Ohio Advocates for Medical Freedom
Advocating for Medical Freedom since 2015

Chairman Huffman, Vice Chair Johnson, and Members of the Senate Health Committee, thank you for hearing my testimony in support of HB 73, The Dave & Angie Patient and Health Provider Protection Act.

During the last eight years of my volunteer service leading the non-profit, grassroots organization, Ohio Advocates for Medical Freedom, we have received thousands of emails from desperate Ohioans seeking help for various issues in the realm of medical freedom. Many of these communications were from health professionals, patients, and family members who were having difficulty obtaining various medications that they desperately needed for their patients or themselves. While most of these pleas for help came during the pandemic, there were many that were unrelated to COVID in the years prior.

Many of our members suffer from Lyme disease and have extreme difficulty finding providers who can effectively treat the myriad of co-infections that are typical of the disease. There are few doctors willing to treat the illness outside of the 'protocol' or 'standard of care' box. Those who have used their training and innovation to find ways to successfully manage Lyme symptoms in a way that restores function to patients have been publicly chastised and threatened by medical boards and health agencies. Many have had their licenses stripped and their credibility destroyed because they dared to go beyond the current medical 'norm' and instead focused on each individual patient and the medications that improved their conditions. It is almost unbelievable that in one of the most medically advanced, and allegedly free, countries in the world, a physician would be punished for making a patient well, but this is true for doctors in Ohio and around the country.

Cancer is another area of medicine in which health providers are limited in their ability to treat patients beyond the traditionally accepted 'protocol.' Many of our members have had to seek treatment outside of the country for off-label treatments known to help their conditions. I have heard from Ohioans who were told by their physician they had no chance of survival and they returned to the US cancer-free and are still with us today. Unfortunately, most average Ohioans cannot afford these extreme and costly measures. Allowing health providers to treat their patients with FDA-approved treatments that may improve the outcomes of potentially terminal patients without fear of backlash is not only 'good medicine,' but it is the only ethical thing to do.

Lastly, and most profoundly, we saw an undeniably criminal handling of the recent pandemic. Family members left tearful voicemails with OAMF pleading for referrals for legal help to get FLCCC protocol treatments to their loved ones in the hospital. We received reports of discrimination and neglect adding insult to their injury. Many families, like Dave & Angie's, watched in horror as their loved ones died in agony after being refused the treatments that were helping so many others and then denied nutrition because they refused ventilation 'protocol.' I can't imagine the level of damage caused to the families and the children who survived these lost parents. Members have told me that even three years after their husband or wife's death by hospital protocol, many of their children still suffer from PTSD and depression. One 12-year-old child had to be put on suicide watch because of a traumatic response to attending a funeral.

While HB 73 cannot return the parents whose lives were stolen from these children, it would bring some level of justice to their families and expand possibilities for those who wish to access off-label treatments during the next pandemic or current or future illness.

Medicine is a complex practice and an art. When medical free thought and free speech are stifled by government health agencies, or pharmacy and medical boards, then medical advancements in treatments are stunted. We understand that committee members have, and will continue to hear arguments, many of which are false, by the lobbyists who advocate to maintain the profit margins and control of hospitals and pharmacies rather than protecting the best interest of the people of Ohio. Ohio patients and their families are the ones who pay the price for the political and financial reasons that rigid 'protocols' are put in place by these entities. It is long past due for patients and their health care providers to have the protections granted under HB 73.

On behalf of our members and the citizens of Ohio, OAMF implores you to pass this life-saving legislation that was written by the people and for the people. OAMF has been deeply involved in all aspects of the Sub HB 73 language, and I am happy to answer whatever questions you have on any provisions of the bill.

Thank you.

Stephanie Stock, LPTA

OAMF President

www.OhioAMF.org

Ohio Senate
State Senator
1 Capitol Square
Columbus, Ohio 43215
(614) 466-6247

Committees
Health, Chair
Medicaid
Insurance
Education

Stephen Huffman
5th District

To: Representative Jennifer Gross
From: Senator Stephen A. Huffman
Date: March 22nd, 2024
Re: Interested Party Meeting Follow-up

Representative Gross,

Thank you for your participation in our IP meeting on H.B. 73 as it was very informative and enlightening. I support the goal of H.B. 73 to increase access of off-label medications with ease and without punishment for the best interest of the patient. The main concerns as many stated in the IP meeting were that as currently written, there are unintended consequences. I will outline my main concerns and what others have expressed. As the sponsor, I will ask you to resolve the issues that are amendable to you by drafting changes directly with LSC. After you have the next version, we can discuss areas that have been addressed and areas where you disagree.

