, is amended by adding Sections 1003.0525 and 1003.0526 to read
1-26 as follows:

1-27 Sec. 1003.0525. ADMINISTRATION OF SUBCHAPTER. The
1-28 department shall administer this subchapter.

1-29 Sec. 1003.0526. INVESTIGATIONAL STEM CELL REGISTRY. The
1-30 department shall establish and maintain an investigational stem
1-31 cell registry that lists each physician who administers an
1-32 investigational stem cell treatment under this subchapter.

1-33 SECTION 2. Section 1003.054(c), Health and Safety Code, is
1-34 amended to read as follows:

1-35 (c) The executive commissioner by rule shall ~~may~~ adopt a
1-36 form for the informed consent under this section. The form must
1-37 provide notice that the department administers this subchapter.

1-38 SECTION 3. Section 1003.055(d), Health and Safety Code, is
1-39 amended to read as follows:

1-40 (d) An institutional review board that oversees
1-41 investigational stem cell treatments administered under this
1-42 subchapter must meet one of the following conditions ~~[be affiliated~~
1-43 ~~with]~~:

1-44 (1) be affiliated with a medical school, as defined by
1-45 Section 61.501, Education Code; ~~or~~

1-46 (2) be affiliated with a hospital licensed under
1-47 Chapter 241 that has at least 150 beds;

1-48 (3) be accredited by the Association for the
1-49 Accreditation of Human Research Protection Programs;

1-50 (4) be registered by the United States Department of
1-51 Health and Human Services, Office for Human Research Protections,
1-52 in accordance with 21 C.F.R. Part 56; or

1-53 (5) be accredited by a national accreditation
1-54 organization acceptable to the Texas Medical Board.

1-55 SECTION 4. Section 1003.058(b), Health and Safety Code, is
1-56 amended to read as follows:

1-57 (b) A governmental entity or an officer, employee, or agent
1-58 of a governmental entity may not interfere with an eligible
1-59 patient's access to or use of an investigational ~~[a]~~ stem cell
1-60 treatment authorized under this subchapter unless the treatment

2-1 uses an adult stem cell product that is considered an adulterated or
2-2 misbranded drug under Chapter 431. For purposes of this subsection,
2-3 a governmental entity may not consider the adult stem cell product
2-4 to be an adulterated or misbranded drug solely on the basis that the
2-5 United States Food and Drug Administration has not approved the
2-6 adult stem cell product.

2-7 SECTION 5. Subchapter B, Chapter 1003, Health and Safety
2-8 Code, is amended by adding Section 1003.060 to read as follows:

2-9 Sec. 1003.060. CONSTRUCTION OF SUBCHAPTER. This subchapter
2-10 may not be construed to:

2-11 (1) prohibit a physician from using adult stem cells
2-12 for their intended homologous use if the stem cells are:

2-13 (A) produced by a manufacturer registered by the
2-14 United States Food and Drug Administration; and

2-15 (B) commercially available; or

2-16 (2) require an institutional review board to oversee
2-17 treatment using adult stem cells registered by the United States
2-18 Food and Drug Administration for their intended homologous use.

2-19 SECTION 6. The Department of State Health Services is not
2-20 required to establish the investigational stem cell registry
2-21 described by Section 1003.0526, Health and Safety Code, as added by
2-22 this Act, until September 1, 2027.

2-23 SECTION 7. This Act takes effect September 1, 2019.

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