

**SUBSTITUTE FOR
SENATE BILL NO. 991**

A bill to authorize access to and use of experimental treatments for patients with an advanced illness; to establish conditions for use of experimental treatment; to prohibit sanctions of health care providers solely for recommending or providing experimental treatment; to clarify duties of a health insurer with regard to experimental treatment authorized under this act; to prohibit certain actions by state officials, employees, and agents; and to restrict certain causes of action arising from experimental treatment.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 1. (1) This act shall be known and may be cited as the
2 "right to try act".

3 (2) As used in this act, and unless the context otherwise

1 requires:

2 (a) "Advanced illness", for purposes of this section only,
3 means a progressive disease or medical or surgical condition that
4 entails significant functional impairment, that is not considered
5 by a treating physician to be reversible even with administration
6 of current federal drug administration approved and available
7 treatments, and that, without life-sustaining procedures, will soon
8 result in death.

9 (b) "Eligible patient" means an individual who meets all of
10 the following conditions:

11 (i) Has an advanced illness, attested to by the patient's
12 treating physician.

13 (ii) Has considered all other treatment options currently
14 approved by the United States food and drug administration.

15 (iii) Has received a recommendation from his or her physician
16 for an investigational drug, biological product, or device.

17 (iv) Has given written, informed consent for the use of the
18 investigational drug, biological product, or device.

19 (v) Has documentation from his or her physician that he or she
20 meets the requirements of this subdivision.

21 (c) "Investigational drug, biological product, or device"
22 means a drug, biological product, or device that has successfully
23 completed phase 1 of a clinical trial but has not yet been approved
24 for general use by the United States food and drug administration
25 and remains under investigation in a United States food and drug
26 administration-approved clinical trial.

27 (d) "Written, informed consent" means a written document that

1 is signed by the patient; parent, if the patient is a minor; legal
2 guardian; or patient advocate designated by the patient under
3 section 5506 of the estates and protected individuals code, 1998 PA
4 386, MCL 700.5506, and attested to by the patient's physician and a
5 witness and that, at a minimum, includes all of the following:

6 (i) An explanation of the currently approved products and
7 treatments for the disease or condition from which the patient
8 suffers.

9 (ii) An attestation that the patient concurs with his or her
10 physician in believing that all currently approved and
11 conventionally recognized treatments are unlikely to prolong the
12 patient's life.

13 (iii) Clear identification of the specific proposed
14 investigational drug, biological product, or device that the
15 patient is seeking to use.

16 (iv) A description of the potentially best and worst outcomes
17 of using the investigational drug, biological product, or device
18 and a realistic description of the most likely outcome. The
19 description shall include the possibility that new, unanticipated,
20 different, or worse symptoms might result and that death could be
21 hastened by the proposed treatment. The description shall be based
22 on the physician's knowledge of the proposed treatment in
23 conjunction with an awareness of the patient's condition.

24 (v) A statement that the patient's health plan or third party
25 administrator and provider are not obligated to pay for any care or
26 treatments consequent to the use of the investigational drug,
27 biological product, or device, unless they are specifically

1 required to do so by law or contract.

2 (vi) A statement that the patient's eligibility for hospice
3 care may be withdrawn if the patient begins curative treatment with
4 the investigational drug, biological product, or device and that
5 care may be reinstated if this treatment ends and the patient meets
6 hospice eligibility requirements.

7 (vii) A statement that the patient understands that he or she
8 is liable for all expenses consequent to the use of the
9 investigational drug, biological product, or device and that this
10 liability extends to the patient's estate, unless a contract
11 between the patient and the manufacturer of the drug, biological
12 product, or device states otherwise.

13 Sec. 2. (1) A manufacturer of an investigational drug,
14 biological product, or device may make available and an eligible
15 patient may request the manufacturer's investigational drug,
16 biological product, or device under this act. This act does not
17 require that a manufacturer make available an investigational drug,
18 biological product, or device to an eligible patient.

19 (2) A manufacturer may do all of the following:

20 (a) Provide an investigational drug, biological product, or
21 device to an eligible patient without receiving compensation.

22 (b) Require an eligible patient to pay the costs of, or the
23 costs associated with, the manufacture of the investigational drug,
24 biological product, or device.

25 Sec. 3. (1) This act does not expand the coverage required of
26 an insurer under the insurance code of 1956, 1956 PA 218, MCL
27 500.100 to 500.8302.

1 (2) A health plan, third party administrator, or governmental
2 agency may, but is not required to, provide coverage for the cost
3 of an investigational drug, biological product, or device, or the
4 cost of services related to the use of an investigational drug,
5 biological product, or device under this act.

6 (3) This act does not require any governmental agency to pay
7 costs associated with the use, care, or treatment of a patient with
8 an investigational drug, biological product, or device.

9 (4) This act does not require a hospital or facility licensed
10 under part 215 of the public health code, 1978 PA 368, MCL
11 333.21501 to 333.21571, to provide new or additional services,
12 unless approved by the hospital or facility.

13 Sec. 4. If a patient dies while being treated by an
14 investigational drug, biological product, or device, the patient's
15 heirs are not liable for any outstanding debt related to the
16 treatment or lack of insurance due to the treatment.

17 Sec. 5. A licensing board or disciplinary subcommittee shall
18 not revoke, fail to renew, suspend, or take any action against a
19 health care provider's license issued under article 15 or 17 of the
20 public health code, 1978 PA 368, MCL 333.16101 to 333.18838 and
21 333.20101 to 333.22260, based solely on the health care provider's
22 recommendations to an eligible patient regarding access to or
23 treatment with an investigational drug, biological product, or
24 device. An entity responsible for medicare certification shall not
25 take action against a health care provider's medicare certification
26 based solely on the health care provider's recommendation that a
27 patient have access to an investigational drug, biological product,

1 or device.

2 Sec. 6. An official, employee, or agent of this state shall
3 not block or attempt to block an eligible patient's access to an
4 investigational drug, biological product, or device. Counseling,
5 advice, or a recommendation consistent with medical standards of
6 care from a licensed health care provider is not a violation of
7 this section.

8 Sec. 7. (1) This act does not create a private cause of action
9 against a manufacturer of an investigational drug, biological
10 product, or device or against any other person or entity involved
11 in the care of an eligible patient using the investigational drug,
12 biological product, or device for any harm done to the eligible
13 patient resulting from the investigational drug, biological
14 product, or device, if the manufacturer or other person or entity
15 is complying in good faith with the terms of this act and has
16 exercised reasonable care.

17 (2) This act does not affect any mandatory health care
18 coverage for participation in clinical trials under the insurance
19 code of 1956, 1956 PA 218, MCL 500.100 to 500.8302.