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:

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

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

(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

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

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

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

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

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

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

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

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

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

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

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

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