

HOUSE BILL NO. 5637

December 14, 2021, Introduced by Rep. Whiteford and referred to the Committee on Health Policy.

A bill to amend 2014 PA 345, entitled
"Right to try act,"
by amending section 1 (MCL 333.26451).

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
4 requires:

5 (a) "Advanced illness", for purposes of this section only,

means a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with ~~the~~ administration of current ~~federal drug administration approved~~ **United States Food and Drug Administration-approved** and available treatments, and that, without life-sustaining procedures, will soon result in death.

(b) "COVID-19 pandemic emergency" means a public health emergency declared by the Secretary of the United States Department of Health and Human Services resulting from coronavirus disease 2019.

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

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

(ii) Has considered all other treatment options currently approved by the United States ~~food~~ **Food** and ~~drug~~ **administration**. **Drug Administration.**

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

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

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

(d) ~~(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 yet been approved for general use by the United States ~~food~~ **Food** and ~~drug~~ **administration**. **Drug Administration** and remains under investigation

1 in a United States ~~food~~**Food** and ~~drug administration approved~~**Drug**
2 **Administration-approved** clinical trial. During a COVID-19 pandemic
3 emergency, investigational drug, biological product, or device also
4 includes both of the following:

5 (i) A drug, biological product, device, or other treatment,
6 that remains under investigation in a United States Food and Drug
7 Administration-approved clinical trial and that a physician
8 recommends as a remedy for coronavirus disease 2019.

9 (ii) A drug, biological product, or device normally prescribed
10 as a remedy to treat an illness other than coronavirus disease 2019
11 that a physician recommends as a remedy for coronavirus disease
12 2019.

13 (e) ~~(d)~~—"Written, informed consent" means a written document
14 that is signed by the patient; parent, if the patient is a minor;
15 legal guardian; or patient advocate designated by the patient under
16 section 5506 of the estates and protected individuals code, 1998 PA
17 386, MCL 700.5506, and attested to by the patient's physician and a
18 witness and that, at a minimum, includes all of the following:

19 (i) An explanation of the currently approved products and
20 treatments for the disease or condition from which the patient
21 suffers.

22 (ii) An attestation that the patient concurs with his or her
23 physician in believing that all currently approved and
24 conventionally recognized treatments are unlikely to prolong the
25 patient's life.

26 (iii) Clear identification of the specific proposed
27 investigational drug, biological product, or device that the
28 patient is seeking to use.

29 (iv) A description of the potentially best and worst outcomes

1 of using the investigational drug, biological product, or device
2 and a realistic description of the most likely outcome. The
3 description ~~shall~~**must** include the possibility that new,
4 unanticipated, different, or worse symptoms might result and that
5 death could be hastened by the proposed treatment. The description
6 ~~shall~~**must** be based on the physician's knowledge of the proposed
7 treatment in conjunction with an awareness of the patient's
8 condition.

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

14 (vi) A statement that the patient's eligibility for hospice
15 care may be withdrawn if the patient begins curative treatment with
16 the investigational drug, biological product, or device and that
17 care may be reinstated if this treatment ends and the patient meets
18 hospice eligibility requirements.

19 (vii) A statement that the patient understands that he or she
20 is liable for all expenses consequent to the use of the
21 investigational drug, biological product, or device and that this
22 liability extends to the patient's estate, unless a contract
23 between the patient and the manufacturer of the drug, biological
24 product, or device states otherwise.