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March 20, 2024

To: Senator Pamela Beidle, Chair
Senate Finance Committee

From: Lauren Calia, Senior Assistant Attorney General
Consumer Protection Division

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

The Consumer Protection Division writes to express concern with House Bill 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, including through 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:

1. **Clinical Trials.** 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.

2. **Expanded Access/ Compassionate Use.** Patients with serious or immediately life-threatening diseases or conditions may also gain access to investigational treatment outside of a clinical trial,[1] and the FDA allows over 99% of these requests to proceed,

[1] *See* discussion of Expanded Use Program under Federal Food, Drug, and Cosmetic Act section at 2, Fiscal and Policy Note (Revised), https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/HB0676.

with emergency approval within hours, and non-emergency approval with an average of 4 days.[2] The FDA requires changes in about 10% of Expanded Access requests for patient protection.[3]

3. **Federal Right to Try Act.** 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 (1) must be diagnosed with a life-threatening disease or condition; (2) must have exhausted approved treatment options and is 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; and (3) must have given written informed consent to the patient's treating physician.

Eligible Patients.

In contrast to the federal Right to Try Act, to be eligible under HB 676, a patient 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 repeals Maryland's Right to Try Act's requirement that the patient is ineligible or unable to participate in a clinical trial, removes the requirement that the physician recommending individualized investigational treatment is a treating physician, and substitutes "life threatening or severely debilitation" for "terminal" for the illness requirement.

Eligible Investigational Drugs.

The federal Act requires that the investigational drug (1) has completed a Phase 1 clinical trial, (2) has not been approved or licensed for sale by the FDA, (3) is the subject of an investigational drug application to the FDA, and (4) is in ongoing active development or production and not on clinical hold by the FDA. Other than the lack of FDA approval or licensure, none of these requirements are true for HB 676. This means the product may have

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[2] "For Physicians: How to Request Single Patient Expanded Access ('Compassionate Use'), current as of 03/26/2020, https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-how-request-single-patient-expanded-access-compassionate-use#:~:text=FDA%20allows%20over%2099%25%20of,placing%20the%20IND%20on%20hold; *See also* "Expanding Patient Access to Investigational Drugs," JACC Basic Transl Sci, 2018 Apr; 3(2): 280-293. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6059004/; "Expanding Access and Right to Try: Access to Investigational Drugs," Congressional Research Service, at 4 ("The primary purpose of expanded access is to provide investigational drugs as treatment for patients who lack therapeutic alternatives."), Updated 03/16/21, https://crsreports.congress.gov/product/pdf/R/R45414.

[3] "Right to Try: A 'well-intentioned' but 'misguided law," HemOncToday, 03/10/2020, https://www.healio.com/news/hematology-oncology/20200303/right-to-try-a-wellintentioned-but-misguided-law. ("Thus, many opponents consider Right to Try to be redundant at best, and potentially dangerous at worst.")

undergone no testing on human subjects, so even the minimal safety data from a Phase 1 trial may not exist. This also means that the product need not be in the pipeline for FDA approval and under the FDA's oversight in an active investigatory clinical trial.

While the bill requires the manufacturer of an individualized investigational treatment to be operating within "an institution operating under a federalwide assurance for the protection of human subjects,"[4] and in compliance with all laws applicable to such an institution, 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. Furthermore, while the bill relates to individualized investigational treatment, *i.e.*, treatment unique to and produced exclusively for an individual based on the individual's genetic profile, the bill and state Right to Try Act relate not only to investigational drugs but investigational biologics and devices.

Expertise Concerns.

The bill would remove the expertise and protection that the FDA has provided patients from unsafe and inefficacious products starting over 100 years ago.[5] Additionally, the highly specialized focus of the bill is likely outside the knowledge base of the vast majority of physicians,[6] 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.

Informed Consent/ Confidentiality.

Because these drugs have not been FDA approved, nor even gone through Phase 1 of a clinical trial, there is no official list, or perhaps even a preliminary list, of side effects, dosing constraints, and other important information which would make consent truly informed. Scant

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[4] H.B. 676 defines "Eligible Facility" as an institution operating under a federalwide assurance for the protection of human subjects in accordance with 42 U.S.C. § 289(a) and 28 C.F.R. Part 46. It is not clear whether the CFR citation is in error. While 28 C.F.R. Part 46 does relate to research involving human subjects, Title **28** relates to *Judicial Administration*. The ***HHS regulations*** related to research involving human subjection are under **45** CFR part 46.

