testimony Favorable HB676 right to try Finance- 20
Uploaded by: Emily Tarsel
Position: FAV

Emily Tarsell, LCPC

2314 Benson Mill Road
Sparks, Maryland 21152
March 21, 2024

Favorable HB676
Right to Try Act - Individualized Investigational Treatments

Dear Chairwoman Beidle and Finance Committee Members,

I am Emily Tarsell, a mother, licensed therapist and founder of Health Choice Maryland. We strongly support HB676 which would allow an individual with a life threatening or severely debilitating illness more individualized medical options based on individual need.

There is nothing more sacred than the right to control and decide what happens to one's own body. This bill protects providers and manufacturers from liability for adverse outcomes from such trials of individualized investigational treatments which would be initiated by the informed individual at their own risk and expense. So why not?

This bill honors individualized medicine and the right to choose especially under dire circumstances.

Please vote **FAVORABLE for HB676. Thank you.**

Emily Tarsell, LCPC

HB 676 - FIN - BOP - LOI.docx (1).pdf
Uploaded by: State of Maryland (MD)
Position: FAV

Maryland
DEPARTMENT OF HEALTH

Board of Physicians

Wes Moore, Governor · Aruna Miller, Lt. Governor · Harbhajan Ajrawat, M.D., Chair

2024 SESSION
POSITION PAPER

BILL NO.:	**HB 676 – Right to Try Act – Individualized Investigational Treatments**
COMMITTEE:	**Finance**
POSITION:	**Letter of Information**

TITLE: **Right to Try Act – Individualized Investigational Treatments**

POSITION & RATIONALE:

The Maryland Board of Physicians (the Board) is submitting a letter of information for House Bill (HB) 676 – Right to Try Act – Individualized Investigational Treatments.

Under Health Occupations §14-404(a)(22), the Board may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee fails to meet appropriate standards of care as determined by appropriate peer review. Although the Board is not taking a position on the merits of this bill, the Board would like to clarify that nothing in this bill limits the ability of the Board to investigate complaints related to the standard of care or discipline physicians who violate the standard of care in the process of using individualized investigational treatment.

Thank you for your consideration.

For more information, please contact Matthew Dudzic, Manager of Policy and Legislation, Maryland Board of Physicians, (410) 764-5042, and Oriell Harris, Health Policy Analyst Associate, OriellT.Harris@maryland.gov.

Sincerely,

Harbhajan Ajrawat, M.D.
Chair, Maryland Board of Physicians

The opinion of the Board expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.

HB0676.pdf
Uploaded by: Suzanne Price
Position: FAV

HB0676 Right to Try Act - Individualized Investigational Treatments
Please support this important bill that has the potential to save lives. An individual should have the right to make this sort of medical decision for themselves, especially if they have exhausted all other means.

Suzanne Price
Anne Arundel, MD

HB676 right to try sponsor testimony_senate.pdf
Uploaded by: Matt Morgan
Position: FWA

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

Health and Government Operations Committee

The Maryland House of Delegates
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THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

Senator Pam Beidle
Chair
Senate Finance Committee
HB 676- Right to Try- Individual Investigational Treatments

FAVORABLE WITH AMENDMENTS

Dear Chair Beidle 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.

The House Health and Government Operations Committee added some amendments which strengthens the informed consent portion, and I support the changes, and feel that we have a very strong bill to present to the Senate Finance Committee today.

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

Lenmeldy FDA Approval Timeline.pdf
Uploaded by: Matt Morgan
Position: FWA

Timeline of Lenmeldy FDA Approval

Lenmeldy is a one-time gene therapy that treats the rare and fatal metachromatic leukodystrophy (MLD)

APRIL 2007

Lenmeldy is granted orphan status by the European Medicines Agency (EMA)

APRIL 2010

Interventional clinical trial begins in Milan, Italy

SEPTEMBER 2020

Keira Riley and her family relocated to Italy where Keira began treatment

DECEMBER 2020

Lenmeldy is granted marketing authorisation in the European Union, UK, Iceland, Lichtenstein, and Norway

SEPTEMBER 2021

First patient is treated in the U.S. with Lenmeldy at the University of Minnesota Medical School

MARCH 2024

Lenmeldy receives FDA approval

Lopez Maryland HB 676 Senate.pdf
Uploaded by: Matt Morgan
Position: FWA

NAOMI LOPEZ
SENIOR FELLOW
GOLDWATER INSTITITUE

Public Comment on HB 676 before the Maryland Senate Finance Committee

March 21, 2024

Good afternoon, Chair Beidle, Vice Chair Klausmeier, and Senators of the Committee. My name is Naomi Lopez and I am a senior fellow in healthcare policy at the Goldwater Institute, which is based in Phoenix, Arizona.

