Committees:
Armed Services and Veterans Affairs
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State and Local Government
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Representative Jennifer Gross
The Ohio House of Representatives

Representative Jennifer Gross – Sub HB 73, Sponsor Testimony: May 8th, 2024

Chairman Huffman, Vice Chair Johnson, Ranking Member Antonio, and members of the Senate Health Committee, thank you for allowing Representative Loychik and I to provide testimony on Substitute House Bill 73– the Dave and Angie's Patient and Health Provider Protection Act.

HB 73 will ensure a patient's access to receive potentially lifesaving off-label use medications prescribed by their health provider which the patient has consented to receive, while also protecting a pharmacist's right to decline to fill any drug that violates their conscience or religion. This bill protects a healthcare provider's ability to prescribe any FDA-approved, non-controlled medication legal for use in the state of Ohio, if that provider determines it to be an appropriate treatment. It also clarifies the expectation that the provider follows federal guidance for highly toxic drugs which are classified as administration risk evaluation and mitigation strategy drugs, or REMS drugs. HB 73 protects providers from repercussions from state or local health agencies or boards for their prescription choices in any situation where there is not gross negligence. The provider's freedom of medical speech, whether publicly or privately expressing a medical opinion, is also protected from retaliation against their license.

HB 73 also has a provision stating that the World Health Organization (WHO) will not have jurisdiction in Ohio and that no state agency shall enforce any mandate, recommendation, or guideline by the WHO regarding the prohibition of issuing a prescription or filling of an off-label drug. This legislation ensures patients are not denied nutrition or fluids during their hospital stays, aside from special circumstances and with the patient's consent. In recent years, many Ohioans reported immeasurable suffering and death from the denial of fluids and nutrition based on whether they agreed to receive a particular intervention. Diet can always be modified to suit a patient's need regardless of their medical condition.

HB 73 mirrors current Ohio law by allowing a pharmacist, hospital, or inpatient facility to refuse to dispense a drug if there are religious or ethical objections but adds clarification that a pharmacist can also refuse to fill in instances where a life-threatening contraindication is present. It is possible that a pharmacist, hospital, or inpatient facility may have a good faith objection to filling a prescription that does not fall into one of the above categories, so a provision was created to give both inpatient and outpatient pharmacists civil and administrative liability protection should any harm come to the patient who consulted with their prescribing physician and still made the choice to take that off-label drug. The only requirement to secure this liability protection is to document the objection in the patient's record.

HB 73 makes provision for cases where the hospital or inpatient facility does not have the drug which the patient is requesting in stock and requires the facility to make a good faith effort in

locating the drug from another US supplier and apply the upfront cost to the patient. In situations where the drug cannot be located, it allows the family to bring the medication into the facility to have it “identified” by the facility pharmacy through the standard process established by that facility. Additionally, this legislation addresses the situation where a patient is too sick to be transferred to another facility and there is no prescriber in the facility willing to prescribe the requested medication. An outside physician, who is willing to prescribe the medication, can apply for “temporary privileges with oversight” at that hospital. Prior to the application process, which is dictated by the bylaws of that facility and can take no more than 5 days, the physician must consult with the hospital or inpatient facility care team to review all the patient's drugs. These physician privileges are limited to treating the patient with the specific off-label drug being prescribed. During the time the outpatient doctor’s temporary privileges are in effect, the on-site pharmacists and treating physicians have complete immunity from any harm caused by the specific treatment decided on by the patient and their outpatient provider. These outpatient provider “temporary privileges” remain in effect until the patient can be safely transferred to a hospital facility where their outpatient physician is credentialed or to another facility that is willing to provide that treatment. Please note that HB 73 clearly states that nothing in the bill language prevents a pharmacist from discussing a prescription with the prescriber who issued the prescription. It also states that the ultimate decision to accept a drug prescribed by the prescriber shall be made by individual who has given informed consent, or the individual’s parent, guardian, or health care power of attorney.

