MATT MORGAN
Legislative District 29A
St. Mary's County

Health and Government Operations Committee

The Maryland House of Delegates
6 Bladen Street, Room 310
Annapolis, Maryland 21401
410-841-3170 · 301-858-3170
800-492-7122 *Ext.* 3170
Matt.Morgan@house.state.md.us

THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

Delegate Joseline Pena- Melnyk
Chair
House Health and Government Operations Committee
HB 676- Right to Try- Individual Investigational Treatments

FAVORABLE

Dear Chair Pena- Melnyk and Members of the Committee:

Thank you for the opportunity to present **HB 676- Right to Try- Individual Investigational Treatments**

HB676 - **Right to Try for Individual Patient**

This bill proposes expanding the Right to Try legislation to encompass gene-specific personalized treatments that wouldn't typically undergo clinical trials due to their personalized nature. Like HB 403, End of Life with Options, the bill mandates close collaboration between patients and physicians, necessitates a diagnosis of a terminal or severely debilitating illness, and mandates written informed consent detailing treatment expenses, potential outcomes, and associated risks. While health benefit plans, insurers, or governmental agencies can cover treatment costs, it's not obligatory.

Background

Maryland passed a Right to Try bill into law in 2017, ensuring patients' access to medications and therapies that are still in clinical trials. This same law was signed into Federal law in 2018.

The Right to Try legislation safeguards the rights of terminally ill patients to explore medications within the FDA's drug approval pipeline. These medications have safety clearance but are not yet approved for market distribution. Essentially, this initiative grants patients access to cutting-edge treatments available in clinical trials.

The passage of the Right to Try was groundbreaking, but today, patients need more. Right to Try allows access to treatments that are in FDA clinical trials and, therefore, does not usually apply to personalized treatments. There are more than 7,000 rare diseases affecting more than 30 million Americans. So many of the new breakthroughs in treatments are personalized medication to a patient's unique genetic code. Today, cutting-edge medical treatments are tailored for each patient, utilizing genetic and disease data.

No specific safety threshold exists for personalized treatments in initial clinical trials, as safety and efficacy are assessed concurrently on individual patients within the trial itself. Therefore, the Right to Try initiative should be elevated and broadened to prevent the unnecessary bureaucratic obstacles that hinder the increasing number of patients searching for personalized treatments.

Extending the Right to Try to individualize patient treatments should be on the policy agendas of every state and federal lawmaker. The current FDA approval process is a regulatory mismatch for individualized treatments for a single patient.

How does it work?

If a patient receives a diagnosis of a life-threatening or severely debilitating illness, several criteria must be met to consider treatment options.

- The patient's physician must confirm the seriousness of the condition and recommend an investigational personalized treatment.

- Written informed consent addressing treatment costs, outcomes, and associated risks is required.

- The manufacturer must agree to produce the treatment in a compliant facility and make it accessible to the patient. The facility's Institutional Review Board must ensure all requirements are met for research, treatment protocol, patient consent, and safety before treatment is administered.

The concept of the Right to Try for personalized medicine parallels that of the original Right to Try: once the FDA ensures basic safety, a terminally ill patient can work directly with her doctor to seek treatment—without having first to get government permission. In a time where we are considering the passage of legislation giving people the ability to have a physician help them die, we should also seriously consider making a different option available- life.

Please give HB 676a FAVORABLE report.

Thank you,

Delegate