HOUSE BILL NO. 4789

August 21, 2025, Introduced by Reps. Thompson, Johnsen, Pavlov, Woolford, Wozniak, Schmaltz, Steckloff, Linting, Herzberg, Morgan, Kunse, Maddock, Frisbie, Alexander, Roth, Prestin, Posthumus and Bruck and referred to Committee on Health Policy.

A bill to amend 2014 PA 345, entitled

"Right to try act,"

by amending the title and sections 1, 2, 3, 4, 5, 6, and 7 (MCL 333.26451, 333.26452, 333.26453, 333.26454, 333.26455, 333.26456, and 333.26457), and by adding section 2a.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

TITLE

An act to authorize access to and use of experimental treatments for patients with an advanced illness **or a life-**

threatening or severely debilitating 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.

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 administration of current ~~federal drug administration~~ **United States Food and Drug Administration-**approved and available treatments, and that, without life-sustaining procedures, will soon result in death.

(b) "Eligible facility" means an institution that is operating under a federalwide assurance for the protection of human subjects under 42 USC 289 and 45 CFR part 46 and is subject to the federalwide assurance laws, regulations, policies, and guidelines.

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

(*i*) Has an advanced illness **or a life-threatening or severely debilitating illness**, attested to by the patient's treating physician.

(*ii*) Has considered all other treatment options currently

approved by the United States ~~food and drug administration.~~**Food and Drug Administration.**

(*iii*) Has received a recommendation from ~~his or her~~ **the individual's** physician for ~~an~~ **1 of the following:**

(A) An investigational drug, biological product, or device.

(B) An individualized investigational treatment.

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

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

(d) "Individualized investigational treatment" means a drug, biological product, or device that is unique to and produced exclusively for use for a patient, based on an analysis of the patient's own genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products, or metabolites. Individualized investigational treatment includes, but is not limited to, an individualized gene therapy antisense oligonucleotide and an individualized neoantigen vaccine.

(e) ~~(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 and drug administration~~ **Food and Drug Administration** and remains under investigation in a United States ~~food and drug administration-approved~~ **Food and Drug Administration-approved** clinical trial.

(f) "Life-threatening or severely debilitating illness" means a disease or condition that meets 1 or more of the following:

(*i*) The likelihood of death is high unless the course of the disease is interrupted.

(*ii*) The outcome is potentially fatal and the end point of the clinical trial analysis is survival.

(*iii*) The disease or condition causes major irreversible morbidity.

(g) ~~(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~~ **the patient's** 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 **or individualized investigational treatment**, 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 **or the individualized investigational treatment**, 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 **or individualized investigational treatment**, 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 **or individualized investigational treatment**, 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~~ **the patient** is liable for all expenses consequent to the use of the investigational drug, biological product, or device **or individualized investigational treatment**, 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 **or individualized investigational treatment** states otherwise.

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

(2) A manufacturer may do ~~all~~ **both** of the following:

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

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

Sec. 2a. (1) A manufacturer operating within an eligible facility and pursuant to applicable federalwide assurance laws and regulations may make available and an eligible patient may request the manufacturer's individualized investigational treatment under this act. This act does not require that a manufacturer make available an individualized investigational treatment to an eligible patient.

(2) An eligible facility or a manufacturer operating within an eligible facility may do both of the following:

(a) Provide an individualized investigational treatment to an eligible patient without receiving compensation.

(b) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the individualized investigational treatment.

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

(2) A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for ~~the~~ **any of the following under this act:**

(a) The cost of an investigational drug, biological product, or device, or ~~the~~ **an individualized investigational treatment.**

(b) The cost of services related to the use of an

investigational drug, biological product, or device ~~under this act.~~ **or an individualized investigational treatment.**

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

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

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

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

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

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

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