Thank you for allowing me to offer my public comments regarding HB 676 as you consider this important issue to protect the right to try to save one's own life without having to beg the federal government for permission to do so.

Imagine that there is a new treatment for a rare disease. It's custom-made for you, based on your own genetic profile. It offers you hope, but you can't access it, even though your doctor says it could save your life. The reason? Federal regulations are ancient by today's standards, and they're not designed to allow these new, genetic treatments.

Maryland, which is home to world class research institutes and hospitals, has an important opportunity to lead the nation in solving this problem—and save lives—by championing a new law called Right to Try for Individualized Treatments.

The federal barriers to lifesaving treatment are not hypothetical. Maryland lawmakers have already been a leader in putting patients' rights first and cutting through medical red tape. Under the original Right to Try Act which Maryland unanimously passed and enacted in 2017, patients gained the right to seek treatments that are safe enough to be used in clinical trials but remain under clinical evaluation for final FDA approval. The federal Right to Try act was later signed into law in 2018 and is now the law of the land.

We know that Right to Try works, and we've seen great examples. An aggressive form of brain cancer, glioblastoma, has a five-year survival rate of only about 5 percent. Too often, patients are left with no promising treatment options.

Thanks to the liability reforms and reduced red tape that is part of the original Right to Try law, some patients who were ineligible for the clinical trial can now access an immunotherapy treatment that is in a clinical trial. Instead of being sent home to put their affairs in order, these Right to Try patients have a median survival of 20 months of life, up from fewer than seven months with conventional treatments.

The trouble is, this law needs to be upgraded and modernized to account for rapid advancements in medicine, such as gene therapy, which aren't covered under the original law. That's where Right to Try for Individualized Treatments—or "Right to Try 2.0"—comes in. This new law does not change, in any way, the successful, original Right to Try law.

It does create a new, safe, and physician-directed pathway for those patients with rare and ultra-diseases who don't have treatment options in clinical trials or who need an individualized treatment approach made specifically for them.

Many of the medical innovations being pioneered today have made it possible to take an individual's genetic information and create a treatment for that individual person. But the current clinical trial evaluation system—created more than a half-century ago—is based on treatments for large populations, not an individual patient.

The result is that an individualized treatment is still subject to the same clinical trial process as a single treatment that is intended for hundreds or thousands of patients. But that doesn't recognize how these new individualized treatments work. Right to Try for Individualized Treatments accounts for new innovations—and it helps get those innovations to the patients who need them TODAY. It is now law in both Arizona and Nevada.

Individualized treatments are being pioneered all over the world. But, too often, U.S. patients such as little Keira Riley and her family must travel to other countries for potentially life-saving treatments, or they succumb to their cruel diseases. It doesn't have to be this way.

Maryland can continue to lead on the important goal of getting the right treatment, to the right patient, at the right time. Removing the government red tape that stands in the way of a doctor's treatment options does not require additional taxpayer investment and can be achieved in a manner that ensures patient safety and informed consent.

Maryland lawmakers have the authority, as well as the legislative vehicle, to unleash the potential of today's medical innovations to further benefit patients.

Maryland HB 676_Hannah Lowe Testimony.pdf
Uploaded by: Matt Morgan
Position: FWA

February 29th, 2024
Health and Government Operations Committee
Chair Joseline Pena-Melnyk
Vice Chair Bonnie Cullison

Dear Chair Pena-Melnyk, Vice Chair Cullison, and Members of the Health and Government Operations Committee,

My name is Hannah Lowe, and I am writing to testify on behalf of my family's story as it relates to House Bill 676.

For families like mine who are facing rare diseases with no treatment or cure, this is an issue we encounter daily. I want to share with you the story of my son, Austin, and how our journey has led us to our own efforts to raise awareness about the urgent need to open new treatment pathways, through the Right to Try for Individualized Treatments Act, which allows patients to access investigational treatments that are individualized just for them.

Austin was born in 2019, and as far as we knew, he was a typical little baby. But when he stopped feeding and gaining weight, and was no longer hitting his developmental milestones of a 5-month old, he was admitted to a local hospital which, fortunately, is near our home.

After weeks of tests, we received the devastating news that Austin had a rare disease called L-CMD, a congenital muscular dystrophy. The disease is so rare that the hospital had never seen a single case, and, at that time, there were only 50 documented cases in the world.

There was no treatment, and there was no cure. In an instant, the life we thought we might enjoy and hopes for our baby boy were shattered. We were told to take Austin home, love him, and cherish the time we had left with him.

But we refused to give up hope. After hundreds of hours of Zoom calls, reading medical articles, meeting with medical experts and sharing conversations with families facing other rare diseases, we have discovered that there is something we can do. We are now collaborating with two research institutions to create a gene therapy for L-CMD.