1. As currently written, H.B. 73 could result in a vast expansion of abortion in the state of Ohio.

   1) The recent passage of Issue one in November, also now documented as Article 1 Section 23 of the Ohio Constitution created an environment that negates any possible impact of House Bill 73. Sadly, abortion pills can be ordered by mail without even having a prescription. HB 73 cannot expand abortion access already in existence here in Ohio since it is now available for most any reason through 40 weeks gestation. In addition, we amended your section of concern regarding "no required testing" before prescribing. The wording was changed to apply to "diseases and illness". Pregnancy is not a disease or illness, so nothing in the amended version prohibits pregnancy testing It was mentioned that Acutane was a concern, but that drug is listed as a REMS drug which is clearly addressed in the (-6) version of HB 73 (Lines 87-91). Please note, HB 73 re-reinforces that moral and religious exemptions for prescription filling are still available. Any pharmacist may use this exemption if there is a moral concern that the drug prescribed will be used for the purpose of abortion.

2. H.B. 73 could result in legalization of physician-assisted suicide in the state of Ohio.

   2.) Euthanasia, mercy killing, or assisted suicide is not authorized by Ohio law. Death of any patient resulting from withholding life-sustaining treatment does not constitute suicide,

murder, or any homicide offense for any purpose. As articulated in Chapter 2133 | Modified Uniform Rights of the Terminally Ill Act; DNR Identification and Do-not-resuscitate Orders in regard to passive euthanasia: (withholding a medical intervention in order to expedite the death of the patient) Passing of House Bill 73 actually gives more rights to patients and protects the sanctity of their lives by ensuring that they are not "denied sufficient means of fluid or nutrition."

In regard to active euthanasia: (administering a medical intervention with the intent of expediting the demise of a patient) Informed consent, is now defined by the amended version of HB 73 further requires that the Physician shall provide "the nature and purpose of the recommended drug, treatment, or intervention; the burdens, risks, and expected benefits of all drugs, treatment, or intervention options, including the option of forgoing treatment; and any conflicts of interest the physician may have regarding the recommended drug, treatment, or intervention"(Line 29-30) In order obtain this level of informed consent, a Physician must disclose that the purpose of the intervention would be to hasten the death of the individual. This act of active euthanasia does not qualify for the legal protection afforded by HB 73. Such actions are excluded, "except in cases of reckless or gross negligence" (Lines 227-228).

In summary, House Bill 73 actually offers additional protection against passive euthanasia and offers no protection for active euthanasia.

3. In its current form, H.B. 73 also allows the use of narcotics and controlled substances to be used off-label for any purpose. This would exempt health care professionals from Ohio's drug trafficking laws.

3) Controlled substances are clearly EXCLUDED in the -6 amended version of HB 73. Furthermore, the entire opioid class of medications has a post market Risk Evaluation and Mitigation Strategies (REMS). House Bill 73, as amended, also specifically now states that the off use of any medication must follow REMS requirements the same as if the medication was being used as indicated. (Lines 87-91)

4 .H.B. 73 would eliminate the requirement for healthcare providers to practice the minimal standard of care. Would you consider a consent form that the patient, medical provider, pharmacist and hospital all sign before the drug is received acknowledging that it is below the prevailing standard of care and current accepted medical literature? The patient would then accept all understanding and responsibility of any harm or death.

4) We object to the idea that HB 73 would somehow "eliminate " the "minimal standard of care". Permitting an alternative standard of care does equate to the practice of sub-standard care. The only deviation that you may perceive to not be "standard of care" is that there is not a requirement to have a positive test for a disease or illness performed prior to the administration of a medical intervention. This is already demonstrated in current practice with the lack of testing prior to the prophylaxis of a disease, or the treatment of individuals exposed to a disease process in the follow situations. For example, a person is not required to test positive for influenza prior to receiving the flu shot. The second Rh-negative child born to a Rh-positive mother is not required to show signs of fetal distress before the administration of RhoGAM. Antibiotics are also commonly administered prophylactically in situations where a resulting infection is possible or likely. Additionally, if the "standard of care" was sufficient at saving lives during the recent pandemic, this bill would not have been written.

