State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-NINTH SESSION

H. F. No. 236

01/20/2015 Authored by Zerwas, Schoen, Isaacson, Lesch, Gruenhagen and others
The bill was read for the first time and referred to the Committee on Health and Human Services Reform

A bill for an act

relating to health; permitting the use of investigational drugs, biological products, or devices by certain eligible patients; proposing coding for new law in Minnesota Statutes, chapter 151.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[151.375] INVESTIGATIONAL DRUG USE.**

Subdivision 1. **Title; citation.** This section may be cited as the "Right to Try Act."

Subd. 2. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given them.

(b) "Eligible patient" means a patient who meets the requirements in subdivision 3.

(c) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial, but has not been approved for general use by the federal Food and Drug Administration (FDA), and is currently under investigation in a FDA clinical trial.

(d) "Terminal disease" means an advanced stage of a disease with a terminal prognosis and no known cure.

Subd. 3. **Eligibility.** In order for a patient to access an investigational drug, biological product, or device under this section, a physician must document in writing that the patient:

(1) has a terminal disease;

(2) has, in consultation with a physician, considered all other treatment options currently approved by the FDA;

(3) has been given a prescription or recommendation by a physician for an investigational drug, biological product, or device; and

(4) has given informed consent, in writing, for the use of the investigational drug, biological product, or device, or if the patient is under the age of 18, or lacks the mental capacity to provide informed consent, a parent or legal guardian has given informed consent, in writing, on behalf of the patient.

Subd. 4. **Availability.** (a) A manufacturer of an investigational drug, biological product, or device has the option of making its investigational drug, biological product, or device available to eligible patients under this section.

(b) Nothing in this section shall be construed to require a manufacturer to make an investigational drug, biological product, or device available.

Subd. 5. **Costs.** (a) A manufacturer may provide an investigational drug, biological product, or device without receiving compensation.

(b) A manufacturer may require an eligible patient to pay the costs associated with manufacturing the investigational drug, biological product, or device.

Subd. 6. **Insurance coverage.** Nothing in this section shall be construed to require private health coverage, or a state public health care program to cover the cost of an investigational drug, biological product, or device.

Subd. 7. **Professional licensing.** A health-related licensing board shall not revoke a license, fail to renew a license, or take any other disciplinary action against a licensee solely based on the licensee providing a prescription or recommendation, or providing treatment to an eligible patient that involves the use of an investigational drug, biological product, or device in accordance with this section.

Subd. 8. **Penalty.** Any official, employee, or agent of the state of Minnesota who attempts to block or who blocks access of an eligible patient to an investigational drug, biological product, or device shall be guilty of a misdemeanor and sentenced to imprisonment for not more than six months, payment of a fine of not more than $2,500, or both.

Subd. 9. **Severability.** If any provision of this section or its application to any person or circumstances is held to be invalid, the invalidity of the provision shall not affect any other provision of this section. The provisions of this section are severable.