[5] High failure rates for drugs suggest that most patients will not receive benefits from investigational drugs. *See* "Expanding Patient Access to Investigational Drugs," JACC Basic Transl Sci, 2018 Apr; 3(2): 280-293 ("Desperate patients have desperate hopes, and yet failure rates for drugs (e.g., 90% failure for anticancer drugs reaching phase I trials) suggests that there is actually little reason to assume that most patients would benefit from receiving drugs in their earliest stages of development, and much more substantial reason to anticipate that many patients would be harmed. ') https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6059004/.; "Informed Consent in Right-To-Try Cases," J Am Acad Psychiatry Law, 44:290-96, 293 (2016) ("[T]he odds are low that a patient would have significant therapeutic benefit from an agent obtained under a right to try law."), https://jaapl.org/content/44/3/290; *See also* Congressional Research Service's Report, *supra*, n. 1, (In "taking FDA out of the equation, the Right to Try Act limits the agency's ability to make suggestions to the protocols under which investigational drugs are provided, potentially compromising patient safety.")

[6] See, "Prescribing unproven cancer drugs: physician perspectives on expanded access and right to try," Journal of Law and Biosciences, 1-18 (2022). https://doi.org/10.1093/jlb/lsac031.

data should pose a concern for physicians too in evaluating risks for their patients.[7] 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. Finally, the bill's informed consent provision requires a statement describing the extent to which confidentiality of records that identify the patient will be maintained rather than requiring that confidentiality *will* be maintained as if treatment were rendered by a HIPAA-covered entity.

Financial and Profit Concerns.

While an insurance carrier or government program may elect to cover the costs of individualized investigational treatment under the bill, the bill is clear that government agencies, hospitals, and other health care facilities are not required to cover these costs. Furthermore, taking or using an experimental drug, biologic, or device may jeopardize the coverage a patient has for care rendered as a result of the experimental treatment. *See* H.B. 676, 21-2B-01(G)(vi). The bill removes language from the Maryland Right to Try Act that explicitly limited the payment required by a manufacturer to the costs of or associated with the manufacture of the specific investigational product and inexplicably repeals the express prohibition on a manufacturer profiting from providing an investigational product to an eligible patient, despite the sponsor's assurance that "profiteering is explicitly forbidden."[8] If the bill is intended to permit the manufacturer to recover more than the cost of producing the drug for the patient, the manufacturer will have less incentive to follow the drug approval process.

Emerging Safety Risks.

The bill repeals the Maryland Right to Try Act's requirement that the manufacturer alert the patient and patient's health care provider of any side effects or risks that emerge after the patient begins taking or using the investigational product that would be required to be disclosed to the FDA during the drug approval process. Given the information gap for patients and health care providers about investigational products, this is a concern. Moreover, given the hurdles in even diagnosing the population who would be most tempted to use an unproven drug, some in this vulnerable population may turn out to have an illness that responds well to approved treatment, but may have permanently compromised their health by taking an unproven drug out of desperation.

Conclusion.

While we are sympathetic to the struggles of patients and their families who seek therapies for life-threatening or severely debilitating illnesses, the last thing that vulnerable patients need is to suffer additional harm from unsafe and ineffective treatments. The federal

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[7] *See* "Informed Consent in Right-To-Try Cases," J Am Acad Psychiatry Law, 44:290-96, 294-95 (2016) https://jaapl.org/content/44/3/290.

[8] For Expanded Access, a charge to a patient must be limited to the direct costs of making the investigational drug available, not for development costs or profit. *See* Congressional Research Service's Report, *supra*, n. 1, at 5.

regulatory framework includes options for these patients, particularly the Expanded Access Use pathway, which provides additional safeguards for patients.

For these reasons, we urge the Committee to consider these concerns and, in the interim, seek the expertise of Maryland's public health experts on the nature of the protections purported to be afforded by this bill before advancing HB 676.

C: Delegate Matt Morgan