HB 73 was drafted after multiple meetings with interested parties and passed the House last June with the overwhelming and bipartisan support of a 75-16 vote. We were asked by the Chairman Huffman in February to participate in a larger interested party meeting and have since drafted the amended Sub Bill language in front of you to provide further clarity to address the concerns that arose during that meeting. You may reference that list of concerns as well as my response to those concerns in the document attached to this testimony which was a collaborative effort of multiple Ohio physicians and pharmacists. Additionally included is a support letter from several physicians for Sub HB 73 (-6 version) as an addendum to this testimony. HB 73 is clinically sound legislation focused on restoring the doctor-patient relationship which has been severely inhibited over the past years by the consolidation of doctors under the hospital umbrella and by board designated, one-size-fits-all “standards of care” that are do not allow for differences between patients. Health providers strive to provide the best care possible for their patients and should be allowed freedom of movement in addressing patient needs, which are highly individualized. As a nurse practitioner, it is my ethical duty to advocate for and to support my patients in their time of need. As a legislator, it is my duty to ensure that the life and liberties of my constituents are protected. This bill accomplishes both.

HB 73 is life-saving legislation that provides the medical freedom needed for prescribers and patients to direct their care and optimize health outcomes, while simultaneously providing protections to pharmacists, hospitals and skilled nursing facilities that may disagree with a prescribers’ choice.

Thank you once again for your time and consideration of Sub HB 73. I’d be happy to answer any questions you may have.

Addendum: Representative Gross - Response to List of Concerns

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. 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. Concerns about Accutane was mentioned, but it is listed as a REMS drug which is addressed in the -6 version of HB 73 (lines 87-91).

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). On Line 20, of the bill, a physician must disclose that the purpose of the intervention and with euthanasia this would be to hasten the death of the individual and 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" (line 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) Narcotics are now 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 meet the "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 following situations. For example, a woman with signs of UTI is not always required to obtain a urine specimen, a Rh-negative child born to a Rh-positive mother is not required to show signs of fetal distress before the administration of RhoGAM, and in many situations, antibiotics are administered prophylactically when a resulting infection is possible or likely.

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) House Bill 73 as passed by the house already stated that an intervention must be legal in the state of Ohio (line 47). Administering veterinarian medication by physicians to humans is not legal in Ohio so it does not need to be a provision in this bill.

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 and the - 6 version has now expanded immunity for other hospital health providers 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 the pharmacist HAS to fill a prescription when they don't want to, but there is not a moral objection or a "life threatening" contraindication allowing them to NOT to fill the drug prescribed (line 97-104). "Except for either" of those two reasons "a pharmacist shall dispense, and a hospital or inpatient facility shall allow the dispensing of…" (lines 96 and 92). There is clearly no need for liability protection if the drug was not filled.

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.) 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 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. 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. Lines 225-228 of the sub-bill-6 states the boards “shall not pursue an administrative or disciplinary action against the prescriber, pharmacist, hospital, or facility, except in cases of recklessness or gross negligence.” 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 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.) 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 legislation to dictate each institutions vetting process for granting privileges. During the vetting process, it is typically required that an applicant have an active medical license in Ohio. Under House Bill 73, a Physician can have their application denied for cause. 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 expedites the 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 rapid credentialing is too long and should 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 argue 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 addressed in the house passed version and is still present in the amended version. Lines 157-162 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 temporary changes in 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) We removed the provision for hospitals 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 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.

16.) 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 clearer.

17. 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 want 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.

17) Does this practice currently exist anywhere in practiced 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 suggested would expand the scope of House Bill 73 to set a dangerous precedent. 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 likely resulted from the “standard of care” administration of Remdesivir, 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? Let's 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 as mentioned above.

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. My office has collaborated with Ohio doctors, pharmacists, lawyers, patients and OAMF on this bill. The Dave & Angie Patient & Health Provider Protection Act is truly the "people's" legislation.

