CANDACE MCLAREN LANHAM
Chief Deputy Attorney General

CAROLYN A. QUATTROCKI
Deputy Attorney General

LEONARD J. HOWIE III
Deputy Attorney General

CHRISTIAN E. BARRERA
Chief Operating Officer

ZENITA WICKHAM HURLEY
Chief, Equity, Policy, and Engagement

PETER V. BERNS
General Counsel

ANTHONY G. BROWN
Attorney General

STATE OF MARYLAND
OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

WILLIAM D. GRUHN
Chief
Consumer Protection Division

Writer's Direct Dial No.
(410) 576-6513
hforsyth@oag.state.md.us

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To: Joseline A. Pena-Melnyk, Chair
House Health and Government Operations Committee

From: Heather Forsyth, Deputy Director, Health Education and Advocacy Unit

RE: HB 676 – Right to Try Act – Individualized Investigational Treatments
(**Letter of Concern**)

The HEAU writes to express concern with HB 676.

The current federal regulatory framework includes options for patients with serious and life-threatening illnesses that do not respond to FDA-approved treatments for their illnesses. First, a physician may prescribe a drug "off-label," meaning that the drug has been approved but not for the illness or disease that the patient has. Second, the federal regulatory framework allows the use of investigational drugs by patients facing life-threatening illnesses through (1) clinical trials, (2) expanded access (compassionate use), or (3) right to try. A patient may participate in a clinical trial of an investigational drug when the patient must terminate the use of an approved product due to severe side effects, the limited treatment options are not efficacious for the patient, early study results for a specific investigational drug are promising, or no approved drug exists to treat the patient's illness or disease.

In 2018, after Maryland passed a Right to Try Act (the predecessor to the current bill), Congress passed a federal Right to Try Act that allows eligible patients to have access to investigational drugs. To be an eligible patient under the federal Right to Try Act, the patient must be diagnosed with a life-threatening disease or condition, must have exhausted approved treatment options,

and must be unable to participate in a clinical trial involving the eligible investigational drug as certified by a physician, who (i) is in good standing with the physician's licensing organization or board; and (ii) will not be compensated directly by the manufacturer for so certifying. In contrast, to be eligible under HB 676, a patient must have a life-threatening or severely debilitating illness, attested to by a treating physician, must have merely considered all other treatment options currently approved by the FDA, and must have received a recommendation from the physician for an individualized investigational treatment. HB 676 removes from the state's Right to Try Act the requirement that the patient is ineligible or unable to participate in a clinical trial and removes the requirement that the physician recommending individualized investigational treatment is a treating physician.

The federal Act requires that the investigational product has completed a Phase 1 clinical trial, is the subject of an investigational drug application to the FDA and is in ongoing active development or production. None of these requirements are true for HB 676. While the bill requires the manufacturer to be operating within a facility "operating under a federal-wide assurance for the protection of human subjects," it is not clear whether these protections would adequately cover a patient receiving an investigational drug under the bill, as opposed to a patient receiving the investigational drug pursuant to biomedical research.

In addition to our concerns that the bill would remove the expertise and protection that the FDA provides patients, the highly specialized focus of the bill is likely outside the knowledge base of the vast majority of physicians, yet the bill broadly allows the use of this pathway if a patient has any physician's recommendation, not even the patient's treating physician. The bill also removes disciplinary authority and protections for cases where individualized investigational treatment is used. Importantly, the bill assumes the Office of the Attorney General can draft sufficient informed consent documents, but because these drugs have not been FDA approved, there is no official list of side effects, dosing constraints, and other important information which would make consent truly informed. (*See* https://rapport.bio/all-stories/right-to-try-20-doubles-down-on-a-bad-idea.) While some may argue that patients with life-threatening or severely debilitating diseases should be permitted the opportunity to try, even if the experimental drug advances mortality, there are unknown risks that could increase suffering before death.

For these reasons, we urge the Committee to consider these concerns before issuing a report to advance HB 676.