

**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. This act shall be known and may be cited as the "right
2 to try act".

3 Sec. 2. As used in this act, and unless the context otherwise

1 requires:

2 (a) "Advanced illness" means a disease or medical or surgical
3 condition with significant functional impairment that is not
4 reversible even with administration of current federal drug
5 administration approved and available treatments that is expected
6 to result in death or a state of unconsciousness from which
7 recovery is not expected. For purposes of this act only, advanced
8 illness has the same general meaning as terminal illness has in the
9 medical community.

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

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

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

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

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

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

22 (vi) Is not being treated in a hospital licensed or certified
23 under part 215 of the public health code, 1978 PA 38, MCL 333.21501
24 to 333.21571, or in a facility subject to 42 CFR 482.25, unless
25 approved by the hospital or facility.

26 (c) "Investigational drug, biological product, or device"
27 means a drug, biological product, or device that has successfully

1 completed phase 1 of a clinical trial but has not yet been approved
2 for general use by the United States food and drug administration
3 and remains under investigation in a United States food and drug
4 administration-approved clinical trial.

5 (d) "Written, informed consent" means a written document that
6 is signed by the patient; parent, if the patient is a minor; legal
7 guardian; or patient advocate designated by the patient under
8 section 5506 of the estates and protected individuals code, 1998 PA
9 386, MCL 700.5506, and attested to by the patient's physician and a
10 witness and that, at a minimum, includes all of the following:

11 (i) An explanation of the currently approved products and
12 treatments for the disease or condition from which the patient
13 suffers.

14 (ii) An attestation that the patient concurs with his or her
15 physician in believing that all currently approved and
16 conventionally recognized treatments are unlikely to prolong the
17 patient's life.

18 (iii) Clear identification of the specific proposed
19 investigational drug, biological product, or device that the
20 patient is seeking to use.

21 (iv) A description of the potentially best and worst outcomes
22 of using the investigational drug, biological product, or device
23 and a realistic description of the most likely outcome. The
24 description shall include the possibility that new, unanticipated,
25 different, or worse symptoms might result and that death could be
26 hastened by the proposed treatment. The description shall be based
27 on the physician's knowledge of the proposed treatment in

1 conjunction with an awareness of the patient's condition.

2 (v) A statement that the patient's health plan or third party
3 administrator and provider are not obligated to pay for any care or
4 treatments consequent to the use of the investigational drug,
5 biological product, or device, unless they are specifically
6 required to do so by law or contract.

7 (vi) A statement that the patient's eligibility for hospice
8 care may be withdrawn if the patient begins curative treatment with
9 the investigational drug, biological product, or device and that
10 care may be reinstated if this treatment ends and the patient meets
11 hospice eligibility requirements.

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

18 Sec. 3. (1) A manufacturer of an investigational drug,
19 biological product, or device may make available and an eligible
20 patient may request the manufacturer's investigational drug,
21 biological product, or device under this act. This act does not
22 require that a manufacturer make available an investigational drug,
23 biological product, or device to an eligible patient.

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

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

27 (b) Require an eligible patient to pay the costs of, or the

1 costs associated with, the manufacture of the investigational drug,
2 biological product, or device.

3 Sec. 4. (1) This act does not expand the coverage required of
4 an insurer under the insurance code of 1956, 1956 PA 218, MCL
5 500.100 to 500.8302.

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

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

14 Sec. 5. If a patient dies while being treated by an
15 investigational drug, biological product, or device, the patient's
16 heirs are not liable for any outstanding debt related to the
17 treatment or lack of insurance due to the treatment.

18 Sec. 6. Notwithstanding any other law, a licensing board shall
19 not revoke, fail to renew, suspend, or take any action against a
20 health care provider's license issued under article 15 or 17 of the
21 public health code, 1978 PA 368, MCL 333.16101 to 333.18838 and
22 333.20101 to 333.22260, based solely on the health care provider's
23 recommendations to an eligible patient regarding access to or
24 treatment with an investigational drug, biological product, or
25 device, as long as the recommendations are consistent with medical
26 standards of care. A board shall not take action against a health
27 care provider's medicare certification based solely on the health

1 care provider's recommendation that a patient have access to an
2 investigational drug, biological product, or device.

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

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

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