Addendum: Letter of Physician Support

Dear Chairman Steve Huffman and esteemed members of the Senate Healthcare Committee:

We appreciate the opportunity to address the objections raised regarding Ohio HB 73, and welcome the chance to provide clarification on the provisions and intent of the legislation as recently amended to address committees' concerns. Below, we will address each concern raised in by the committee:

1. Abortion and Right to Reproductive Freedom: The Right to Reproductive Freedom with Protections for Health and Safety has created an environment that negates any possible impact of House Bill 73. It's essential to clarify that Ohio HB 73 does not interfere with reproductive rights or access to pregnancy testing. The legislation specifically focuses on expanding access to necessary medical interventions while upholding ethical and legal standards.

2. Euthanasia: Ohio HB 73 is designed to protect patients' rights and ensure that they receive appropriate care, including the provision of necessary medical interventions. The legislation explicitly prohibits active euthanasia while reinforcing the importance of informed consent and patient autonomy. By emphasizing the sanctity of life and providing safeguards against inappropriate interventions, Ohio HB 73 strengthens the ethical framework within which healthcare is delivered in our state.

3. Exclusion of Narcotics: The exclusion of narcotics in the amended version of Ohio HB 73 reflects a commitment to responsible prescribing practices and addressing the opioid crisis. The legislation acknowledges the importance of risk evaluation and mitigation strategies for medications while ensuring access to appropriate treatments for patients in need.

4. Standard of Care: Ohio HB 73 does not deviate from established standards of care but rather recognizes the evolving nature of healthcare practice. The legislation emphasizes the importance of informed decision-making and patient-centered care while allowing for flexibility in treatment approaches. By prioritizing patient well-being and safety, Ohio HB 73 promotes responsible and effective healthcare delivery.

5. Legal Compliance: Ohio HB 73 requires that all medical interventions comply with state laws and regulations, including those governing the use of medications. The legislation does not condone or authorize the use of veterinarian medications on humans, and it emphasizes the importance of adherence to legal and ethical guidelines in healthcare practice.

6. Immunity for Healthcare Providers: Ohio HB 73 includes provisions to protect healthcare providers from unwarranted legal liability while ensuring accountability for their actions. The legislation strikes a balance between providing necessary protections for providers and safeguarding patient rights and interests.

7. Prophylactic Interventions: Ohio HB 73 recognizes that medical interventions may be necessary for prophylactic or preventive purposes, even in the absence of a positive test result for

a specific disease or condition. The legislation allows for flexibility in treatment decisions while promoting evidence-based practice and patient safety.

8. Drug Shortages: Ohio HB 73 acknowledges the challenges posed by drug shortages and emphasizes the importance of ensuring access to essential medications for patients. The legislation encourages collaboration among healthcare providers and stakeholders to address shortages effectively while prioritizing patient care and safety.

9. License Accountability: Ohio HB 73 does not shield healthcare providers from accountability for recklessness or gross negligence in patient care. The legislation maintains existing mechanisms for investigating and addressing instances of substandard care, thereby ensuring accountability, and promoting continuous improvement in healthcare delivery.

10. Informed Consent: Ohio HB 73 upholds the principle of informed consent and emphasizes the importance of clear communication between healthcare providers and patients. The legislation ensures that patients have the necessary information to make informed decisions about their care while respecting their autonomy and preferences.

11. Medical Staff Bylaws: Ohio HB 73 enhances the self-governance of physicians while respecting the authority of medical institutions to establish and enforce their bylaws. The legislation does not interfere with institutional processes for credentialing and privileging physicians but rather streamlines the process to ensure timely access to care for patients.

In conclusion, Ohio HB 73 represents a comprehensive effort to enhance access to healthcare services while maintaining high standards of quality, safety, and ethical practice. The legislation addresses legitimate concerns while upholding the rights and interests of patients and healthcare providers alike. We urge the Senate healthcare committee to support Ohio HB 73 and its goals of improving healthcare delivery and patient outcomes across our state. Thank you for your attention to these matters, and we remain available to provide any further information or clarification as needed.

Sincerely,
Joseph J Sreenan, MD
David Powell, DO
Shawn Ward, DPM
Matt Akers, MD
Rob Neidich, MD