

SENATE BILL 152

By Pody

AN ACT to amend Tennessee Code Annotated, Title 53;
Title 63 and Title 68, relative to stem cell
treatment.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding
the following as a new part:

63-6-901. Part definitions.

As used in this part:

(1) "Commissioner" means the commissioner of health;

(2) "Governmental entity" means this state or an agency or political
subdivision of this state;

(3) "Investigational stem cell treatment" means an adult stem cell
treatment that:

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

(B) Has not yet been approved for general use by the United
States food and drug administration;

(4) "Severe chronic disease" means a condition, injury, or illness that:

(A) May be treated;

(B) Is never cured or eliminated; and

(C) Entails significant functional impairment or severe pain; and

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

63-6-902. Patient eligibility.

A patient may access and use an investigational stem cell treatment under this part if:

(1) The patient has a severe chronic disease or terminal illness listed in the rules adopted under § 63-6-907 and attested to by the patient's treating physician; and

(2) The patient's treating physician:

(A) In consultation with the patient, has considered all other treatment options currently approved by the United States food and drug administration and determined that those treatment options are unavailable or unlikely to alleviate the significant impairment or severe pain associated with the severe chronic disease or terminal illness; and

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

63-6-903. Informed consent.

(a) Before receiving an investigational stem cell treatment, an eligible patient must sign a written informed consent.

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

(c) The commissioner may develop and make available to physicians a form for the informed consent under this section.

63-6-904. Effect on other law.

(a) This part does not affect the coverage of enrollees in clinical trials under § 56-7-2365.

(b) This part does 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 § 39-15-208.

63-6-905. Action against physician license prohibited.

Notwithstanding another law, the board of medical examiners and the board of osteopathic examination shall not revoke, fail to renew, suspend, or take any action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to or use of an investigational stem cell treatment if the care provided or recommendations made to the patient meet the standard of care and the requirements of this part.

63-6-906. Governmental interference prohibited.

A governmental entity or an officer, employee, or agent of a governmental entity shall not interfere with an eligible patient's access to or use of an investigational stem cell treatment authorized under this part.

63-6-907. Rules.

The commissioner shall promulgate rules to effectuate this part. The rules must include designating the medical conditions that constitute a severe chronic disease or terminal illness for purposes of this part. Rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. The headings to sections in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. This act takes effect upon becoming a law, the public welfare requiring it.