5. There needs to be a clarification that off-label drugs in this bill only apply to drugs approved by the FDA for human use, medications only approved for animal use need to be excluded.

5) Federal law clearly states that veterinary prescription drugs can only be used by or on the order of a licensed veterinarian in the context of a veterinarian-client-patient relationship (21 U.S.C. 353(f)). Secondly, House Bill 73 as passed by the house, already stated that the prescribed drug must be "legal in the state of Ohio" (Line 47). Ohio law currently authorizes the Veterinary Medical Licensing Board to discipline any veterinarian who (1) makes any prescription drug available to any person other than for the specific treatment of an animal patient or (2) sells any veterinary prescription drug or biologic or prescribes any off-label use of any over the counter or prescription drug in the absence of a valid veterinary-client-patient relationship (R.C. 4741.22(A)(22) and (27).

Additionally, regarding Chairman Huffman's concern that "patient" is not defined as "a human" in this legislation, there has been no previous questioning of legislation that referred to patients in hospitals and nursing homes as to whether the "patient" was a human. However, the Ohio Legislative commission confirmed that there are multiple sections of state code that define "patient" as "a person"(RC 5121.30), (R.C. 3701.248), an "adult" (R.C. 2133.01), and an "individual" (R.C. 2305.51).

Furthermore, hospitals and physicians administered mRNA based, and other emergency use drugs that were not fully "approved" by the FDA for "human use", yet these products were not only accepted as "standard of care" but were also granted complete liability protection under the U.S. "Cares Act". If "approval for human use" was truly a significant concern, then where was the pushback when those interventions were implemented?

6. H.B. 73 grants immunity to the provider, but it neglects to grant immunity to the hospital, pharmacist, and other health care providers in and out of the hospital.

6.) The house passed version HB 73 already included immunity for hospital pharmacists in Section C(2) and the -6 version has now expanded to include immunity for hospitals and health facilities when an outside physician is providing care under "temporary privileges"(Lines 196-201).

7. HB.73 needs to directly address the issue and define when a pharmacist has an, "objective, good faith and scientific objection to the administration or dosage of the drug for that patient." This appears to say that a pharmacist does not have to distribute a drug if it does not meet the minimal standard of care which is the same as a scientific objection.

7.) The documentation of a "good faith objection" is the requirement to have liability protection secured for the pharmacist in both the inpatient and outpatient setting. The liability protection is only given "when a pharmacist must dispense" when they object but do not have a moral objection or a "life threatening" contraindication that allows them to NOT have to fill the drug prescribed (Lines 97-104). "Except for either" of those 2 reasons (Line 96) "a pharmacist shall dispense, and a hospital or inpatient facility shall allow the dispensing of…"(Line 92).

8. All conflicts with federal law and the DEA for pharmacists need to be resolved in some way. Particularly, it needs to be addressed as it pertains to narcotics, drug trafficking, and controlled substances. This needs to include the federal laws concerning medication reconciliation requirements.

8.) Again, narcotics are clearly excluded in the current HB 73 -6 version. There is nothing in House Bill 73 that inhibits, prevents, or encumbers drug reconciliation. REMS drugs were also addressed in the (-6) version as mentioned in concern #3.

9. There needs to be a mechanism to track the use of off-label prescribing that is below the standard of care prescribing. Currently, H.B. 73 removes the ability of the State Pharmacy Board and the State Medical Board to take any investigative or disciplinary action for adverse outcomes. What can they do when a drug is prescribed ten times and each time the patient dies, should the State Pharmacy Board and State Medical Board continue to allow this to happen? What is the morbidity and m01iality rate acceptable before the state can take action?

9.) Each hospital already has a mechanism of tracking every medication and dosage given to the patient including any off label use drugs or home medications. The assertion that a doctor prescribes a drug 10 times and each time the person dies is outlandish. A doctor that continues to kill patients with the same drug would constitute “gross negligence”, which is clearly stated in both the previous and current -6 version of the bill. Nothing in this legislation says that the Pharmacy board or medical board cannot “investigate” a doctor. It only states they cannot take “administrative or disciplinary action” against their license unless they are found to be grossly negligent. HB 73 (-6 version) states that “health related licensing” boards “shall not pursue an administrative or disciplinary action against the prescriber, pharmacist, hospital, or facility, except in cases of recklessness or gross negligence” (Lines 225-228). In addition, prescribers are not immune from liability from their patients. Doctors are not any more likely to risk being sued by a patient under this legislation than they would be without this legislation.