The technology is there, it just needs to be mapped to the gene that commonly affects our condition. We are now in a race against time to continue to raise money and conduct the research. This is where you can help families like ours.

My home state of Maryland has some of the world's leading facilities and researchers, but the current regulatory framework for developing new medical treatments is slow and cumbersome,

which is not acceptable for families like mine who are facing rare diseases with no treatment or cure. Although it is now federal law that patients have a right to seek these, Maryland's state laws must be changed to better accommodate custom treatments for these devastating illnesses that we battle day in and day out.

We need laws that would allow medical treatments to be developed faster, with appropriate safety measures, to make it legal to seek these individualized treatments. Simply because these treatments do not reach us through the traditional FDA approval pipeline does not mean that we are any less deserving of access to them, especially when they may significantly prolong life with these conditions.

Because our disease has such a small patient population, we can't wait for clinical trials which, even if they do happen, are more than a decade away. Pharmaceutical and biotech firms are typically not interested in treatments where large-scale commercialization is unlikely, so it falls to families like ours to push research and innovation forward.

We need your help to make this Herculean task more attainable. For any of you who are parents, you would do anything for your children. That is what we are doing, too.

Our families and nonprofits are scraping together the money and making breakthroughs happen out of pure grit, determination, and love, but we need your help to put this money to use.

We are not asking for a handout. We are asking for laws that would allow medical treatments to be developed faster, with appropriate safety and efficacy measures, to give hope to families like ours.

Please help us in our fight to find a cure for Austin, other L-CMD patients, and the millions more with other rare diseases. Thank you for your consideration of this important reform.

Thank you,
Hannah Lowe

President
L-CMD Research Foundation

Maryland Catholic Conference_INF_HB676_SenateCross
Uploaded by: Diane Arias
Position: INFO

MARYLAND CATHOLIC CONFERENCE

March 21, 2024

House Bill 676
Right to Try Act – Individualized Investigational Treatments
Senate Finance Committee

Position: Information

The Maryland Catholic Conference (MCC) is the public policy representative of the three (arch)dioceses serving Maryland, which together encompass over one million Marylanders. Statewide, their parishes, schools, hospitals, and numerous charities combine to form our state's second largest social service provider network, behind only our state government.

House Bill 676 alters certain provisions of law authorizing certain activity by manufacturers of investigational drugs, biological products, or devices under the Right to Try Act to apply to manufacturers of certain individualized investigational treatments; altering the definition of "eligible patient" under the Right to Try Act to include individuals who have life-threatening or severely debilitating illnesses, rather than only individuals who have terminal illnesses; etc.

Further examination of similar Right to Try legislation is necessary to ensure the integrity of the integration, particularly to ascertain that treatments used before U.S. Food and Drug Administration (FDA) approval did not result in premature death or excessive harm. Concerns also arise about the potential for healthcare facilities and professionals to face severe litigation due to the expedited nature of the experimental process in shortened clinical trials. Additionally, there is a worry that patients may be exposed prematurely to pain and suffering through experimental treatments lacking the rigorous evaluation conducted by the FDA. Adherence to proper protocols and procedures offers families assurance and hope in considering treatment options. Given the inherent trial-and-error nature of science, this bill could jeopardize the medical profession and biomedical sciences.

Introducing individualized investigational treatment may create prejudice, as patients could potentially be held liable for all expenses, extending even to the patient's estate. This could impose economic burdens on individuals with illnesses and restrict accessibility for those unable to cover the financial expenses associated with treatment development. There is a need for additional information regarding potential costs and economic implications for patients.

The Catholic Conference, committed to preserving the integrity of all human life, draws inspiration from St. Pope John Paul II's teachings emphasizing the sacred responsibility of preserving life on earth. St. Pope John Paul II teaches, "After all, life on earth is not an 'ultimate' but a 'penultimate' reality; even so, it remains a sacred reality entrusted to us, to be preserved with a sense of responsibility and brought to perfection in love and in the gift of ourselves to God and to our brothers and sisters."[1] When exploring experimental drugs and devices, it is crucial to uphold the scientific integrity of the discovery process and avoid prematurely exposing individuals to potentially lethal treatments.

For these reasons, the MCC asks the committee to consider this information on **HB 676**.

Thank you for your consideration.

[1] Complex Considerations: 'Right to Try' Laws Raise Ethical Concerns (chausa.org)

HB676.CrossOver.LOC.LC.20240320.pdf
Uploaded by: Lauren Calia
Position: INFO

CANDACE MCLAREN LANHAM
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Chief, Equity, Policy, and Engagement

PETER V. BERNS
General Counsel

WILLIAM D. GRUHN
Chief
Consumer Protection Division

ANTHONY G. BROWN
Attorney General

STATE OF MARYLAND
OFFICE OF THE ATTORNEY GENERAL
CONSUMER PROTECTION DIVISION

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