10. H.B. 73 needs to address what the State Pharmacy Board should do when a drug is prescribed for an off-label use that does not meet the standard of care during a drug shortage. When a drug is prescribed in this way, it may jeopardize many more lives by creating critical shortages that deny these patients a life-saving drug.

10.) Why would the Pharmacy Board need to take any action when there is a drug shortage, when here is already a mechanism in place for drug shortages? All healthcare providers are currently notified by hospitals and pharmaceutical manufacturers when a drug shortage is experienced. At that point healthcare providers use their best clinical judgment on how to triage recourses. If an individual pharmacist feels a moral imperative not to dispense a scarce medication, then he/she can evoke the protection of moral objection to fill under section 4743.10. At this current time we have over 125 drug shortages due to active and inert ingredient availability. This is a common occurrence and was over 300 plus meds during Covid due to supply chain issues. Fortunately, there is usually more than one choice of medication treatment for a disease or condition.

11. H.B. 73 needs to define, "good faith effort to acquire a drug." The meaning of this can be different depending on the patient and hospital. Is this within the county, the state, within the US,

or anywhere in the world? A hospital could be taken to court if the only way to obtain a drug is from India and a patient believes that this would be a good faith effort.

11.) A “good faith effort” holds the same definition as already stated in the Ohio revised code… a good faith effort is described as "what a reasonable person would determine is a diligent and honest effort under the same set of facts or circumstances." In addition, the version we amended for the Senate now clearly states “from another hospital or inpatient facility, or another United States distributor.” (Lines 127-128)

12. Bringing in a medical provider that does not have privileges into a hospital is a concern. I believe that the medical provider should have an active license in the state of Ohio, not under investigation or pending actions from the State Medical Board, and not under investigation for fraudulent research practices.

12.) Every Ohio medical institution has a process to vet Physicians prior to granting them privileges at their perspective institution. This vetting process is unique to each institution and should not be altered by inserting new requirements under HB 73. We feel it would be an overreach for this 5 legislation to dictate each institutions vetting process for granting privileges. During the vetting process, it is typically required in

facility bylaws that an applicant have an active medical license in Ohio. Under House Bill 73, a Physician can have their application denied if facility bylaw standards are not met. You alluded in concern 10 that a “drug shortage” could deny “these patients a life-saving drug”. We feel it equally dangerous to deny a patient access to a Physician willing to administer a life-saving drug. House Bill 73 does not alter the process of credentialing physicians; it only requires that the hospital allow outside doctors to apply via and expedited process. It is appropriate to note that 5 of the physicians we have consulted with, on HB73, feel that the amount of time allotted for “temporary privileges” credentialing is actually too long and could be 1-3 days.

13. Off-label prescribing that is below the standard of care should be limited to physicians and no mid-level provider or any other medical provider.

13.) No medical provider at any “level” should be giving substandard care. Expanding treatment options to providers does not make them more likely to prescribe irresponsibly. If an Ohio patient chooses a “mid-level” provider that should not dictate whether that provider is able to give the best possible care they see fit for their consenting patient. Every Ohioan deserves to receive food, fluids, and access to the medications that can help them. One could easily ague that if the hospital “standard of care” implemented during COVID had been sufficient, then Ohio hospitals would not have ranked 35th for Covid-19 Mortality by State, then many Ohioans like Dave and Angie might still be with us, and this bill would never have been written. “Standard of Care” would be best determined by the doctor who knows their patient and has the fully informed consent of that patient or their guardian to receive that care. Please also note that outside prescribers seeking inpatient ‘temporary privileges” only refers to “physicians”. (Lines 151-157)

14. In a hospital setting when there is a drug used for off-label below the standard of care, there needs to be a consultation between at least the prescribing physician, patient (or durable power of health care), pharmacist, Chief Medical Officer (or their designate), Chief of Staff, and Department Head to discuss the risks, benefits, and alternatives of the drug. At an outpatient level, a physician, patient (or durable power of health care), and pharmacist (maybe others) should have a consultation.

14) The repeated use of the term “below the standard of care” is not reflective of the reality of a doctor trying to provide his/her patient with an alternative treatment pathway. This issue was clearly addressed in the house passed version and is still present in the amended version. Lines 157-162 clearly state “then the patient's outpatient physician prescriber, after a prompt consultation with the patient's hospital or inpatient facility care team and a review of all of the patient's drugs, shall be allowed to immediately begin applying for temporary privileges with oversight, based on criteria within the hospital or inpatient facility..”

15. **Initiating changes in temporary five days is reasonable,** but a hospital must be able to abide by their current bylaws or risk being sanctioned by CMS. The providers also need to know that the results may mean that the physician is reported to the National Practitioner Data Bank, the Department of Health, or other authority as required by State and Federal law. If a hospital does not have a mechanism of temporary or emergency privileges, then H.B. 73 needs to directly address how a hospital will address this.

15) The house passed version of the bill already specified that the temporary privileges would be dictated by each individual facility’s bylaws. We removed the provision for hospital to report when a doctor applies for temporary credentials and is not approved. This was replaced with a physician self-reporting “complaint” option in instances where they feel their denial was wrongful. These complaints are saved for 7 years and able to be public records requested to determine whether certain hospitals deny credentials based solely on the drug the doctor wants to treat with. This change was clearly defined in the LSC comp document that was sent with the newly amended bill version.

16. bringing in outside medications by the patient or physician also needs to be better defined. Many hospitals already have a mechanism to do this, and H.B. 73 needs to state if the hospital needs to follow them or what mechanism they need to follow to verify the strength, sterility, and ability to confirm what the drug actually is.

17.) Pharmacists in hospitals already identify medications routinely. Every pill or capsule has a unique combination of color, size, shape, and markings. There is no need to micromanage hospital protocols for identification that are already in place. This is defined in the house passed version and the current version is even more clearly defined.

18. H.B. 73 states that the patient must first pay for the cost of the drug at a reasonable cost. The patient also should also agree in writing to pay for the increased cost of any adverse reaction or increased length of stay. Medicaid, private insurance, or the hospital should not accrue these additional costs because a patient and physician wants to take or prescribe a medication for off-label use that is below the standard of care. This should also apply for when a patient takes a medication off-label as an outpatient that causes an inpatient admission.

18) Does this practice currently exist anywhere in medicine? The patient or their legal representative, who has given informed consent, understands that there are risks in the imperfect practice of medicine. The term “practice of medicine” represents that healthcare providers blend art and science to treat a varied array of individuals and conditions. Adding the language you’re suggesting would expand the scope of House Bill 73 to set a dangerous precedence. If a patient consents to a newly FDA approved cancer treatment protocol, are they responsible to pay for any resulting side effects that lead to a hospitalization? Were the hospitals responsible to pay for renal failure treatments and dialysis that was required as a result of the “standard of care” protocol administration of

Remdisvir, or did that fall on the patient and their insurance company? How about hospital acquired secondary infections? Do hospitals cover the costs of the treatment and interventions required for patients who develop hospital acquired MRSA or bacterial pneumonia resulting from ventilation?

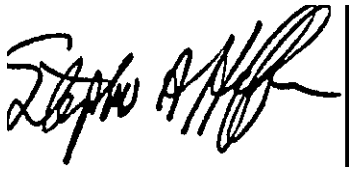
Be careful not to ask HB 73 to set a liability standard for patients and doctors choosing an alternative use for an FDA approved drug, that would not also apply to those who benefit financially from current "standard of care" protocols that could also cause harm.

Thank you for your consideration on this matter, and I look forward to continued discussion on this piece of legislation.

In summary, the Sub-bill for HB 73 (-6) encompasses all the reasonable concerns included in your letter. The additional requests suggested would significantly alter the bill and create loopholes that would lead to a complete compromise of the intent of the bill and leave Doctors and their patients at the mercy of hospital board protocols and pharmacists dictating what treatments patients can receive from their provider. HB 73 is a collaborated effort with Ohio doctors, pharmacists, lawyers, patients and OAMF. The Dave & Angie

Patient & Health Provider Protection Act is truly the "people's" legislation.

Best Regards,



Stephen A. Huffman
State Senator 5th Dis